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, 2022

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)**

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

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

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange On Which Registered
Common Stock, par value $0.0001 per share	HARP	NASDAQ Global Select Market

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 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2022, was $26,764,582.

The number of outstanding shares of the Registrant's common stock, par value $0.0001, as of February 28, 2023 was 37,447,535.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the 2023 Annual Meeting of Stockholders of the registrant are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2022

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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, safety profiles, expected results and any wind downs of our preclinical studies, clinical trials and our research and development programs, as affected by various factors, including patient enrollment, rate of dose escalation, adverse events, and available drug supply;
- our ability to advance product candidates into, and successfully complete, preclinical studies and clinical trials;
- our estimates regarding expenses, capital requirements and needs for additional financing and our ability to obtain additional capital;
- 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;
- our ongoing corporate restructuring plans and the potential benefits of such restructuring;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our technology platforms, including TriTAC, ProTriTAC and TriTAC-XR and our 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 ability to retain the continued service of our key executives and to identify, hire and retain additional qualified professionals;
- our estimates regarding the market opportunity for our product candidates;
- our financial performance;
- the ongoing effects of the COVID-19 pandemic on our business, results of operations and 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 in the "Risk Factor Summary" below and under the heading "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. "TriTAC" is a registered trademark and "Harpoon Therapeutics," "Harpoon," the

Harpoon logo and ProTriTAC are among the trademarks owned by Harpoon Therapeutics, Inc. This report also contains trademarks and trade names that are property of their respective owners.

RISK FACTOR SUMMARY

Investing in common stock involves numerous risks, including the risks described in "Item 1A. Risk Factors" of this Annual Report on Form 10-K. Below are some of these risks, any one of which could materially adversely affect our business, financial condition, results of operations and prospects.

- 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 may be unable to commercialize our product candidates on a timely basis or at all.
- 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.
- Our TriTAC, ProTriTAC and TriTAC-XR 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.
- Results of earlier preclinical studies of our product candidates may not be predictive of future trial results.
- 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.
- 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.
- Monitoring safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize.
- We may not be successful in our efforts to use and expand our technology platforms, including TriTAC, ProTriTAC and TriTAC-XR to build a pipeline of product candidates.
- 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 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.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates, including future proceeds from the licensing of our technologies.
- Holders of our preferred stock may have interests and rights that are different from our common stockholders.
- We have in the past and may in the future fail to continue to meet the listing standards of Nasdaq, and as a result our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.
- 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.
- 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.
- 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, information privacy and security and other healthcare laws and regulations, which could expose us to substantial penalties.

- The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the United States Food and Drug Administration, or 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.
- We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenues or profits; increases in the costs of our products; reductions in the use or adoption of our products; and other adverse business consequences.
- Our recent corporate restructuring undertaken to reduce operating expenses, focus our resources on our clinical pipeline and extend our cash runway may not be successful.

Please refer to the section titled “Risk Factors” below for additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face.

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. We are developing a pipeline of novel T cell engagers initially focused on the treatment of solid tumors and hematologic malignancies. In addition to our product candidates utilizing our TriTAC technology, we have also nominated our first clinical candidate using our proprietary ProTriTAC platform, a prodrug version of our TriTAC platform, designed to expand the target space for T cell engagers and bring the benefits of TriTACs to a broader number of patients.

A summary of our TriTAC product candidates is as follows:

- HPN217, currently in a Phase 1 dose escalation clinical trial targeting B-cell maturation antigen, or BCMA, for the treatment of multiple myeloma, and the subject of a Development and Option Agreement or the Development and Option Agreement, with AbbVie Biotechnology Ltd., or AbbVie. Under our agreement with AbbVie, we are responsible for conducting the Phase 1 trial of HPN217 and we have already received an upfront payment of $30 million and a development milestone payment of $50 million, as we dosed our first patient in the Phase 1 clinical trial of HPN217 in April 2020. Additionally, we are eligible to receive future payments totaling up to $430 million upon AbbVie's exercise of an exclusive license option and achievement of certain development, regulatory, and commercial milestones, in addition to receipt of royalties on commercial sales. In January 2021, HPN217 received orphan drug designation for the treatment of multiple myeloma. In March 2022, HPN217 received fast track designation for the treatment of relapsed, refractory multiple myeloma. In December 2022, we presented updated interim data from this trial at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition. We intend for this Phase 1 study to reach completion in the first half of 2023 and identify a recommended Phase 2 dose by the end of 2023. Data presentation expected in the second half of 2023.

- HPN328, currently in a Phase 1/2 dose escalation clinical trial for the treatment of small cell lung cancer, or SCLC, and other Delta-like canonical Notch ligand 3, or DLL3-expressing tumors, including neuroendocrine prostate cancer and other neuroendocrine tumors. In March 2022, we received orphan drug designation for the treatment of SCLC. We plan to present interim clinical data in the second half of 2023 with the goal of identifying a recommended Phase 2 dose in the monotherapy setting by the end of 2023. We also plan to being enrolling additional cohorts in our ongoing Phase 1/2 clinical trial evaluating HPN328 in combination with atezolizumab for the treatment of patients with SCLC in the second half of 2023.

- In March 2022, we announced the discontinuation of our clinical development program for HPN424, our Prostate-Specific Membrane Antigen (PSMA)-targeting TriTAC, and in August 2022, we announced the discontinuation of enrollment and initiation of efforts to seek a partner for further development on our HPN536 program, our mesothelin targeting TriTAC.

A summary of our ProTriTAC product candidate is as follows:

- HPN601, is the first drug candidate from the ProTriTAC platform. HPN601 targets the epithelial cell adhesion molecule, or EpCAM, and is being developed for the treatment of multiple solid tumor indications. IND timeline to enable a Phase 1 dose exploration study will be dependent on available resources.
- Two new candidates for IND-enabling studies from the ProTriTAC platform have been identified against the targets trophoblast cell surface antigen 2 (TROP2) and Integrin-β6 (ITGB6). TROP2 is a glycoprotein that spans the epithelial membrane surface and plays a role in cell self-renewal, proliferation, and transformation. ITGB6 is a protein that is encoded by the ITGB6 gene and are adhesion receptors that function in signaling from the extracellular matrix to the cell.

Our TriTACs are designed to advance the therapeutic potential of T cell engagers, a therapeutic approach with an established and proven mechanism of action. We developed our proprietary TriTAC platform to incorporate the strengths of proven, commercially available T cell engagers 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 to treat 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 major histocompatibility complex, or 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.
- ***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 cytokine release syndrome, or 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.

We seek to selectively collaborate with leading biopharmaceutical companies to leverage our technology platforms. For example, in November 2019 we entered into a Development and Option Agreement with AbbVie, pursuant to which we granted to AbbVie an option to license worldwide exclusive rights to HPN217. We will be responsible for developing HPN217 through a Phase 1 trial. Upon exercise of the option, which AbbVie may exercise following our delivery of a specified data package arising from the Phase 1 trial, AbbVie would be responsible for all future clinical development, manufacturing and commercialization activities. The Development and Option Agreement represents a potential transaction value of up to $510 million in upfront, option and milestone payments, of which $80 million has been received to date, plus royalties on potential global commercial sales.

