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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2018

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	**47-3458693**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

4000 Shoreline Court, Suite 250
South San Francisco, CA 94080

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

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Each Class	**Name of Each Exchange On Which Registered**
Common Stock, par value $0.0001 per share	**The NASDAQ Stock Market LLC (NASDAQ Global Select Market)**

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

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

The Registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the Registrant's common equity as of such date.

The number of outstanding shares of the Registrant's common stock, par value $0.0001, as of February 28, 2019 was 24,339,830.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TABLE OF CONTENTS

		Page
PART I		
Item 1.	Business	4
Item 1A.	Risk Factors	32
Item 1B.	Unresolved Staff Comments	75
Item 2.	Properties	75
Item 3.	Legal Proceedings	75
Item 4.	Mine Safety Disclosures	75
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	76
Item 6.	Selected Financial and Other Data	77
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	79
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	91
Item 8.	Financial Statements and Supplementary Data	91
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	93
Item 9A.	Controls and Procedures	93
Item 9B.	Other Information	94
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	95
Item 11.	Executive Compensation	101
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	113
Item 13.	Certain Relationships and Related Transactions, and Director Independence	115
Item 14.	Principal Accounting Fees and Services	119
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	120
Item 16	Form 10-K Summary	122
	Exhibit Index	121
	Signatures	123

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K 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 Annual Report on Form 10-K. 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 annual 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 Annual Report on Form 10-K to the "company," "Harpoon," "we," "us" and "our" refer to Harpoon Therapeutics, Inc.

PART I

Item 1. Business

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 Tri-specific T cell Activating Construct, or 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. Since commencing operations in 2015, we have created four TriTAC product candidates, each of which we expect to be in clinical development by the end of 2020. Our lead TriTAC product candidate, HPN424, is currently in a Phase 1 clinical trial for the treatment of metastatic castration-resistant prostate cancer, or mCRPC. In January 2019, we announced preliminary data from this trial that supports the proposed mechanism of action of HPN424. Our second TriTAC product candidate, HPN536, is expected to enter clinical development in the first half of 2019 for the treatment of ovarian cancer and other MSLN-expressing solid tumors.

In January 2019, we announced preliminary data from seven patients who had been enrolled in our Phase 1 clinical trial of HPN424, as of December 31, 2018. Safety and tolerability are the primary objectives of the trial and as of December 31, 2018, all seven patients remained on the study, receiving weekly treatments of HPN424 with no dose limiting toxicities. Our secondary objectives include pharmacokinetic and pharmacodynamic data, as well as preliminary anti-tumor activity. The clinical trial results to date include measurement of HPN424 serum exposure that supports weekly dosing and changes in cell and serum biomarkers consistent with T cell activation.

Our TriTACs are designed to advance the therapeutic potential of T cell engagers, an established and meaningful mechanism of action. The first bi-specific T cell engager, or BiTE, to be approved by the FDA was, Amgen's Blincyto. Blincyto was approved in 2014 as a monotherapy for the treatment of acute lymphoblastic leukemia. Since then, other BiTEs have shown promising therapeutic potential in clinical trials. We developed our proprietary TriTAC platform to incorporate the strengths of BiTEs and improve upon their critical shortcomings, such as a short half life. We believe our TriTAC platform offers the following features for the discovery and development of novel immunotherapies for the treatment of a wide array of diseases, including cancer:

- ***Active at Low Levels of Target Expression.*** We designed TriTACs to be active at low levels of antigen expression where other treatment modalities lose efficacy. In our preclinical studies, TriTACs did not require high levels of target antigen expression to engage T cells to kill disease cells.
- ***MHC Independence.*** We designed TriTACs to specifically direct T cells to kill target cells independent of MHC expression. Tumor cells frequently acquire mutations that change the MHC molecule or reduce the level of MHC expressed on their surfaces, thus making the tumor cells less susceptible to being killed by either endogenous T cells or engineered T cells that require MHC recognition. We believe that because TriTACs do not require a T cell clone with specific T cell receptor or MHC recognition to kill tumor cells, they will be able to generate greater and more durable therapeutic responses than MHC dependent approaches.
- ***Extended Half-Life and Stability.*** We designed TriTACs to be stable in the bloodstream and to have a long-serum half-life in order to achieve efficacy without requiring the continuous IV administration that is a limiting requirement of other T cell engagers, such as BiTEs.
- ***Small Size and Tissue Penetration.*** TriTACs are small in size, and we believe this is critical for their efficient penetration of, and diffusion within, solid tumors.
- ***Modularity.*** The TriTAC structure is modular and its antigen binding domain can easily be switched out to enable the rapid discovery and development of new TriTAC product candidates across a wide variety of targets.
- ***Safety Design Elements.*** We designed TriTACs to enable T cell engagement while minimizing off-target toxicity and the potential for CRS, which is a potentially lethal reaction of the body to the hypersecretion of inflammatory cytokines.
- ***Conventional Manufacturing.*** TriTACs are "off-the-shelf" therapies, the manufacturing of which is significantly less complex than that of personalized or cell-based therapies.

Our lead TriTAC product candidate, HPN424, is in clinical development for the treatment of prostate cancer. Nearly all prostate cancer-specific deaths occur after patients develop mCRPC, which kills an estimated 29,000 patients in the United States each year. We have designed HPN424 to target PSMA, which is present in 80-95% of patients with mCRPC tumor lesions. In April 2018, data presented at the American Association for Cancer Research Conference demonstrated encouraging clinical responses of Amgen's BiTE targeting PSMA in mCRPC patients. However, this product candidate, AMG212, requires continuous IV infusion, which could limit its adoption and accessibility. In contrast, we designed our TriTACs to benefit from extended serum half-life to enable more convenient dosing, and HPN424 is currently in a Phase 1 clinical trial for the treatment of mCRPC with once-weekly IV dosing. In January 2019, we announced preliminary data from seven patients who had been enrolled in this clinical trial as of December 31, 2018. The clinical trial results to date include measurement of HPN424 serum exposure that supports weekly dosing. We expect to provide additional preliminary data from this clinical trial at a medical conference in the second half of 2019.

Our second TriTAC product candidate, HPN536, is in development for the treatment of ovarian cancer and other MSLN-expressing tumors. MSLN, a clinically validated target, is expressed on malignant cells of mesothelioma, ovarian carcinoma, pancreatic carcinoma, NSCLC and TNBC, among others. In our preclinical studies, we have observed HPN536's promising *in vitro* and *in vivo* activity in MSLN-expressing cancers. Our IND for HPN536 took effect in January 2019, and we plan to initiate a Phase 1/2a clinical trial in the first half of 2019.

We also have two TriTAC product candidates in preclinical development targeting tumor-associated antigens for the treatment of multiple myeloma and SCLC, for which we expect to file INDs in 2019 and 2020, respectively.

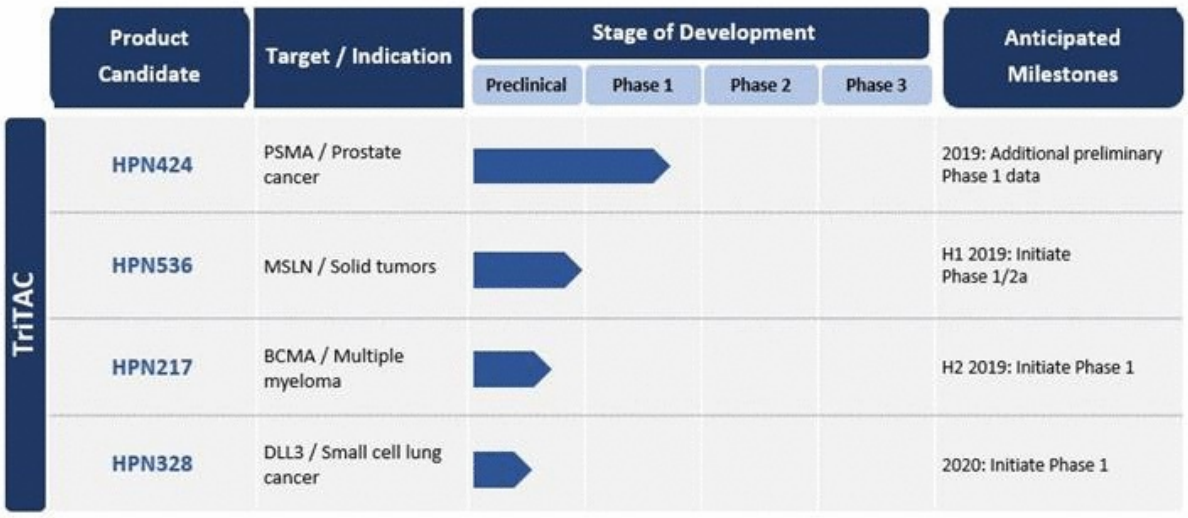
To further expand the universe of addressable targets and indications, we are actively developing our proprietary ProTriTAC platform, which applies a prodrug concept that creates a therapeutic T cell engager that is designed to remain inactive until it reaches the tumor. We are in the discovery phase with respect to several ProTriTAC product candidates and expect to advance our first ProTriTAC product candidate into IND-enabling studies in 2019.

We aim to selectively collaborate with leading biopharmaceutical companies to leverage our platform. For example, in October 2017 we entered into the Collaboration Agreement with AbbVie, pursuant to which we granted to AbbVie worldwide exclusive rights to develop and commercialize products that incorporate our proprietary TriTAC technology together with soluble 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. In addition to an upfront payment of $17 million, AbbVie will be required to make further payments to us 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. We 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.

Our company is led by a strong management team with deep experience in immunotherapy, redirected T cell therapies, biologics drug discovery and development and protein engineering. Our management team has experience at leading biopharmaceutical companies such as Aduro BioTech Inc., Amgen Inc., Dyax Corp., Nektar Therapeutics, Onyx Pharmaceuticals Inc., Pfizer Inc., Seattle Genetics, Inc. and Tularik Inc. This team brings a strong history of research and development innovation and a proven track record at other companies in the discovery, development and commercialization of oncology therapeutics including Adcetris, Blincyto, Cometriq, Kyprolis, Sorafenib and Sutent.

Our Pipeline

We are leveraging our proprietary TriTAC and ProTriTAC platforms to discover and develop product candidates to treat cancer and other diseases. The following table summarizes key information about our product candidates to date, all of which were developed using our TriTAC platform. We own the intellectual property rights to both our TriTAC and ProTriTAC platforms and the underlying critical components of our product candidates. We currently hold worldwide rights to all of our product candidates.



Our Strategy

Our strategy is to harness innovations in immunotherapy and protein engineering to rapidly advance our novel TriTAC product candidates through clinical development, regulatory approval and commercialization, with an initial focus on cancer. This strategy encompasses the following key elements:

- ***Rapidly advance our TriTAC product candidates, HPN424 and HPN536, which target clinically validated tumor-associated antigens through clinical development and regulatory approval.*** We are developing our lead TriTAC product candidate, HPN424, to target PSMA for the treatment of prostate cancer. HPN424 is in a Phase 1 clinical trial for the treatment of mCRPC, and in January 2019 we announced preliminary data that supports the proposed mechanism of action of HPN424. We are developing our second TriTAC product candidate, HPN536, to target MSLN for the treatment of ovarian carcinoma and other MSLN-expressing solid tumors. Our IND for HPN536 took effect in January 2019, and we plan to initiate a Phase 1/2a clinical trial in the first half of 2019.
- ***Rapidly advance our other TriTAC product candidates into and through clinical development***. Our TriTAC platform enables us to rapidly identify and develop pipeline product candidates. Our earlier stage TriTAC product candidates include HPN217, which targets BCMA for the treatment of multiple myeloma, and HPN328, which targets DLL3-for the treatment of SCLC. We expect to advance rapidly these programs into clinical development and to file INDs for these TriTAC product candidates in 2019 and 2020, respectively.
- ***Leverage our novel TriTAC and ProTriTAC platforms to expand our pipeline of immunotherapy product candidates to target a broad range of disease associated antigens.*** Through our TriTAC and ProTriTAC platforms, we intend to address numerous targets that are difficult to treat with traditional therapeutic modalities due to safety and efficacy challenges. Current T cell engagers have had limited success in certain indications, but we believe we are transforming this modality into one that will address large unmet medical needs, initially by designing a class of therapeutics focused on solid tumors. We believe our proprietary TriTAC and ProTriTAC platforms enable us to rapidly move additional potential pipeline therapeutics into the clinic.

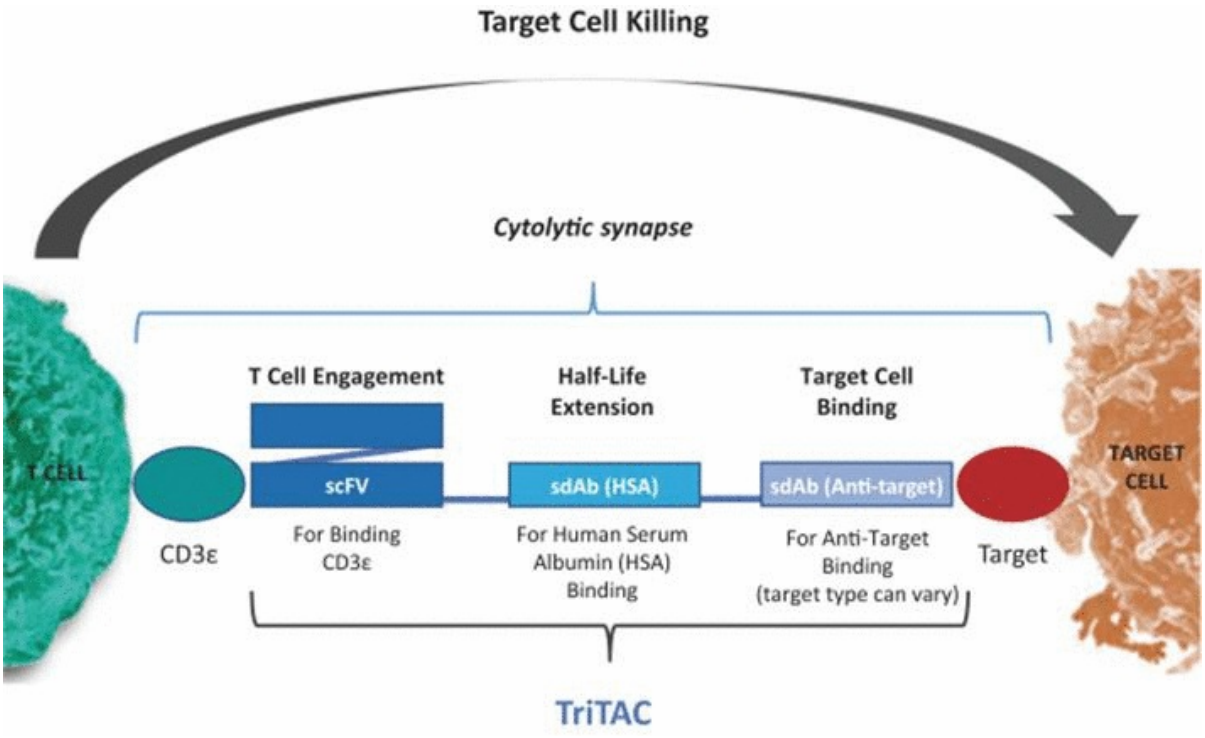
- ***Selectively collaborate with leading biopharmaceutical companies to leverage our platform, advance our product candidates and maximize their commercial potential.*** We intend to retain significant ownership of our current pipeline product candidates and to partner and collaborate with leading biopharmaceutical companies on select programs such that we retain significant economic and commercial rights to our portfolio in the United States and certain other geographies. Through strategic collaborations, we believe we can broaden the reach of our TriTAC and ProTriTAC platforms to other novel targets in oncology or other areas that are not a focus for our company. For example, we entered into a collaboration with AbbVie in October 2017 that expands the utility for our TriTAC platform by developing candidates against novel soluble TCR targets.

Our TriTAC Platform

Our proprietary TriTAC platform offers the potential to develop drugs that could dramatically change the way in which we combat a variety of diseases. It is well accepted that the immune system can be harnessed to eradicate and prevent the proliferation of cancer cells. Recent successes using immunologic approaches have revealed methods of modulating a cancer patient's immune system to battle the growth and spread of tumors. In most cases, T cells have been central to this approach, and the pathways to unleash the tumor-killing properties of T cells have resulted in multiple recent drug approvals.

We believe our TriTACs represent the evolution of a validated cancer-killing modality that engages T cells to kill tumors. The first approved T cell engager, a BiTE developed by Amgen and marketed as Blincyto, was approved in 2014 for the treatment of acute lymphoblastic leukemia. In April 2018, data presented at the American Association for Cancer Research Conference demonstrated encouraging clinical responses with Amgen's PSMA-targeting product candidate in mCRPC patients. More recently, data presented at the Myeloma 2018 and American Society of Hematology 2018 conferences demonstrated encouraging clinical responses to a BiTE targeting BCMA in patients with relapsed/refractory multiple myeloma. With our TriTAC platform, we set out to design a T cell engager that incorporates the strengths of BiTEs (including small size and activity at low levels of antigen expression) and improves upon their critical shortcomings (including short half-life and limited stability).

We designed our TriTAC product candidates with three primary components: a CD3 binding domain for T cell engagement, a proprietary half-life extension domain and an antigen-bonding domain. TriTACs consist of a single-chain polypeptide designed to bind to a cancer surface antigen, human serum albumin and the CD3 epsilon subunit of the TCR. Tumor-targeting and albumin-binding are achieved by single domain antibodies, or sdAbs, while CD3 is bound by a single-chain variable fragment, or scFv. When TriTACs simultaneously bind cell surface antigens and T cells, they induce the formation of a cytolytic synapse that mimics the natural interaction between TCRs and MHCs. This interaction activates T cells to kill target cells, as demonstrated in the figure below.



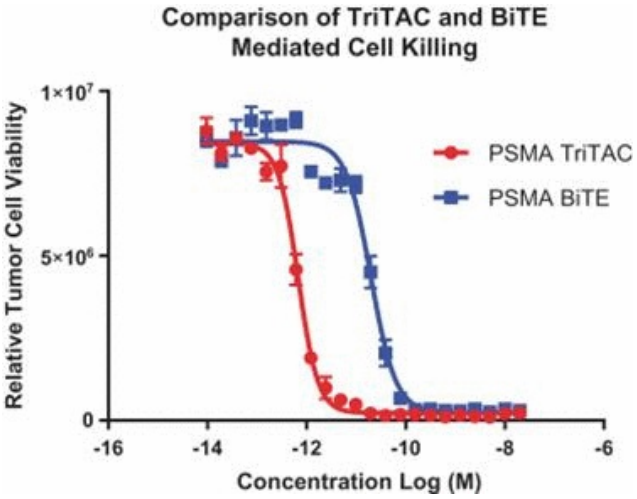
We believe our TriTAC platform offers the following features for the discovery and development of novel immunotherapies for the treatment of a wide array of diseases, including cancer:

- ***Active at Low Levels of Target Expression.*** We designed TriTACs to be active at low levels of antigen expression where other treatment modalities lose efficacy. Tumors often utilize an escape mechanism involving the downregulation of target antigen expression to avoid immuno-surveillance. In our preclinical studies, TriTACs did not require high levels of target antigen expression to engage T cells to kill disease cells.
- ***MHC Independence.*** We designed TriTACs to specifically direct T cells to kill target cells independent of MHC expression. T cells recognize target cells naturally through binding to an antigen-derived peptide complexed with MHC on the target cell. The reduction of MHC expression is a frequent mechanism by which cancer cells escape T cell recognition. We believe that because TriTACs do not require a T cell clone with specific T cell receptor or MHC recognition to kill tumor cells, they will be able to generate greater and more durable therapeutic responses than MHC dependent approaches.
- ***Extended Half-Life and Stability.*** We designed TriTACs to have a long-serum half-life in order to achieve efficacy without requiring continuous IV administration, which is a limiting requirement of other T cell engagers such as BiTEs. Our TriTACs utilize noncovalent binding to serum albumin, which has been validated as an effective way to extend the serum half-life of other proteins for up to several weeks. We also designed TriTACs as single-chain polypeptides that incorporate antibody fragments called sdAbs to improve their stability under physiological conditions. The stability of the molecule is critical to how long it can circulate within the body and remain effective.
- ***Small Size and Tissue Penetration.*** We believe the small size of our TriTACs enables effective solid tumor penetration. Despite having three binding domains, a TriTAC is only about one third of the size of a monoclonal antibody and similar in size to BiTEs, which have recently shown clinical promise in the treatment of solid tumors. We believe this small size allows for faster diffusion into human tumor tissues than is possible with full-length antibodies given the high interstitial pressure and dense extracellular matrix in solid tumors. To achieve the same level of tumor penetration, larger modalities require higher concentrations on the periphery, which can lead to increased off-target toxicity and a limited therapeutic window. We believe TriTACs' small size is critical for their penetration of tumors and, ultimately, for clinical efficacy.
- ***Modularity.*** We designed the TriTAC construct to be able to easily switch out target antigen binding domains. We believe this modularity will allow us to rapidly expand into new indications in oncology and other therapeutic areas upon the successful generation of binders for disease-specific target antigens. We expect to have four TriTAC product candidates in clinical development by the end of 2020.
- ***Safety Design Elements.*** We designed TriTACs to enable T cell engagement while minimizing off-target toxicity and the potential for CRS. Safety design elements of our TriTACs include the following:
  - *No Fc Domain.* TriTACs do not use the Fc domain of an antibody for half-life extension, as compared to other half-life extended T cell engagers. Fc receptor binding can lead to unintended target activation of T cells and off-target toxicity.
  - *sdAb Fragments.* TriTACs utilize sdAb fragments, which are very stable domains, for target binding and half-life extension. In contrast, other T cell engagers rely more heavily on scFv antibody fragments, which are prone to aggregate and activate T cells non-specifically, potentially leading to off-target toxicity.
  - *Monovalent for CD3.* Because TriTACs have a single anti-CD3 domain, TriTACs are monovalent for CD3. As a result, TriTACs cannot cluster CD3 and activate T cells non-specifically in the absence of target engagement, reducing the likelihood of unintended T cell activation and off-target toxicity.
- ***Conventional Manufacturing.*** We designed TriTACs as highly potent and stable yet flexible single-chain polypeptides engineered to use conventional antibody manufacturing approaches. TriTACs are "off-the-shelf" therapies, the manufacturing of which is significantly less complex than that of personalized or cell-based therapies.

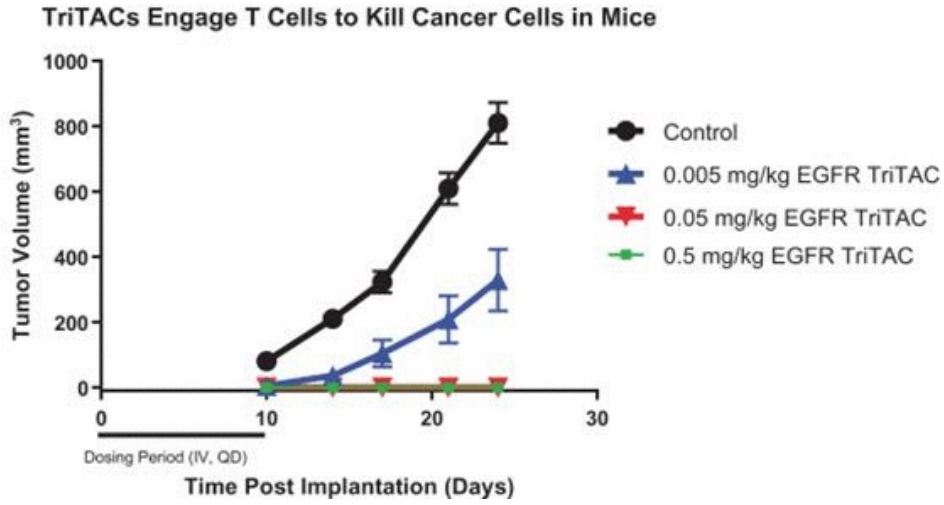
Preclinical Validation of our TriTAC Platform

In validation of our TriTAC platform, we have demonstrated that our TriTACs can induce T cells to kill tumor cells in both cell-based and animal models.

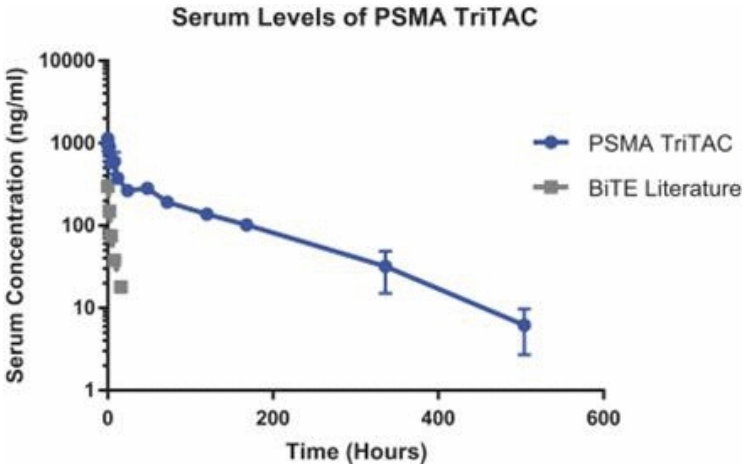
The figure below shows data from a cell-based experiment in which resting T cells from a healthy human donor were incubated together with the prostate cancer cell line LNCaP. In this experiment, we compared our PSMA-targeting TriTAC with a PSMA-targeting BiTE molecule that we manufactured internally based on protein sequences published by Amgen. We observed our PSMA-targeting TriTAC to be more potent than the comparative molecule.



Our TriTACs have also demonstrated high potency in animals. The figure below shows data from a xenograft experiment in which mice bearing human colon cancer tumors derived from the HCT116 cell line were dosed with epidermal growth factor receptor, or EGFR, targeting TriTACs. We observed that EGFR-targeting TriTACs controlled tumor growth in a dose-dependent manner.



To demonstrate that our TriTAC design can extend the half-life of our product candidates as compared to BiTEs, we performed pharmacokinetic studies in animals. As shown in the figure below, when administered by short IV bolus infusion of 0.1 mg/kg, TriTACs were observed to have a terminal half-life of over 80 hours, compared to less than two hours reported in the literature for Blincyto. We believe we can administer once-weekly dosing and overcome one of the major limitations of BiTEs, which is the requirement of continuous IV infusion.



Overall, we believe our preclinical data demonstrate that TriTACs are a novel modality that is well-suited for development as potential treatments for solid tumors.

Our TriTAC Product Candidates

HPN424: PSMA-targeting TriTAC

We are developing our lead TriTAC product candidate, HPN424, for the treatment of prostate cancer. Our IND for HPN424 took effect in July 2018 and we treated the first patient in our ongoing Phase 1 clinical trial of HPN424 for the treatment of mCRPC in August 2018. HPN424 targets PSMA, a protein for which expression is largely restricted to both normal and malignant prostate-derived cells. HPN424 provides a differentiated mechanism of action compared to the current standard of care, as this targeted approach is designed to safely engage and direct T cells to kill cancer cells. In April 2018, data presented at the American Association for Cancer Research Conference demonstrated the encouraging clinical responses of Amgen's BiTE targeting PSMA in mCRPC patients. However, this product candidate, AMG212, requires continuous IV infusion, which could limit its adoption and accessibility. We believe HPN424 has the potential to move into earlier lines of therapy for prostate cancer.

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, which preliminary data supports the proposed mechanism of action of HPN424. Safety and tolerability are the primary objectives of the trial, and as of December 31, 2018, all seven patients remained on the study with weekly treatments of HPN424 with no dose limiting toxicities have been observed. Our secondary objectives include pharmacokinetics and pharmacodynamics, as well as preliminary potential anti-tumor activity and biomarker data. The clinical trial results to date indicate that HPN424 serum exposure supports weekly dosing, and we observed changes in blood-derived tumor cell and serum biomarkers consistent with T cell activation. We expect to provide additional preliminary data from this clinical trial at a medical conference in the second half of 2019.