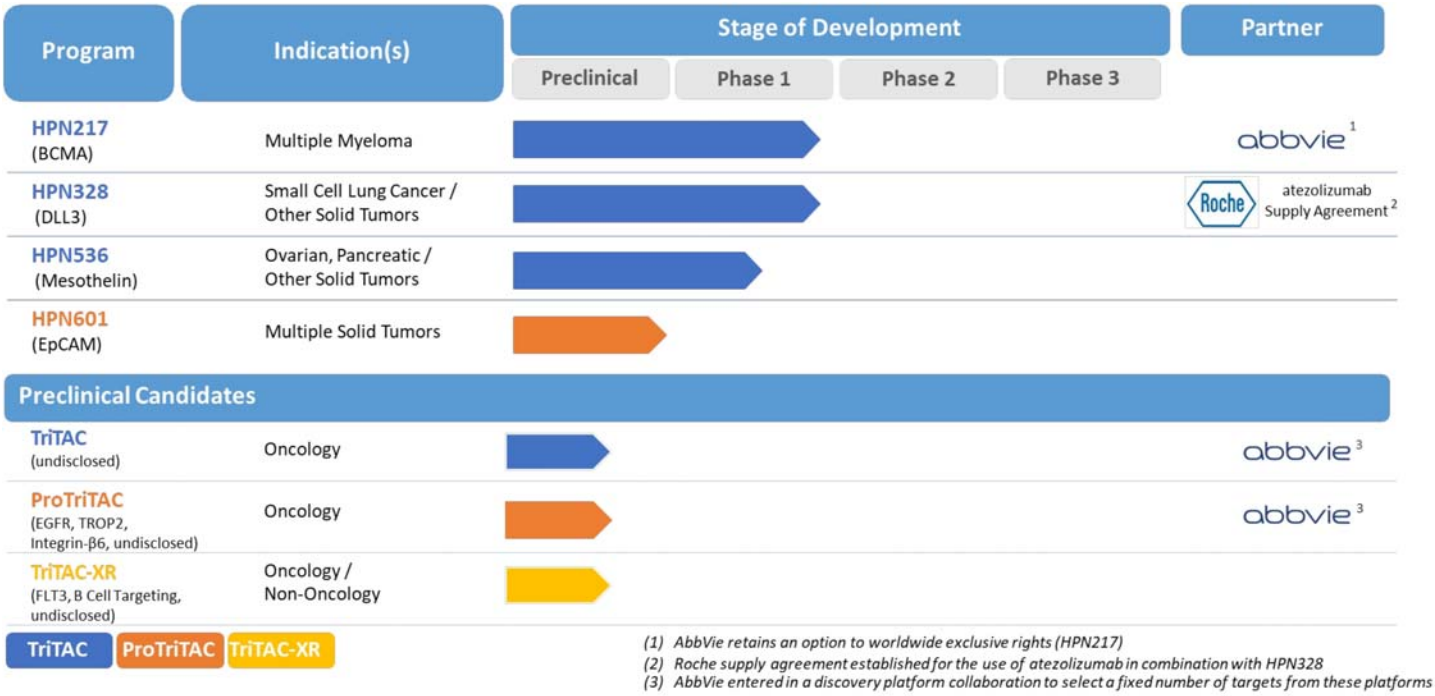
In addition, in November 2019, we expanded our existing collaboration with AbbVie by entering into an Amended and Restated Discovery Collaboration and License Agreement, or the Restated Collaboration Agreement. The Restated Collaboration Agreement, amends and restates the Discovery Collaboration and License Agreement we had entered into with AbbVie in October 2017, or the Original Collaboration Agreement. The expansion of the collaboration grants to AbbVie the right to select two further targets and an option to select up to four further targets, in addition to the two targets previously selected by AbbVie under the Collaboration Agreement. Consistent with the Collaboration Agreement, we and AbbVie will conduct certain initial research and discovery activities for each designated target, after which AbbVie will be solely responsible for further development and commercialization efforts. We have received a total of $37 million in upfront payments under this collaboration to date.

COVID-19

We are continuing to monitor the overall impact of the COVID-19 pandemic on our business. Our assessment to date continues to support that we have not experienced any material delays or significant financial impacts directly related to the pandemic other than some minor disruptions to clinical operations, including some disruptions in our manufacturing supply chain that affected and may continue to affect our drug supply, disruptions in patient enrollment in some of our clinical trials and delays in collecting, receiving and analyzing data from patients enrolled in our clinical trials due to limited staff at our clinical trial sites. We will continue to monitor any potential impacts of the COVID-19 pandemic on our third-party contract manufacturers, contract research organizations and other third parties that assist us with clinical trials and our clinical trial sites. See "Part II Item 1A—Risk Factors" for more information regarding the potential impact of the COVID-19 pandemic on our business and operations. We continue to actively monitor this situation and the possible effects on our business and operations.

Our Pipeline

We are leveraging our proprietary TriTAC, ProTriTAC and TriTAC-XR 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 our TriTAC, ProTriTAC and TriTAC-XR platforms and the underlying critical components 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:

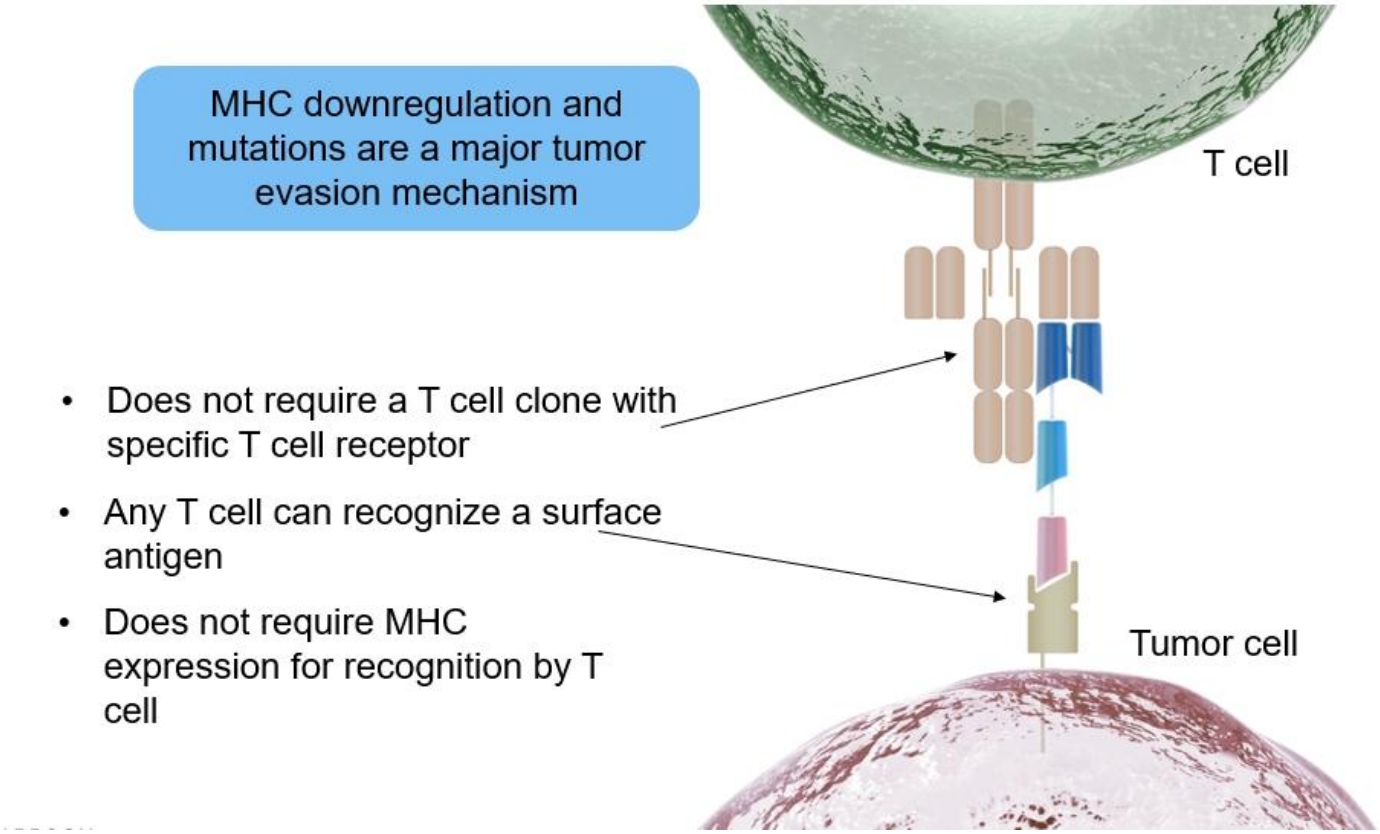
- ***Advance our TriTAC product candidates directed at clinically validated targets from discovery through clinical development and regulatory approval.*** Our clinical development efforts are focused on advancing a portfolio of therapeutic product candidates through clinical development, and ultimately, to treat patients suffering from cancer. We currently are advancing two product candidates through the clinic, to treat solid and hematologic malignancies. These programs are directed against targets that are both clinically validated and which are ideally suited for our TriTAC platform due to limited expression on healthy tissue.
- ***Expand the pipeline of oncology candidates for our TriTAC, ProTriTAC and TriTAC-XR technology platforms and develop other novel platforms.*** Our current research efforts are focused on supporting our discovery research collaboration with AbbVie. In 2022, we evaluated potential new product candidates based on our ProTriTAC technology, of which two IND candidates were nominated in the first quarter of 2023.
- ***Leverage our novel technology platforms to target a broad range of disease.*** Our TriTAC and other platforms may have the ability to address disease targets outside of oncology. We intend to evaluate opportunities that will further the research in these areas through strategic partnerships and licensing.
- ***Selectively collaborate with leading biopharmaceutical companies to leverage our platforms, expand our portfolio, advance our product candidates and maximize their commercial potential.*** While we intend to retain significant ownership of our current pipeline product candidates, we recognize the benefits of collaborations. We seek collaborations that can:

1) Broaden the reach of our technology 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, which was expanded in November 2019, that widens the utility for our TriTAC platform by developing candidates against novel soluble T cell receptor, or TCR, and antibody targets for the treatment of cancer. We are also seeking a partner to further develop our HPN536 program, our mesothelin-targeting TriTAC.
2) Provide us with strategic access to clinical and commercial capabilities, particularly in geographic areas we are unlikely to pursue on our own. For example, multiple myeloma is an indication with several therapeutic approaches competing both clinically and commercially. AbbVie has an extensive presence in hematologic malignancies, including multiple myeloma, which can benefit us as we develop a clinical plan that best positions HPN217 for commercial success.
3) Expedite commercial presence and distribution of our products, if approved. Utilizing an existing commercial marketing and distribution organization may be more cost effective in certain indications and geographies we are pursuing, rather than building our own commercial infrastructure.

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 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.



Our TriTAC Product Candidates

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.

In December 2022, we announced the interim results of ongoing Phase 1 clinical trial of HPN217 at ASH. As of the October 17, 2022 data cut-off date, 62 patients had been treated across fixed and step doses up to 2.86 mg/week in fixed dosing cohorts and 24 mg/week target dose in step dosing cohorts. Premedication to minimize cytokine release syndrome, or CRS, includes dexamethasone and other standard therapies. Enrolled patients had a median of 6 prior therapies. The most frequent treatment-emergent adverse events, or TEAEs, occurring in greater than 15% were anemia (44%), fatigue (32%), and transient CRS (27%), No grade 3 or higher CRS was reported in this patient population as of the October 17, 2022 data cut-off date. Two dose limiting toxicities, or DLTs, of reversible transaminitis were reported at a fixed dose of 2.86 mg. A maximum tolerated dose, or MTD, has not been reached at the target dose in step dosing regimens.

HPN217 was active across a wide dose range (2.15 to 24 mg), with 77% (10/13) overall response rate, or ORR, observed across the highest step doses (12 and 24 mg). Additionally, 86% (18/21) of responders remain on study treatment with sustained response, with many responders on treatment for over a year. Three patients in the study were evaluated for minimal residual disease, or MRD, and all three were MRD negative ($<10^5$).

HPN217 demonstrated a dose proportional increase with a median serum half-life of 66 hours, confirming half-life extension. Half-life, clearance rate, and volume of distribution were dose-independent, suggesting linear pharmacokinetics, or PK. Pharmacodynamic, or PD, analysis showed a trend of attenuation in cytokine and chemokine (IL-6, IL-8, TNFα) spikes upon administration of target doses compared to step doses.

Following ASH, one patient experienced Grade 3 CRS and Grade 1 Immune Effector Cell Associated Neurotoxicity (ICANS), which was followed by a post-traumatic Grade 5 subdural hematoma. Overall, a well-tolerated safety profile continues to emerge, with low incidence of CRS across the patient population studied to date.

In January 2021, HPN217 received orphan drug designation for the treatment of multiple myeloma. In March 2022, HPN217 received fast track designation for the treatment of relapsed, refractory multiple myeloma. Dose exploration is continuing with ongoing patient enrollment in the escalation phase of the Phase 1 trial expected to reach completion in the first half of 2023 and identification of a recommended Phase 2 dose by the end of 2023.

In November 2019, we entered into an exclusive worldwide Development and Option Agreement with AbbVie for HPN217. Under the terms of the agreement, we granted to AbbVie an option to license worldwide exclusive rights to HPN217. We will be responsible for agreed-upon development activities of HPN217 through an initial Phase 1 trial. Upon exercise of the option, AbbVie will be responsible for all future clinical development, manufacturing and commercialization activities. AbbVie may exercise its license option at any time during a period commencing on the effective date of the agreement and expiring after a specified period following delivery by us of a specified data package arising from the first Phase 1 trial for the HPN217 Products. AbbVie paid an upfront payment of $30 million and a development milestone payment of $50 million triggered upon dosing the first patient in the Phase 1 trial within a specified time period. If AbbVie exercises its option, AbbVie will pay us an option exercise fee of $200 million, and potential future payments of $230 million for the achievement of certain development, regulatory and commercial sales milestones for HPN217 Products, along with high single-digit to very low double-digit royalties on commercial sales.

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 176,000 new cases of multiple myeloma diagnosed and approximately 117,000 deaths each year. The American Cancer Society estimated that, in the United States in 2023, approximately 36,000 new cases would be diagnosed and approximately 13,000 deaths were expected to occur from multiple myeloma. 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% creating need for multiple lines of therapy.