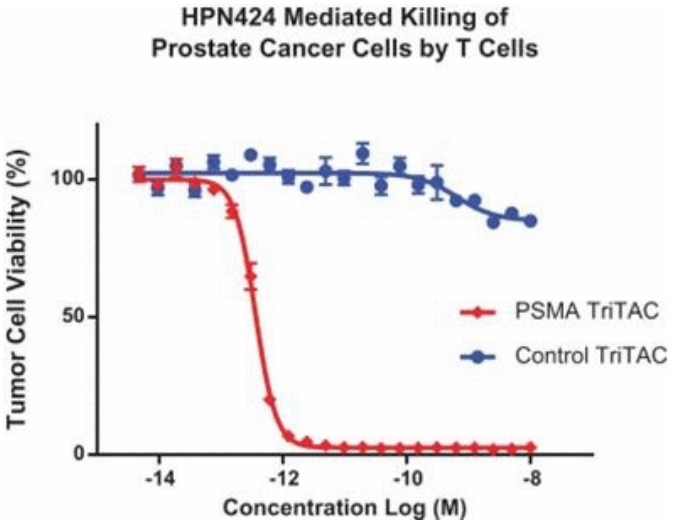
Market Opportunity

The Surveillance, Epidemiology and End Results Program of the National Cancer Institute, or SEER, estimates that there will be over 164,000 new diagnoses and over 29,000 deaths as a result of prostate cancer in the United States in 2018. Prostate cancer is expected to have the second highest incidence rate in 2018 and the third highest mortality rate in 2018, and is the second leading cause of male cancer death in the United States.

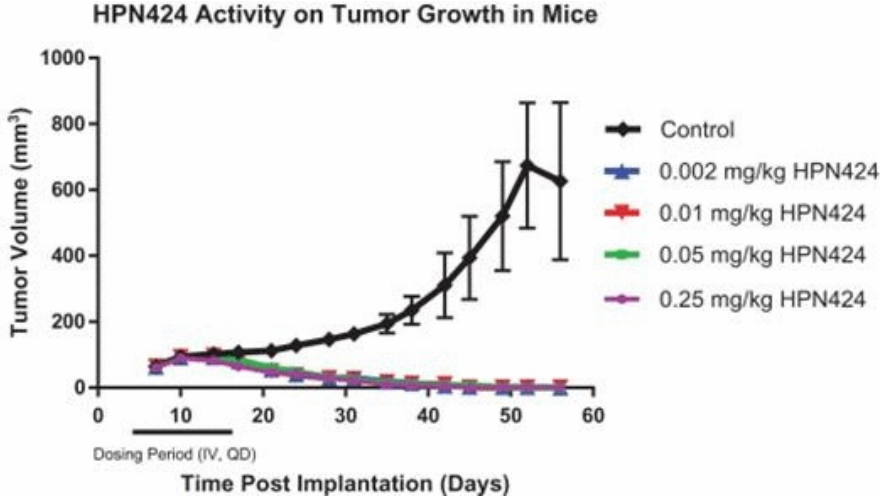
While the five-year survival rate of local and regional prostate cancer is nearly 100%, more aggressive forms of the disease, of which approximately 23% are initially diagnosed, have a five-year survival rate of approximately 30%. While these more aggressive forms of prostate cancer can initially be treated, nearly all of these patients experience a recurrence in tumor growth that results in the subsequent development of mCRPC. Nearly all prostate cancer-specific deaths occur after patients develop mCRPC, for which the median overall survival period is only 13 months. Later-generation anti-androgen drugs such as Johnson & Johnson's Zytiga and Pfizer's/Astellas' Xtandi have widely become the standard of care and generated combined global sales of over $5 billion in 2017. There is a significant need for treatments that offer a novel mechanism of action with the potential to modify or cure the disease.

Preclinical Data

To demonstrate the potency and specificity of HPN424, a T cell-dependent cellular cytotoxicity, or TDCC, assay was used to evaluate its *in vitro* potency in a panel of PSMA-expressing prostate cancer cell lines. The specificity was observed by the lack of killing in a control (non-PSMA binding) TriTAC on PSMA-positive cell lines and HPN424 on PSMA-negative cell lines. The figure below shows a representative TDCC assay result where HPN424, but not the control TriTAC, mediated the killing of the prostate cancer cell line LNCaP.



The *in vivo* antitumor activity of HPN424 was evaluated using a subcutaneous xenograft tumor model in an immuno-deficient mouse co-implanted with the 22Rv1 prostate cancer cells and human peripheral blood mononuclear cells, or PBMCs. As depicted in the figure below, HPN424 completely suppressed the growth of the prostate cancer cells at doses of 2 µg/kg/day and higher.



Clinical Development Plan

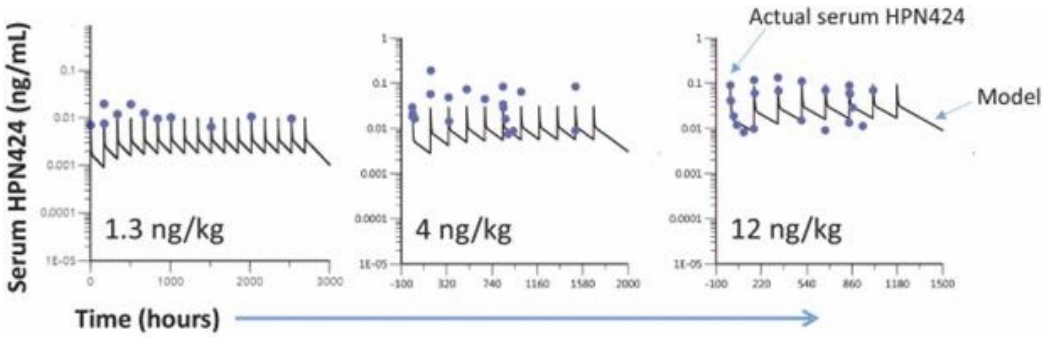
In August 2018, we initiated a Phase 1, multicenter, open-label dose escalation and dose expansion trial of the safety, tolerability and pharmacokinetics of HPN424 in mCRPC patients. Eligible patients must have mCRPC, have received at least two prior treatment regiments for mCRPC and have evidence of disease progression on the most recent systemic treatment regimen. We expect to enroll approximately 40 patients in the trial, with approximately 20 patients in each of the dose escalation and dose expansion phases. The dose escalation phase began with single patient cohorts but, as a result of the grade 3 adverse event described below, is now proceeding per protocol using a 3+3 design with dose cohorts that enroll three to six patients per cohort, starting with the fourth cohort. 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. As of December 31, 2018, we had enrolled seven patients in the trial. Our primary objective is to assess safety and tolerability at increasing dose levels. Our secondary objectives include pharmacokinetics and pharmacodynamics, as well as preliminary potential anti-tumor activity and biomarker data.

Phase 1 Preliminary Results

As of December 31, 2018, we made the following preliminary Phase 1 trial observations:

Patient Treatment and Tolerability: Seven patients have been treated in the dose escalation portion of the trial at doses ranging from 1.3 to 24 ng/kg. All seven patients were treated previously with a second-generation anti-androgen therapy. All seven patients remain on study treatment, with the time on treatment ranging from one to more than 20 weeks, and the number of doses received ranging from one to 22 weekly treatments. Adverse events were consistent with the expected mechanism of action, with three patients reporting grade 2 rigors or fevers that were manageable. One patient from the fourth cohort experienced a grade 3 CRS event (rigors and hypotension), which resolved within eight hours of dosing. This patient was re-administered HPN424 consistent with protocol guidelines. The patient experienced no further reactions and continues to be enrolled in the study. All patients experiencing adverse events were successfully re-treated (the patient who had reported a grade 3 CRS event was given Dexamethasone prior to being re-treated) after one week without further complications. No dose limiting toxicities have been observed, with four dose levels tested.

Serum Drug Exposure: Preliminary pharmacokinetic analysis supports weekly dosing. We created a simulated model using the pharmacokinetic parameters from the patient treated with a dose of 12 ng/kg, including apparent volume of distribution, clearance rate and half-life. As depicted in the figure below, actual measurements of serum concentration of HPN424 in the trial closely correlated with the simulated model, and maximum serum concentration of HPN424 was found to be proportional to the dose. The volume of distribution and clearance rates appear to be similar among different dose levels suggesting linear pharmacokinetic properties.



T Cell Engagement: Transient and dose-dependent increases in peripheral cytokines (interleukin-6, interleukin-8, interleukin-10) and chemokines (macrophage inflammatory protein-1-alpha, macrophage inflammatory protein-1-beta, monocyte chemoattractant protein-1) were observed, consistent with the expected mechanism of action related to T cell activation.

Tumor Assessments: Radiographic assessment of disease burden is performed at nine-week intervals. For the first three patients in the trial, radiographic and PSA data have shown stable disease for two patients and one patient exhibited unconfirmed progressive disease. The other four patients are early in their treatment and not yet evaluable. The table below shows circulating tumor cell, or CTC, levels of patients treated with different doses of HPN424 over the course of the trial. As depicted in the table, whole blood samples from three of four patients with measurable baseline CTC levels showed a reduction in CTC following treatment with HPN424.

	Patient 001 1.3 ng/kg	Patient 002 4 ng/kg	Patient 003 12 ng/kg	Patient 006 12 ng/kg	Patient 005 24 ng/kg
	(CTC/mL of whole blood)				
Day 1 (pre-treatment, baseline)	0	17.3	7.5	4.3	11
Day 15 (7 days after 2nd dose)	4.6	1.6	1.7	12.6	6.9
Day 43 (7 days after 6th dose)	0	0.5	0.7	TBD	TBD
Day 85 (7 days after 12th dose)	0.8	0	TBD	TBD	TBD

HPN536: MSLN-Targeting TriTAC

We are developing HPN536 for the treatment of ovarian cancer and other MSLN-expressing tumors, which include mesothelioma, pancreatic carcinoma, NSCLC and TNBC, among others. HPN536 targets MSLN, a cell-surface protein whose normal expression is largely restricted to mesothelial cell layers lining certain organs. MSLN is an attractive drug target for target-based therapeutics because it is expressed on a wide variety of tumor cells but has limited expression in normal tissue. Early signs of clinical efficacy generated by other treatment modalities have validated MSLN as an attractive tumor target, but therapies with improved efficacy are required to treat MSLN-expressing tumors. In 2018, we completed an IND-enabling, multi-dose GLP toxicology study in animals. HPN536, which has been observed to bind to cynomolgus monkey MSLN with comparable affinities as human MSLN, delivered clear histological evidence of target engagement. Our IND for HPN536 took effect in January 2019, and we plan to initiate a Phase 1/2a clinical trial in the first half of 2019.

Market Opportunity

MSLN-expressing tumors include ovarian cancer, NSCLC, pancreatic carcinoma, mesothelioma and TNBC, among others. While MSLN is found in approximately 30% of all cancers, these specific cancers have particularly high levels of MSLN expression. The following table shows the MSLN expression level of, and the number of patients diagnosed in the United States in 2018 with, each of these cancers:

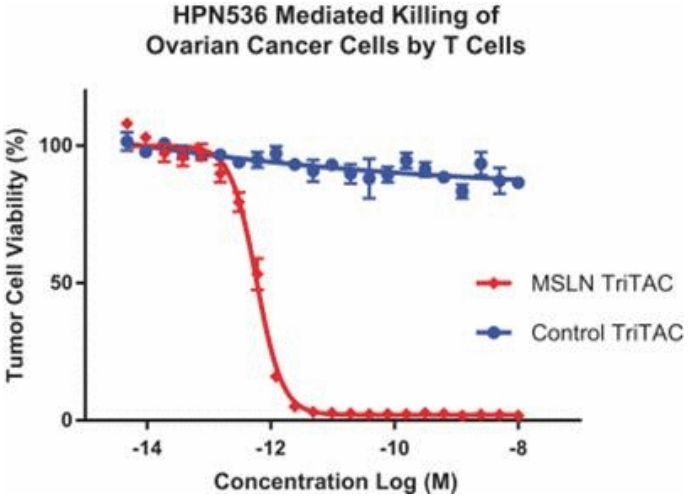
Cancer Type	New Patients Diagnosed in the United States		MSLN Expression Level (%)
Ovarian Cancer	22,000		60-65
Non-Small Cell Lung Cancer	199,000		60-65 *
Pancreatic Carcinoma	55,000		80-85
Mesothelioma	2,600		85-90
Triple Negative Breast Cancer	40,000	**	34-42

* Represents MSLN expression levels across all lung cancer types.
** Calculated as 15% of SEER-estimated breast cancer incidence.

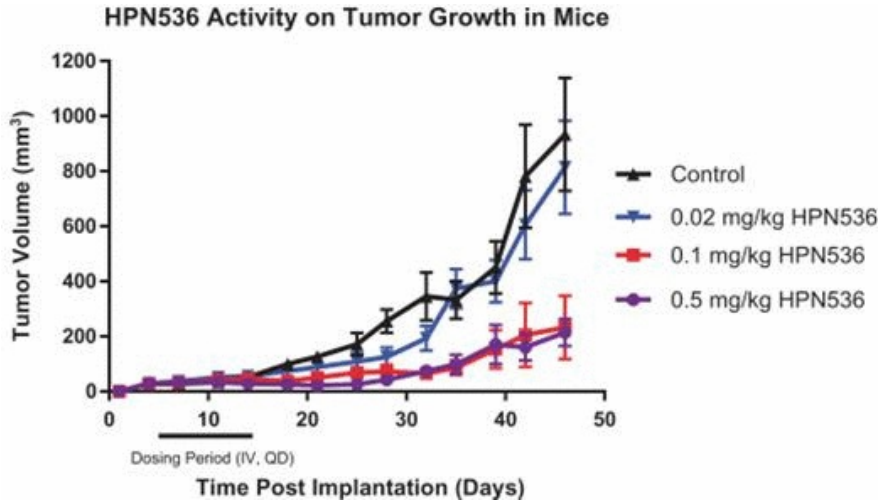
Ovarian cancer is the fifth leading cause of cancer-related death among women in the United States and is the deadliest of gynecologic cancers with more than 70% of patients diagnosed with an advanced stage and over 14,000 patients dying from the disease each year. According to SEER, the five-year survival rate for women diagnosed with ovarian cancer is approximately 47%. NSCLC is the most common type of lung cancer, estimated to comprise 80-85% of all lung cancer diagnoses. The five-year survival rate for late-stage NSCLC is about 10%. Pancreatic cancer is one of the most fatal cancers in the world. In 2016, the seven major markets (the United States, France, Germany, Italy, Spain, the United Kingdom and Japan) saw 149,780 new cases of pancreatic cancer and in 2018, there were approximately 55,440 new cases in the United States. SEER estimates that fewer than 9% of patients diagnosed with pancreatic cancer survive five years. Mesothelioma is a rare and aggressive cancer that affects the lining or membrane that covers and protects certain organs in the body. Effective treatment options for patients with mesothelioma are very limited. TNBC is referred to as “triple-negative” because it is ER-, PR- and HER2-, and is unlikely respond to hormonal or HER2-targeted therapies. TNBC accounts for 10-20% of all breast cancers and is more aggressive and likely to recur compared to receptor-positive breast cancers. The five-year survival rate for TNBC is 77% as compared to 93% for other types of breast cancers.

Preclinical Data

To demonstrate the *in vitro* potency and specificity of HPN536, we used TDCC assays in a panel of MSLN-expressing ovarian cancer cell lines. The specificity was observed by the lack of killing by the control TriTAC on MSLN-positive cell lines and by the lack of killing by HPN536 on MSLN-negative cell lines. The figure below shows a representative TDCC assay result where HPN536, but not the control TriTAC, mediated killing of the ovarian cancer cell line (Caov-3).



A subcutaneous xenograft tumor model with the H292 cell line was used to evaluate the *in vivo* antitumor activity of HPN536 in MSLN-expressing lung cancer cell lines co-implanted with human PBMCs. The mice were dosed once-daily beginning on day six for ten days. As depicted in the figure below, HPN536 had a significant effect on tumor growth at doses of 0.1 mg/kg and higher.



Clinical Development Plan

We submitted our IND in December 2018, which took effect in January 2019. We intend to initiate a Phase 1/2a open-label, multicenter, dose escalation and dose expansion trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary clinical activity of HPN536, initially recruiting patients with ovarian cancer who have failed standard available therapy. We expect to enroll approximately 20 platinum resistant/refractory ovarian cancer patients in the dose escalation phase, which is designed to determine the maximum tolerated dose and a recommended Phase 2 dose. Once a recommended Phase 2 dose is determined, we expect to initiate the dose expansion phase with three parallel 20-patient cohorts, conducted according to a Simon 2-stage design. The cohorts will be indication-specific, and we expect to enroll patients with ovarian cancer, mesothelioma and pancreatic carcinoma.

HPN217: BCMA-Targeting TriTAC

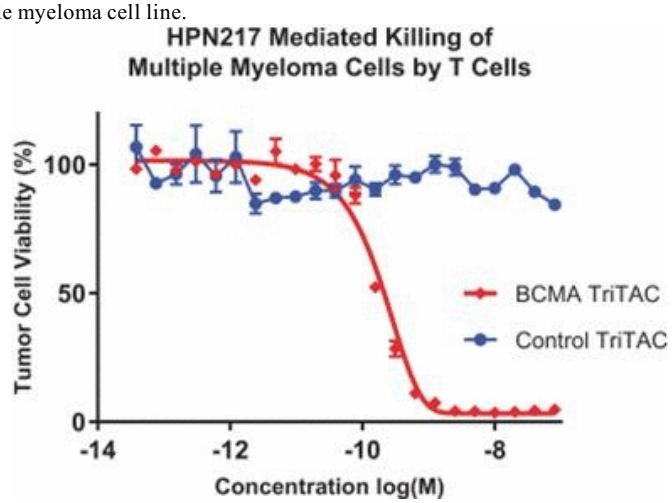
We are developing HPN217 for the treatment of multiple myeloma. HPN217 targets BCMA, a clinically validated target. BCMA is a tumor necrosis factor receptor super family member and is a receptor protein expressed on nearly all multiple myeloma cells. Early data from CAR-T and ADC have clinically validated the target. Recently, data presented at the ASH 2018 Annual Meeting demonstrated encouraging clinical responses to a BiTE targeting BCMA in patients with relapsed/refractory multiple myeloma. A complete response or stringent complete response was observed in seven patients with a response duration up to eight cycles (48 weeks). Of these seven patients, six were treated with the dose level ³100 µg/d. Further, five of the seven patients achieved a stringent complete response and were negative for minimal residual disease. We believe this demonstrates early promise of BCMA-targeting T cell engagers to overcome the limitations of other modalities to achieve superior efficacy and safety. We are currently conducting IND-enabling studies and expect to initiate a Phase 1 clinical trial of HPN217 in the second half of 2019.

Market Opportunity

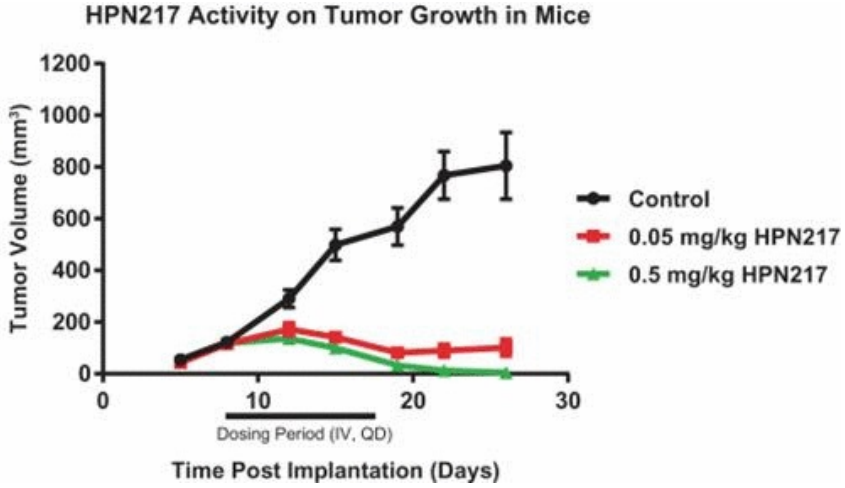
Multiple myeloma is a type of blood cancer formed by the accumulation of malignant plasma cells in the bone marrow, crowding out normal plasma cells that play an important role in the immune system. Multiple myeloma is the second most prevalent blood cancer after Non-Hodgkin's lymphoma. There are approximately 229,000 people living with myeloma worldwide, with 114,000 new cases diagnosed and 87,000 deaths each year. The American Cancer Society estimates that approximately 30,700 new cases will be diagnosed and approximately 12,770 deaths are expected to occur from multiple myeloma in the United States in 2018. Despite advances in the treatment of multiple myeloma over the past decade, we believe there remains a significant unmet need as the five-year survival rate is only approximately 50%.

Preclinical Data

To demonstrate the in vitro potency and specificity of HPN217, we used TDCC assays in a panel of BCMA-expressing cell lines derived from multiple myeloma or lymphoma patients. The specificity was observed by the lack of killing by the control TriTAC on BCMA-positive cell lines and by the lack of killing by HPN217 on BCMA-negative cell lines. The figure below shows a representative TDCC assay result where HPN217, but not the control TriTAC, mediated killing of the NCI-H929 multiple myeloma cell line.



Subcutaneous xenograft tumor models (RPMI8226) involving BCMA-expressing multiple myeloma or lymphoma cell lines co-implanted with human PBMCs were used to evaluate the *in vivo* antitumor activity of HPN217. The mice were dosed once daily beginning seven days after tumor implantation. As depicted in the figure below, HPN217 had a significant effect on tumor growth at doses of 0.05 mg/kg and higher. At 0.5 mg/kg, HPN217 induced complete tumor regression and suppression of tumor growth.



HPN328: DLL3-Targeting TriTAC

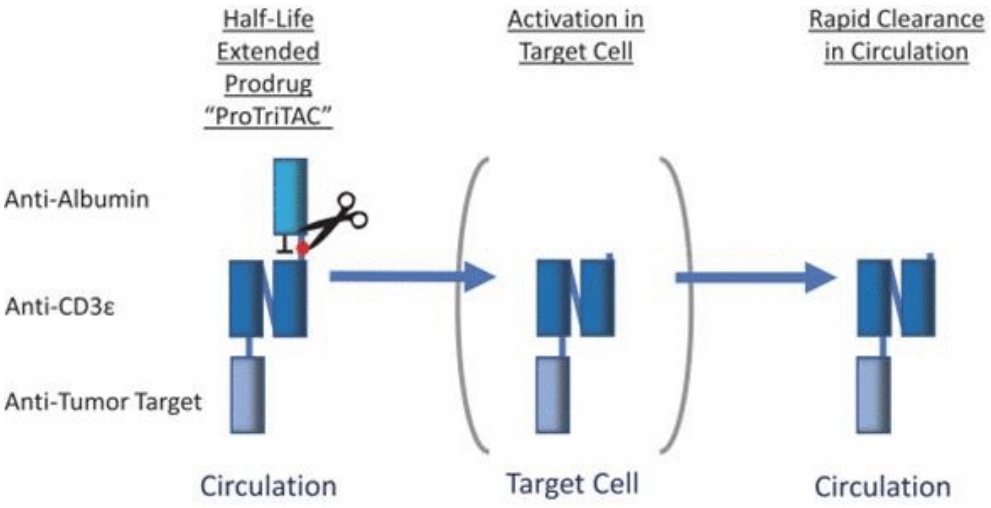
We are developing HPN328 for the treatment of SCLC. DLL3 is a protein highly expressed in a majority of SCLC tumors and cancer stem cells, but not expressed in normal tissue. This selective expression makes DLL3 an attractive drug target for T cell engagers. We are currently conducting IND-enabling studies and expect to initiate a Phase 1 clinical trial of HPN328 in 2020.

Market Opportunity

Approximately 30,000 patients are diagnosed with SCLC annually in the United States, representing 10-15% of lung cancer diagnoses. The five-year relative survival rate for patients with Stage I, II, III and IV SCLC is approximately 31%, 19%, 8% and 2%, respectively. The recent approval of Opdivo, a T cell-targeting checkpoint inhibitor developed by BMS, supports immunotherapy as a new treatment alternative for SCLC. We believe there is still a significant unmet need remains for new therapies for these patients.

ProTriTAC—An Expansion of TriTAC's Capabilities

In order to expand the universe of addressable targets and indications, we are actively developing our proprietary ProTriTAC platform. Our ProTriTAC platform applies a prodrug concept to create a therapeutic T cell engager that remains inactive until it reaches the tumor. ProTriTACs therefore have the potential for additional tumor specificity and enhanced safety profiles because they are designed to have limited interaction with their molecular targets in healthy tissue, allowing us to target tumor-associated antigens that may be more broadly expressed. When a ProTriTAC penetrates a tumor, tumor-associated proteases cleave off the blocking domain of the ProTriTAC, thereby enabling the engagement of T cells to subsequently kill tumor cells. This activation process also diminishes the half-life of the resulting T cell engager so active molecules that leave the tumor are rapidly eliminated from circulation without causing off-tissue side effects.



License and Collaboration Agreements

Collaboration Agreement with AbbVie Biotechnology

On October 10, 2017, we entered into 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 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 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 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.

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, we 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 us. 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.

Asset Transfer Agreement with Maverick Therapeutics, Inc.

In December 2016, we entered into an asset transfer agreement, or the Asset Transfer Agreement, with Maverick Therapeutics, Inc., or Maverick. Under the Asset Transfer Agreement, we transferred one provisional patent application (and any subsequently filed patent applications that claim priority to the provisional patent application) and certain know-how to Maverick solely for use in connection with a specific type of conditionally active T cell engagers having an activation mechanism that we believe is not used by the T cell engagers that are incorporated in the products that we are developing (such permitted use by Maverick, the Maverick Field), and Maverick assumed liabilities from us relating to this transferred intellectual property and other transferred assets. Maverick granted back to us a royalty-free, non-exclusive, sublicenseable license under this transferred intellectual property for use in all fields outside of the Maverick Field, which include all fields in which we are developing products. We further granted Maverick royalty-free, exclusive and non-exclusive licenses to certain other patents that we own, in all cases solely for use in the Maverick Field. In consideration for our transfer and license of such intellectual property, Maverick issued a promissory note to us in the amount of $6.8 million, which we collected in full in January 2017, and all of its outstanding capital stock to us and this stock was distributed to our stockholders (such distribution, the "Distribution"). The Asset Transfer Agreement includes a covenant not to compete, which provides that we will not directly or indirectly research, develop, manufacture or commercialize products in the Maverick Field for four years after the Distribution. The Asset Transfer Agreement is not terminable and all rights transferred or licensed by a party to the other party under the Asset Transfer Agreement are irrevocable. For more information about the distribution of Maverick, see "Management's Discussion and Analysis of Results of Operations—Asset Transfer Agreement with Maverick Therapeutics, Inc."

On November 25, 2018, we received a letter from Maverick's counsel alleging that our ProTriTAC program, as described in a poster we presented at a recent conference, is in the Maverick Field and, accordingly, is subject to the non-compete provision of the Asset Transfer Agreement. The letter demands that we assign to Maverick any patent applications we filed on our ProTriTAC technology, to the extent any such applications are related exclusively to the Maverick Field, and that we immediately cease any and all work on any molecules within the Maverick Field. 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, 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. We will vigorously defend the claims asserted against us.

Agreements with AGC Biologics, Inc.

In October 2015, we entered into the AGC License Agreement with AGC, pursuant to which AGC granted us a non-exclusive, worldwide license under its proprietary Chinese hamster EF-1 protein expression technology, or the CHEF1 Technology, which is used in connection with the manufacturing process for HPN424, HPN536 and our other current preclinical product candidates, or collectively, the Products, for use in connection with our development of the Products, including our clinical trials. Subsequently, in July 2016, we entered into a development and manufacturing services agreement with AGC, or the Manufacturing Agreement, under which AGC conducts cGMP manufacturing of the Products utilizing the CHEF1 Technology. Under the terms of the AGC License Agreement, we have an option, exercisable for each Product, to be granted a non-exclusive license to use the CHEF1 Technology in connection with the commercialization of such Product for human therapeutics or diagnostics. If we exercise such option during a specified period, we will make a one-time upfront payment in the mid tens of thousands of dollars to AGC (solely in connection with the first Product) for such commercial license for the first Product, or if we exercise such commercial option after the expiration of such period, our commercial license will be subject to the payment of a higher option exercise fee.

We retain the right, at any time, to manufacture the Products using the CHEF1 Technology ourselves, or through an affiliate or third party manufacturer for development purposes, and subject to exercising our commercial option, for commercialization purposes.