Preclinical Data

In December 2021, we presented "The Effects of BCMA Expression, Soluble BCMA, and Combination Therapeutics on the Anti-Tumor Activity of HPN217, a BCMA-Targeting T Cell Engager Against Multiple Myeloma" showcased translational studies to examine factors that may impact the therapeutic efficacy of HPN217 at the 63rd ASH Annual Meeting and Exposition. These factors include the target BCMA, in membrane-bound or soluble form, and concomitant or combination therapeutics such as gamma secretase inhibitor, or GSI, and dexamethasone. Preclinical data from this presentation for HPN217 demonstrated:

- In a patient derived cell culture system, HPN217 was able to mediate multiple myeloma cell killing by autologous T cells in 80% of the cultures.
- Presence of dexamethasone appeared to have limited effect on the anti-tumor activity of HPN217-redirected T cells.
- GSI increased the expression of BCMA on multiple myeloma cells and enhanced the effect of HPN217.

HPN328: DLL3-Targeting TriTAC

We are developing HPN328 for the treatment of SCLC and other neuroendocrine tumors associated with DLL3 expression. DLL3 is a protein highly expressed in a majority of SCLC tumors and cancer stem cells, but only minimally expressed in normal tissue. This selective expression makes DLL3 an attractive drug target for T cell engagers. In January 2021, we announced that the first patient had been dosed with HPN328 in a Phase 1/2 clinical trial as an investigational treatment of SCLC and other tumors associated with DLL3 expression.

In March 2022, we received orphan drug designation for the treatment of SCLC.

In June 2022, we provided a clinical update on our ongoing Phase 1/2 clinical trial. As of the April 21, 2022, data-cutoff date, 18 patients had been enrolled in dose cohorts ranging from 15 μg to 1200 μg per week in both fixed and step dose cohorts administered once weekly by intravenous infusion. Eighteen patients with a median of 2 lines (range 1 to 5) of prior therapy have been enrolled and eligible patients include small cell lung cancer patients who have relapsed after platinum chemotherapy and patients with other malignancies with high grade neuroendocrine tumors associated with DLL3 expression. HPN328 has been generally well tolerated with Grade 1-2 CRS reported in 27% of patients. No dose-limiting toxicities, or DLTs, were observed and a maximum tolerated dose, or MTD, has not been reached. Seven of 18 patients (39%) had a decrease in sum of target lesion diameters, with 3 of 11 patients (27%) with SCLC across all dose cohorts experiencing a greater than 30% decrease in sum of target lesion diameters. Additionally, 4 of 6 patients (67%) with SCLC treated at greater than or equal to 1215 μg per week experienced a decrease in sum of target lesion diameters, including one confirmed Partial Response (cPR) per RECIST criteria (Response Evaluation Criteria In Solid Tumors). The patient with a cPR experienced a target lesion reduction of 53% at week 10.

In November 2022, we reported two events of Grade 3 cytokine release syndrome (CRS) following an initial 2mg priming dose of HPN328 during the dose escalation portion of the study. CRS in one patient resolved with treatment. CRS in a second patient was complicated by a requirement for oxygen prior to dosing and other complications that led to an additional event of respiratory failure, which led to the patient's death. The events were reported to regulatory authorities, as required, and after lowered lowering the priming dose from 2mg to 1mg, the enrollment in the study continued.

In December we lowered the priming dose to 1mg and excluded patients requiring oxygen prior to dosing and dose escalation enrollment continued.

In February 2023, we confirmed a second SCLC patient had a partial response per RECIST criteria. Patient enrollment is on track with monotherapy cohorts at the 12mg target dose. We plan to enroll additional cohorts in our ongoing Phase 1/2 clinical trial evaluating HPN328 in combination with atezolizumab for the treatment of patients with SCLC in the second half of 2023. We plan to present initial interim clinical data in the second half of 2023 with the goal of identify a recommended Phase 2 dose by the end of 2023.

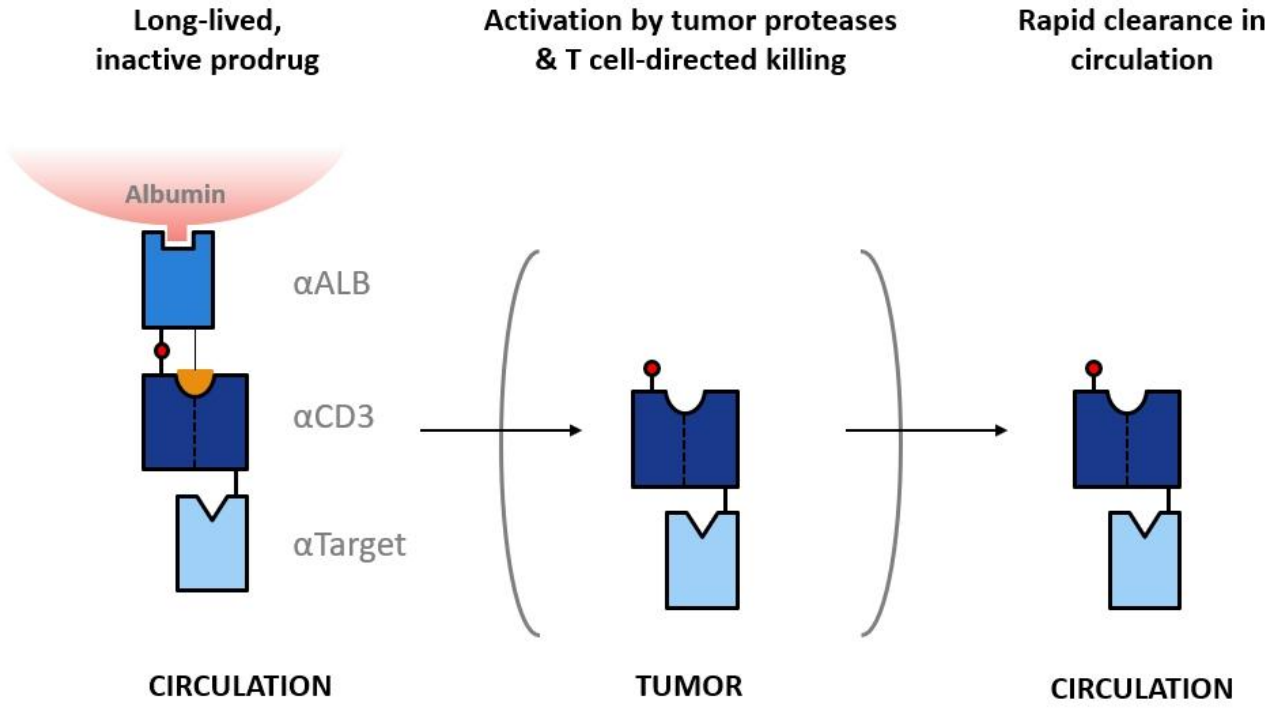
Market Opportunity

Globally, approximately 330,000 patients are diagnosed with SCLC annually, representing 10-15% of lung cancer diagnoses. The five-year relative survival rate for patients at the time of diagnosis with Localized, Regional and Distant disease is approximately 29%, 18% and 3%, respectively. T cell targeting checkpoint inhibitors, such as Tecentriq and Imfinzi, have been approved for use in SCLC patients, supporting immunotherapy as a new treatment alternative for SCLC. We believe there is still a significant unmet need remains for new therapies for these patients.

Our ProTriTAC Platform

ProTriTAC—An Expansion of TriTAC's Capabilities

In order to expand the universe of addressable targets and indications, we have developed 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.



Our ProTriTAC Product Candidate

HPN601

HPN601 is the first drug candidate from our ProTriTAC platform. HPN601 targets the epithelial cell adhesion molecule, or EpCAM, and is being developed for the treatment of multiple solid tumor indications. EpCAM is a tumor antigen that is broadly and uniformly expressed in many solid tumors; however, expression on some normal tissues has hindered its potential as a therapeutic target due to on-target, off-tumor toxicity as observed in clinical studies from past EpCAM targeted T cell engagers. The goal of developing HPN601, a conditionally active T cell engager, is to target all EpCAM-positive metastatic tumors by systemic administration and have an acceptable safety profile. IND filing timeline to enable a Phase 1 dose exploration study will be dependent on available resources.

Two new candidates for IND-enabling studies from the ProTriTAC platform have been identified against the targets trophoblast cell surface antigen 2 (TROP2) and Integrin-β6 (ITGB6). TROP2 is a glycoprotein that spans the epithelial membrane surface and plays a role in cell self-renewal, proliferation, and transformation. ITGB6 is a protein that is encoded by the ITGB6 gene and are adhesion receptors that function in signaling from the extracellular matrix to the cell.

Market Opportunity

EpCAM is a tumor antigen that is broadly and uniformly expressed in many solid tumors. Thyroid, small cell lung cancer, non-small cell lung cancer, prostate, ovarian, endometrial, pancreatic, gastric, gallbladder, biliary, esophageal, colorectal, and breast cancer

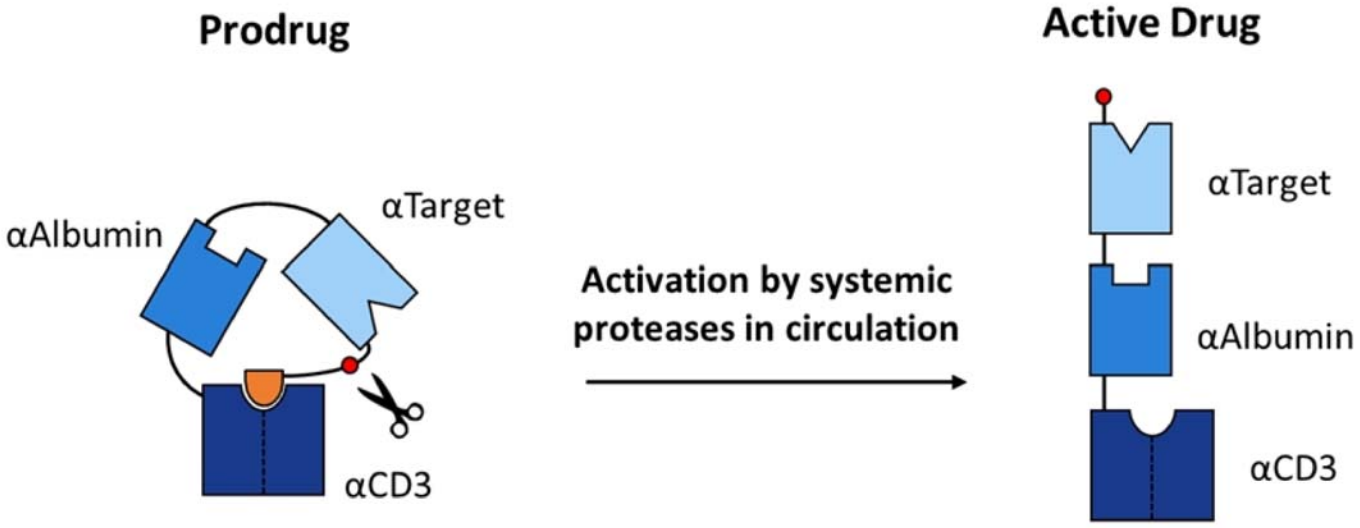
all have greater than 70% prevalence for EpCAM expression. These cancers combined represent approximately 345,000 patient deaths in the United States each year.

Preclinical Data

In November 2020, we presented preclinical data on HPN601 for the treatment of solid tumors at the 35th Society for Immunotherapy of Cancer (SITC) virtual annual meeting. The oral presentation described in vivo studies demonstrating the expansion of therapeutic index of our EpCAM-targeting ProTriTAC over a non-masked T cell engager control when anti-tumor efficacy and clinically relevant toxicity endpoints were assessed simultaneously in the same tumor-bearing animal. HPN601 was also demonstrated to have improved tolerability in non-human primates compared to a non-masked T cell engager control and exhibits potent anti-tumor activity across multiple EpCAM-expressing tumor models. IND-enabling activities for HPN601 are currently ongoing.

Our TriTAC-XR Platform

TriTAC-XR is Harpoon's newest inducible T cell engager platform. While the TriTAC platform was developed to address off-target toxicities, and the ProTriTAC platform was developed to minimize on-target tissue toxicities, TriTAC-XR is specifically aiming to reduce on-target cytokine release syndrome, or CRS. On-target CRS can occur when high concentrations of T cell engager, T cells and target cells are in the same biological compartment, which can be common for instance in the treatment of leukemia and lymphomas. In those scenarios, CRS can require dose reductions and ultimately limit efficacy. TriTAC-XR is a protease activated prodrug form of a T cell engager, whose active form is half-life extended and is slowly released by systemic protease in all biological compartments. This is intended to lead to better tolerated treatments with potentially more efficacy in certain indications. Harpoon is also exploring ways to employ this technology in non-oncology indications, such as autoimmune or inflammatory diseases.



Preclinical Data

In April 2022, we presented preclinical data on TriTAC-XR at the Society for Immunotherapy of Cancer (SITC) American Association for cancer Research (AACR) annual meeting. The poster presentation demonstrated that TriTAC-XR and its underlying extended-release mechanism represents a new approach to managing CRS, either alone or in combination with other existing CRS-mitigation approaches. The expected safety improvements would enable T cell engagers targeting immune cells to broaden its adoption from oncology to autoimmune and other non-oncology diseases.

Collaboration and License Agreements

Development and Option Agreement with AbbVie Biotechnology

On November 20, 2019, we entered into a Development and Option Agreement with AbbVie in connection with our HPN217 program, which targets B cell maturation antigen, or BCMA. Pursuant to such Agreement, we granted to AbbVie an option to a worldwide, exclusive license under our patents and know-how applicable to the HPN217 program to develop, manufacture and commercialize products arising from the HPN217 program targeting BCMA, or HPN217 Products. Under the Development and Option Agreement, we will file an IND for HPN217 and conduct development activities pursuant to a mutually-agreed development plan, including conducting a Phase 1 trial of HPN217, in order for AbbVie to determine whether it wishes to exercise its option to take a worldwide, exclusive license to such HPN217 program.

Under the Development and Option Agreement, AbbVie may exercise its license option at any time during a period commencing on the effective date of the agreement, and expiring after a specified period, following delivery by us of a specified data package arising from the first Phase 1 trial for the HPN217 Products. Following AbbVie's exercise of its option, and except for completion of certain development activities by us under the development plan, AbbVie will be solely responsible, at its cost, for the development, manufacture and commercialization of HPN217 Products and any other HPN217 Products. AbbVie is required to use commercially reasonable efforts to develop and obtain regulatory approval for one HPN217 product, for at least one indication, for use in each Major Market (as defined in the Development and Option Agreement).