Under the terms of our agreements with AGC, so long as AGC is the exclusive manufacturer of our Products, we will not owe AGC any milestone or royalty payments to AGC under the AGC License Agreement for the use of the CHEF1 Technology. However, if AGC is no longer our exclusive manufacturer for the Products, and we still use the CHEF1 Technology, we will owe AGC specified development and regulatory milestones of up to $350,000 per Product, and a royalty on net sales of Products of less than 1%, payable for the longer of ten years from first commercial sale of such Product, or the expiration of the patent rights in the CHEF1 Technology covering such Product in the relevant country, subject to a reduction in the event of no patent coverage. If we are not using AGC as our exclusive manufacturer of a given Product, such that we owe a royalty to AGC, we have an option, exercisable at any time prior to the end of the first royalty period in which a royalty is due for such Product, to buy out our royalty obligations in lieu of an ongoing royalty payment, by making a one-time payment to AGC in a dollar amount in the mid-single digit millions.

The Manufacturing Agreement can be terminated by either party in the event of an uncured material breach by the other party, or in the event of insolvency. We have the right to terminate the Manufacturing Agreement or any portion of the services at any time on 60 business days' notice, and AGC has the right to terminate the agreement on 60 business days' notice if it reasonably concludes that the services are not scientifically or technically feasible despite its commercially reasonable efforts and after we and AGC attempt to resolve the scientific or technical problem in good faith. The AGC License Agreement expires on the later of the expiration of all licensed patents or our use of trade secrets relating to the CHEF1 Technology or manufacture of Products. The AGC License Agreement terminates immediately in the event of either party's insolvency, and AGC may terminate the AGC License Agreement for our material breach on 30 days' notice to us.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any GMP manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational product candidates and, if marketing approval is obtained, our commercial products. We believe this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of new product candidates.

To date, we have obtained bulk drug substance, or BDS, for HPN424 and HPN536 from a single-source third-party contract manufacturer, AGC. While any reduction or halt in supply of BDS from this contract manufacturer could limit our ability to develop our product candidates until a replacement contract manufacturer is found and qualified, we believe that we have sufficient BDS to support our current clinical trial programs. We have obtained final drug product for these product candidates from one of two engaged third-party contract manufacturers. We are in the process of developing our supply chain for each of our product candidates and intend to put in place agreements under which our third-party contract manufacturers will generally provide us with necessary quantities of BDS and drug product on a project-by-project basis based on our development and commercial supply needs.

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.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer immunotherapies. Any product candidates that we successfully develop and commercialize will compete with new immunotherapies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immuno-oncology treatments. There are many other companies that have commercialized and/or are developing immuno-oncology treatments for cancer including large pharmaceutical and biotechnology companies, such as AstraZeneca/MedImmune, Bristol-Myers Squibb, Merck, Novartis, Pfizer and Roche/Genentech.

We face significant competition from pharmaceutical and biotechnology companies that target specific tumor-associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell redirecting therapeutics (*e.g.*, T cell engagers), adoptive cellular therapies (*e.g.*, CAR-Ts), antibody drug conjugates, targeted radiopharmaceuticals, targeted immunotoxin and targeted cancer vaccines.

With respect to our lead TriTAC product candidate, HPN424, we are aware of other competing PSMA-targeting clinical stage therapeutics, which include, but are not limited to: T cell engagers from Amgen Inc.; CAR-Ts from Poseida Therapeutics, Inc., Sorrento Therapeutics, Inc. and Tmunity Therapeutics, Inc.; antibody drug conjugates from MedImmune LLC; and radiopharmaceuticals from Endocyte Inc./Novartis AG.

With respect to our second TriTAC product candidate, HPN536, we are aware of other competing MSLN-targeting clinical stage therapeutics, which include, but are not limited to: CAR-T from Novartis AG; antibody drug conjugates from Bayer AG and Bristol-Myers Squibb Company; and other modalities from AbbVie Inc., Bayer AG and Selecta Biosciences Inc.

With respect to our earlier stage pipeline BCMA-targeting TriTAC product candidate HPN217, we are aware of other competing BCMA-targeting clinical stage therapeutics, which include, but are not limited to: T cell engagers from Amgen Inc., Pfizer Inc., Janssen Pharmaceuticals, Inc., Celgene Corp. and Regeneron Pharmaceuticals, Inc.; CAR-Ts from Autolus Therapeutics PLC, bluebird bio, Juno Therapeutics Inc./Celgene Corp., Gilead Sciences Inc., Legend Biotech/Janssen Pharmaceuticals, Inc. and Novartis AG; antibody drug conjugates from GlaxoSmithKline PLC and AstraZeneca/MedImmune LLC; and other modalities from Affimed N.V. and Unum Therapeutics Inc./Seattle Genetics Inc.

With respect to our earlier stage pipeline DLL3-targeting TriTAC product candidate, HPN328 we are aware of other competing DLL3-targeting clinical stage therapeutics. These include, but are not limited to: T cell engagers from Amgen Inc.; CAR-T from Amgen Inc.; and antibody-drug conjugates from AbbVie Inc.

We are also currently developing a pipeline of ProTriTACs and other protease-activated therapeutics that face increasing competition from other biologic prodrug developers, which include, but are not limited to, Akrevia Therapeutics Inc., Amunix Operating Inc., Bayer AG, BioAtla, LLC, Chugai Pharmaceutical Co., Ltd., CytomX Therapeutics, Inc., Genentech, Inc., Nektar Therapeutics, Pandion Therapeutics, Inc., Revitope Oncology, Inc., Roche Holding AG and Seattle Genetics Inc.

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

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics, if required, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual Property

The proprietary nature and protection of our platforms, product candidates and discovery programs, as well as our processes and know-how, are important to our business. We have sought patent protection in the United States and internationally for our TriTAC platform, binding domains and related TriTAC product candidates, as well as the proprietary technology in our ProTriTAC platform and any other inventions to which we have rights, where available and when appropriate. For our product candidates, we generally pursue patent protection covering compositions of matter, methods of use and manufacture. Our policy is to pursue, maintain and defend patent rights in strategic areas, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We may also rely on trade secrets that may be important to the development of our business.

To date, we have spent considerable effort securing intellectual property rights, including rights related to our TriTAC and ProTriTAC platforms, binding domains and specific targets pertaining to our product candidates. Below is a summary of how we view our protections and ongoing prosecution efforts.

TriTAC Platform

For our TriTAC platform, as of December 31, 2018 we own one patent family directed to composition-of-matter coverage and method of use of our core TriTAC platform technology. This family includes one issued U.S. patent, one U.S. non-provisional patent application and over ten foreign application counterparts. The issued patent in this family is projected to expire in 2036, not including any patent term adjustments and any patent term extensions.

In addition to patent protection on our core TriTAC platform technology, as of December 31, 2018, we owned two patent families that relate to the CD3 and albumin binding domains of the TriTAC platform. Specifically, these two families are directed to composition-of-matter, method of use and sequence coverage to our anti-CD3 single-variable fragment, scFv, and anti-albumin single domain antibody, sdAb, binding domains. These patent families include three issued U.S. patents and over twenty foreign application counterparts. The issued patents in these two patent families are projected to expire in 2037, not including any patent term adjustments and extensions.

HPN424

For our lead TriTAC product candidate, HPN424, as of December 31, 2018, we owned three patent families directed to composition-of-matter coverage of HPN424, its PSMA binding domain and related molecules, as well as methods of use for prostate cancer. These patent families include one non-expired U.S. provisional application, two U.S. non-provisional patent applications and two PCT international applications. Any patents issuing from these three patent families are projected to expire in 2037 and 2039, not including any patent term adjustments and extensions. In addition to these three patent families, our patents on our core TriTAC platform technology and our anti-CD3 and albumin binding domains, provide additional patent coverage on HPN424.

HPN536

For our second TriTAC product candidate, HPN536, as of December 31, 2018, we owned two patent families directed to composition-of-matter coverage of HPN536, its MSLN-binding domain and related molecules, as well as methods of use for cancers. These patent families include two U.S. non-provisional patent applications and two PCT international applications. Any patents issuing from these two patent families are projected to expire in 2038, not including any patent term adjustments and extensions. In addition to these two patent families, our patents on our core TriTAC platform technology and our anti-CD3 and albumin binding domains provide additional patent coverage on HPN536.

HPN217

For our pipeline BCMA-Targeting TriTAC product candidate HPN217, as of December 31, 2018, we owned two patent families directed to composition-of-matter coverage of HPN217, its BCMA binding domain and related molecules, as well as methods of use for cancers. These patent families include two U.S. non-provisional patent applications and two PCT international applications. Any patents issuing from these two patent families are projected to expire in 2038, not including any patent term adjustments and extensions. In addition to these two patent families, our patents on our anti-CD3 and albumin binding domains provide additional patent coverage on HPN217.

HPN328

For our pipeline DLL3-targeting TriTAC, HPN328, as of December 31, 2018, we owned two patent families directed to composition-of-matter coverage of this TriTAC, its DLL3 binding domain and related molecules, as well as methods of use for cancers. These patent families include two non-expired U.S. provisional patent applications. Any patents issuing from these two patent families are projected to expire in 2039, not including any patent term adjustments and extensions. In addition to these two patent families, our patents on our anti-CD3 and albumin binding domains provide additional patent coverage on this TriTAC.

ProTriTAC Platform

Our patent portfolio for our ProTriTAC platform is at an early stage, with no issued patents as of December 31, 2018, and includes six patent families directed to composition-of-matter coverage of the ProTriTAC binding moieties, applications in various protein and cellular therapy formats and methods of use thereof. These patent families include eight non-expired U.S. provisional patent applications. Any patents issuing from these six patent families are projected to expire in 2039, not including any patent term adjustments and extensions.

On November 25, 2018, we received a letter from Maverick's counsel alleging that our ProTriTAC program is subject to the non-compete provision of the Asset Transfer Agreement. The letter demands that we assign to Maverick any patent applications we filed on our ProTriTAC technology, to the extent any such applications are related exclusively to the Maverick Field, and that we immediately cease any and all work on any molecules within the Maverick Field (as defined in the Asset Transfer Agreement). 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, 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. See "Business—License and Collaboration Agreements—Asset Transfer Agreement with Maverick Therapeutics, Inc." We will vigorously defend the claims asserted against us.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against any third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those products. While we plan to seek patent term extensions on any of our issued patents in any jurisdiction where these are available, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted and, if granted, the length of such extensions.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. We may therefore not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specified circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development, commercial strategies, drugs or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention.

For more information on these risks and other comprehensive risks related to our intellectual property, see "Risk Factors—Risks Relating to Our Intellectual Property."

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

U.S. Biologics Regulation

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent IRB or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current good manufacturing practices, or cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

In addition to the IND submission process, certain human clinical trials involving recombinant or synthetic nucleic acid molecules had historically been subject to review by the Recombinant DNA Advisory Committee, or RAC, of the National Institutes of Health, or NIH, Office of Biotechnology Activities, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or the NIH Guidelines. On August 17, 2018, the NIH issued a notice in the Federal Register and issued a public statement proposing changes to the oversight framework for gene therapy trials, including changes to the applicable NIH Guidelines to modify the roles and responsibilities of the RAC with respect to human clinical trials of gene therapy products, and requesting public comment on its proposed modifications. During the public comment period, which closes October 16, 2018, the NIH has announced that it will no longer accept new human gene transfer protocols for review as a part of the protocol registration process or convene the RAC to review individual clinical protocols. These trials will remain subject to the FDA's oversight and other clinical trial regulations, and oversight at the local level will continue as set forth in the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase 1.* The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- *Phase 2.* The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3.* The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In 2017, the FDA established a new regenerative medicine advanced therapy, or RMAT, designation as part of its implementation of the 21st Century Cures Act. The RMAT designation program is intended to fulfill the 21st Century Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (i) the drug qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through: the submission of clinical evidence, preclinical studies, clinical trials, patient registries or other sources of real world evidence such as electronic health records; the collection of larger confirmatory datasets; or post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, breakthrough therapy designation, priority review and RMAT designation do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Regulation of Diagnostic Tests

We expect that our drug candidates may require use of a diagnostic to identify appropriate patient populations for our product candidates. These diagnostics, often referred to as companion diagnostics, are medical devices, often in vitro devices, which provide information that is essential for the safe and effective use of a corresponding drug. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. We expect that any companion diagnostic developed for our drug candidates will utilize the PMA pathway.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance, for novel drugs such as our drug candidates, a companion diagnostic device and its corresponding drug should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

Biosimilars and Reference Product Exclusivity

The ACA includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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 licensed 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 licensed. 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 that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute, the federal False Claims Act, HIPAA and similar foreign, federal and state fraud and abuse, transparency and privacy laws.

The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value, including stock options. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. 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. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including federal healthcare programs, that are false or fraudulent. For example, the federal False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. In addition, HIPAA, as amended by HITECH, and their implementing regulations, impose certain requirements on HIPAA covered entities, which include certain healthcare providers, healthcare clearing houses and health plans, and individuals and entities that provide services on their behalf that involves individually identifiable health information, known as business associates, relating to the privacy, security and transmission of individually identifiable health information.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, 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.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. 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.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product. No regulatory authority has granted approval for a personalized cancer immunotherapy based on a vaccine approach, and there is no model for reimbursement of this type of product.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. 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 Act was enacted, which, among other things, removes penalties for not complying with ACA's requirement to carry health insurance, known as the "individual mandate", effective January 1, 2019. 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.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers. 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.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the 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 At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, the Right to Try Act, which was enacted on May 30, 2018, 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.

Employees

As of February 28, 2019, we had 45 full time employees, 36 of whom were engaged in research and development activities and nine of whom were engaged in general and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated as a Delaware corporation in March 2015. Our principal executive offices are located at 4000 Shoreline Court, Suite 250, South San Francisco, California 94080, and our telephone number is (650) 443-7400. Our website address is www.harpoontx.com. The information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider any information contained on, or that can be accessed through, our website as part of this Annual Report on Form 10-K.

"Harpoon Therapeutics," "Harpoon," the Harpoon logo, TriTAC, ProTriTAC and our other registered or common law trademarks, trade names or service marks appearing in this report are owned by us. This report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report, including logos, artwork and other visual displays, generally appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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 $27.4 million, $16.8 million, and $11.4 million for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, we had an accumulated loss of $62.6 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 mCRPC;
- initiate a 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 initial public offering 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, initiate a 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 at least 12 months from the date of this Annual Report. 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 our planned 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 and in different geographical areas. 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 we intend to initiate a 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 Securities and Exchange Commission, or 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 February 28, 2019, we had 45 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, plan to initiate 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. We also plan to initiate a Phase 1/2a trial of HPN536, which targets MSLN. MSLN is also 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, or REMS, 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, which could generate adverse events that may cause us to delay the trial or halt further development. As of December 31, 2018, seven patients were enrolled in the clinical trial, a very small number relative to the number of patients required for a full clinical development program. We have observed three patients reporting grade 2 rigors or fevers and one patient reporting a grade 3 CRS event (rigors and hypotension). None of these patients discontinued the trial due to adverse events, and all were re-treated (the patient who had reported a grade 3 CRS event was given Dexamethasone prior to being re-treated) after one week without further complications. While these adverse events have not had a material impact on patient enrollment in this clinical trial, 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 will 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 expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials 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, or the FDCA, 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, or AMP;
- 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 bone marrow transplantation, 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. 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. See "Business—License and Collaboration Agreements—Asset Transfer Agreement with Maverick Therapeutics, Inc." We will vigorously defend the claims asserted against us.

However, in the event that the injunction is granted, we would be unable to proceed with development of our ProTriTAC platform until the injunction is lifted, if ever. 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 initial public offering in February 2018 at a price of $14.00 per share, the reported high and low sales prices of our common stock has ranged from $13.25 to $17.85 through February 28, 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 commencement, enrollment or results of our Phase 1 trial of HPN424, our planned Phase 1/2a trial of HPN536, 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;
- 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;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- 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 February 28, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates owned approximately 61.2% 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 February 28, 2019, we had outstanding 24,339,830 shares of common stock. The resale of 18,568,524 shares, or 76% 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 initial public offering. 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 initial public offering. 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. For more information, see “Shares Eligible for Future Sale.”

The holders of approximately 16,618,448 shares, or 68% 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 initial public offering.

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 Global Select Market 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 this or 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 have 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 initial public offering. 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 initial public offering.

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, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We early adopted ASU 2014-09, *Revenue from Contracts with Customers* (Accounting Standards Codification Topic 606), ASU 2016-09, *Stock Compensation*—Improvements *to Employee Share-Based Payment Accounting,* and ASU 2018-07*, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting,* 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. 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.

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, or the Dodd-Frank Act, the listing requirements of The NASDAQ Global Select Market, or 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, each of which will be in effect immediately after the completion of our initial public offering, 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 will be 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, or the DGCL, 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 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We currently sublease approximately 13,522 square feet of office and laboratory space in South San Francisco, California under a sublease that expires in April 2020. In August 2018, we executed an eight-year lease agreement for approximately 34,988 square feet of office and laboratory space in South San Francisco, California. The rental term for the lease will commence on the later date of (i) the date the premises is ready for occupancy or (ii) July 1, 2019. The lease expires on the 8th anniversary of the commencement date. Under the lease agreement we are given an option to extend the lease term for an additional period of 8 years, when certain conditions are met. We believe this space is sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

Item 3. 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 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, 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. 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 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for the Registrant's Common Equity, related stockholder matters and issuer purchases of equity securities

Market Information for Common Stock

Our common stock has been listed on The NASDAQ Global Select Market under the symbol "HARP" since February 8, 2019. Prior to that, there was no public trading market for our common stock.

Holders of Record

As of February 28, 2019, there were approximately 45 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital 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. Any future determination to pay dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our capital stock may be limited by the terms of any future debt or preferred securities.

Securities Authorized for Issuance under Equity Compensation Plans

The information called for by this item regarding equity compensation plans is incorporated by reference to the information set forth in PART III Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

From January 1, 2018 through December 31, 2018, we sold and issued the following unregistered securities, which share numbers have been adjusted, as appropriate, to reflect the 4.9175-for-one reverse stock split which became effective on January 28, 2019:

(1) We granted stock options to purchase an aggregate of 1,762,147 shares of common stock with a weighted-average exercise price of $2.06 per share to a total of 52 employees, directors and consultants. Options to purchase an aggregate of 198,943 shares of common stock have been exercised for aggregate consideration of approximately $0.5 million.

(2) We issued an aggregate of 3,128,540 shares of Series B convertible preferred stock (convertible into 3,128,540 shares of common stock) in July 2018 to 7 accredited investors at a price of $6.39 per share for aggregate consideration of approximately $20.0 million. In connection with the completion of our initial public offering, all 3,128,540 shares of Series B convertible preferred stock automatically converted into an equivalent number of shares of our common stock.

(3) We issued an aggregate of 6,499,935 shares of Series C convertible preferred stock (convertible into 6,499,935 shares of common stock) in November 2018 to 17 accredited investors at a price of $10.77 per share for aggregate consideration of approximately $70.0 million. In connection with the completion of our initial public offering, all 6,499,935 shares of Series C convertible preferred stock automatically converted into an equivalent number of shares of our common stock.

The offers, sales and issuances of the securities described in this Item 5 were deemed to be exempt from registration under the Securities Act under either (i) Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701 or (ii) Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) as transactions by an issuer not involving any public offering. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates and instruments issued in such transactions.

Use of Proceeds from Registered Securities

On February 7, 2019, our Registration Statement on Form S-1 (File No. 333-229040) relating to the initial public offering of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 5,769,201 shares of our common stock at a price of $14.00 per share for aggregate cash proceeds of approximately $70.7 million, net of underwriting discounts and commissions and offering costs, which includes the partial exercise by the underwriters of their option to purchase additional shares.

There has been no material change in the expected use of the net proceeds from our initial public offering, as described in our final prospectus filed with the SEC on February 8, 2019 pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data.

We have derived the following selected statements of operations data for the years ended December 31, 2018, 2017 and 2016 and the selected balance sheet data as of December 31, 2018 and 2017 from our audited financial statements included elsewhere in this report. The selected balance sheet data as of December 31, 2016 is derived from our audited financial statements which are not included in this report.

Our historical results are not necessarily indicative of the results that may be expected in any future period. You should read this data together with the information under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this report.

	Year Ended December 31,		
	2018	2017	2016
	(in thousands, except per share numbers)		
Statement of operations data:			
Revenue			
Collaboration and license revenue	$ 4,750	$ 708	$ —
Total revenue	4,750	708	—
Operating expenses			
Research and development	26,368	13,622	7,778
General and administrative	6,106	3,614	3,369
Total operating expenses	32,474	17,236	11,147
Loss from operations	(27,724)	(16,528)	(11,147)
Interest income	395	78	6
Interest expense	—	(285)	(261)
Other expense	(37)	(95)	(4)
Net loss	$ (27,366)	$ (16,830)	$ (11,406)
Net loss per share, basic and diluted(1)	(25.65)	(18.81)	(21.61)
Weighted-average shares used in computing net loss per share, basic and diluted (1)	1,066,877	894,901	527,931

(1) See Notes 2 and 11 to our audited financial statements included elsewhere in this report for an explanation of the calculations of our basic and diluted net loss per share and the weighted-average number of shares used in computing the per share amounts.

	As of December 31,		
	2018	2017	2016
	(in thousands)		
Balance sheet data:			
Cash and cash equivalents	$ 89,493	$ 29,423	$ 985
Working capital(1)	78,275	22,731	4,432
Total assets	102,580	31,872	8,384
Convertible preferred stock	129,577	39,841	14,926
Accumulated deficit	(62,591)	(35,225)	(18,395)
Total stockholders' deficit	(53,479)	(26,943)	(10,444)

(1) We define working capital as current assets less current liabilities. See our audited financial statements and related notes included elsewhere in this report for further details regarding our current assets and current liabilities.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" and "Risk Factors" for a discussion of forward-looking statements and important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements.

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.

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 and payments received under our discovery collaboration agreement with AbbVie.

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 $27.4 million, $16.8 million and $11.4 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $62.6 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 our initial public offering 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 initial public offering 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 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.

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, $4.3 million and $0.7 million of revenue was recognized during the years ended 2018 and 2017, respectively, and, as of December 31, 2018, we had $12.0 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 of directors, is the interim Chief Executive Offer and Chairman of the board of directors of Werewolf. Dr. Baeuerle, a member of our board of directors, 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.

For the year ended December 31, 2018, $0.5 million of revenue under the Werewolf Agreement related to the upfront payment has been recognized in the accompanying statement of operations and comprehensive loss. Royalties on net sales will be recognized when the underlying sales occur. No royalty revenue was recognized under the Werewolf Agreement as of December 31, 2018.

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 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 Years Ended December 31, 2018 and 2017

	Year Ended December 31,			
	2018	2017	Change ($)	Change (%)
	(dollars in thousands)			
Revenue:				
Collaboration revenue	$ 4,750	$ 708	$ 4,042	571%
Total revenue	4,750	708	4,042	571%
Operating expenses:				
Research and development	26,368	13,622	12,746	94%
General and administrative	6,106	3,614	2,492	69%
Total operating expenses	32,474	17,236	15,238	88%
Loss from operations	(27,724)	(16,528)	11,196	68%
Interest income	395	78	317	406%
Interest expense	—	(285)	(285)	*
Other expense	(37)	(95)	(58)	61%
Net loss	$ (27,366)	$ (16,830)	$ 10,536	63%

* Not meaningful

Revenue

Collaboration and license revenue of $4.8 million for the year ended December 31, 2018 consisted of the amortized portion of the deferred $17.0 million upfront payment received by us in October 2017 under the Collaboration Agreement, and the $0.5 million upfront payment received by us in May 2018 under the Werewolf Agreement. Collaboration revenue of $0.7 million for the year ended December 31, 2017 consisted entirely of the amortized portion of the deferred $17.0 million upfront payment received by us in October 2017 under the Collaboration Agreement.

Research and Development

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

	Year Ended December 31,	
	2018	2017
	(In thousands)	
Product and clinical development	$ 8,504	$ 4,287
Research and technology services	3,401	772
Laboratory supplies and equipment	1,828	1,420
Pharmacology services	1,054	989
Personnel-related	5,830	3,050
Facility and other allocated expenses	3,366	2,206
Consulting	2,385	898
Total research and development expenses	$ 26,368	$ 13,622

Research and development expenses increased by $12.7 million, or 94%, in 2018 compared to 2017. The increase was primarily due to a $4.2 million increase in pharmacology services and product and clinical development expense due to development of four identified product candidates, including conducting preclinical studies and manufacturing runs to support preparation for potential NDA filings for our lead product candidates, a $2.6 million increase in research and technology services due to an increase in experimental studies, a $2.8 million increase in personnel-related expenses due to an increase in headcount, a $1.5 million increase in consulting expenses due to increased activity related to project management, quality assurance and regulatory matters, a $1.2 million increase in facility and other allocated expenses related to the new lease entered into in March 2017, and a $0.4 million increase in laboratory supplies and equipment to support increased activity related to all of our product candidates.

General and Administrative

General and administrative expenses increased by $2.5 million, or 69%, in 2018 compared to 2017. The increase was primarily due to a $1.4 million increase in consulting and accounting services related to quarterly reviews and year-end audits associated with preparations for our initial public offering, $0.2 million increase in patent legal costs, and $0.9 million increase in personnel-related expenses due to an increase in headcount.

Interest Income

Interest income was $0.4 million during the year ended December 31, 2018 and consisted of interest earned on our cash deposit accounts during the period.

Interest Expense

Interest expense in 2017 pertained to interest on convertible notes. There were no convertibles notes outstanding during the year ended December 31, 2018.

Other Expense

Other expense did not significantly fluctuate period over period.

Comparison of the Years Ended December 31, 2017 and 2016

	Year Ended December 31,			
	2017	2016	Change ($)	Change (%)
	(dollars in thousands)			
Revenue:				
Collaboration revenue	$ 708	$ —	$ 708	*
Total revenue	708	—	708	*
Operating expenses:				
Research and development	13,622	7,778	5,844	75%
General and administrative	3,614	3,369	245	7%
Total operating expenses	17,236	11,147	6,089	55%
Loss from operations	(16,528)	(11,147)	5,381	48%
Interest income	78	6	72	*
Interest expense	(285)	(261)	24	9%
Other expense	(95)	(4)	91	*
Net loss	$ (16,830)	$ (11,406)	$ 5,424	48%

* Not meaningful

Revenue

Collaboration revenue of $0.7 million for the year ended December 31, 2017 consisted entirely of the amortized portion of the deferred $17.0 million upfront payment received by us in October 2017 under the Collaboration Agreement. We had no collaboration and license revenue for the year ended December 31, 2016.

Research and Development

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

	Year Ended December 31,	
	2017	2016
	(In thousands)	
Product and clinical development	$ 4,287	$ 694
Research and technology services	772	795
Laboratory supplies and equipment	1,420	1,230
Pharmacology services	989	116
Personnel-related	3,049	2,825
Facility and other allocated expenses	2,207	1,649
Consulting	898	469
Total research and development expenses	$ 13,622	$ 7,778

Research and development expenses increased by $5.8 million, or 75%, in 2017 compared to 2016. The increase was primarily due to a $4.6 million increase in costs supporting the continuing product and clinical development of our four identified product candidates and pharmacology services, including conducting preclinical studies and manufacturing runs to support preparation for potential IND filings for our lead product candidates. The remaining increase was primarily due to increases in facilities expenses of $0.6 million, consulting expenses of $0.4 million and personnel-related expenses of $0.2 million, all of which were the result of increased activities associated with the continued advancement of our product candidate pipeline.

General and Administrative

General and administrative expenses were primarily related to personnel-related expenses and did not significantly fluctuate period over period. There was no significant change in headcount between the periods.

Interest Income

Interest income was $0.1 million during the year ended December 31, 2017 and consisted of interest earned on our cash deposit accounts during the period.

Interest Expense

Interest expense in 2017 and 2016 pertained to interest on convertible notes and did not significantly fluctuate period over period.

Other Expense

Other expense did not significantly fluctuate period over period.

Liquidity and Capital Resources

Liquidity

Since our inception and through December 31, 2018, we have financed our operations primarily through the issuance of convertible notes, the sale of convertible preferred stock, and upfront payments received by us under the Collaboration Agreement and Werewolf Agreement. As of December 31, 2018, we had $89.5 million in cash and cash equivalents, an accumulated deficit of $62.6 million and working capital of $78.3 million. In February 2019, we closed on the initial public offering of our common stock on the NASDAQ Global Select Market, 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. 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 out 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 and cash equivalents, will be sufficient to fund our planned operations for at least the next 12 months from the issuance date of these financials. 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

	Year Ended December 31,		
	2018	2017	2016
	(In thousands)		
Net cash (used in) provided by:			
Operating activities	$ (27,126)	$ 1,714	$ (10,794)
Investing activities	(663)	4,475	(553)
Financing activities	88,326	22,249	9,985
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 60,537	$ 28,438	$ (1,362)

Cash Flows from Operating Activities

In 2018, cash used in operating activities was $27.1 million, which consisted of a net loss of $27.4 million and a net change of $1.1 million in our net operating assets and liabilities, partially offset by $1.3 million in non-cash charges. The non-cash charges consisted of stock-based compensation of $0.7 million and depreciation and amortization of $0.6 million. The change in operating assets and liabilities was primarily due to a decrease in deferred revenue of $4.3 million resulting from the recognition of collaboration revenue, an increase in accounts payable and accrued liabilities of $3.6 million, and an increase in prepaid expenses and other current assets of $0.5 million resulting from the timing of payments made for research and development activities.