AbbVie paid an upfront payment of $30 million and a development milestone payment of $50 million in June 2020 as we dosed our first patient in the Phase 1 trial of HPN217 in April 2020. If AbbVie exercises its option, AbbVie will pay us an option exercise fee of $200 million. Following option exercise, AbbVie will be required to make further payments to us of up to $230 million in the aggregate for the achievement of specified development, regulatory and commercial sales milestones for HPN217 Products. We will also receive tiered royalties on net sales by AbbVie, its affiliates and sublicensees of HPN217 Products at percentages ranging from the high single digits to the very low double digits, subject to specified offsets and reductions. Royalties will be payable under the Development and Option Agreement on a product-by-product and country-by-country basis commencing on the date of first commercial sale of each HPN217 Product, and ending on the later of expiration of all valid claims of specified licensed patents in such country, expiration of regulatory exclusivity in such country, or ten years following first commercial sale of such HPN217 Product in such country.

The Development and Option Agreement will terminate upon the date of the expiration of all AbbVie's royalty payment obligations in all countries, or upon expiration of the license option period and the failure of AbbVie to exercise its license option. The Development and Option 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 Development and Option Agreement by the other party. AbbVie may also terminate the Development and Option Agreement in its entirety or on a country-by-country basis for any reason on 90 days' written notice to us.

Amended and Restated Discovery Collaboration Agreement with AbbVie Biotechnology

On August 16, 2021, we entered into Amendment No. 1 to the Amended and Restated Discovery Collaboration and License Agreement with AbbVie, or the First Amendment, which amends our Amended and Restated Discovery Collaboration and License Agreement entered on November 20, 2019, with AbbVie, or as amended by the First Amendment, the Restated Collaboration Agreement. The Restated Collaboration Agreement amends and restates our Discovery Collaboration and License Agreement entered into with AbbVie, dated October 20, 2017 and amended April 3, 2019, or the Original Collaboration Agreement. Pursuant to the First Amendment, we and AbbVie agreed to include the ProTriTAC technology within the Restated Collaboration Agreement. Pursuant to the Original 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 Original Collaboration Agreement, AbbVie was granted the right to designate up to two targets for development of TriTAC constructs, which it selected in 2017 and 2019, respectively. Pursuant to the Restated Collaboration Agreement, AbbVie is permitted to designate two further targets, with an option to select up to four additional targets, selected during a specified period following the effective date, to be the subject of activities under the collaboration, and is granted a worldwide, exclusive license to develop and commercialize products that incorporate either our proprietary TriTAC platform technology, or (as a result of and pursuant to the First Amendment) our ProTriTAC platform technology, to pursue available T cell receptors, or TCRs and/or antibody targets. Such products may incorporate antibodies provided by AbbVie or by us. During a period of up to four years following the date of AbbVie's designation of each target for the products, and subject to 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 or ProTriTAC technologies, as applicable, in conjunction with the soluble TCR or antibody sequences directed at the agreed upon targets of interest. We may not, including through any third party, develop or commercialize any competing product that binds to any of the included targets. As was the case under the Original Collaboration Agreement, 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 each Major Market (as defined in the Restated Collaboration Agreement).

In addition to the upfront payment of $17.0 million already paid under the Original Collaboration Agreement, we received an upfront payment of $20.0 million under the Restated Collaboration Agreement for AbbVie's right to select two further targets and an option to select up to four further targets. AbbVie will be required to make payments to us, upon target selection, of $10.0 million for each target, for up to four additional targets selected by AbbVie. For each of the up to eight targets selected, we are eligible to receive up to $300.0 million in the aggregate for the achievement of specified development, regulatory and commercial sales milestones for licensed products indicated for human therapeutic or prophylactic use. We will also be eligible to 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. Royalties will be payable under the First Amendment and Restated Collaboration Agreement on a product-by-product and country-by-country basis commencing on the date of first commercial sale of each product, and ending on the later of expiration of all valid claims of specified licensed patents in such country, expiration of regulatory exclusivity in such country or ten years following first commercial sale of such product in such country. 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 Restated Collaboration Agreement will terminate upon the date of the expiration of all AbbVie's royalty payment obligations in all countries. The Restated 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 such agreement by the other party. AbbVie may also terminate the Restated 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 Restated 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.

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. Luke Evnin, a member of our Board until June 2020, is also the Chairman of 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.

In December 2019, we and Werewolf amended the Werewolf Agreement by entering into a Second Amended and Restated Assignment and License Agreement, or the Amended Werewolf Agreement, to include the grant to Werewolf of an exclusive, royalty-bearing, sublicensable license under certain 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 protein. This license provides Werewolf with certain rights to enforce and defend these licensed patents. If Werewolf commercializes products covered by these 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, and this royalty cannot be added to any other royalty owed to us under the Amended Werewolf Agreement. In addition, each party granted to the other a non-exclusive, royalty-free, sublicensable, perpetual license under certain other patents relating to a certain binding domain of a certain protein, to make, use, and commercialize products that are covered by such patents in a field defined by a certain type of molecule for each party. The Amended Werewolf Agreement also includes a mutual release of claims regarding certain patent prosecution matters.

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, 2022.

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 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 current good manufacturing practice, or 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 cGMP 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 HPN328 and HN217, 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, ProTriTACs and TriTAC-XRs are or will be manufactured from a vial of a master cell bank of that product's production cell line. We have or intend to have one master cell bank for each TriTAC, ProTriTAC and TriTAC-XR that was or will be produced and tested in accordance with 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 AbbVie, Amgen, AstraZeneca/MedImmune, Bristol-Myers Squibb, Johnson & Johnson, 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 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. and Boehringer Ingelheim; and CAR-T from Allogene Therapeutics.

With respect to 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., Bristol-Myers Squibb Company, AbbVie (TeneoBio, Inc.) and Regeneron Pharmaceuticals, Inc., CAR-Ts from Autolus Therapeutics PLC, Arcellx, bluebird bio, Inc./Bristol Myers Squibb Company, Legend Biotech/Janssen Pharmaceuticals, Inc., Novartis AG, and Allogene Therapeutics; antibody drug conjugates from GlaxoSmithKline PLC and Celgene/Sutro Pharmaceuticals; and other modalities from Unum Therapeutics Inc./Seattle Genetics Inc.

With respect to HPN601, we are aware of other competing conditionally active or tumor micro environment activated therapeutics, which include, but are not limited to: BioAtla, LLC, Amunix/Sanofi, and CytomX Therapeutics, 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 and TriTAC-XR 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, ProTriTAC and TriTAC-XR 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, 2022 we owned one patent family directed to composition-of-matter coverage and method of use of our core TriTAC platform technology. This family includes two issued U.S. patent, one U.S. non-provisional patent application and over twenty foreign application counterparts. The issued patents in this family are 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, 2022, 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 five issued U.S. patents, two U.S. non-provisional patent applications 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.

HPN217

For our pipeline BCMA-targeting TriTAC product candidate HPN217, as of December 31, 2022, we owned three patent families directed to composition-of-matter coverage of HPN217, its BCMA binding domain and related molecules, as well as methods of use and dosing regimens for cancers. These patent families include two issued U.S. patents, two U.S. non-provisional patent applications, one PCT international application and over fifty foreign application counterparts. The issued patents are projected to expire in 2038, not including any patent term adjustments and extensions. In addition to these three 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, 2022, 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 and dosing regimens for cancers. These patent families include one issued U.S. patent, one U.S. non-provisional patent application, two non-expired U.S. provisional patent applications, one PCT international application and over ten foreign application counterparts. The issued patent is 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.

HPN536

For our pipeline MSLN-targeting TriTAC product candidate, HPN536, as of December 31, 2022, we owned three patent families directed to composition-of-matter coverage of HPN536, its MSLN-binding domain and related molecules, as well as methods of use and dosing regimens for cancers. These patent families include two issued U.S. patents, two U.S. non-provisional patent application, one patent PCT international application and over twenty foreign application counterparts. The issued patents are projected to expire in 2038, 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 HPN536.

ProTriTAC Platform

Our patent portfolio for our ProTriTAC platform (including our first ProTriTAC candidate, HPN601) is at an early stage, with no issued patents as of December 31, 2022, and includes nine 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 six U.S. non-provisional patent applications, two PCT international applications, one non-expired U.S. provisional patent applications and over twenty foreign application counterparts. Any patents issuing from these nine patent families are projected to expire in 2039 to 2043, not including any patent term adjustments and extensions.

TriTAC-XR Platform

Our patent portfolio for our TriTAC XR platform is at an early stage, with no issued patents as of December 31, 2022, and includes one patent family directed to composition-of-matter coverage of the TriTAC XR molecules and methods of use thereof. This patent family includes one PCT international application. Any patents issuing from this patent family are projected to expire in 2042, not including any patent term adjustments and extensions.

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 equivalent regulatory authorities in countries outside the U.S., 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. Moreover, compliance with government regulations governing personal information and information security requires the expenditure of substantial time and financial resources.

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 Institutional Review Board (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 Biologics License Application, or BLA, after completion of all pivotal clinical trials;
- 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 Advisory Committee review, if applicable;

- 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 good clinical practices, or 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 or biologic 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.

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.

A regenerative medicine advanced therapy, or RMAT, designation is intended to facilitate an efficient development program for, and expedited 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 Companion Diagnostic Tests

We expect that our product candidates may require use of a diagnostic to identify appropriate patient population. 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 use with our product 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.

According to the FDA guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices," 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 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 therapeutic 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product.

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.

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.

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, Data Privacy and Security Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare and data privacy as well as information security 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, the Health Insurance Portability and Accountability Act of 1996, or HIPAA and similar foreign, federal and state fraud and abuse, transparency, privacy and information security 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, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, 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 the Health Information Technology for Economic and Clinical Health Act of 2009, or 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 and their subcontractors that use, disclose, access or otherwise process individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

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 the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), 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, including those governing the privacy and security of personal information (including key-coded data and health information), 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, significant 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.

Compliance with applicable privacy and data security laws and regulations will involve substantial costs. For example, the European General Data Protection Regulation, or GDPR, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. European data protection laws, such as the GDPR, also impose strict rules on the transfer of personal data out of the European Economic Area, Switzerland and United Kingdom. Further, the GDPR authorizes the imposition of penalties (such as restrictions or prohibitions on personal data processing) and large fines for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR has increased our responsibility and potential liability in relation to personal data that we process or control compared to prior EU law, including in clinical trials, and we may be required to

put in place additional mechanisms to ensure compliance with the GDPR and similar data protection laws, which could divert management's attention and increase our cost of doing business. Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, or CCPA, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States. Although the CCPA exempts certain data processed in the context of clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to the personal information we maintain about California residents. In any event, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable information security or privacy laws in light of the lack of applicable precedent and regulations. Federal, state and foreign enforcement bodies have increased their scrutiny of biotechnology companies, which has led to a number of investigations, prosecutions, convictions, fines, penalties and settlements in the industry.

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. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. 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. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Further, prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance

coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to additional judicial and Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

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 until 2031 unless additional action is taken by Congress. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Further, Congress is considering additional health reform measures.

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 Presidential executive orders, 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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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.

Employees

As of February 28, 2023, we had 50 full time employees, 37 of whom were engaged in research and development activities and 13 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 131 Oyster Point Blvd, Suite 300, 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.

Item 1A. Risk Factors

In investment in our common stock involves a high degree of risk. You should carefully review the risks and uncertainties described below before making an investment decision. The risks described below are not the only ones facing us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment.

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 may 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 early stage clinical trials 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 contract research organizations, or 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, 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 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 and timely delivery of 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;
- the impact of public health epidemics, such as the COVID-19 pandemic; 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. We could also encounter delays if supplies of a product candidate are not sufficient for the needs of our clinical trials. This may, for example, occur as a result of delays from the third-party manufacturers we work with or due to changes in the design of our clinical trials.

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.

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 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 also disclose interim data from our 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. As a result, any interim/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. 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.

Our TriTAC, ProTriTAC and TriTAC-XR 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, ProTriTAC or TriTAC-XR 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, ProTriTACs and TriTAC-XRs platforms may have different effectiveness rates in various indications. Our approach involves using biologics to improve efficacy against solid tumors, which is unproven and may not be successful. Further, our TriTAC, ProTriTAC and TriTAC-XR technology could have less efficacy in tumor types with fewer T cells, such as pancreatic cancer. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of our TriTACs, ProTriTACs or TriTAC-XRs platforms 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.

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 have in the past and may in the future 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 HPN601, given the expression of EpCAM on both normal and cancerous cells, we may observe unacceptable levels of toxicity in our future clinical trial of HPN601. 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.

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 have in the past and may in the future be subject to delays as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. We have multiple ongoing Phase 1/2 clinical trials, which could generate adverse events that may cause us to delay these trials or halt further development. For example, in November 2022, we voluntarily paused enrollment into our ongoing Phase 1/2 safety study of HPN328 following two events of Grade 3 cytokine release syndrome following an initial 2mg priming dose of HPN328. CRS in one patient resolved with treatment. CRS in a second patient was complicated by a requirement for oxygen prior to dosing and other complications that led to an additional event of respiratory failure, which led to the patient's death. Although we have resumed enrollment in the study, we cannot be certain that our mitigation efforts, including, reduction of the priming dose and a protocol amendment to exclude patients requiring supplemental oxygen therapy, will avoid future toxicities or deaths, particularly as we escalate the target dose. Regulatory authorities, including the FDA and IRBs, may impose a clinical hold or suspend the trial, preventing further enrollment.

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

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

Our product candidates may have serious adverse, undesirable or unacceptable side effects or other properties which may delay or prevent marketing approval. Such side effects could result in us need to abandoning our development of related 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 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. Our product candidates target protein expression on tumor cells, which expression may also be present on healthy cells. Accordingly, our product candidates can result in high or unacceptable levels of toxicity when tested in humans. Cytokine release syndrome is a common toxicity occurring with CAR-T therapies and has occurred with our product candidates. For example, in November 2022, we announced two events in our HPN328 study of Grade 3 cytokine release syndrome (CRS) following an initial 2mg priming dose of HPN328 during the dose escalation portion of the study. CRS in one patient resolved with treatment. CRS in a second patient was complicated by a requirement for oxygen prior to dosing and other complications that led to an additional event of respiratory failure, which led to the patient's death.