In 2017, cash provided by operating activities was $1.7 million, which consisted of a net loss of $16.8 million, partially offset by $1.0 million in non-cash charges and a net change of $17.5 million in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of $0.4 million, depreciation and amortization of $0.4 million and accrued interest on convertible notes payable of $0.2 million. The change in operating assets and liabilities was primarily due to an increase in deferred revenue of $16.3 million resulting from the upfront payment received by us under the Collaboration Agreement, an increase in accounts payable of $0.8 million due to an increase in the level of research and development expenses and a decrease in prepaid expenses and other current assets of $0.3 million resulting from the timing of payments made for research and development activities.

In 2016, cash used in operating activities was $10.8 million, which consisted of a net loss of $11.4 million, partially offset by $0.5 million in non-cash charges and a net change of $0.1 million in our net operating assets and liabilities. The non-cash charges primarily consisted of depreciation and amortization of $0.2 million, accrued interest on convertible notes payable of $0.2 million and stock-based compensation of $0.1 million. The change in our operating assets and liabilities was primarily due to an increase in accounts payable of $0.6 million resulting from a higher level of research and development activities, partially offset by a decrease in accrued liabilities of $0.3 million due to the final payment under a research license agreement and an increase in prepaid expenses and other current assets of $0.3 million resulting from the timing of payments made for research and development activities.

Cash Flows from Investing Activities

In 2018, cash used in investing activities of $0.7 million related to purchases of property and equipment consisting primarily of laboratory equipment.

In 2017, cash provided by investing activities of $4.5 million was related to $6.8 million in gross proceeds received from the payment by Maverick of its outstanding promissory note, partially offset by $2.3 million in purchases of property and equipment consisting primarily of laboratory equipment.

In 2016, cash used in investing activities of $0.6 million related to the purchase of property and equipment.

Cash Flows from Financing Activities

In 2018, cash provided by financing activities of $88.3 million was related primarily to $69.8 million in net cash proceeds received from the November 2018 issuance of our Series C convertible preferred stock, $20.0 million in net cash proceeds received from the July 2018 issuance of our Series B convertible preferred stock as a result of our IND filing for HPN424, and $0.2 million in proceeds from the issuance of common stock upon the exercise of stock options, partially offset by $1.7 million in deferred offering costs related to our initial public offering.

In 2017, cash provided by financing activities of $22.2 million was related primarily to $19.7 million in net proceeds received from the issuance of our Series B convertible preferred stock and $2.5 million in net cash proceeds received from the issuance of convertible notes. These convertible notes were settled in 2017 in shares of our Series B convertible preferred stock.

In 2016, cash provided by financing activities of $10.0 million was related to $7.4 million in net proceeds from the issuance of our Series A convertible preferred stock, $2.5 million in net cash proceeds received from the issuance of convertible notes and $0.1 million in proceeds from the issuance of common stock upon the exercise of stock options. The outstanding convertible notes were settled in 2016 and 2017 in shares of our Series A and Series B convertible preferred stock.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2018:

	Payments due by period				
	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	Total
	(In thousands)				
Operating lease obligations	$ 1,308	$ 7,975	$ 5,549	$ 7,433	$ 22,265
Total	$ 1,308	$ 7,975	$ 5,549	$ 7,433	$ 22,265

The obligations noted above represent operating lease obligations related to our currently occupied premises at 4000 Shoreline Court in South San Francisco, California that commenced in March 2017 and expires in April 2020. 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 anticipate moving into the new facility on June 1, 2019 and the lease expires eight years from that date. We estimate 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 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. 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 initial public offering. See “Item 13-Certain Relationships and Related Transactions, and Director Independence—Royalty Transfer Agreement with MPM Oncology Charitable Foundation and UBS Optimus Foundation.”

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. See "Business—License and Collaboration Agreements—Agreements with AGC Biologics, Inc."

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.

Quantitative and Qualitative Disclosures about Market Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of $89.5 million and $29.4 million as of December 31, 2018 and 2017, respectively. We generally hold our cash in interest-bearing money market accounts. Historical fluctuations in interest rates have not been significant for us. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Critical Accounting Polices and Estimates

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

While our significant accounting policies are described in the notes to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Revenue Recognition

Effective January 1, 2017, we early adopted on a full retrospective basis Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, or Topic 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. In accordance with ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform 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 we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods and services we transfer to the customer. At contract inception, we assess the goods or services promised within each contract that falls under the scope of Topic 606, determine those that are performance obligations and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

We enter into corporate collaborations under which we may obtain upfront license fees, research and development funding, and development, regulatory and commercial milestone payments and royalty payments. Our 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 our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize 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, we utilize 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, upfront fees. We evaluate the measure of proportional performance each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.
- *Milestone Payments.* At the inception of each arrangement that includes development, regulatory or commercial milestone payments, we evaluate 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 us to use the same approach for all contracts. We expect 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 our 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. We recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability or achievement of each such milestone and any related constraint, and if necessary, adjust our 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, we recognize revenue when the related sales occur. To date, we have not recognized any royalty revenue resulting from our 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 we perform our obligations under these arrangements. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional.

Research and Development Expenses and Accrued Research and Development Costs

We expense research and development costs as incurred. Research and development expenses consist of personnel costs for our research and product development employees. Also included are non-personnel costs such as professional fees payable to third parties for preclinical and preclinical studies, clinical trials and research services, laboratory supplies and equipment maintenance and depreciation, intellectual property licenses and other consulting costs. We estimate 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 our behalf. We estimate these expenses based on discussions with management and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. We record the estimated costs of research and development activities based upon the estimated amount services provided but not yet invoiced, and include these costs in development expenses. We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements established with our third-party service provides under the service agreements. We make significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, we adjust our accrued liabilities. We have not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from our estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our 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

We maintain a stock-based compensation plan as a long-term incentive for employees, consultants and members of our board of directors. The plan allows for the issuance of non-statutory options, or 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. Our fair-value-based measurements of awards to employees and directors as of the grant date utilize the single-option award-valuation approach, and we use 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 us 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 our common stock, the related risk-free interest rate and the expected dividend. We have elected to recognize forfeitures of share-based payment awards as they occur.

Effective January 1, 2018, we early adopted ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). 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, we record 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. For stock-based awards issued to non-employees prior to January 1, 2018, we recorded expense related to stock options based on the fair value of the options calculated using the Black-Scholes option-pricing model over the service performance period.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

- *Expected term.* The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.
- *Expected volatility*. Since we have been privately held and do not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.
- *Risk-free interest rate*. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.
- *Expected dividend*. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

Fair Value of Common Stock

Prior to our initial public offering in February 2019, the fair values of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. Given the absence of a public trading market for our common stock prior to our February 2019 initial public offering, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; our actual operating results and financial performance; progress of our research and development efforts; conditions in the industry and economy in general; the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock; the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions; equity market conditions affecting comparable public companies; the lack of marketability of our common stock and the results of independent third-party valuations. Valuations of our common stock were prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

For our valuations performed prior to December 31, 2018, we used the OPM Backsolve method to estimate the fair value of our common stock. In an option pricing method, or OPM, framework, the backsolve method for inferring the equity value implied by a recent financing transaction involves making assumptions for the expected time to liquidity, volatility and risk-free rate and then solving for the value of equity such that value for the most recent financing equals the amount paid. Furthermore, as of each of the valuation dates prior to December 31, 2018, we were at an early stage of development and future liquidity events were difficult to forecast. We applied a discount for lack of marketability to account for a lack of access to an active public market.

Subsequent to the completion of our initial public offering in February 2019, our board of directors determines the fair value of our common stock based on the closing price of our common stock as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Income Taxes

We provide for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards, and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. We record a valuation allowance to reduce our deferred tax assets to reflect the net amount that we believe is more likely than not to be realized. Realization of our deferred tax assets is dependent on the generation of future taxable income, the amount and timing of which are uncertain. The valuation allowance requires an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. Based upon the weight of available evidence at December 31, 2018, we continue to maintain a full valuation allowance against all of our deferred tax assets after management considered all available evidence both positive and negative, including but not limited to our historical operating results, income or loss in recent periods, cumulative income in recent years, forecasted earnings, future taxable income, and significant risk and uncertainty related to forecasts.

We account for uncertain tax positions in accordance with ASC 740-10, Accounting for Uncertainty in Income Taxes. We recognize the tax effects of an uncertain tax position only if it is more likely than not to be sustained based solely on its technical merits as of the reporting date and only in an amount more likely than not to be sustained upon review by the tax authorities. evaluate uncertain tax positions on a quarterly basis and adjust the liability for changes in facts and circumstances, such as new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, significant amendment to an existing tax law, or resolution of an examination. To the extent that the final tax outcome of these matters is different than the amounts recorded, such differences will impact the income tax provision in the period in which such determination is made. The resolution of our uncertain income tax positions is dependent on uncontrollable factors such as law changes, new case law, and the willingness of the income tax authorities to settle, including the timing thereof and other factors. Although we do not anticipate significant changes to our uncertain income tax positions in the next twelve months, items outside of our control could cause our uncertain income tax positions to change in the future, which would be recorded in our statements of operations. Interest and/or penalties related to income tax matters are recognized as a component of income tax expense.

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act, or the Tax Act that instituted fundamental changes to the taxation of multinational corporations. The Tax Act includes changes to the taxation of foreign earnings by implementing a dividend exemption system, expansion of the current anti-deferral rules, a minimum tax on low-taxed foreign earnings and new measures to deter base erosion. The Tax Act also includes a permanent reduction in the corporate tax rate to 21%, repeal of the corporate alternative minimum tax, expensing of capital investment, and limitation of the deduction for interest expense. Furthermore, as part of the transition to the new tax system, a one-time transition tax is imposed on a U.S. shareholder's historical undistributed earnings of foreign affiliates. Although the Tax Act is generally effective January 1, 2018, GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017.

As a result of the impacts of the Tax Act, the SEC provided guidance that allows the Company to record provisional amounts for those impacts, with the requirement that the accounting be completed in a period not to exceed one year from the date of enactment. Based on provisions of the Tax Act, the Company remeasured its deferred tax assets and liabilities to reflect the lower statutory tax rate. However, since the Company established a valuation allowance to offset its deferred tax assets, there was no impact to the effective tax rate, as any changes to deferred taxes would be offset by the valuation allowance. The deferred tax remeasurement was provisional and was subject to revision as the Company completes its analysis of the Tax Act, collects and prepares necessary data and interprets any additional guidance issued by standard-setting bodies. The Company has completed its analysis and determined no adjustment is required related to the tax effects of the Tax Act in 2018.

As of December 31, 2018 our total deferred tax assets were $14.3 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses, or NOLs. Utilization of NOLs may be limited by the "ownership change" rules, as defined in Section 382 of the Code. Similar rules may apply under state tax laws. Our ability to use our remaining NOLs may be further limited if we experience an ownership change in connection with future offerings or as a result of future changes in our stock ownership.

Recent Accounting Pronouncements

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

Emerging Growth Company Status

We are an emerging growth company, as defined in 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. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We early adopted ASU 2014-09, *Revenue from Contracts with Customers* (Accounting Standards Codification Topic 606), ASU 2016-09, *Stock Compensation—Improvements to Employee Share-Based Payment Accounting*, and ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting,* as the JOBS Act does not preclude an emerging growth company from early adopting a new or revised accounting standard earlier than the time that such standard applies to private companies. In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *(Topic 842), Leases*. For public entities, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. We are considering early adoption of this standard in the first half of 2019 and are currently evaluating the effect the new guidance will have on our financial statements. 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 initial public offering, (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 7A. Quantitative and Qualitative Disclosures about Market Risk.

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. We are exposed to market risks in the ordinary course of our business. Our market risk exposure is primarily the result of fluctuations that may cause the principal amount of these assets to fluctuate. We held cash and cash equivalents of $89.5 million and $29.4 million as of December 31, 2018 and 2017, respectively. We generally hold our cash in interest-bearing money market accounts. Historical fluctuations in interest rates have not been significant for us. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Item 8. Financial Statements and Supplemental Data

The information required to be filed in this item appears under "Exhibits, Financial Statement Schedules" in Part IV, Item 15 of this Annual Report on Form 10-K and is set forth on pages F-1 to F-41.

The following financial statements of the registrant, related notes and report of independent registered public accounting firm are set forth beginning on page F-1 of this report

	Page
Report of Independent Registered Public Accounting Firm	F-2
Financial Statements:	
Balance Sheets	F-3
Statements of Operations and Comprehensive Loss	F-4
Statements of Convertible Preferred Stock and Stockholders' Deficit	F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	F-7

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our chief executive officer and our chief financial officer have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, 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 SEC rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

Except as described under "Remediation Efforts on Previously Identified Material Weakness," below 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 year ended December 31, 2018 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.

Management's Annual Report on Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Remediation Efforts on Previously Identified Material Weakness

In connection with the audit of our 2016 and 2017 financial statements, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting. The material weakness was 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. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. If we fail to establish and maintain effective internal control over financial reporting in the future, our operating results and our ability to operate our business could be harmed.

During the year ended December 31, 2018, we implemented measures designed to improve our internal control over financial reporting to remediate 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. These additional resources and procedures were designed to enable us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to enhance our internal control procedures. After completing our assessment of the effectiveness of the new measures, we concluded that we have remediated the previously identified material weakness as of December 31, 2018. 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, 2018, 2017, or 2016 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot provide assurance that we have identified all, or that we will not in the future have additional, material weaknesses.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Set forth below are the names, ages and positions of our current executive officers and directors as of December 31, 2018:

Name	Age	Position(s)
Executive Officers:		
Gerald McMahon, Ph.D.	64	President, Chief Executive Officer and Director
Georgia Erbez	52	Chief Financial Officer
Natalie Sacks, M.D.	54	Chief Medical Officer
Holger Wesche, Ph.D.	51	Chief Scientific Officer
Non-Employee Directors:		
Luke Evnin, Ph.D. (2)	55	Chairman of our Board of Directors
Patrick Baeuerle, Ph.D.	61	Director
Mark Chin(1),(2),(3)	37	Director
Jonathan Drachman, M.D.(3)	57	Director
Julie Eastland(1),(3)	54	Director
Ron Hunt(2)	54	Director
Scott Myers(1)	52	Director

(1) Member of our audit committee
(2) Member of our compensation committee
(3) Member of our nominating and corporate governance committee

Executive Officers

Gerald McMahon, Ph.D. has served as our President, Chief Executive Officer and a member of our board of directors since December 2016. From May 2012 to its acquisition by Celldex Therapeutics, Inc. in November 2016, Dr. McMahon was the President and Chief Executive Officer of Kolltan Pharmaceuticals, Inc., an oncology biologics company where he played a key role in the development of the business. From October 2010 to May 2012, he served as Senior Vice President of Oncology at MedImmune LLC, a subsidiary of AstraZeneca. Prior to MedImmune, he served as the Chairman and Chief Executive Officer of NeoRx Corporation, a pharmaceutical company, and as a venture partner at Bay City Capital, a venture capital firm, and in executive leadership roles at Poniard Pharmaceuticals and SUGEN (acquired by Pfizer), both biopharmaceutical companies, where he was a key player in the development and commercialization of innovative oncology drugs Sutent and Palladia. Dr. McMahon earned a B.S. in Biology and a Ph.D. in Biochemistry from the Rensselaer Polytechnic Institute. He holds an academic appointment at the Yale Comprehensive Cancer Center at Yale University, and previously held post-graduate appointments at Tufts University School of Medicine, department of hematology and oncology at the New England Medical Center, and the Massachusetts Institute of Technology. Our board of directors believes that Dr. McMahon's expertise and experience as our President and Chief Executive Officer, his depth and expertise in the life sciences industry, his experience in leadership, scientific innovation and creative deal-making and his educational background provide him with the qualifications and skills to serve on our board of directors.

Georgia Erbez has served as our Chief Financial Officer since October 2018. From September 2016 to May 2018, Ms. Erbez served as the Chief Business Officer and Chief Financial Officer at Zosano Pharma Corp., a pharmaceutical company, after serving as its Interim Chief Financial Officer from June 2016 to September 2016. Ms. Erbez also served as the Senior Vice President and Chief Financial Officer at Revolution Medicines, a biotechnology company, from May 2016 to September 2016, the Executive Vice President and Chief Financial Officer at Asterias Biotherapeutics, a biotechnology company, from November 2015 to March 2016, and the Chief Financial Officer at Raptor Pharmaceuticals, a pharmaceutical company, from September 2012 to November 2014. From November 2014 to October 2018, Ms. Erbez was also a Managing Director at Axiom Financial Partners, a life sciences consulting firm. Ms. Erbez currently serves as a member of the board of directors of AltiBio, Inc. and Artelo Biosciences Inc. (OTCMKTS: ARTL). Ms. Erbez holds a B.A. in International Relations, with an emphasis in Economics, from the University of California, Davis.

Natalie Sacks, M.D. has served as our Chief Medical Officer since October 2018. From September 2016 to September 2018, Dr. Sacks was the Chief Medical Officer at Aduro Biotech, Inc., an immunotherapy company. Prior to Aduro, she was Vice President of Clinical Development at Onyx Pharmaceuticals (acquired by Amgen), a biopharmaceutical company, from April 2011 to February 2014, where she played a key role in the development and approval of Kyprolis, an FDA-approved therapy for the treatment of relapsed or refractory multiple myeloma, and in business development strategy. From September 2009 to March 2011, she served as

Vice President of Clinical Research for Exelixis, Inc., a genomics pharmaceutical company. From November 2002 to April 2009, Dr. Sacks served as Vice President of Clinical Development at Cell Genesys, Inc., an immuno-oncology company. Dr. Sacks currently serves as a member of the board of directors of the public company Zymeworks, Inc. (NYSE: ZYME) and Caribou Biosciences, Inc. Dr. Sacks has served in a variety of research and analytical roles at academic institutions and companies, including Massachusetts General Hospital, Medical College of Pennsylvania, and ICI-Stuart Pharmaceuticals. From 2004 to 2016, Dr. Sacks has served as an assistant clinical professor of medicine in the Division of Hematology/Oncology at the University of California, San Francisco. She holds a B.A. in Mathematics from Bryn Mawr College, an M.S. in Biostatistics from Harvard University School of Public Health and an M.D. from the University of Pennsylvania School of Medicine.

Holger Wesche, Ph.D. has served as our Chief Scientific Officer since October 2018. From January 2017 to October 2018, he served as our Senior Vice President of Research, and from April 2015 to January 2017, he served as our Vice President of Research. From March 2013 to April 2015, Dr. Wesche was a Scientific Director at Amgen, a biopharmaceutical company, where he was responsible for cross-functional organization and coordination of the next generation BiTE platform, a T cell engaging antibody platform. Dr. Wesche's experience has focused on target validation, drug discovery and drug development as well as multi-site project management in the fields of oncology and inflammation, and he has led several drug discovery projects through pre-clinical development. Dr. Wesche is also the co-author of numerous publications and several U.S. patents. Dr. Wesche holds an M.S. equivalent in Biochemistry, Biophysical Chemistry and Immunology and earned a Ph.D. equivalent for his work on the IL-1 receptor complex, each from the University of Hannover in Germany.

Non-employee Directors

Luke Evnin, Ph.D. co-founded our company and has served as the Chairman of our board of directors since our inception in 2015. Since October 2017, Dr. Evnin has served as the interim Chief Executive Officer of Werewolf. Prior to co-founding our company, Dr. Evnin co-founded MPM Capital, an early-stage life sciences venture investing firm, in 1997, where he is currently a Managing Director. Prior to MPM Capital, Dr. Evnin spent seven years as a venture capitalist at Accel Partners, a venture capital firm, including four years as general partner, where he focused on emerging healthcare companies. Dr. Evnin has previously served on the board of the companies Syndax Pharmaceuticals, Inc. (NASDAQ: SNDX), Enteromedics Inc, Epix Medical, Inc., Intercell AG, Metabasis Therapeutics, Inc. (acquired by Ligand Pharmaceuticals, Inc.), Oscient Pharmaceuticals Corp., Pacira Pharmaceuticals, Inc., Restore Medical, Inc. (acquired by Medtronic, Inc.), Sonic Innovations, Inc. and Signal Pharmaceuticals, Inc. (acquired by Celgene Corporation). He also serves on a number of private company boards, including as the Chairman of the board of directors of Werewolf and of the Scleroderma Research Foundation, as board advisor for the Lewis-Sigler Institute for Quantitative Genomics at Princeton University and as a director for QB3 and Mission Bay Capital at the University of California, San Francisco. Dr. Evnin holds an A.B. in molecular biology from Princeton University and a Ph.D. in Biochemistry from the University of California, San Francisco. Our board of directors believes that Dr. Evnin's perspective and experience as our co-founder, his depth and expertise in the life sciences and venture capital industries, and his educational background provide him with the qualifications and skills to serve on our board of directors.

Patrick Baeuerle, Ph.D. co-founded our company and has served as a member of our board of directors since our inception in 2015. Dr. Baeuerle has been an executive partner of MPM Capital, an early-stage life —sciences venture investing firm, since April 2015. He has also co-founded numerous MPM capital portfolio companies such as iOmx, Maverick and TCR2. Prior to MPM, Dr. Baeuerle served as Vice President of Research, and the General Manager at Amgen Research Munich GmbH, a biopharmaceutical company, from March 2012 to March 2015, where he oversaw the development of T cell engaging BiTE antibody Blincyto (blinatumomab), which was approved by the FDA for therapy of relapsed and refractory acute lymphoblastic leukemia. Prior to that, Dr. Baeuerle served as Chief Scientific Officer for Micromet, Inc., a biotechnology company, from October 1998 through its acquisition by Amgen in 2012. Dr. Baeuerle has served as a professor and the Chairman of Biochemistry at Freiburg University in Germany and is an honorary professor of immunology of the Medical Faculty at Munich University. Dr. Baeuerle currently serves as a member of the board of directors of Werewolf. Dr. Baeuerle holds a B.S. from the University of Konstanz, Germany, and an M.S. and a Ph.D. in Biology from the University of Munich, and conducted post-doctoral research at the Whitehead Institute at the Massachusetts Institute of Technology. Our board of directors believes that Dr. Baeuerle's perspective and experience as our co-founder, scientific and professional expertise and his educational background provide him with the qualifications and skills to serve on our board of directors.

Mark Chin has served as a member of our board of directors since May 2017. Since July 2016, Mr. Chin has been an investment director at Arix Bioscience, a venture capital firm. Prior to Arix Bioscience, he was a principal at Longitude Capital, a healthcare venture capital firm, from January 2012 to August 2018, where he focused on investments in both private and public biotechnology and medical technology companies. Prior to Longitude Capital, Mr. Chin was a consultant at the Boston Consulting Group, a global management consulting firm, from January 2011 to January 2012, where he managed strategy and corporate development projects for pharmaceutical and biotechnology companies, and prior to Boston Consulting Group, he worked in corporate development at Gilead Sciences, a biotechnology company, and in market planning at Genentech, a biotechnology company. Mr. Chin currently serves as a member of the board of directors of Iterum Therapeutics (NASDAQ: ITRM). Mr. Chin holds a B.S. in Management Science from the University of California at San Diego, an M.S. in Biotechnology from the University of Pennsylvania and an M.B.A. from The Wharton School at the University of Pennsylvania. Our board of directors believes that Mr. Chin's expertise and experience in the life sciences industry, experience as a director of other companies in our industry and his educational background provide him with the qualifications and skills to serve on our board of directors.

Jonathan Drachman, M.D. has served as a member of our board of directors since September 2018. Dr. Drachman served as the Chief Medical Officer and Executive Vice President, Research and Development of Seattle Genetics, a biotechnology company, from October 2013 until May 2018, after serving as their Senior Vice President, Research and Translational Medicine and various other positions of increasing authority since November 2004. Dr. Drachman also served as a Strategic Advisor for Innovation to Seattle Genetics from May 2018 through December 2018. Prior to Seattle Genetics, Dr. Drachman was Associate Professor in the Hematology Division, Department of Medicine at the University of Washington in Seattle, where he remains a Clinical Professor of Medicine. He also served as Senior Investigator in the Division of Research and Education and Medical Director of the Umbilical Cord Blood Program at the Puget Sound Blood Center. Dr. Drachman currently serves on the board of public company Calithera Biosciences, Inc. (NASDAQ: CALA). Dr. Drachman holds a B.A. in Biochemistry from Harvard University and an M.D. from Harvard Medical School. He completed his residency in Internal Medicine and fellowship in Medical Oncology at the University of Washington School. Our board of directors believes that Dr. Drachman's scientific and professional expertise and his educational background provide him with the qualifications and skills to serve on our board of directors.

Julie Eastland has served as a member of our board of directors since October 2018. Ms. Eastland has been the Chief Financial and Business Officer of Rainier Therapeutics, Inc., a biotechnology company, since August 2018. Prior to Rainier Therapeutics, Ms. Eastland served as Chief Business Officer and Chief Financial Officer for Cascadian Therapeutics, Inc., a biotechnology company, from September 2010 through its acquisition by Seattle Genetics in March 2018. Prior to Cascadian, Ms. Eastland served as the Chief Financial Officer and Vice President of Finance and Administration for VLST Corporation, a biotechnology company, from January 2006 to September 2010. Prior to VLST Corporation, Ms. Eastland was the Vice President of Strategic Planning at Dendreon Corporation, a biotechnology company, from October 2000 to October 2005. Prior to Dendreon, Ms. Eastland was the Controller at Amgen, a biopharmaceutical company, from March 1996 to April 1998. Ms. Eastland currently serves on the board of the TSX-listed company Pascal Biosciences Inc. (TSX: PAS). Ms. Eastland holds a B.S. in Finance from Colorado State University and an M.B.A. from Heriot-Watt University of the Edinburgh University in Scotland. Our board of directors believes that Ms. Eastland's extensive professional experience and expertise provide her with the qualifications and skills to serve on our board of directors.

Ron Hunt has served as a member of our board of directors since May 2017. Mr. Hunt co-founded and has served as a Managing Director of New Leaf Venture Partners, a venture capital fund focused on biopharmaceuticals, since 2005. From 1998 to 2005, Mr. Hunt was a partner at the Sprout Group, an institutional venture capital firm. Prior to Sprout, Mr. Hunt was a consultant within the pharmaceutical industry practice at Coopers & Lybrand Consulting, a consulting firm, and a consultant with The Health Care Group (a division of the Interpublic Group), a consulting firm. Prior to The Health Care Group, Mr. Hunt held a number of roles in the sales and marketing divisions of Johnson & Johnson and SmithKline Beecham Pharmaceuticals, both pharmaceutical companies. Mr. Hunt currently serves on the boards of public companies Iterum Therapeutics (NASDAQ: ITRM) and Neuronetics, Inc. (NASDAQ: STIM) and has previously served as a director for Relypsa, Inc. (NASDAQ: RLYP) and Durata Therapeutics, Inc. (NASDAQ: DRTX). Mr. Hunt holds a B.S. from Cornell University and an M.B.A. from The Wharton School at the University of Pennsylvania. Our board of directors believes that Mr. Hunt's expertise and experience in the venture capital industry, and his educational background provide him with the qualifications and skills to serve on our board of directors.

Scott Myers has served as a member of our board of directors since August 2018. Since June 2018 and September 2018, respectively, Mr. Myers has served as Chairman of the board and the Chief Executive Officer of Rainier Therapeutics, Inc., an oncology biotechnology company focused on late-stage bladder cancer. Mr. Myers served as Chief Executive Officer, President and Director for Cascadian Therapeutics, Inc., an oncology company, from April 2016 through its acquisition by Seattle Genetics in March 2018. Prior to Cascadian, Mr. Myers served as the Chief Executive Officer of Aerocrine AB, a medical device company from September 2011 through its acquisition by Circassia Pharmaceuticals plc in July 2015. Mr. Myers served as a director for Orexo AB, a pharmaceutical company, from April 2012 to April 2014. Mr. Myers holds a B.A. in Biology from Northwestern University and an M.B.A. from the Graduate School of Business at the University of Chicago. Our board of directors believes that Mr. Myers' experience in the biotechnology industry and his extensive experience in the leadership of both commercial and development stage biopharmaceutical companies provide him with the qualifications and skills to serve on our board of directors.

Family Relationships

There are no family relationships among any of the directors or executive officers.

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of eight members. Certain members of our board of directors were elected pursuant to the provisions of an amended and restated voting agreement, or the voting agreement, among us and certain of our stockholders. Under the terms of the voting agreement, the stockholders who are party to the voting agreement have agreed to vote their respective shares so as to elect directors as follows: (i) one person designated by MPM BioVentures 2014, L.P., currently Dr. Evnin, (ii) one person designated by UBS Oncology Impact Fund L.P., currently

Dr. Baeuerle, (iii) one person designated by New Leaf Ventures III, L.P., currently Mr. Hunt, (iv) one person designated by Arix Bioscience Inc., currently Mr. Chin, (v) one person who shall be our Chief Executive Officer, currently Dr. McMahon, and (vi) two persons who are not affiliated with us or the other parties to the voting agreement, currently Dr. Drachman and Mr. Myers. The voting agreement terminated pursuant to its terms immediately prior to the closing of our initial public offering. Following the close of our initial public offering, no stockholder had any special rights regarding the election or designation of members of our board of directors. Our current directors continue to serve as directors until their respective death, resignation or removal or until their successor is duly elected and qualified.

Our board of directors is divided into three classes with staggered three-year terms:

- Class I, whose members will be Dr. Baeuerle and Mr. Chin. The terms of the Class I directors will expire at our 2020 annual meeting of stockholders;
- Class II, whose members will be Dr. Drachman, Dr. Evnin and Mr. Hunt. The terms of the Class II directors will expire at our 2021 annual meeting of stockholders; and
- Class III, whose members will be Ms. Eastland, Dr. McMahon and Mr. Myers. The terms of the Class III directors will expire at our 2022 annual meeting of stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in our control.

Board Oversight of Risk

One of the key functions of our board of directors is informed oversight of our risk management process. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure. Our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its oversight function directly as a whole. Our board of directors administers its oversight through various standing committees that address risks inherent in their respective areas of oversight. For example, our audit committee oversees the management of risks associated with our financial reporting, accounting and auditing matters; our compensation committee oversees the management of risks associated with our compensation policies and programs; and our nominating and corporate governance committee oversees the management of risks associated with director independence, conflicts of interest, composition and organization of our board of directors and director succession planning.

Director Independence

Generally, under the listing requirements and rules of NASDAQ, independent directors must comprise a majority of a listed company's board of directors within one year of the closing of our initial public offering. Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Our board of directors has determined that, other than Dr. McMahon, by virtue of his position as our President and Chief Executive Officer, and Dr. Baeuerle, by virtue of his consulting agreement with us, none of our directors has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each is "independent" as defined under the listing requirements of NASDAQ. Accordingly, a majority of our directors is independent, as required under the applicable rules of NASDAQ. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director and its affiliates, and the transactions described under "Item 13-Certain Relationships and Related Transactions, and Director Independence."

Committees of our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Each committee of our board of directors has a written charter approved by our board of directors. Copies of each charter are posted in the Investors—Corporate Governance portion of our website at https://ir.harpoontx.com. The inclusion of our website address in this Annual Report does not include or incorporate by reference the information on our website into this Annual Report. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our audit committee consists of Mr. Chin, Ms. Eastland and Mr. Myers. Our board of directors has determined that each of the members of our audit committee satisfies the independence requirements under the listing standards of NASDAQ and Rule 10A-3(b)(1) of the Exchange Act. Our board of directors has determined that Mr. Chin is independent even though he falls outside the "safe harbor" definition set forth in Rule 10A-3(e)(1)(ii) under the Exchange Act because Arix Bioscience Holdings Limited owns in excess of 10% of our common stock. Among other things, our board of directors considered Mr. Chin's history of service and the percentage of common stock held by others, and it determined that he is not an "affiliated person" of the Company who would be ineligible to serve on our audit committee. The chair of our audit committee is Ms. Eastland. Our board of directors has determined that each of Ms. Eastland and Mr. Myers is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our board of directors examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of our audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial statement audits, and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee include:

- reviewing and approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- evaluating the performance of our independent registered public accounting firm and deciding whether to retain their services;
- monitoring the rotation of partners on our engagement team of our independent registered public accounting firm;
- reviewing our annual and quarterly financial statements and reports and discussing the statements and reports with our independent registered public accounting firm and management, including a review of disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations";
- considering and approving or disapproving all related party transactions;
- reviewing, with our independent registered public accounting firm and management, significant issues that may arise regarding accounting principles and financial statement presentation, as well as matters concerning the scope, adequacy and effectiveness of our financial controls;
- conducting an annual assessment of the performance of our audit committee and its members, and the adequacy of its charter; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters.

Compensation Committee

Our compensation committee consist of Mr. Chin, Dr. Evnin and Mr. Hunt. The chair of our compensation committee is Mr. Hunt. Our board of directors has determined that each of the members of our compensation committee is independent under the listing standards of NASDAQ and a "non-employee director" as defined in Rule 16b-3 under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- determining the compensation and other terms of employment of our chief executive officer and our other executive officers and reviewing and approving corporate performance goals and objectives relevant to such compensation;
- reviewing and recommending to our full board of directors the compensation of the members of our board of directors;
- evaluating and administering the equity incentive plans, compensation plans and similar programs advisable for us, as well as reviewing and recommending to our board of directors the adoption, modification or termination of our plans and programs;
- establishing policies with respect to equity compensation arrangements;
- reviewing with management our disclosures under the caption "Compensation Discussion and Analysis" and recommending to our full board of directors its inclusion in our periodic reports to be filed with the SEC; and
- reviewing and evaluating, at least annually, the performance of our compensation committee and the adequacy of its charter.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee are Mr. Chin, Dr. Drachman and Ms. Eastland. The chair of our nominating and corporate governance committee is Mr. Chin. Each member of our nominating and governance committee is independent under the rules and regulations of the SEC and the listing standards of The NASDAQ Stock Market LLC, applicable to nominating and governance committee members.

Specific responsibilities of our nominating and corporate governance committee include:

- reviewing periodically and evaluating director performance on our board of directors and its applicable committees, and recommending to our board of directors and management areas for improvement;
- interviewing, evaluating, nominating and recommending individuals for membership on our board of directors;
- reviewing and recommending to our board of directors any amendments to our corporate governance policies; and
- reviewing and assessing, at least annually, the performance of our nominating and corporate governance committee and the adequacy of its charter.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics is posted on our website at www.harpoontx.com. We intend to disclose on our website any future amendments of our Code of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Business Conduct and Ethics as and to the extent required by applicable rules and exchange requirements.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee are currently, or have been at any time, one of our officers or employees. None of our executive officers currently serve, or have served during the past fiscal year, as a member of the board of directors or the compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or our compensation committee. Each of Mr. Chin, Dr. Evnin and Mr. Hunt may be deemed to have an interest in certain transactions requiring disclosure under Item 404 of Regulation S-K under the Securities Act. These transactions are disclosed in "Certain Relationships and Related Party Transactions," and such disclosure is incorporated by reference herein.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports of ownership on Forms 3, 4 and 5 with the SEC. Officers, directors and greater than 10% stockholders are required to furnish us with copies of all Forms 3, 4 and 5 they file.

We did not have a class of equity securities registered pursuant Section 12 of the Exchange Act during the fiscal year ended December 31, 2018, as our initial public offering was completed in February 2019. As a result, our executive officers and directors, and persons who own more than 10% of a registered class our common stock, were not subject to Section 16(a) during the fiscal year ended December 31, 2018.

Item 11. Executive Compensation

The following table shows information regarding the compensation of our named executive officers for services performed in our fiscal years ended December 31, 2018 and 2017. On January 28, 2019, we effected a reverse stock split of shares of our common stock at a ratio of 4.9175-for-one pursuant to an amendment to our amended and restated certificate of incorporation approved by our board of directors and stockholders. All issued and outstanding common shares and per share amounts have been retroactively adjusted to reflect this reverse stock split for all periods presented.

Name and Principal Position	Year	Salary	Bonus	Option Awards(4)	Non-Equity Incentive Plan Compensation(5)	All Other Compensation	Total
Gerald McMahon, Ph.D.	2018	$ 427,500	$ —	$ 226,176	$ 226,600	$ —	$880,276
President and Chief Executive Officer(1)	2017	415,000	—	417,861	177,700	113,179(6)	1,123,740
Natalie Sacks, M.D.	2018	100,000	50,000(7)	508,581	46,800	—	705,381
Chief Medical Officer(2)							
Holger Wesche, Ph.D.	2018	297,170	—	137,555	122,300	—	557,025
Chief Scientific Officer	2017	270,000	30,000(3)	59,743	86,700	—	446,443

(1) Dr. McMahon became our President and Chief Executive Officer in January 2017.

(2) Dr. Sacks became our Chief Medical Officer in October 2018. The salary reported reflects the pro rata portion of Dr. Sack's annual salary of $400,000 earned during 2018.

(3) Represents the payment to Dr. Wesche of a $30,000 installment of a signing bonus pursuant to his offer letter with us. See "Employment and Change of Control Arrangements—Employment Agreements and Potential Payments and Benefits Upon Termination or Change in Control—Holger Wesche, Ph.D."

(4) Represents the aggregate grant date fair value of option awards granted to the officer in the applicable fiscal year, computed in accordance with FASB ASC Topic 718. See Note 9 to our audited financial statements included in this Annual Report for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(5) Represents payments made to our named executive officers upon the achievement of certain company performance objectives approved by our board of directors. Such payments for 2018 will be paid by us in 2019.

(6) Represents relocation expenses paid to Dr. McMahon in connection with his joining our company.

(7) Represents the payment to Dr. Sacks of a $50,000 signing bonus pursuant to her offer letter with us. See "Employment and Change of Control Arrangements—Employment Agreements and Potential Payments and Benefits Upon Termination or Change in Control—Natalie Sacks, M.D."

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding the outstanding equity awards held by our named executive officers as of December 31, 2018. See "—Equity, Benefit and Retirement Plans" below for more information.

		Option Awards				Stock Awards		
Name	Grant Date	Number of Securities Underlying Exercisable Options	Number of Securities Underlying Unexercisable Options	Option Exercise Price	Option Expiration Date	Number of Shares of Stock that Have Vested	Number of Shares of Stock that Have Not Vested	Market Value of Shares of Stock that Have Not Vested(9)
Gerald McMahon, Ph.D.	11/16/2018	—	156,583(7)	$ 2.12	11/16/2028	—	—	—
	6/22/2017	11,671(2)	100,377(2)	1.63	6/22/2027	—	—	—
	1/4/2017	488,052(3)	—	0.60	1/4/2027	—	—	—
Natalie Sacks, M.D. (1)	11/16/2018	—	73,004(7)	2.12	11/16/2028	—	—	—
	10/17/2018	233,858(8)	—	2.12	10/17/2028	—	—	—
Holger Wesche, Ph.D.	11/16/2018	—	95,170(7)	2.12	11/16/2028	—	—	—
	6/22/2017	2,139(2)	18,399(2)	1.63	6/22/2027	—	—	—
	1/13/2017	61,006(4)	—	0.60	1/13/2027	—	—	—
	4/6/2016	21,691(5)	10,845(5)	0.60	4/6/2026	—	—	—
	6/16/2015					48,279	4,389(6)	$ 9,281

(1) Dr. Sacks became our Chief Medical Officer in October 2018.

(2) The options commenced vesting on July 16, 2018 (the milestone closing of the issuance and sale of our Series B convertible preferred stock) in equal monthly installments over four years, subject to continuous service through each vesting date.

(3) 25% of the options vested on the first anniversary of December 19, 2016, the vesting commencement date, and the remaining 75% vests in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date. This option award is subject to an early exercise provision and is immediately exercisable in exchange for shares of restricted common stock.

(4) 25% of the options vested on May 24, 2018 (the first anniversary of the initial closing of the issuance and sale of our Series B convertible preferred stock), and the remaining 75% will vest in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date. This option award is subject to an early exercise provision and is immediately exercisable in exchange for shares of restricted common stock.

(5) 25% of the options vested on the first anniversary of the date of grant, and the remaining 75% vests in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date.

(6) 25% of the shares of vested on June 16, 2016 (the first anniversary of the date of grant), and the remaining 75% vests in equal monthly installments over the three years following June 16, 2016, subject to continuous service through each vesting date.

(7) 25% of the options will vest on the first anniversary of November 16, 2018, the vesting commencement date, and the remaining 75% will vest in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date. Not reflected in the table above is a stock option award to purchase an aggregate of 108,388 shares that our board of directors granted to Dr. McMahon in February 2019 in connection with our initial public offering, with an exercise price equal to $14.00. 25% of the options will vest on the first anniversary of the date of grant, and the remaining 75% vests in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date.

(8) 25% of the options will vest on the first anniversary of October 17, 2018, the vesting commencement date, and the remaining 75% will vest in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date. This option award was subject to an early exercise provision and was immediately exercisable in exchange for shares of restricted common stock. This option was exercised with respect to 45,754 shares on December 4, 2018. Upon a termination of service, unvested shares may be repurchased by us for $2.12 per share.

(9) The market value of shares that have not yet vested is calculated based on the fair market value of our common stock of $2.12, as approved by our board of directors on December 19, 2018.

Emerging Growth Company Status

We are an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we will be exempt from certain requirements related to executive compensation, including, but not limited to, requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our Chief Executive Officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Act.

Employment and Change of Control Arrangements

Set forth below are the employment and change of control arrangements for our named executive officers and our Chief Financial Officer, who joined our company in October 2018.

Employment Agreements and Potential Payments and Benefits Upon Termination or Change in Control

Gerald McMahon, Ph.D.

On December 10, 2016, we entered into an offer letter with Dr. McMahon setting forth the terms and conditions of his employment. The offer letter provides for a base salary of $415,000 per year and a target bonus of 40% of his base salary. Effective upon the completion of our initial public offering in February 2019, Dr. McMahon's salary was increased to his current base salary of $500,000 per year with a target bonus of 50% of his base salary. The offer letter provides that if within 90 days prior to or within 12 months after a "change in control" (as defined in the offer letter) Dr. McMahon's employment is terminated by us without "cause" or by Dr. McMahon for "good reason" (each as defined in the offer letter), then his outstanding equity awards will vest in full at the maximum level and he will receive 12 months of base salary, a pro rata target bonus and up to 12 months of reimbursement of COBRA premiums, subject to the execution of an effective release. Upon a termination without cause or for good reason at any other time, Dr. McMahon will receive 12 months of salary, a pro rata target bonus and up to nine months of reimbursement of COBRA premiums, subject to the execution of an effective release. The offer letter provides for the grant of an option to purchase 325,368 shares of common stock, which option was granted on January 4, 2017. The offer letter also provides for the grant of an option to purchase 162,684 shares of our common stock if a spinout housing all or part of the Maverick technology is created and if that company is led by a different team, which option was granted on January 4, 2017. Dr. McMahon has also executed our standard confidential information, invention assignment and arbitration agreement.

Separate from the offer letter described above is a stock option award to purchase an aggregate of 108,388 shares that our board of directors has authorized and granted to Dr. McMahon in February 2019 in connection with our initial public offering, with an exercise price equal to $14.00. 25% of the options will vest on the first anniversary of the date of grant, and the remaining 75% vests in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date.

Natalie Sacks, M.D.

On September 13, 2018, we entered into an offer letter with Dr. Sacks setting forth the terms and conditions of her employment. The offer letter provides for a base salary of $400,000 per year and for eligibility to receive a discretionary bonus of up to 35% of her base salary. Dr. Sacks' current base salary is $400,000 and she remains eligible to receive a discretionary bonus of up to 35% of her base salary. Dr. Sacks was paid a $50,000 signing bonus in October 2018, which amount is subject to repayment to us on a prorated basis in the event Dr. Sacks resigns without "good reason" (as defined in the offer letter) during her first year of employment with us. The offer letter provides that if within 60 days prior to or within 12 months after a "change in control" (as defined in the offer letter) Dr. Sacks' employment is terminated by us without "cause" or by Dr. Sacks for "good reason" (each as defined in the offer letter), then (i) her outstanding equity awards will vest in full, (ii) she will receive a lump sum severance payment equal to 12 months of her then-current base salary and (iii) up to 12 months of reimbursement of COBRA premiums for herself and her eligible dependents (or in our discretion, cash payments in lieu thereof for up to nine months), in each case subject to the execution of an effective release. Upon a termination of Dr. Sacks' employment without cause or for good reason at any other time, Dr. Sacks will receive (i) a lump sum severance payment equal to 12 months of her then-current base salary, (ii) up to 12 months of reimbursement of COBRA premiums for herself and her eligible dependents (or in our discretion cash payments in lieu thereof for up to nine months) and (iii) the unvested portion of each of her then-outstanding equity awards that otherwise would have vested had she remained employed for 12 months following the date of such termination will immediately vest, in each case subject to the execution of an effective release. The offer letter provides for the grant of an equity award in the form of a restricted stock award or a stock option to purchase 279,613 shares of our common stock at an exercise price per share equal to the fair market value of a share of our common stock on the date of grant, which award was granted in full in the form of a restricted stock award on October 17, 2018. 25% of the shares subject to the restricted stock award are scheduled to vest on the first anniversary of Dr. Sacks' commencement of employment with us, and 1/48th of the shares subject to the restricted stock award are scheduled to vest each month thereafter, subject to Dr. Sacks' continuous service through each applicable vesting date. In addition, the offer letter provides that in the event of a change in control where the successor corporation fails to assume or substitute for Dr. Sacks' equity awards, such equity awards will vest immediately prior to the effective time of the change in control. Dr. Sacks has also executed our standard confidential information, invention assignment and arbitration agreement.

Holger Wesche, Ph.D.

On March 17, 2015, we entered into an offer letter with Dr. Wesche setting forth the terms and conditions of his employment, and we entered into an amendment to this offer letter on January 26, 2018. The offer letter provides for a base salary of $245,000 per year and a target bonus of 25% of his base salary. His current base salary is $325,000 and his target bonus is 35% of his base salary, both of which reflect his promotion to Chief Scientific Officer in October 2018. Dr. Wesche was also paid a $90,000 signing bonus in three equal installments, the final of which was paid in May 2017. The offer letter provides that if within 90 days prior to or within 12 months after a "change in control" (as defined in the offer letter) Dr. Wesche's employment is terminated by us without "cause" or by Dr. Wesche for "good reason" (each as defined in the offer letter), then his outstanding equity awards will vest in full at the maximum level and he will receive nine months of base salary and up to nine months of reimbursement of COBRA premiums, subject to the execution of an effective release. Upon a termination without cause or for good reason at any other time, Dr. Wesche will receive nine months of salary and up to nine months of reimbursement of COBRA premiums, subject to the execution of an effective release. The offer letter provides for the grant of an option to purchase 52,668 shares of common stock, which was granted in the form of restricted stock on June 16, 2015. Dr. Wesche has also executed our standard confidential information, invention assignment and arbitration agreement.

Georgia Erbez

On October 20, 2018, we entered into an offer letter with Ms. Erbez setting forth the terms and conditions of her employment. The offer letter provides for a base salary of $325,000 per year and for eligibility to receive a discretionary bonus of up to 35% of her base salary. Effective upon the completion of our initial public offering in February 2019, Ms. Erbez's base salary was increased to her current base salary of $365,000 per year and she remains eligible to receive a discretionary bonus of up to 35% of her base salary. The offer letter provides that if within 60 days prior to or within 12 months after a "change in control" (as defined in the offer letter) Ms. Erbez's employment is terminated by us without "cause" or by Ms. Erbez for "good reason" (each as defined in the offer letter), then she will receive (i) full vesting acceleration of her outstanding options and restricted stock, (ii) severance pay equivalent to 9 months of her then-current base salary, payable ratably in installments and (iii) up to 9 months of reimbursement of COBRA premiums, except such reimbursements will not exceed the amount we then pay for health insurance coverage for our active employees (or in our discretion cash payments in lieu thereof for up to nine months), in each case subject to the execution of an effective release. Upon a termination of Ms. Erbez's employment without cause or for good reason at any other time, Ms. Erbez will receive (i) severance pay equivalent to 9 months of her then-current base salary, payable ratably in installments and (ii) up to 9 months of reimbursement of COBRA premiums, except such reimbursements will not exceed the amount we then pay for health insurance coverage for our active employees, in each case subject to the execution of an effective release. The offer letter provides for the grant of a stock option to purchase 218,200 shares of our common stock at an exercise price per share equal to the fair market value of a share of our common stock on the date of grant. 25% of the shares subject to the option are scheduled to vest on the first anniversary of the vesting commencement date, and 1/48th of the shares subject to the option are scheduled to vest each month thereafter, subject to Ms. Erbez's continuous service through each applicable vesting date. Ms. Erbez has also executed our standard confidential information, invention assignment and arbitration agreement.

Separate from the offer letter described above is a stock option award to purchase an aggregate of 4,067 shares that our board of directors has authorized and granted to Ms. Erbez in February 2019 in connection with our initial public offering, with an exercise price equal to $14.00. 25% of the options will vest on the first anniversary of the date of grant, and the remaining 75% vests in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date.

Equity, Benefit and Retirement Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants, and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant stock options and other equity-based awards helps us to attract, retain, and motivate employees, consultants, and directors and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans and our 401(k) plan are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which, other than the 401(k) plan, are incorporated herein by reference.

2019 Equity Incentive Plan

Our board of directors adopted and our stockholders approved our 2019 Plan in January 2019. As of immediately prior to the execution of the underwriting agreement for our initial public offering in February 2019, the 2015 Plan was terminated and no further grants were made under our 2015 Plan, as described under "2015 Equity Incentive Plan" below. However, all outstanding stock awards granted pursuant to the 2015 Plan will continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards. No awards have been granted and no shares of our common stock have been issued under our 2019 Plan other than the grant, which was made upon the pricing of our initial public offering, of stock options to purchase an aggregate of 120,589 shares of common stock under our 2019 Plan, with an exercise price equal to $14.00, to certain of our employees (including our Chief Executive Officer and Chief Financial Officer). 25% of the options will vest on the first anniversary of the date of grant (the

date of the pricing of our IPO) and the remaining 75% will vest in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date.

Stock Awards

Our 2019 Plan provides for the grant of incentive stock options (within the meaning of Section 422 of the Code), nonstatutory stock options, stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity compensation, which are collectively referred to as stock awards. Our 2019 Plan also provides for the grant of performance cash awards. Incentive stock options may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

Share Reserve

The aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2019 Plan is 5,656,381, which is the sum of (1) 2,200,000 shares plus (2) the number of shares reserved, and remaining available for issuance, under our 2015 Plan at the time our 2019 Plan became effective and (3) the number of shares subject to stock options or other stock awards granted under our 2015 Plan that would have otherwise returned to our 2015 Plan (such as upon the expiration or termination of a stock award prior to vesting. The number of shares of our common stock reserved for issuance under our 2019 Plan will automatically increase on January 1 of each year, beginning on January 1, 2020 (assuming our 2019 Plan becomes effective before such date) and continuing through and including January 1, 2029, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of incentive stock options under our 2019 Plan is 8,000,000 shares.

If a stock award granted under our 2019 Plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under our 2019 Plan. In addition, the following types of shares under our 2019 Plan may become available for the grant of new stock awards under our 2019 Plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under our 2019 Plan may be previously unissued shares or reacquired shares bought by us on the open market.

Administration

Our board of directors, or a duly authorized committee thereof, has the authority to administer our 2019 Plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, (2) determine the number of shares of common stock to be subject to such stock awards and (3) specify the other terms and conditions, including the strike price or purchase price and vesting schedule, applicable to such awards. Subject to the terms of our 2019 Plan, our board of directors or the authorized committee, referred to as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2019 Plan. Subject to the terms of our 2019 Plan, the plan administrator has the authority, without stockholder approval, to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options

Incentive and nonstatutory stock options are evidenced by stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of our 2019 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under our 2019 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under our 2019 Plan, up to a maximum of ten years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term will automatically be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy.

If an option holder's service relationship with us or any of our affiliates ceases due to disability or death, or an option holder dies within a certain period following cessation of service, the option holder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the option holder, (4) a net exercise of the option if it is an nonqualified stock option and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An option holder may designate a beneficiary, however, who may exercise the option following the option holder's death.

Tax Limitations on Incentive Stock Options

The aggregate fair market value, determined at the time of grant, of our common stock with respect to incentive stock options that are exercisable for the first time by an option holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will be treated as nonqualified stock options. No incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the term of the incentive stock option does not exceed five years from the date of grant.

Restricted Stock Awards

Restricted stock awards are evidenced by restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (1) cash, check, bank draft or money order, (2) services rendered to us or our affiliates or (3) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule as determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock unit awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Restricted Stock Unit Awards

Restricted stock unit awards evidenced by restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration or for no consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Rights under a restricted stock units award may be transferred only upon such terms and conditions as set by the plan administrator. Restricted stock unit awards may be subject to vesting as determined by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights

SARs are evidenced by SAR grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a SAR, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a SAR, we will pay the participant an amount in cash or stock equal to (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the SAR is exercised. A SAR granted under our 2019 Plan vests at the rate specified in the SAR agreement as determined by the plan administrator.

The plan administrator determines the term of SARs granted under our 2019 Plan, up to a maximum of ten years. Unless the terms of a participant's SAR agreement provides otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested SAR for a period of three months following the cessation of service. The SAR term will be further extended in the event that exercise of the SAR following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our

affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested SAR for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, SARs generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a SAR be exercised beyond the expiration of its term.

Unless the plan administrator provides otherwise, SARs generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. A SAR holder may designate a beneficiary, however, who may exercise the SAR following the holder's death.

Performance Awards.

Our 2019 Plan permits the grant of performance-based stock and cash awards. Our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected include one or more of the following: (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) total stockholder return; (v) return on equity or average stockholder's equity; (vi) return on assets, investment, or capital employed; (vii) stock price; (viii) margin (including gross margin); (ix) income (before or after taxes); (x) operating income; (xi) operating income after taxes; (xii) pre-tax profit; (xiii) operating cash flow; (xiv) sales or revenue targets; (xv) increases in revenue or product revenue; (xvi) expenses and cost reduction goals; (xvii) improvement in or attainment of working capital levels; (xviii) economic value added (or an equivalent metric); (xix) market share; (xx) cash flow; (xxi) cash flow per share; (xxii) share price performance; (xxiii) debt reduction; (xxiv) customer satisfaction; (xxv) stockholders' equity; (xxvi) capital expenditures; (xxvii) debt levels; (xxviii) operating profit or net operating profit; (xxix) workforce diversity; (xxx) growth of net income or operating income; (xxxi) billings; (xxxii) pre-clinical development related compound goals; (xxxiii) financing; (xxxiv) regulatory milestones, including approval of a compound; (xxxv) stockholder liquidity; (xxvi) corporate governance and compliance; (xxxvii) product commercialization; (xxxviii) intellectual property; (xxxix) personnel matters; (xl) progress of internal research or clinical programs; (xli) progress of partnered programs; (xlii) partner satisfaction; (xliii) budget management; (xliv) clinical achievements; (xlv) completing phases of a clinical study (including the treatment phase); (xlvi) announcing or presenting preliminary or final data from clinical studies; in each case, whether on particular timelines or generally; (xlvii) timely completion of clinical trials; (xlviii) submission of INDs and New Drug Applications and other regulatory achievements; (xlix) partner or collaborator achievements; (l) internal controls, including those related to the Sarbanes-Oxley Act of 2002; (li) research progress, including the development of programs; (lii) investor relations, analysts and communication; (liii) manufacturing achievements (including obtaining particular yields from manufacturing runs and other measurable objectives related to process development activities); (liv) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; (lv) establishing relationships with commercial entities with respect to the marketing, distribution and sale of our products (including with group purchasing organizations, distributors and other vendors); (lvi) supply chain achievements (including establishing relationships with manufacturers or suppliers of active pharmaceutical ingredients and other component materials and manufacturers of our products); (lvii) co-development, co-marketing, profit sharing, joint venture or other similar arrangements; (lviii) individual performance goals; (lix) corporate development and planning goals; and (lx) other measures of performance selected by our board of directors or committee thereof.

The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any items that are unusual in nature or occur infrequently as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by our achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

Other Stock Awards

The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Changes to Capital Structure

In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under our 2019 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of incentive stock options and (4) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions

In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate or for no consideration; or
- make a payment equal to the excess of (1) the value of the property the participant would have received upon exercise of the stock award over (2) the exercise price or strike price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under our 2019 Plan, a significant corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our assets, (2) a sale or other disposition of at least 50% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control

The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability or settlement in the event of a change in control. Under our 2019 Plan, a change in control is generally (1) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction, (2) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity or (3) a consummated sale, lease or exclusive license or other disposition of all or substantially all of our assets.

Amendment and Termination

Our board of directors has the authority to amend, suspend or terminate our 2019 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent and provided further that certain types of amendments will require the approval of our stockholders. No incentive stock options may be granted after the tenth anniversary of the date that our board of directors adopts our 2019 Plan.

2015 Equity Incentive Plan

In April 2015, our board of directors and our stockholders adopted our 2015 Plan, which was subsequently amended on March 30, 2016. Our 2015 Plan (as amended to increase the share reserve in each of October 2018, November 2018 and December

2018) provides for the issuance of up to a maximum of 3,902,175 shares. Our 2015 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the Code to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory options, restricted stock awards, restricted stock unit awards and stock appreciation rights our employees, consultants and directors.

Shares issued under our 2015 Plan may be authorized but unissued or reacquired. Shares subject to stock awards granted under our 2015 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2015 Plan. Additionally, shares issued pursuant to stock awards under our 2015 Plan that we repurchase or that are forfeited, as well as shares reacquired by us as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under our 2015 Plan.

Administration

Our board of directors, or a duly authorized committee thereof, will have the authority to administer our 2015 Plan. Subject to the terms of our 2015 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under our 2015 Plan.

Changes to Capital Structure

In the event there is a specified type of change in our capital structure, such as a split, reverse split or recapitalization, appropriate adjustments will be made to the number and class of shares of stock that may be delivered under our 2015 Plan and the number, class and price of shares covered by each outstanding event.

Corporate Transactions

Our 2015 Plan provides that in the event of a merger of our company into another corporation or entity, or a change in control (as defined in our 2015 Plan), the administrator will determine how to treat each outstanding stock award. The administrator may:

- arrange for the assumption or substitution of a stock award by a successor corporation;
- provide that upon written notice that a participant's awards will terminate upon or immediately prior to the transaction;
- accelerate the vesting of the stock award;
- cancel the stock award prior to the transaction in exchange for a payment, which may be reduced by the exercise price payable in connection with the stock award; or
- a combination of any of the foregoing.

If awards are not assumed or substituted, they will vest and become exercisable in full. The administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner.

Amendment or Termination

Our board of directors has the authority to amend, suspend or terminate our 2015 Plan, provided that, with respect to an amendment, such action does not materially impair the existing rights of any participant without such participant's written consent. Unless terminated sooner by our board of directors, our 2015 Plan will automatically terminate on the day before the tenth anniversary of the later of (i) the effective date of our 2015 Plan or (ii) the earlier of the most recent board of directors or stockholder approval of an increase in the number of shares reserved for issuance under our 2015 Plan. Our 2015 Plan will be terminated on the date that our 2019 Plan becomes effective. In connection with the 4.9175-for-one reverse stock split of our common stock, that was effected on January 28, 2019, the terms of certain awards granted under our 2015 Plan were equitably adjusted in accordance with the provisions thereof.

2019 Employee Stock Purchase Plan

Our board of directors adopted and our stockholders approved our 2019 Employee Stock Purchase Plan, or 2019 ESPP, in January 2019, and the 2019 ESPP became effective in connection with our initial public offering in February 2019. No offering periods under the 2019 ESPP have been commenced to date.

Share Reserve

The maximum number of shares of our common stock that may be issued under our 2019 ESPP is 250,000 shares. Additionally, the number of shares of our common stock reserved for issuance under our 2019 ESPP will automatically increase on January 1 of each year, beginning on January 1, 2020 and continuing through and including January 1, 2029, by the lesser of (1) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (2) 750,000 shares of our common stock or (3) such lesser number of shares of common stock as determined by our board of directors. Shares subject to purchase rights granted under our 2019 ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under our 2019 ESPP.

Administration

Our board of directors, or a duly authorized committee thereof, will administer our 2019 ESPP. Our board of directors has delegated its authority to administer our 2019 ESPP to our compensation committee under the terms of the compensation committee's charter.

Limitations

Our employees, including executive officers, and the employees of any of our designated affiliates are eligible to participate in our 2019 ESPP, provided they may have to satisfy one or more of the following service requirements before participating in our 2019 ESPP, as determined by the administrator: (1) customary employment with us or one of our affiliates for more than 20 hours per week and five or more months per calendar year or (2) continuous employment with us or one of our affiliates for a minimum period of time, not to exceed two years, prior to the first date of an offering. An employee may not be granted rights to purchase stock under our 2019 ESPP (a) if such employee immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of all classes of our common stock or (b) to the extent that such rights would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

Our 2019 ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Code. The administrator may specify offerings with a duration of not more than 27 months, and may specify one or more shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for the employees who are participating in the offering. The administrator, in its discretion, will determine the terms of offerings under our 2019 ESPP.

A participant may not transfer purchase rights under our 2019 ESPP other than by will, the laws of descent and distribution or as otherwise provided under our 2019 ESPP.

Payroll Deductions

Our 2019 ESPP permits participants to purchase shares of our common stock through payroll deductions up to 15% of their earnings. Unless otherwise determined by the administrator, the purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the first day of an offering or on the date of purchase. Participants may end their participation at any time during an offering and will be paid their accrued contributions that have not yet been used to purchase shares. Participation ends automatically upon termination of employment with us.

Corporate Transactions

In the event of certain specified significant corporate transactions, such as a merger or change in control, a successor corporation may assume, continue or substitute each outstanding purchase right. If the successor corporation does not assume, continue or substitute for the outstanding purchase rights, the offering in progress will be shortened and a new exercise date will be set. The participants' purchase rights will be exercised on the new exercise date and such purchase rights will terminate immediately thereafter.

Amendment and Termination

Our board of directors has the authority to amend, suspend or terminate our 2019 ESPP, at any time and for any reason, provided certain types of amendments will require the approval of our stockholders. Our 2019 ESPP will remain in effect until terminated by our board of directors in accordance with the terms of our 2019 ESPP.

401(k) Plan

We maintain a 401(k) plan pursuant to which our employees (subject to certain exceptions) are eligible to participate. Our named executive officers are eligible to participate in the 401(k) plan. Participants may defer up to 96% of their salary (subject to limits set forth in the Code). We may, in our discretion, make profit sharing contributions to the plan.

Health and Welfare Benefits

All of our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental and vision insurance plans, in each case on the same basis as all of our other full-time employees.

We believe the perquisites described above are necessary and appropriate to provide a competitive compensation package to our named executive officers.

No Tax Gross-Ups

We do not make gross-up payments to cover our named executive officers' personal income taxes that may pertain to any of the compensation or perquisites paid or provided by us.

Indemnification of Directors and Officers

Our amended and restated certificate of incorporation authorizes us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws, provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws also provide that, upon satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that our amended and restated certificate of incorporation, our amended and restated bylaw provisions and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

Rule 10b5-1 Sales Plans

Our directors and officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they do not possess of material nonpublic information, subject to compliance with the terms of our insider trading policy.

Non-Employee Director Compensation

Other than as described below, we did not pay any cash compensation to our non-employee directors or to Dr. McMahon for service on our board of directors during the fiscal year ended December 31, 2018. All compensation paid to Dr. McMahon is for services rendered as our President and Chief Executive Officer.

During 2018, we granted each of Dr. Evnin, Dr. Baeuerle, Mr. Chin and Mr. Hunt options to purchase 20,335 shares of our common stock at an exercise price per share of $2.12. One-third of the options will vest on each of the first, second and third anniversary of the date of grant, subject to continuous service through each vesting date. During 2018, we also granted Dr. Drachman and Mr. Myers options to purchase 55,312 shares and 27,656 shares, respectively, of our common stock at an exercise price per share of $1.78 and granted Ms. Eastland options to purchase 27,656 shares of our common stock at an exercise price per share of $2.12. 25% of the options will vest on the first anniversary of the date of grant, and the remaining 75% will vest in equal monthly installments over the three years following such first anniversary, subject to continuous service through each vesting date.

The following table presents all payments or equity awards made to our non-employee directors during the fiscal year ended December 31, 2018. Pablo Cagnoni and Dan Hicklin, Ph.D., who resigned from our board of directors in August 2018 and September 2018, respectively, are included in the table.

Name	Fees Earned or Paid In Cash	Option Awards(1)	Other Compensation	Total
Luke Evnin, Ph.D.	—	29,147	—	29,147
Patrick Baeuerle, Ph.D.	—	29,147	120,827 (2)	149,974
Pablo Cagnoni	—	-	—	-
Mark Chin	—	29,147	—	29,147
Jonathan Drachman, M.D.	—	66,364	—	66,364
Julie Eastland	12,500	39,779	—	52,279
Dan Hicklin, Ph.D.	—	—	—	—
Ron Hunt	—	29,147	—	29,147
Scott Myers	12,500	32,550	—	45,050

(1) Represents the aggregate grant date fair value of option awards granted to the officer in the applicable fiscal year, computed in accordance with FASB ASC Topic 718. See Note 9 to our audited financial statements included this Annual Report for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards. As of December 31, 2018, Dr. Evnin, Dr. Baeuerle, Mr. Chin, Dr. Drachman, Ms. Eastland and Mr. Hunt held options to purchase 20,335, 20,335, 20,335, 55,312, 27,656 and 20,335 shares of our common stock, respectively. Our non-employee directors did not hold any other stock options or option awards as of December 31, 2018.

(2) Represents payments made to Dr. Baeuerle pursuant to his consulting agreement with our company. See "Item 13- Certain Relationships and Related Transactions, and Director Independence—Consulting Agreement with Dr. Baeuerle."

Non-Employee Director Compensation Policy

Our board of directors adopted a Non-Employee Director Compensation Policy, referred to herein as the policy, effective as of February 7, 2019, the execution of the underwriting agreement related to our initial public offering. Under the policy, each of our non-employee directors are eligible to receive compensation for service on our board of directors and committees of our board of directors.

Starting at the beginning of the first calendar quarter following the execution of the underwriting agreement related to our initial public offering, the policy provides our non-employee directors with the following cash compensation for their services:

- $35,000 per year for each non-employee director;
- $65,000 per year for chairman of the board of directors (if applicable) in lieu of the annual amount above;
- $15,000 per year for chairman of the audit committee or $7,500 per year for each other member of the audit committee;
- $10,000 per year for chairman of the compensation committee or $5,000 per year for each other member of the compensation committee; and
- $8,000 per year for chairman of the nominating and governance committee or $4,000 per year for each other member of the nominating and governance committee.

The cash compensation above is payable to our eligible non-employee directors in equal quarterly installments, prorated for any partial quarter of service.

Each non-employee director may elect to receive all (but not less than all) of his or her annual cash compensation under the policy in the form of a stock option, referred to herein as an election option. Each such election must be made no later than prior to the calendar year to which the election applies. Each election option will be granted on the date of the annual meeting of our stockholders occurring in the calendar year to which the election relates, subject to the non-employee director's continuous service through such date. However, for the calendar year 2019, the election option is granted on the date of the execution of the underwriting agreement of our initial public offering, subject to the non-employee director's continuous service through such date. Each election option will have a grant date value calculated based on the Black-Scholes option valuation methodology equal to the annual cash compensation the election option is granted in lieu of, provided the number of shares subject to the election option will be rounded down to the nearest whole share. Twenty-five percent of each election option will vest on the last day of each calendar quarter following the grant date of the election option, subject to the non-employee director's continuous service through such date.

Each non-employee director who first joins our board of directors after the date of the execution of the underwriting agreement related to our initial public offering automatically, upon the date of his or her initial election or appointment to be a non-employee director, be granted a one-time stock option to purchase 20,335 shares of our common stock, referred to herein as an initial grant. Each initial grant will vest in 3 equal annual installments over the 3 year period following the grant date, subject to the non-employee director's continuous service through each applicable vesting date.

In addition, on the date of each annual meeting of our stockholders, each person who is then a non-employee director of ours will automatically be granted a stock option to purchase 10,167 shares of our common stock, referred to herein as an annual grant. However, if a non-employee director was elected or appointed for the first time to be a non-employee director after the date of the execution of the underwriting agreement related to our IPO and as of the date of an annual meeting of our stockholders (or for the 2019 calendar year, June 3, 2019), 6 months or less have elapsed since the date of grant of the initial grant the non-employee director received, then the non-employee director will not be granted a full annual grant and instead will be granted a prorated annual grant that will be subject to 5,083 shares of our common stock, referred to herein as a prorated annual grant, except if as of the date of an annual meeting of our stockholders (or for the 2019 calendar year, June 3, 2019), less than 3 months have elapsed since the date of grant of the initial grant the non-employee director received (or the non-employee director has not yet received an initial grant but is then eligible to receive an initial grant), then the non-employee director will not receive a prorated annual grant (or an annual grant). Each annual grant or prorated annual grant will vest on the first anniversary of the date of grant, subject to the non-employee director's continuous service through such date.

Each option awarded to a non-employee director under the policy will become fully vested upon a Change in Control (as defined in the 2019 Plan), subject to the non-employee director's continuous service through immediately prior to the closing of the Change in Control.

Each option granted under the policy will be a nonstatutory stock option and will have an exercise price per share equal to the fair market value of a share of our common stock on the date of grant. Each stock option will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of the eligible director's continuous service with us.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information with respect to the beneficial ownership of our shares as of February 28, 2019 by:

- each of our named executive officers;
- each of the members of our board of directors;
- each person or entity known by us to own beneficially more than 5% of our common stock; and
- all of our executive officers and directors as a group.

The number of shares of common stock "beneficially owned" by each stockholder is determined under rules issued by the SEC regarding the beneficial ownership of securities. This information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership of shares of our common stock includes (1) any shares as to which the person or entity has sole or shared voting power or investment power and (2) any shares as to which the person or entity has the right to acquire beneficial ownership within 60 days after February 28, 2019. The percentage of beneficial ownership in the table below is based on 24,339,830 shares of common stock deemed to be outstanding as of February 28, 2019. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated, the address of each beneficial owner named in the table below and footnotes is c/o Harpoon Therapeutics, Inc., 4000 Shoreline Court, Suite 250, South San Francisco, California 94080.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on

information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders:		
Entities affiliated with MPM Capital, Inc.(1)	4,524,425	18.6%
UBS Oncology Impact Fund L.P. (2)	3,898,422	16.0%
Entities associated with New Leaf Venture Partners (3)	2,921,405	12.0%
Arix Bioscience Holdings Limited (4)	2,892,119	11.9%
Entities associated with OrbiMed (5)	2,446,409	10.1%
Named Executive Officers:		
Gerald McMahon, Ph.D. (6)	509,067	2.0%
Natalie Sacks, M.D. (7)	279,612	1.1%
Holger Wesche, Ph.D. (8)	141,935	*
Non-Employee Directors:		
Luke Evnin, Ph.D. (1)	4,524,425	18.6%
Patrick Baeuerle, Ph.D. (9)	349,515	1.4%
Mark Chin(4)	2,892,119	11.9%
Jonathan Drachman, M.D.(10)	8,071	*
Julie Eastland(11)	27,656	*
Ron Hunt(3)	2,921,405	12.0%
Scott Myers	27,656	*
All current directors and executive officers as a group (10 persons)(12)	11,681,461	46.3%

* Represents beneficial ownership of less than 1%.

(1) Consists of (a) 3,811,429 shares of common stock, held by MPM BioVentures 2014, L.P., (b) 254,211 shares of common stock, held by MPM BioVentures 2014 (B), L.P., (c) 138,246 shares of common stock, held by MPM Asset Management Investors BV2014 LLC, and (d) 322,063 shares of common stock held by MPM Asset Management LLC. MPM BioVentures 2014 LLC is the Managing Member of MPM BioVentures 2014 GP LLC, which is the General Partner of MPM BioVentures 2014, L.P. and MPM BioVentures 2014 (B), L.P. MPM BioVentures 2014 LLC is also the Manager of MPM Asset Management Investors BV2014 LLC. Dr. Evnin, a member of our board of directors, Ansbert Gadicke and Todd Foley are the members of MPM BioVentures 2014 LLC and share voting and dispositive power over the shares held by each of MPM BioVentures 2014, L.P., MPM BioVentures 2014 (B), L.P. and MPM Asset Management Investors BV2014 LLC. MPM Asset Management LLC was retained as a manager to manage the operations of MPM BioVentures 2014, L.P., MPM BioVentures 2014 (B), L.P. and MPM Asset Management Investors BV2014 LLC. Dr. Evnin and Dr. Gadicke are the members of MPM Asset Management LLC and share voting and dispositive power over the shares held by MPM Asset Management LLC. The address for each of the entities listed in this footnote is c/o MPM Capital LLC, 450 Kendall Street, Cambridge, Massachusetts 02142.

(2) Consists of 3,898,869 shares of common stock. MPM Oncology Impact Management GP LLC is the General Partner of MPM Oncology Impact Management LP, the General Partner of Oncology Impact Fund (Cayman) Management L.P., the General Partner of UBS Oncology Impact Fund, L.P. Ansbert Gadicke is a Managing Member and the Managing Director of MPM Oncology Impact Management GP LLC and has voting and dispositive power over the shares held by UBS Oncology Impact Fund, L.P. The address of UBS Oncology Impact Fund, L.P. is 450 Kendall Street, Cambridge, MA 02142.

(3) Consists of (a) 2,242,839 shares of common stock held by New Leaf Ventures III, L.P. and (b) 678,566 shares of common stock held by New Leaf Biopharma Opportunities II, L.P. New Leaf Venture Associates III, L.P., or Associates III, is the general partner of New Leaf Ventures III, L.P., or New Leaf III. New Leaf Venture Management III, L.L.C., or Management III, is the General Partner of Associates III and exercises investment discretion over New Leaf III. The Managers of Management III, Mr. Hunt, a member of our board of directors, Vijay K. Lathi and Liam T. Ratcliffe, may each be deemed to share voting and dispositive power over the shares held by New Leaf III. Each of the Managers of Management III is also a limited partner of Associates III. New Leaf BPO Associates II, L.P., or BPO Associates II, is the General Partner of New Leaf BioPharma Opportunities II, L.P., or New Leaf BPO II. New Leaf BPO Management II, L.L.C., or BPO Management II, is the general partner of BPO Associates II. The Managers of BPO Management II, Mr. Hunt, Mr. Lathi, Isaac J. Manke and Mr. Ratcliffe, may each be deemed to share voting and dispositive power of the shares held by New Leaf BPO II. Each of the Managers of BPO Management II is also a limited partner of BPO Associates II. The address for each of the entities listed is 7 Times Square, Suite 3502, New York, New York 10036.

(4) On October 22, 2018, Arix Bioscience Inc. transferred all of its shares to Arix Bioscience Holdings Limited, a wholly owned subsidiary of Arix Bioscience plc. Mr. Jonathan Peacock, Dr. Joe Anderson and Sir Christopher Evans comprise the Investment Committee of Arix Bioscience Holdings Limited and share voting and dispositive power over the shares held by Arix Bioscience Holdings Limited, along with Mr. Chin, a member of our board of directors and an investment director for Arix Bioscience plc. The address of Arix Bioscience Holdings Limited is 250 West 55th Street, 33rd Floor, New York, New York 10019.

(5) Consists of (a) 1,360,704 shares of common stock held by OrbiMed Private Investments VII, LP ("OPI VII") and (b) 1,085,705 shares of common stock held by Worldwide Healthcare Trust PLC ("WWH"). OrbiMed Capital GP VII LLC ("GP VII") is the general partner of OPI VII. OrbiMed Advisors LLC ("OrbiMed Advisors") is the managing member of GP VII. OrbiMed Capital LLC ("OrbiMed Capital") is the Portfolio Manager of WWH. OrbiMed Advisors and OrbiMed Capital are entities under common control by a management committee comprised of Carl L. Gordon, Sven H. Borho and Jonathan T. Silverstein. Messrs. Gordon, Borho and Silverstein may each be deemed to share voting and dispositive power over the shares held by OPI VII and WWH. The address of these entities is 601 Lexington Avenue, 54th floor, New York, New York 10022.

(6) Consists of 509,067 shares of common stock issuable pursuant to options exercisable within 60 days of February 28, 2019.

(7) Consists of (a) 45,754 shares of common stock and (b) 233,858 shares of common stock issuable pursuant to options exercisable within 60 days of February 28, 2019.

(8) Consists of (a) 52,669 shares of common stock and (b) 89,266 shares of common stock issuable pursuant to options exercisable within 60 days of February 28, 2019.

(9) Consists of shares held in an entity of which Dr. Baeuerle is Managing Director. Dr. Baeuerle has sole voting and investment power over these shares. 79,449 of these shares were subject to a right of repurchase as of February 28, 2019.

(10) Consists of 8,071 shares of common stock issuable pursuant to options exercisable within 60 days of February 28, 2019.

(11) Consists of 27,656 shares of common stock issuable pursuant to options exercisable within 60 days of February 28, 2019.

(12) Consists of (a) 10,813,543 shares of common stock, and (b) 867,918 shares of common stock issuable pursuant to stock options exercisable within 60 days of February 28, 2019 held by directors and executive officers.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

In addition to the compensation arrangements with our directors and executive officers described elsewhere in this Annual Report, the following is a summary of transactions since January 1, 2017 to which we have been a participant, in which:

- the amount involved exceeded or will exceed the lesser of $120,000 or one percent of our total assets at year end; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of the foregoing persons, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under "Executive Compensation" or that were approved by our compensation committee.

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable in arm's-length transactions.

Financing

Preferred Stock Financings

In November 2018, we issued and sold an aggregated of 6,499,935 shares of our Series C convertible preferred stock for $10.77 per share, for aggregate gross consideration of approximately $70.0 million. The table below sets forth the number of shares of Series C convertible preferred stock issued to any of our directors, executive officers or stockholders who held more than 5% of any class of our voting securities and their affiliates. For each share of Series C convertible preferred stock set forth in the table below, the holder received, upon conversion, one share of our common stock immediately prior to closing of our initial public offering.

Purchaser	Number of Shares	Aggregate Purchase Price
Entities associated with New Leaf Venture Partners (1)	928,562	$ 10,000,000
Arix Bioscience Holdings Limited (2)	742,850	8,000,000
Entities affiliated with MPM Capital, Inc.(3)	417,852	4,499,999
UBS Oncology Impact Fund L.P.	417,853	4,499,999
Taiho Ventures, LLC (4)	185,712	2,000,000

(1) Consists of (a) 464,281 shares purchased by New Leaf Ventures III, L.P. and (b) 464,281 shares purchased by New Leaf Biopharma Opportunities II, L.P. Entities affiliated with New Leaf Venture Partners hold more than 5% of our capital stock. Mr. Hunt, a member of our board of directors, is a manager of New Leaf Venture Management III, L.L.C, which is the general partner of New Leaf Venture Associates III, L.P., which is the general partner of New Leaf Ventures III, L.P. Further, Mr. Hunt is a manager of New Leaf BPO Management II, L.L.C., which is the general partner of New Leaf BPO Associates II, L.P., which is the general partner of Near Leaf Biopharma Opportunities II, L.P.

(2) Mr. Chin, a member of our board of directors, is an investment director for Arix Bioscience plc, the parent company of Arix Bioscience Holdings Limited.
(3) Consists of (a) 13,741 shares purchased by MPM Asset Management Investors BV2014 LLC, (b) 378,843 shares purchased by MPM BioVentures 2014, L.P. and (c) 25,268 shares purchased by MPM BioVentures 2014 (B), L.P. Entities affiliated with MPM Capital, Inc. hold more than 5% of our capital stock. Dr. Evnin, a member of our board of directors, is a member of MPM BioVentures 2014 LLC, which is the Managing Member of MPM BioVentures 2014 GP LLC, which is the General Partner of MPM BioVentures 2014, L.P. and MPM BioVentures 2014 (B), L.P. MPM BioVentures 2014 LLC is also the Manager of MPM Asset Management Investors BV2014 LLC.
(4) As of February 28, 2019, Taiho Ventures, LLC owned less than 5% of our common stock.

Between May 2017 and July 2018, we issued and sold an aggregate of 7,068,184 shares of our Series B convertible preferred stock for $6.39 per share, for aggregate gross consideration of approximately $45.2 million (including the conversion of certain of our indebtedness). The table below sets forth the number of shares of Series B convertible preferred stock issued to any of our directors, executive officers or stockholders who held more than 5% of any class of our voting securities and their affiliates. For each share of Series B convertible preferred stock set forth in the table below, the holder received, upon conversion, one share of our common stock immediately prior to the closing of our initial public offering.

Purchaser	Number of Shares	Aggregate Purchase Price
Arix Bioscience Holdings Limited (1)	1,720,698	$ 11,000,002
Entities affiliated with MPM Capital, Inc.(2)	1,578,751	10,092,603
UBS Oncology Impact Fund L.P.	1,578,755	10,092,603
Entities associated with New Leaf Venture Partners (3)	1,564,272	10,000,000
Taiho Ventures, LLC (4)	625,708	3,999,999

(1) Mr. Chin, a member of our board of directors, is an investment director for Arix Bioscience plc, the parent company of Arix Bioscience Holdings Limited.
(2) Consists of (a) 51,919 shares purchased by MPM Asset Management Investors BV2014 LLC, (b) 1,431,365 shares purchased by MPM BioVentures 2014, L.P. and (c) 95,467 shares purchased by MPM BioVentures 2014 (B), L.P. Entities affiliated with MPM Capital, Inc. hold more than 5% of our capital stock. Dr. Evnin, a member of our board of directors, is a member of MPM BioVentures 2014 LLC, which is the Managing Member of MPM BioVentures 2014 GP LLC, which is the General Partner of MPM BioVentures 2014, L.P. and MPM BioVentures 2014 (B), L.P. MPM BioVentures 2014 LLC is also the Manager of MPM Asset Management Investors BV2014 LLC.
(3) Mr. Hunt, a member of our board of directors, is a manager of New Leaf Venture Management III, L.L.C, which is the general partner of New Leaf Venture Associates III, L.P., which is the general partner of New Leaf Ventures III, L.P.
(4) As of February 28, 2019, Taiho Ventures, LLC owned less than 5% of our common stock.

License and Collaboration Agreements

License Agreement with TCR2 Therapeutics, Inc.

In June 2017, we entered into a license agreement with TCR2 Therapeutics, Inc., or TCR2, a portfolio company of MPM Capital, Inc., a holder of more than 5% of our capital stock, or the TCR2 Agreement. Dr. Baeuerle, a member of our board of directors, is a member of the board of directors of TCR2. Under the TCR2 Agreement, we granted to TCR2 a license under certain patents that we own to develop and commercialize products that contain a specific binding domain to the Mesothelin antigen, and TCR2 granted to us a license under certain patents that it owns to develop and commercialize products that contain a specific binding domain to the B-cell maturation antigen. Each license is non-exclusive, worldwide, royalty free and sublicensable. Each party, in its sole discretion, will be responsible for the development and commercialization of its respective products under the TCR2 agreement, but neither party has any diligence obligations with respect to such development and commercialization. Upon request by the other party, each party is required to share information related to a binding domain in connection with regulatory approval of a product incorporating such binding domain.

The TCR2 Agreement will continue on a product-by-product basis until the expiration of all the patents licensed under this agreement, and it may be earlier terminated by either party for the other party's uncured material breach or insolvency. If the TCR2 Agreement is terminated, all licenses and rights granted under the agreement to the terminated party will automatically terminate and revert to the terminating party.

License Agreement with Werewolf Therapeutics, Inc.

In March 2018, we entered into an assignment and license agreement with Werewolf Therapeutics, Inc., or Werewolf, a portfolio company of MPM Capital, Inc., a holder of more than 5% of our capital stock, or the Werewolf Agreement. Dr. Evnin, a member of our board of directors, is the interim Chief Executive Officer and Chairman of the board of directors of Werewolf. Dr. Baeuerle, a member of our board of directors, 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 $500,000. 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.

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

Royalty Transfer Agreement with MPM Oncology Charitable Foundation and UBS Optimus Foundation

In December 2016, we entered into a royalty transfer agreement with MPM Oncology Charitable Foundation, Inc., or MPMOCF, and UBS Optimus Foundation, or UBS, a holder of more than 5% of our capital stock, or the Royalty Transfer Agreement. Under the Royalty Transfer Agreement, we will pay 0.5% of our annual global net sales to each of MPMOCF and UBS for products that incorporate or utilize intellectual property that was discovered or developed by us prior to our initial public offering. Our payment obligations for each product will continue on a country-by-county basis upon the later of the twelfth anniversary of the first commercial sale of such product in such country or the expiration of the last to expire claim of certain patents owned or controlled by us covering such product in such country. If there are no such patent claims covering our product during this term, then our payment obligations will be reduced by 50% such that we would pay 0.25% of our annual global Net Sales to each of MPMOCF and UBS for the remainder of this term.

Our payment obligations to MPMOCF will terminate immediately upon the winding up or dissolution of MPMOCF. Our payment obligations to UBS will terminate immediately upon the expiration or termination of a certain contribution agreement between UBS and the Oncology Impact Fund (Cayman) Management L.P., or OIF. Additionally, the Royalty Transfer Agreement will terminate immediately if for any reason the MPM Oncology Management GP, LP ceases to serve as the general partner for OIF.

Asset Transfer Agreement with Maverick Therapeutics, Inc.

In December 2016, we entered into the Asset Transfer Agreement with Maverick, a portfolio company of MPM Capital, Inc., a holder of more than 5% of our capital stock. Dr. Evnin, a member of our board of directors, was a member of the board of directors of Maverick, and Dr. Baeuerle, a member of our board of directors, was an observer of the board of directors of Maverick, through their resignations in December 2018. Under the Asset Transfer Agreement, we transferred one provisional patent application (and any subsequently filed patent applications that claim priority to the provisional patent application) and certain know-how to Maverick solely for use in connection with a specific type of conditionally active T cell engagers having an activation mechanism that is not used by the T cell engagers we are developing (such permitted use, the Maverick Field), and Maverick assumed liabilities from us relating to this transferred intellectual property and other transferred assets. Maverick granted back to us a royalty-free, non-exclusive, sublicenseable license under this transferred intellectual property for use in all fields outside of the Maverick Field, which include all fields in which we are developing products. We further granted Maverick royalty-free, exclusive and non-exclusive licenses to certain other patents that we own, in all cases solely for use in the Maverick Field. In consideration for our transfer and license of such intellectual property, Maverick issued a promissory note to us in the amount of $6.8 million, which we collected in full in January 2017, and all of its outstanding capital stock to us and this stock was distributed to our stockholders (such distribution, the Distribution). Under the Asset Transfer Agreement, we agreed not to directly or indirectly research, develop, manufacture or commercialize products in the Maverick Field for four years after the Distribution. The Asset Transfer Agreement is not terminable and all rights transferred or licensed by a party to the other party under the Asset Transfer Agreement are irrevocable.

Sublease with Tizona Therapeutics, Inc.

In February 2017, we entered into a sublease with Tizona Therapeutics, Inc., or Tizona, a portfolio company of MPM Capital, Inc., a holder of more than 5% of our capital stock. Dr. Evnin, a member of our board of directors, is the Executive Chairman of Tizona. Under the terms of the sublease, which expires in April 2020, our monthly payment (which is currently approximately $67,000) increases by 3% each year. We paid Tizona an aggregate of approximately $1.1 million and $0.8 million under the sublease for the year ended 2018 and 2017, respectively.

Consulting Agreement with Dr. Baeuerle

On April 1, 2015, we entered into a consulting agreement with Dr. Baeuerle, a member of our board of directors. The consulting agreement was amended on October 1, 2015, February 1, 2016, November 1, 2016, January 1, 2017, February 1, 2017 and March 5, 2018. Pursuant to the consulting agreement, Dr. Baeuerle performs certain consulting, advisory and related services for us as we may request from time to time. The consulting agreement had an initial term of one year, which automatically extends for additional one-year periods unless earlier terminated by us or Dr. Baeuerle. Either party may terminate the consulting agreement upon 30-days' written notice to the other party. As compensation for his services, we pay Dr. Baeuerle a monthly consulting fee of €8,333 per month. In addition, Dr. Baeuerle was eligible to receive a bonus at the discretion of our board of directors in connection with the closing of our Series B convertible preferred stock financing, which we paid in the amount of $32,959 in 2017. We paid Dr. Baeuerle an aggregate of $120,827, $118,415, and $313,634 under the consulting agreement in 2018, 2017, and 2016, respectively.

Consulting Agreement with Mr. Picht

On September 12, 2018, we entered into a consulting agreement with Mr. Picht, our former Chief Financial Officer. Pursuant to the consulting agreement, Mr. Picht performs certain consulting, advisory and related services for us as we may request from time to time. The consulting agreement has an initial termination date of March 15, 2019 and may be renewed pursuant to its terms by us or Mr. Picht. As compensation for his services, we pay Mr. Picht a consulting fee of $250 per hour, in addition to a one-time bonus payment of $59,096 if Mr. Picht provides a minimum of ten hours of service per month through December 2018. We paid Mr. Picht an aggregate of $50,437 under the consulting agreement for the year ended December 31, 2018.

Amended and Restated Investors' Rights Agreement

On November 9, 2018, we entered into an amended and restated investors' rights agreement, or the investors' rights agreement, with the holders of our Series B convertible preferred stock and Series C convertible preferred stock. The investors' rights agreement provides, except with respect to our initial public offering, that the holders of common stock issuable upon conversion of our Series A convertible preferred stock, Series B convertible preferred stock and Series C convertible preferred stock have the right to demand that we file a registration statement or request that their shares of common stock be covered by a registration statement that we are otherwise filing. In addition to registration rights, the investors' rights agreement provides for certain information rights, board observation rights, a right of first offer and a market stand-off provision imposing restrictions on the ability of the parties thereto to offer, sell or transfer our equity securities for a period of 180 days following the date of our initial public offering. The investors' rights agreement terminated pursuant to its terms immediately prior to the completion of our initial public offering, other than those provisions relating to registration rights, which will terminate no later than three years after the completion of our initial public offering, the closing of a deemed liquidation event (as defined in our amended and restated certificate of incorporation) or, with respect to any particular holder, at such time that such holder can sell its shares, under Rule 144 under the Securities Act or otherwise, during any 90-day period without registration.

Amended and Restated Voting Agreement

On November 9, 2018, we entered into an amended and restated voting agreement, or the voting agreement, with the holders of our Series B convertible preferred stock and Series C convertible preferred stock and certain of our other stockholders, including Dr. Hicklin, a former member of our board of directors, Dr. McMahon, Dr. Sacks and Dr. Wesche, each an executive officer of our company, and Mr. Picht, a former executive officer of our company, with respect to the election of our board of directors and certain other matters. All current members of our board of directors were elected pursuant to the terms of the voting agreement prior to the completion of our initial public offering. The voting agreement terminated in February 2019 pursuant to its terms immediately prior to the completion of our initial public offering. See "Item 10- Directors, Executive Officers and Corporate Governance—Board Composition."

Amended and Restated Right of First Refusal and Co-Sale Agreement

On November 9, 2018, we entered into an amended and restated right of first refusal and co-sale agreement, or the co-sale agreement, with the holders of our Series B convertible preferred stock and Series C convertible preferred stock and certain of our

other stockholders, including Dr. Hicklin, a former member of our board of directors, Dr. McMahon, Dr. Sacks and Dr. Wesche, each an executive officer of our company, and Mr. Picht, a former executive officer of our company. The co-sale agreement provided the holders of our convertible preferred stock with rights of purchase and co-sale in respect of certain sales of our securities by the other parties to the co-sale agreement. The co-sale agreement terminated in February 2019 upon the completion of our initial public offering.

Offer Letters

We have entered into offer letters with certain of our executive officers. See "Item 11-Executive Compensation—Employment and Change of Control Arrangements."

Equity Grants

We have granted stock options and warrants to certain of our executive officers and members of our board of directors. See "Item 11-Executive Compensation" and "Item 10- Directors, Executive Officers and Corporate Governance—2017 Non-Employee Director Compensation."

Indemnification Agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of the members of our board of directors, and our amended and restated bylaws, provides that we indemnify each of our officers and the members of our board of directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws also provides our board of directors with discretion to indemnify our employees and other agents when it determines to be appropriate. In addition, we have entered into indemnification agreements with each of our executive officers and the members of our board of directors requiring us to indemnify them. See "Item 11-Executive Compensation— Indemnification of Directors and Officers."

Policies and Procedures for Transactions with Related Persons

We have adopted a policy that our executive officers, directors, nominees for election as a director and beneficial owners of more than 5% of any class of our common stock, as well as any members of the immediate family of any of the foregoing persons, are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with any of such persons, in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest, must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than those generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction. All of the transactions described above were entered into prior to the adoption of such policy, but after presentation, consideration and approval by our board of directors.

Item 14. Principal Accounting Fees and Services.

The following table sets forth all fees billed for professional audit services and other services rendered by Ernst & Young LLP for each of the years ended December 31, 2018 and 2017:

	2018	2017	2016
Audit Fees(1)	$ 1,227,650	$ 315,499	$ 100,000
Audit-Related Fees	—	—	—
Tax Fees	—	—	—
All Other Fees	—	—	—
Total Fees	$ 1,227,650	$ 315,499	$ 100,000

(1) Audit Fees: Includes all fees for services incurred in connection with our initial public offering and 2016-2018 year-end audits.

Pre-Approval of Audit and Non-Audit Services

Consistent with requirements of the SEC and the Public Company Accounting Oversight Board regarding auditor independence, our audit committee is responsible for the appointment, compensation and oversight of the work of our independent registered public accounting firm. In recognition of this responsibility, our audit committee, or the chair if such approval is needed between meetings of the audit committee, pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements:

The following financial statements and schedules of the Registrant are contained in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K:

	Page
Report of Independent Registered Public Accounting Firm	F-2
Financial Statements:	
Balance Sheets	F-3
Statements of Operations and Comprehensive Loss	F-4
Statements of Convertible Preferred Stock and Stockholders' Deficit	F-5
Statements of Cash Flows	F-6
Notes to the Financial Statements	F-7

2. Financial Statement Schedules

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes thereto.

(b) Exhibits

The exhibits listed in the following "Exhibit Index" are filed, furnished or incorporated by reference as part of this Annual Report.

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	8-K	001-3880	3.1	2/13/2019	
3.2	Amended and Restated Bylaws of the Registrant	8-K	001-3880	3.2	2/13/2019	
4.1	Form of Common Stock Certificate.	S-1	333-229040	4.1	1/29/2019	
4.2	Amended and Restated Investors' Rights Agreement, dated as of November 9, 2018, by and among the Registrant and certain of its stockholders.	S-1	333-229040	4.2	12/27/2018	
4.3	Warrant to Purchase Common Stock issued on July 13, 2016 to Danforth Advisors, LLC.	S-1	333-229040	4.3	12/27/2018	
4.4	Form of Warrant to Purchase Common Stock issued to entities affiliated with MPM Capital, Inc. on March 24, 2015, July 23, 2015, August 17, 2015 and December 16, 2015 in connection with convertible promissory note financings.	S-1	333-229040	4.4	12/27/2018	
4.5	Form of Warrant to Purchase Common Stock issued to entities affiliated with MPM Capital, Inc. and UBS Oncology Impact Fund L.P. on November 1, 2016 and January 10, 2017 in connection with note and warrant financings.	S-1	333-229040	4.5	12/27/2018	
10.1+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers	S-1	333-229040	10.4	1/4/2019	
10.2+	Harpoon Therapeutics, Inc. 2015 Equity Incentive Plan and related form agreements	S-1	333-229040	10.1	12/27/2018	
10.3+	Harpoon Therapeutics, Inc. 2019 Equity Incentive Plan and related form agreements	S-1	333-229040	10.2	1/29/2019	
10.4+	Harpoon Therapeutics, Inc. Amended and Restated Employee Stock Purchase Plan and related form agreements	S-1	333-229040	10.3	1/29/2019	
10.5+	Employment Offer Letter by and between Gerald McMahon and the Registrant, dated as of December 10, 2016	S-1	333-229040	10.5	12/27/2018	
10.6+	Employment Offer Letter by and between Holger Wesche and the Registrant, dated as of March 17, 2015, as amended	S-1	333-229040	10.6	12/27/2018	
10.7+	Employment Offer Letter by and between Natalie Sacks and the Registrant, dated as of September 13, 2018	S-1	333-229040	10.7	12/27/2018	
10.8+	Consulting Agreement by and between William Picht, Jr. and the Registrant, dated as of September 12, 2018	S-1	333-229040	10.8	12/27/2018	
10.9+	Third Amended and Restated Consulting Agreement by and between Patrick Baeuerle and the Registrant, dated as of February 1, 2017, as amended	S-1	333-229040	10.9	12/27/2018	
10.10+	Non-Employee Director Compensation Policy	S-1	333-229040	10.10	1/29/2019	
10.11¥	Discovery Collaboration and License Agreement between the Registrant and AbbVie Biotechnology Ltd., dated as of October 10, 2017.	S-1	333-229040	10.11	12/27/2018	
10.12¥	License Agreement between the Registrant and TCR2 Therapeutics, Inc., dated as of June 21, 2017	S-1	333-229040	10.12	12/27/2018	
10.13	Royalty Transfer Agreement by and between the Registrant, MPM Oncology Charitable Foundation, Inc. and the UBS Optimus Foundation, dated as of December 1, 2016, as amended	S-1	333-229040	10.13	12/27/2018	
10.14¥	First Amended and Restated Assignment and License Agreement between the Registrant and Werewolf Therapeutics, Inc., dated as of October 19, 2018	S-1	333-229040	10.14	12/27/2018	
10.15¥	CHEF 1 Collaboration and License Agreement between the Registrant and CMC ICOS Biologics, Inc., dated October 26, 2015	S-1	333-229040	10.15	12/27/2018	

Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.16¥	Amendment to CHEF1 Collaboration and License Agreement and Development and Manufacturing Services Agreement between Registrant and AGC Biologics, Inc. (previously CMC ICOS Biologics, Inc.), dated as of December 12, 2018	S-1	333-229040	10.21	1/29/2019	
10.17¥	Development and Manufacturing Services Agreement between the Registrant and CMC ICOS Biologics, Inc., dated July 5, 2016	S-1	333-229040	10.16	12/27/2018	
10.18	Sublease between Registrant and Tizona Therapeutics, Inc., dated as of February 6, 2017	S-1	333-229040	10.17	12/27/2018	
10.19	Lease by and between AP3-SF1 4000 Shoreline, LLC and Tizona Therapeutics, Inc., dated as of December 21, 2015, as amended	S-1	333-229040	10.18	12/27/2018	
10.20	Lease by and between the Registrant and HCP Oyster Point III LLC, dated as of July 27, 2018	S-1	333-229040	10.19	12/27/2018	
10.21+	Employment Offer Letter by and between Georgia Erbez and the Registrant, dated as of October 19, 2018	S-1	333-229040	10.20	1/4/2019	
21.1	List of subsidiaries of the Registrant	S-1	333-229040	21.1	12/27/2018	
23.1	Consent of Independent Registered Public Accounting Firm					x
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 Annual Report on Form 10-K, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Harpoon Therapeutics, Inc. 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 Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

\+ Indicates management contract or compensatory plan.

¥ Confidential treatment has been granted as to certain portions of this exhibit, which portions have been omitted and submitted separately to the Securities and Exchange Commission.

* 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.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 14, 2019

HARPOON THERAPEUTICS, INC.

By: /s/ Gerald McMahon, Ph.D.
Gerald McMahon, Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Gerald McMahon, Ph.D. and Georgia Erbez, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and either of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Gerald McMahon, Ph.D. Gerald McMahon, Ph.D.	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 14, 2019
/s/ Georgia Erbez Georgia Erbez	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2019
/s/ Luke Evnin, Ph.D. Luke Evnin, Ph.D.	Chairman of the Board of Directors	March 14, 2019
/s/ Patrick Baeuerle, Ph.D. Patrick Baeuerle, Ph.D.	Director	March 14, 2019
/s/ Mark Chin Mark Chin	Director	March 14, 2019
/s/ Jonathan Drachman, M.D. Jonathan Drachman, M.D.	Director	March 14, 2019
/s/ Julie Eastland Julie Eastland	Director	March 14, 2019
/s/ Ron Hunt Ron Hunt	Director	March 14, 2019
/s/ Scott Myers Scott Myers	Director	March 14, 2019

HARPOON THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm	F-2
Financial Statements:	
Balance Sheets	F-3
Statements of Operations and Comprehensive Loss	F-4
Statements of Convertible Preferred Stock and Stockholders' Deficit	F-5
Statements of Cash Flows	F-6
Notes to the Financial Statements	F-7

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Harpoon Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Harpoon Therapeutics, Inc. (the Company), as of December 31, 2018 and 2017, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

San Jose, California
March 14, 2019

HARPOON THERAPEUTICS, INC.
Balance Sheets
(In thousands, except share and per share amounts)

	December 31,	
	2018	2017
Assets		
Current assets		
Cash and cash equivalents	$ 89,493	$ 29,423
Prepaid expenses and other current assets	730	224
Total current assets	90,223	29,647
Property and equipment, net	2,998	2,087
Tenant improvement allowance receivable	5,784	—
Other assets	3,575	138
Total assets	$ 102,580	$ 31,872
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities		
Accounts payable	$ 4,357	$ 1,174
Accrued liabilities	3,341	1,492
Deferred revenue, current	4,250	4,250
Total current liabilities	11,948	6,916
Deferred revenue, noncurrent	7,792	12,042
Other long-term liabilities	6,742	16
Total liabilities	26,482	18,974
Commitments and contingencies (Note 6)		
Convertible preferred stock, $0.0001 par value; 82,000,000 shares and 50,000,000 shares authorized at December 31, 2018 and 2017, respectively; 16,618,448 and 6,989,973 shares issued and outstanding as of December 31, 2018 and 2017, respectively; aggregate liquidation preference of $130,178 as of December 31, 2018	129,577	39,841
Stockholders' deficit		
Common stock, $0.0001 par value; 114,000,000 and 75,000,000 shares authorized as of December 31, 2018 and 2017, respectively; 1,383,221 and 1,193,629 shares issued and outstanding at December 31, 2018 and 2017, respectively	1	1
Additional paid-in capital	9,111	8,309
Note receivable from stockholder	—	(28)
Accumulated deficit	(62,591)	(35,225)
Total stockholders' deficit	(53,479)	(26,943)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 102,580	$ 31,872

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

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

	For the year ended December 31,		
	2018	**2017**	**2016**
Revenue			
Collaboration and license revenue	$ 4,750	$ 708	$ —
Total revenue	4,750	708	—
Operating expenses			
Research and development	26,368	13,622	7,778
General and administrative	6,106	3,614	3,369
Total operating expenses	32,474	17,236	11,147
Loss from operations	(27,724)	(16,528)	(11,147)
Interest income	395	78	6
Interest expense	—	(285)	(261)
Other expense	(37)	(95)	(4)
Net loss and comprehensive loss	$ (27,366)	$ (16,830)	$ (11,406)
Net loss per share, basic and diluted	(25.65)	(18.81)	(21.61)
Weighted-average common shares used in computing net loss per share, basic and diluted	1,066,877	894,901	527,931

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

HARPOON THERAPEUTICS, INC.
Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Note Receivable from Stockholder	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2015	—	$ —	186,832	$ —	$ 92	$ —	$ (6,989)	$ (6,897)
Issuance of Series A convertible preferred stock at $4.92 per share, net of issuance costs of $74	1,525,164	7,426	—	—	—	—	—	—
Issuance of Series A convertible preferred stock at $4.92 per share upon extinguishment of 2015 Notes	1,525,165	7,500	—	—	—	—	—	—
Capital transaction with related party upon extinguishment of 2015 Notes	—	—	—	—	337	—	—	337
Issuance of warrants related to sale of 2016 Notes	—	—	—	—	199	—	—	199
Reclassification of warrants from liability	—	—	—	—	23	—	—	23
Issuance of common stock for exercise of stock options	—	—	17,556	—	10	—	—	10
Issuance of common stock for services and a license agreement	—	—	201,118	1	152	—	—	153
Vesting of early exercised stock options	—	—	58,714	—	35	—	—	35
Stock-based compensation	—	—	—	—	99	—	—	99
Vesting of Founder's shares	—	—	357,624	—	—	—	—	—
Proceeds from Maverick spin-off transaction	—	—	—	—	7,031	—	—	7,031
Note receivable from stockholder	—	—	—	—	—	(28)	—	(28)
Net loss and comprehensive loss	—	—	—	—	—	—	(11,406)	(11,406)
Balance at December 31, 2016	3,050,329	14,926	821,844	1	7,978	(28)	(18,395)	(10,444)
Issuance of Series B convertible preferred stock at $6.39 per share, net of issuance costs of $271	3,128,541	19,729	—	—	—	—	—	—
Issuance of Series B convertible preferred stock at $6.39 per share upon extinguishment of 2016 Notes and 2017 Notes, net of issuance costs of $271	811,103	5,186	—	—	—	—	—	—
Capital transaction with a related party upon extinguishment of 2016 and 2017 Notes	—	—	—	—	(204)	—	—	(204)
Issuance of warrants related to 2017 Notes	—	—	—	—	144	—	—	144
Issuance of common stock for exercise of stock options	—	—	7,897	—	4	—	—	4
Issuance of common stock	—	—	3,050	—	2	—	—	2
Vesting of early exercised stock options	—	—	30,502	—	18	—	—	18
Stock-based compensation	—	—	—	—	367	—	—	367
Vesting of Founder's shares	—	—	85,001	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	—	(16,830)	(16,830)
Balances at December 31, 2017	6,989,973	39,841	948,294	1	8,309	(28)	(35,225)	(26,943)
Issuance of Series B convertible preferred stock at $6.39 per share upon extinguishment of 2016 Notes and 2017 Notes, net of issuance costs of $8	3,128,540	19,992	—	—	—	—	—	—
Issuance of Series C convertible preferred stock at $10.77 per share, net of issuance costs of $256	6,499,935	69,744	—	—	—	—	—	—
Issuance of common stock for exercise of stock options	—	—	125,533	—	122		—	122
Vesting of early exercised stock options	—	—	56,025	—	36	—	—	36
Stock-based compensation	—	—	—	—	644	28	—	672
Vesting of Founder's shares	—	—	81,567	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	—	(27,366)	(27,366)
Balances at December 31, 2018	16,618,448	129,577	1,211,419	1	9,111	—	(62,591)	(53,479)

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

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

	For the year ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities			
Net loss	$ (27,366)	$ (16,830)	$ (11,406)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities			
Stock-based compensation expense	672	367	99
Depreciation and amortization	644	366	198
Accrued interest on convertible notes payable	—	153	185
Amortization of debt discount	—	132	76
Change in fair value of warrant liability	—	—	4
Changes in operating assets and liabilities			
Prepaid expenses and other assets	(507)	335	(327)
Other assets	—	(138)	76
Accounts payable	2,555	804	570
Accrued liabilities	1,048	257	(317)
Deferred revenue	(4,250)	16,292	—
Other long-term liabilities	78	(24)	48
Net cash (used in) provided by operating activities	(27,126)	1,714	(10,794)
Cash flows from investing activities			
Purchases of property and equipment	(663)	(2,275)	(553)
Proceeds from repayment of note receivable	—	6,750	—
Net cash (used in) provided by investing activities	(663)	4,475	(553)
Cash flows from financing activities			
Proceeds from issuance of convertible preferred stock, net of issuance costs	89,828	19,729	7,426
Proceeds from issuance of convertible notes, net of issuance costs	—	2,496	2,478
Proceeds from issuance of common stock upon exercise of stock options, net	158	22	81
Proceeds from issuance of common stock	—	2	—
Payments of deferred initial public offering costs	(1,660)	—	—
Net cash provided by financing activities	88,326	22,249	9,985
Net increase (decrease) in cash, cash equivalents, and restricted cash	60,537	28,438	(1,362)
Cash, cash equivalents, and restricted cash at beginning of period	29,423	985	2,347
Cash, cash equivalents, and restricted cash at end of period	$ 89,960	$ 29,423	$ 985
Supplemental disclosures of non-cash investing and financing information			
Issuance of Series A preferred stock on extinguishment of 2015 Notes	$ —	$ —	$ 7,500
Issuance of Maverick promissory note to Harpoon	$ —	$ —	$ 6,750
Derecognition of net liabilities related to Maverick spin-off transaction	$ —	$ —	$ 281
Issuance of Series B convertible preferred stock upon extinguishment of 2016 Notes and 2017 Notes	$ —	$ 5,186	$ —
Capital transaction with a related party upon extinguishment of Notes	$ —	$ (204)	$ 337
Issuance of common stock in exchange for license and services	$ —	$ —	$ 552
Reacquisition of unvested common stock on extinguishment of note receivable from stockholder	$ —	$ —	$ 62
Purchases of property and equipment included in accounts payable	$ 28	$ —	$ 23
Deferred initial public offering costs included in accounts payable and accrued liabilities	$ 1,309	$ 78	$ 10
Tenant improvements provided by landlord	$ 6,648	$ —	$ —
Series C preferred stock issuance costs included in accounts payable and accrued liabilities	$ 92	$ —	$ —

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

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, or 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 statements on Form S-1 relating to its initial public offering ("IPO") was declared effective by the Securities and Exchange Commission ("SEC") and the shares of its common stock began trading on the NASDAQ Global Select Market 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 December 31, 2018, the Company had an accumulated deficit of $62.6 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 December 31, 2018, the Company had unrestricted cash and cash equivalents of $89.5 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 December 31, 2018, provide sufficient capital resources to continue its operations for at least 12 months from the issuance date of these 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 financial statements have been prepared in accordance with U.S. generally accepted accounting principles.

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 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 expenses during the reporting period. Significant estimates and assumptions made in the accompanying 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, 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 and zero as of December 31, 2018 and 2017, respectively. This amount as of December 31, 2018 is 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 6.

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 December 31,		
	2018	2017	2016
	(in thousands)		
Balance Sheets			
Cash and cash equivalents	$ 89,493	$ 29,423	$ 985
Restricted cash (included in other assets)	467	—	—
Cash, cash equivalents and restricted cash in Statements of Cash Flows	$ 89,960	$ 29,423	$ 985

Concentration of Credit Risk

Cash and cash equivalents 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.

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, 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, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. 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 payable 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 provides 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, we early adopted ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). 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, we record 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 11, 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)

The Company has no components of comprehensive income (loss) other than net loss. Thus, comprehensive loss is the same as net loss for all periods presented.

Deferred Offering Costs

The Company has deferred offering costs consisting of legal, accounting and other fees directly attributable to the Company's IPO. The deferred offering costs were offset against the proceeds received upon completion of the IPO. As of December 31, 2018 and December 31, 2017, $3.0 million and zero of deferred offering costs were included in other assets on the condensed balance sheet, 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 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, these 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 2014-09, *Revenue from Contracts with Customers* (Accounting Standards Codification Topic 606), ASU 2016-09, *Stock Compensation—Improvements to Employee Share-Based Payment Accounting*, and ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting,* 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. In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *(Topic 842), Leases*. For public entities, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. The Company is considering early adoption of this standard in the first half of 2019. The Company is currently evaluating the effect the new guidance will have on its financial statements. The Company expects to use the extended transition period for any other new or revised accounting standards during the period in which it remains an emerging growth company.

Recently Adopted Accounting Pronouncements

On January 1, 2018, the Company early adopted ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 was issued to align the accounting for share-based payment awards issued to employees and nonemployees, particularly with regard to the measurement date and the impact of performance conditions. 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 and outstanding prior to January 1, 2018, we recorded expense related to stock options based on the fair value of the options calculated using the Black-Scholes option-pricing model over the service performance period. For public entities, ASU 2018-07 is effective for fiscal years beginning after December 15, 2018. Early adoption is permitted, as the Company has also adopted ASC Topic 606. The adoption did not have a material impact on the Company's financial statements.

On January 1, 2018, the Company adopted ASU 2017-09, *Stock Compensation – Scope of Modification Accounting* ("ASU 2017-09"), which clarifies the scope of modification accounting for share-based payment arrangements. The new guidance clarifies that modification accounting is not applied if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. ASU 2017-09 is effective for fiscal years beginning after December 15, 2017. The Company elected to adopt this guidance prospectively to awards modified on or after the adoption date. The adoption did not have a material impact on the Company's financial statements.

Recently Issued 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 will also require 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. For public entities, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. The Company is considering early adoption of this standard in the first half of 2019. Management expects that the adoption of this standard will result in the recognition of a right-of-use asset for leased facilities and recognition of a liability for the lease payments remaining on the leases. These changes will be reflected on the balance sheets. The Company is currently evaluating the effect the new guidance will have on its financial statements.

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. Additionally, under the new guidance, an entity will be required to provide certain disclosures regarding stranded tax effects. The guidance is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect the new guidance will have on 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 December 31, 2018			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Money market funds	$ 60,396	$ 60,396	$ —	$ —
Total	$ 60,396	$ 60,396	$ —	$ —

	Fair Value Measurements at December 31, 2017			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Money market funds	$ 28,575	$ 28,575	$ —	$ —
Total	$ 28,575	$ 28,575	$ —	$ —

The Company classifies money market funds as Level 1. The Company has no Level 2 or Level 3 assets or liabilities as of December 31, 2018 or 2017. There were no transfers between Level 1 and Level 2 during the years ended December 31, 2018 and 2017.

There were no unrealized or realized gains or losses during the years ended December 31, 2018 and 2017.

The Company did not have any financial liabilities subject to fair value measurements on a recurring basis as of December 31, 2018 and 2017.

4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31,	
	2018	2017
	(in thousands)	
Laboratory equipment	$ 2,402	$ 1,752
Furniture and fixtures	312	268
Computer equipment and software	32	32
Leasehold improvements	360	327
Construction in progress	906	78
	4,012	2,457
Less: Accumulated depreciation and amortization	(1,014)	(370)
Total property and equipment, net	$ 2,998	$ 2,087

Depreciation and amortization expense for property and equipment amounted to $0.7 million and $0.4 million for the years ended December 31, 2018 and 2017, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2018	2017
Accrued research and development	$ 504	$ 522
Accrued personnel costs	1,593	871
Accrued professional and consulting fees	333	—
Accrued offering costs	709	—
Other	202	99
Total accrued liabilities	$ 3,341	$ 1,492

5. Convertible Notes

In November 2016, the Company issued an aggregate of $2.5 million in convertible promissory notes (the "2016 Notes") to existing shareholders. In January 2017, the Company issued an additional $2.5 million in convertible promissory notes (the "2017 Notes") to the same investors. Interest accrued on the aggregate principal balance of $5.0 million at an annual rate of 8%. Principal and interest were due and payable upon the earliest of (i) the one-year anniversary of the issuance date, (ii) an event of default or (iii) on demand. Principal and accrued interest thereon automatically converted into shares of convertible preferred stock in a Qualified Financing (defined as the first issuance of convertible preferred stock with gross proceeds to the Company of at least $25.0 million).

In May 2017, the outstanding principal balance of the 2016 Notes and 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 Financing (see Note 8). The conversion of the 2016 Notes and the 2017 Notes into shares of Series B convertible preferred stock was accounted for as an extinguishment. The difference of $0.2 million between the net carrying value of the 2016 Notes and the 2017 Notes and accrued interest thereon, and the reacquisition price, was recorded through additional paid-in capital for the year ending December 31, 2017 as the extinguishment was deemed to be a capital transaction with a related party.

Warrants Issued with 2016 and 2017 Notes

In connection with the issuance of the 2016 Notes and the 2017 Notes, the Company issued warrants for the purchase of 152,514 shares of the Company's common stock and for the purchase of 101,675 shares of the Company's common stock, respectively, at an exercise price of $0.05 per share. The warrants are exercisable after the first issuance of convertible preferred stock with gross proceeds to the Company of at least $5.0 million until the ten-year anniversary of the issuance date, and were classified in equity as they meet the equity classification requirements. Upon issuance, the Company estimated the fair value of these warrants using the Black-Scholes option-pricing model to be $0.2 million and $0.1 million for the 2016 Notes and the 2017 Notes, respectively. Such amounts were recorded as a reduction to the carrying value of the 2016 Notes and the 2017 Notes, and such debt discount was accreted using the effective interest method.

For the years ended December 31, 2018 and 2017, the Company recognized total amortization expense relating to the discount created by the warrants and debt issuance costs of zero and $0.1 million, respectively, through interest expense in the statements of operations and comprehensive loss. As of December 31, 2018 and 2017, the unamortized debt discount was zero as the 2016 and 2017 Notes were converted into shares of convertible preferred stock as noted above and no convertible promissory notes existed as of December 31, 2018 and 2017.

As of December 31, 2018 and 2017, warrants for the purchase of an aggregate of 565,270, of the Company's common stock were outstanding, of which 565,270 shares were exercisable. The weighted-average exercise price of the outstanding warrants was $0.05 per share as of both December 31, 2018 and 2017. In connection with the Company's IPO, the Company's outstanding warrants of 565,270 shares automatically net exercised at the IPO price of $14.00 per share.

6. Commitments and Contingencies

Leases

In February 2017, the Company entered into an operating lease agreement with Tizona Therapeutics, Inc. ("Tizona") 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 August 2018, the Company entered into a lease agreement for the office and laboratory space in South San Francisco, California. 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 such, the total tenant improvement allowance of $6.6 million granted to the Company was recognized as a tenant improvement allowance receivable and a related deferred rent liability. As of December 31, 2018, the portion of the tenant improvement allowance utilized under this lease was $0.9 million, which was recorded as construction in progress and a reduction to the tenant improvement allowance receivable on the balance sheet. The Company will amortize the deferred rent liability as a reduction of rent expense over the expected lease term. In addition, the lease requires the Company to maintain a letter of credit for the benefit of the landlord in the amount of $0.5 million, commencing on the effective date of the agreement until the expiration of the lease. This amount is included within the other assets on the balance sheet. 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.

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease term and records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Where leases contain escalation clauses, rent abatements, and/or concessions such as rent holidays and landlord or tenant incentive and allowances, the Company applies them in the determination of straight-line rent expense over the lease term. The Company records tenant improvement allowances as deferred rent and associated expenditures as leasehold improvements that are being amortized over the shorter of their estimated useful life or the term of the lease. The Company does not assume renewals in its determination of the lease term unless the renewals are deemed by management to be reasonably assured at lease inception.

As of December 31, 2018, future minimum payments under the Company's non-cancelable operating lease are as follows (in thousands):

Year Ended December 31, 2018		
2019	$	1,308
2020		2,762
2021		2,566
2022		2,647
2023		2,731
Thereafter		10,251
	$	22,265

Rent expense for each of the years ended December 31, 2018, 2017, and 2016 was $1.2 million, $0.8 million, and $0.8 million, respectively.

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.

7. 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. 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.

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 December 31, 2018. For the year ended December 31, 2018 and 2017, $4.3 million and $0.7 million of revenue has been recognized in the accompanying statement of operations and comprehensive loss, respectively. As of December 31, 2018, the Company has recorded $12.0 million in deferred revenue, of which $7.8 million is classified as long-term and $4.2 million as short-term deferred revenue, in the accompanying balance sheet. As of December 31, 2017, the Company recorded $16.3 million in deferred revenue, of which $12.1 million was classified as long-term and $4.2 million as short-term deferred revenue.

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 December 31, 2018, 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 year ended December 31, 2018.

License Agreement with Werewolf Therapeutics, Inc.

In March 2018, the Company entered into an assignment and license agreement (the "Werewolf Agreement" or "License 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 License 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 will be recognized upfront upon delivery of the license to Werewolf and royalties on net sales will be recognized when the underlying sales occur. For the year ended December 31, 2018, $0.5 million of revenue related to the upfront payment has been recognized in the accompanying condensed statement of operations and comprehensive loss. No royalty revenue was recognized under the Werewolf Agreement during the year ended December 31, 2018.

8. Convertible Preferred Stock

In May 2017, the Company entered into a Series B Preferred Stock Purchase Agreement (the "Series B Agreement"), pursuant to which the Company issued 3,128,540 shares of its Series B convertible preferred stock at a purchase price of $6.39 per share for net proceeds of $19.7 million, of which $7.5 million was sold to related party investors of the Company. In addition, as discussed in Note 5, the Company issued an aggregate of 811,103 shares of Series B convertible preferred stock upon the extinguishment of the 2016 Notes and the 2017 Notes in an aggregate of $5.2 million. Included in the terms of the Series B Agreement were certain rights ("Tranche Rights") granted to the initial purchasers of Series B convertible preferred stock that became exercisable upon the achievement by the Company of certain regulatory milestones. The Tranche Rights provided the purchasers of Series B convertible preferred stock the right to purchase, and obligated the Company to sell, 3,128,540 additional shares of Series B convertible preferred stock at $6.39 per share upon the filing of an IND for HPN424. This milestone was achieved in July 2018, resulting in the Company issuing 3,128,540 shares of Series B convertible preferred stock to its existing Series B investors at a price per share of $6.39 for net proceeds of $20.0 million. The Company concluded the Tranche Rights did not meet the definition of a freestanding financial instrument, as the Tranche Rights were not legally detachable from the Series B convertible preferred stock.

In November 2018, the Company entered into a Series C Preferred Stock Purchase Agreement, pursuant to which the Company issued and sold approximately 6,499,935 million shares of its Series C convertible preferred stock at a purchase price of $10.77 per share for net proceeds of approximately $69.7 million, of which approximately $29.0 million was sold to related party investors of the Company.

Convertible preferred stock consists of the following:

	As of December 31, 2018			
	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Aggregate Liquidation Preference
	(In thousands, except share data)			
Series A	15,000,000	3,050,329	$ 14,926	$ 15,008
Series B	35,000,000	7,068,184	44,906	45,166
Series C	32,000,000	6,499,935	69,745	70,004
	82,000,000	16,618,448	$ 129,577	$ 130,178

	As of December 31, 2017			
	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Aggregate Liquidation Preference
	(In thousands, except share data)			
Series A	15,000,000	3,050,329	$ 14,926	$ 15,008
Series B	35,000,000	3,939,644	24,915	25,174
	50,000,000	6,989,973	$ 39,841	$ 40,182

The Company classifies the convertible preferred stock outside of total stockholders' deficit because, in the event of certain "liquidation events" that are not solely within the control of the Company (including a merger, acquisition or sale of all or substantially all of the Company's assets), the shares would become redeemable at the option of the holders. The Company did not adjust the carrying values of the convertible preferred stock to the deemed liquidation values of such shares since a liquidation event was not probable at either of the reporting dates. Subsequent adjustments to increase or decrease the carrying values to the ultimate liquidation values will be made only if and when it becomes probable that such a liquidation event will occur.

On the completion of the IPO (see Note 1), all outstanding shares of convertible preferred stock were automatically converted into 16,618,448 shares of common stock.

9. Equity

Stock-Based Compensation

In 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the Board and consultants of the Company under terms and provisions established by the Board. Under the terms of the 2015 Plan, options may be granted at an exercise price not less than fair market value. The Company generally grants stock-based awards with service conditions only. Options granted typically vest over a four-year period but may be granted with different vesting terms. In January 2019, the Company's board of directors adopted and stockholders approved the Company's 2019 Equity Incentive Plan (the "2019 Plan"), which became effective immediately prior to the execution of the underwriting agreement for the Company's IPO in February 2019, at which point the 2015 Plan was terminated and no further grants were made under the Company's 2015 Plan. However, all outstanding stock awards granted pursuant to the 2015 Plan will continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards.

As of December 31, 2018 and 2017, there were 132,394 shares and 237,182 shares reserved by the Company to grant under the 2015 Plan, respectively.

The following summarizes option activity under the 2015 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, 2016	286,739	$ 0.59	9.35	$ 70
Options granted	1,686,997	1.16		
Options exercised	(97,373)	0.59		
Options cancelled	(85,064)	0.59		
Balance as of December 31, 2017	1,791,299	1.13	9.24	$ 881
Options granted	1,762,147	2.06		
Options exercised	(198,943)	1.35		
Options cancelled	(30,515)	1.29		
Balance as of December 31, 2018	3,323,988	1.61	9.07	$ 1,675
Vested and expected to vest as of December 31, 2018	3,323,988	1.61	9.07	$ 1,675
Exercisable as of December 31, 2018	548,332	0.93	8.11	$ 651

As of December 31, 2018, 3,902,175 of options 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, as determined by the Board of Directors. The intrinsic value of options exercised for the years ended December 31, 2018, 2017 and 2016 was $0.1 million, zero, and zero, respectively. There is no future tax benefit related to options exercised, as the Company has accumulated net operating losses at December 31, 2018, 2017 and 2016.

During the years ended December 31, 2018, 2017 and 2016, the estimated weighted-average grant-date fair value of the employee options vested was $0.81, $0.72 and $0.68 per share, respectively, and the estimated weighted-average grant-date fair value of employee options granted was $1.41, $0.92 and $0.67 per share, respectively. As of December 31, 2018, there was $3.2 million of unrecognized stock-based compensation related to unvested stock options that is expected to be recognized over a weighted-average period of 3.4 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:

	Year Ended December 31,		
	2018	2017	2016
Expected term (years)	6.06	6.33	6.03
Expected volatility	76.08%	73.39%	91.35%
Risk-free interest rate	2.89%	2.03%	1.37%
Expected dividend	0%	0%	0%

The fair value of the shares of common stock underlying stock options has historically been determined by the Board. Because there has been no public market for the Company's common stock, the Board has determined fair value of the common stock at the time of grant of the option by considering a number of objective and subjective factors including important developments in the Company's operations, valuations performed by an independent third party, sales of convertible preferred stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company's common stock, among other factors.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Expected Term—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.

Expected Volatility—Since the Company is privately held and does not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected Dividend—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Total stock-based compensation was as follows:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Operating Expenses			
Research and development	$ 325	$ 145	$ 43
General and administrative	347	222	56
Total stock-based compensation	$ 672	$ 367	$ 99

Stock-based compensation related to non-employee awards, which is included in the table above, was $0.1 million, $0.1 million and insignificant for the years ended December 31, 2018, 2017 and 2016, respectively.

2019 Equity Incentive Plan

The board of directors adopted, and the Company's stockholders approved the Company's 2019 Plan in January 2019, which became effective as of immediately prior to the execution of the underwriting agreement for the Company's IPO in February 2019, after which, no further grants were made under the Company's 2015 Plan. No awards had been granted and no shares of our common stock had been issued under our 2019 Plan as of December 31, 2018. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2019 Plan is 5,656,381, which is the sum of (1) 2,200,000 shares plus (2) the number of shares reserved, and remaining available for issuance, under our 2015 Plan at the time our 2019 Plan becomes effective and (3) the number of shares subject to stock options or other stock awards granted under our 2015 Plan that would have otherwise returned to our 2015 Plan (such as upon the expiration or termination of a stock award prior to vesting. The number of shares of our common stock reserved for issuance under our 2019 Plan will automatically increase on January 1 of each year, beginning on January 1, 2020 and continuing through and including January 1, 2029, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of incentive stock options under our 2019 Plan is 8,000,000 shares.

2019 Employee Stock Purchase Plan

The board of directors adopted, and the Company's stockholders approved, the 2019 Employee Stock Purchase Plan, (the "2019 ESPP") in January 2019. The 2019 ESPP became effective in February 2019.

The initial reserve for purchase by participating employees under the 2019 ESPP an aggregate number of shares of common stock shall not exceed 250,000 shares. The maximum aggregate number of shares of common stock that may be issued under the 2019 ESPP is 750,000 shares. Additionally, the number of shares of common stock reserved for issuance under the 2019 ESPP will increase automatically each year, beginning on January 1, 2020 and continuing through and including January 1, 2029, in an amount equal to the lesser of (i) 1% of the total number of shares of the Registrant's capital stock outstanding on December 31 of the preceding calendar year, (ii) 750,000 shares of Common Stock and (iii) a number of shares of Common Stock designated by action of the Registrant's board of directors prior to the first day of any calendar year. The board of directors may act prior to the first day of any calendar year to provide that there will be no January 1 increase or that the increase will be for a lesser number of shares than would otherwise occur. Shares subject to purchase rights granted under the 2019 ESPP that terminate without having been exercised in full, the shares of Common Stock not purchased under such Purchase Right will again become available for issuance under the Plan.

An employee may not be granted rights to purchase stock under the 2019 ESPP if such employee (i) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of all classes of stock of the Company or (ii) holds rights to purchase stock under the 2019 ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

The administrator may approve offerings with a duration of not more than 27 months, and may specify one or more shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of common stock will be purchased for the employees who are participating in the offering. The administrator, in its discretion, will determine the terms of offerings under the 2019 ESPP.

The 2019 ESPP permits participants to purchase shares of our common stock through payroll deductions with up to 15% of their earnings. The purchase price of the shares will be not less than 85% of the lower of the fair market value of our common stock on the first day of an offering or on the date of purchase.

Restricted Stock

In 2015, the Company issued restricted stock awards to employees and directors under 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' 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, 2016	316,836
Restricted stock awards vested	(85,001)
Unvested shares repurchased	(118,678)
Restricted shares- December 31, 2017	113,157
Restricted stock awards vested	(81,623)
Unvested shares repurchased	(9,356)
Restricted shares- December 31, 2018	22,178

As of December 31, 2018, the Company had reserved common stock, on an as-converted basis, for issuance as follows:

Convertible preferred stock (as converted)	16,618,448
Common stock options issued and outstanding	3,323,988
Restricted Stock subject to future vesting	22,178
Early exercised stock options subject to future vesting	149,565
Warrants to purchase shares of common stock	565,270
Shares available for future grant under the 2015 Plan	132,394
Total	20,811,843

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 our 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 December 31, 2018 and 2017, there was $188,000 and $78,000, 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, 149,565 and 132,180 shares had not vested and were subject to repurchase as of December 31, 2018 and 2017, respectively.

Note Receivable from Stockholder

In August 2016, the Company received a recourse promissory note from our then CEO and President, in connection with this individual's purchase of 152,516 shares of our common stock at a price of $0.59 per share. The principal amount of the note was approximately $90,000, and accrued simple interest at a rate of 1.22% per year. The note, along with accrued interest, can be prepaid without penalty and is due on the earlier of (i) August 29, 2022, (ii) the pricing of an IPO or the closing of an acquisition of the Company, in either case if the note's existence would violate any applicable law, (iii) the date the Company determines that any change in the Company's status or the individual's status would cause the note to be deemed a prohibited extension of credit under Section 402 of the Sarbanes-Oxley Act of 2002, as amended, or any applicable law or (iv) on demand by the Company in certain circumstances. In 2016, upon the individual ceasing to be employed by the Company, the Company repurchased 105,067 shares of common stock at a price per share of $0.59 per share for a total cash payment of $62,000. As of December 31, 2016 and 2017, the outstanding loan balance was $28,000, which is recorded as a component of total stockholders' deficit in the accompanying balance sheets. As of December 31, 2018 the outstanding balance of $28,000 was cancelled and the cancellation was recorded as stock-based compensation on the Company's statement of operations and comprehensive loss.

10. Income Taxes

Since inception, the Company has only generated pretax losses. For the years ended December 31, 2018 and 2017, the Company recorded no provision for income taxes due to the losses incurred. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2018 and 2017 consisted of the following:

	December 31,	
	2018	2017
	(in thousands)	
Deferred tax assets:		
Net operating loss carry forwards	$ 10,351	$ 6,494
Stock-based compensation	91	45
Deferred revenue	$ 3,370	—
Tax credits	—	984
Other	469	165
Total deferred tax assets	14,281	7,688
Less: valuation allowance	(14,173)	(7,675)
Net deferred tax assets	108	13
Deferred tax liability	(108)	(13)
Net deferred tax assets	$ —	$ —

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At present, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the accompanying balance sheets. The valuation allowance increased by approximately $6.5 million and 4.0 million during the years ended December 31, 2018 and 2017.

The Company has net operating carryforwards for federal and California income tax purposes of approximately $74.0 million and $46.5 million as of December 31, 2018 and 2017. The federal net operating loss carryforwards of $23.1 million, if not utilized, will expire beginning in 2035 and $13.9 million is carryforward indefinitely with the yearly net operating loss utilization limited to 80 percent of taxable income. The state net operating loss carryforwards, if not utilized, will expire beginning in 2035.

Federal and California tax laws impose significant restrictions on the utilization of net operating loss carryforwards in the event of a change in ownership of the Company, as defined by Internal Revenue Code Section 382 ("Section 382"). The Company believes a change in ownership, as defined by Section 382, has occurred but a formal study has not been completed. In addition, in the future the Company may experience ownership changes, which may limit the utilization of net operating loss carryforwards or other tax attributes.

The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying financial statements. The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

	December 31,	
	2018	2017
Computed expected tax benefit (at federal statutory income tax rate of 21%)	$ (6,631)	$ (7,088)
Increase in valuation allowance	6,498	4,018
Other	133	329
Federal rate change (pursuant to the Tax Act)	—	2,741
Total provision for income taxes	$ —	$ —

The Tax Cuts and Jobs Act (the "Tax Act") enacted in December 2017, among other changes, lowers our federal tax rate from 34% to 21%. Based on provisions of the Tax Act, the Company remeasured its deferred tax assets and liabilities to reflect the lower statutory tax rate. However, since the Company established a valuation allowance to offset its deferred tax assets, there was no impact to the effective tax rate, as any changes to deferred taxes would be offset by the valuation allowance. The deferred tax remeasurement was provisional and was subject to revision as the Company completes its analysis of the Tax Act, collects and prepares necessary data and interprets any additional guidance issued by standard-setting bodies. The Company has completed its analysis and determined no adjustment is required related to the tax effects of the Tax Act in 2018.

Uncertain Tax Benefits

The Company recognizes uncertain tax positions when it is more likely than not, based on the technical merits, that the position will not be sustained upon examination. No liability related to uncertain tax positions is recorded on the financial statements related to uncertain tax positions.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	December 31,		
	2018	2017	2016
	(in thousands)		
Balance at beginning of year	$ 422	$ 197	$ 46
Increases related to current year tax positions	3,016	225	151
Balance at end of year	$ 3,438	$ 422	$ 197

The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months.

Income tax returns are filed in the U.S. and California. The years 2015 through 2018 remain open to examination by the domestic taxing jurisdictions to which the Company is subject. Net operating losses generated on a tax return basis by the Company for 2015 through 2018 remain open to examination by the domestic taxing jurisdictions.

11. 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 December 31,		
	2018	2017	2016
Convertible preferred stock (as converted)	16,618,448	6,989,973	3,050,329
Common stock options issued and outstanding	3,323,988	1,791,299	286,739
Restricted Stock subject to future vesting	22,178	113,157	316,836
Early exercised stock options subject to future vesting	149,565	132,180	244,825
Warrants to purchase shares of common stock	565,270	565,270	470,753
Total	20,679,449	9,591,879	4,369,482

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):

	As of December 31,		
	2018	2017	2016
Net loss	(27,366)	(16,830)	(11,406)
Weighted-average shares used to compute basic and diluted net loss per share	1,066,877	894,901	527,931
Basic and diluted net loss per common share	(25.65)	(18.81)	(21.61)

12. Subsequent Event

Initial Public Offering

On February 7, 2019, the Company's registration statement on Form S-1 (File No. 333-229040) relating to the IPO was declared effective by the Securities and Exchange Commission (the "SEC"). The shares began trading on The NASDAQ Global Select Market on February 8, 2019. The public offering price of the shares sold in the IPO was $14.00 per share. The IPO closed on February 12, 2019 and included 5,400,000 shares of common stock. Following the close of the offering, the underwriters exercised in part their option to purchase additional shares for a total of 369,201 shares at the IPO price. In aggregate, the shares issued in the offering generated approximately $70.7 million in net proceeds, which amount is net of $5.6 million in underwriters' discount and offering costs of $4.5 million, Upon the closing of the IPO, all shares of preferred stock then outstanding were automatically converted into 16,618,448 shares of common stock and all warrants then outstanding were automatically net exercised for 563,043 shares of common stock.

The table below shows, on a pro forma basis, the impact of the Company's IPO on certain condensed balance sheet items as if all of the transactions occurred on December 31, 2018:

	As of December 31, 2018	Pro forma As of December 31, 2018
Cash and cash equivalents	$ 89,493	$ 160,149
Deferred offering costs	2,969	—
Convertible preferred stock	129,577	—
Common stock	1	3
Additional paid-in capital	9,111	209,341
Total stockholders' deficit (equity)	$ (53,479)	$ 146,754

In January 2019, the board of directors adopted and the Company's stockholders approved the Company's 2019 Equity Incentive Plan, or the 2019 Plan, which took effect immediately prior to the execution of the underwriting agreement for the Company's IPO in February 2019. The Plan is intended as the successor to and continuation of the 2015 Equity Incentive Plan. See footnote 9 for further discussion on the 2019 Plan.

In January 2019, the board of directors adopted and the Company's stockholders approved the 2019 ESPP Plan. The 2019 ESPP became effective in February 2019. The Company has initially reserved 250,000 shares of common stock for issuance under the 2019 ESPP. See footnote 9 for further discussion of the 2019 ESPP.

Commitments and Contingencies

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of its business. On January 3, 2019, Maverick filed a complaint against the Company 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 the Company's ProTriTAC technology impermissibly competes in the Maverick Field (as defined in the Asset Transfer Agreement), a preliminary and permanent injunction and unspecified damages. On January 18, 2019, the Court denied Maverick's motion for a temporary restraining order. The Company disputes Maverick's allegations and intends to vigorously defend the claims asserted against it. In view of the uncertainty regarding the possible outcome of this case and the nature of the relief sought, the Company does not believe that it is currently possible to determine a reasonable estimate of the possible loss or range of loss, or other possible adverse result, if any, that may be incurred with respect to this matter. The Company is not currently a party to any other material legal proceedings.

13. Quarterly Results (Unaudited)

The following table is in thousands, except per share amounts:

	Quarters Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Statement of operations data:				
Revenue				
Collaboration and license revenue	$ 1,561	$ 1,063	$ 1,063	$ 1,063
Total revenue	1,561	1,063	1,063	1,063
Operating expenses				
Research and development	5,533	6,151	5,967	8,717
General and administrative	982	967	1,942	2,215
Total operating expenses	6,515	7,118	7,909	10,932
Loss from operations	(4,954)	(6,055)	(6,846)	(9,869)
Interest income	73	66	108	148
Interest expense	—	—	—	—
Other expense	(2)	(5)	(22)	(8)
Net loss and comprehensive loss	$ (4,883)	$ (5,994)	$ (6,760)	$ (9,729)
Net loss per share, basic and diluted	(5.04)	(5.89)	(6.23)	(8.15)
Weighted-average common shares used in computing net loss per share, basic and diluted	969,235	1,017,336	1,084,477	1,193,797

	Quarters Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Statement of operations data:				
Revenue				
Collaboration and license revenue	$ —	$ —	$ —	$ 708
Total revenue	—	—	—	708
Operating expenses				
Research and development	2,154	2,801	3,876	4,791
General and administrative	843	847	1,012	912
Total operating expenses	2,997	3,648	4,888	5,703
Loss from operations	(2,997)	(3,648)	(4,888)	(4,995)
Interest income	6	2	13	57
Interest expense	(173)	(112)	—	—
Other expense	(86)	—	(5)	(4)
Net loss and comprehensive loss	$ (3,250)	$ (3,758)	$ (4,880)	$ (4,942)
Net loss per share, basic and diluted	(3.86)	(4.24)	(5.35)	(5.27)
Weighted-average common shares used in computing net loss per share, basic and diluted	840,905	886,332	912,728	938,372

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-229592) pertaining to the 2015 Equity Incentive Plan, the 2019 Equity Incentive Plan and the 2019 Employee Stock Purchase Plan of Harpoon Therapeutics, Inc. of our report dated March 14, 2019 with respect to the financial statements of Harpoon Therapeutics, Inc., included in this Annual Report (Form 10 K) for the year ended December 31, 2018.

/s/ Ernst & Young LLP
San Jose, California
March 14, 2019

Exhibit 31.1

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

I, Gerald McMahon, certify that:

1. I have reviewed this annual report on Form 10-K 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: March 14, 2019

By: /s/ Gerald McMahon, Ph.D.
Gerald McMahon, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Georgia Erbez, certify that:

1. I have reviewed this annual report on Form 10-K 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: March 14, 2019

By: /s/ Georgia Erbez
Georgia Erbez
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of Harpoon Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Gerald McMahon, President and Chief Executive Officer of the Company, and Georgia Erbez, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 14, 2019

By: /s/ Gerald McMahon, Ph.D.
Gerald McMahon, Ph.D.
President and Chief Executive Officer

Date: March 14, 2019

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