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

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

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

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

For our ongoing clinical trial and planned clinical trials, we have and expect to continue 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 may not be successful in our efforts to use and expand our technology platforms, including TriTAC, ProTriTAC and TriTAC-XR, to build a pipeline of product candidates.

A key element of our strategy is to use and expand our technology platforms, including TriTAC, ProTriTAC and TriTAC-XR, 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 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.

Risks Related to Our Financial Condition and Need for Additional Capital

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 trials of HPN217 and HPN328, and as we continue to research and develop other potential technologies and product candidates, including HPN601. As a result, we may at times reevaluate our corporate priorities and development plans. For example, in August 2022, based on our decision to prioritize certain assets in our portfolio, we announced that we intend to seek a partnership to further develop our HPN536 program in monotherapy and combination settings. Then, in November 2022, we announced a corporate restructuring and a reduction in workforce designed to reduce operating expenses and focus our resources on our clinical pipeline.

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 continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. 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 and marketable securities will be sufficient to fund our planned operations for at least the next 12 months from the date of this Annual Report on Form 10-K. We have based this estimate on assumptions that may prove to be wrong, including our assumptions related to our corporate restructuring, 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 financings, including our March 2023 private placement transaction, or the Private Placement, or pursuant to our Controlled Equity Offering℠ Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, may result in dilution to our stockholders, the imposition of burdensome covenants and repayment obligations, and other restrictions that may affect our business. For example, in March 2023, we raised $25.0 million through a Private Placement pursuant to which we sold 25,000 shares of preferred stock, or the Series A Preferred Stock with rights that are superior to those of our common stockholders and warrants to purchase up to 7,485,762 shares of our common stock (the "Warrants"). 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, pursuant to the terms of our Series A Preferred Stock, we will be required to use a portion of the net proceeds from certain licensing or collaboration arrangements to redeem shares of Series A Preferred Stock, and, accordingly, we may require additional

capital to fund our operating plans. 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 HPN217, Phase 1/2 trial of HPN328, and the winddown of our Phase 1/2a trials of HPN536 and HPN424;
- 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 collaborations 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 (including a partnership arrangement for the development of our HPN536 program) 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.

Further decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. 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
- further reduce staff, 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.

Any of these impacts could materially affect our business, financial condition and results of operations.

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 $67.7 million, $116.7 million and $49.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we had an accumulated loss of $352.5 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:

- continue to conduct our ongoing Phase 1 trial of HPN217 for the treatment of relapsed, refractory multiple myeloma;
- continue to conduct our ongoing Phase 1/2 trial of HPN328 for the treatment of small cell lung cancer and other DLL3 expressing tumors;
- plan for the start up of a the Phase 1 study of HPN601 for the treatment of EpCAM expressing tumors;
- continue the development of our product candidates beyond Phase 1 trials;
- continue the research and development of our other product candidates;
- seek to enhance our TriTAC, ProTriTAC and TriTAC-XR 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 payments received under collaboration and licensing agreements and the sale of capital stock, including from our March 2023 Private Placement, our 2021 follow on offering and sales pursuant to our Sales Agreement with Cantor Fitzgerald. We have devoted a significant portion of our financial resources and efforts to developing our TriTAC, ProTriTAC and TriTAC-XR 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, ProTriTAC or TriTAC-XR 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.

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 collaborations 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. For example, in March 2023, we raised $25.0 million in a Private Placement where we sold 25,000 shares of Series A Preferred Stock with rights that are superior to those of our common stockholders and warrants to purchase up to 7,485,762 shares of our common stock; in the event of our voluntary or involuntary liquidation, dissolution or winding up, or the occurrence of a Deemed Liquidation Event (as defined in our certificate of designation), holders of our Series A Preferred Stock then outstanding are entitled to be paid prior to common stock holders. In addition, the possibility of additional such issuances 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.

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 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 ongoing early stage clinical trials, 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.

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, information privacy and security and other healthcare laws and regulations, which could expose us to substantial penalties.

Healthcare providers, healthcare facilities and institutions, 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 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, including the False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, and civil monetary penalties laws, including the civil False Claims Act, which prohibit, among other things, 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 and their subcontractors that use, disclose, access, or otherwise process individually identifiable health information;
- the U.S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous U.S. state, foreign and local 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, foreign and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of personal 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. 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, privacy and information security 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, 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.

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.

Any clinical trial could fail to produce results satisfactory to the FDA or comparable foreign regulatory authorities for a number of 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 as 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.

In addition, the FDA also has substantial discretion in the approval process and may decide that our data is insufficient for approval or insufficient to proceed to a pivotal clinical trial, and the FDA may require additional preclinical, clinical or other studies. Furthermore, we may encounter delays or rejections based upon changes in policy, which could cause delays in the clinical

development of any of our product candidates. For example, the FDA launched Project Optimus in 2021 as an initiative to reform the dose optimization and dose selection paradigm in oncology drug development. Project Optimus was driven by the FDA's concerns that the current paradigm for dose selection may result in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating pivotal trials. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies or may request other data or studies pre- or post-approval. The FDA also continues to develop and finalize guidance documents and implement initiatives regarding the development and clinical research of oncology product candidates. If the FDA does not believe we have sufficiently demonstrated that the selected doses for our product candidates maximize, not only the efficacy of the product candidate, but the safety and tolerability as well, our ability to complete existing trials or initiate new trials may be delayed. Even if we conduct any additional studies or generate any additional information requested by the FDA, the FDA could disagree that we have satisfied their requirements, all of which will cause significant delays and expense to our programs.

Moreover, 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. Any of these factors, 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.

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 based on the physician's independent medical judgement. 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. Previously, the prior presidential administration took 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 whether or how these orders will be implemented, or rather rescinded or replaced under the Biden Administration. The policies and priorities of a new administration are unknown and could materially impact the regulation of our product candidates. 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 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.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that there will be additional health reform measures. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, and the healthcare reform measures of the Biden administration 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. For example, 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 and will remain in effect until 2031, unless additional action is taken by Congress. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. 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. Presidential executive orders, 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. In July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, The Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. 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. 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, pricing and reimbursement schemes vary widely from country to country. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular drug candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. In December 2021 the HTA Regulation, which is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. was adopted and entered into force on January 11, 2022. It will apply from 2025.

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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenues or profits; increases in the costs of our products; reductions in the use or adoption of our products; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal information and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, and data we collect about clinical trial participants in connection with clinical trials. As a result, we, our service providers and any collaborators are or may become subject to or affected by numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, certifications, and other obligations that govern the processing of personal information by us or on our behalf. These obligations are rapidly evolving, subject to differing interpretations and could result in conflicting compliance obligations among various jurisdictions. Compliance with federal, state, and foreign data protection laws and regulations and other data protection obligations could require us to take on more onerous obligations in our contracts; increase our costs of legal compliance; restrict our ability to collect, use and disclose personal information; and, in some cases, impact our, our service providers' or collaborators' ability to operate in certain jurisdictions.

In the United States, numerous federal, state, and local governments have enacted numerous data privacy and security laws, including personal information privacy laws (including those related to health), data breach notification laws, and state consumer protection laws. For example, the California Consumer Privacy Act of 2018, or the CCPA, imposes obligations on businesses to which it applies, including, but not limited to, requirements to provide specific disclosures in privacy notices and affording California residents certain rights related to their personal information. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to other personal information we maintain about California residents. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). In addition, the California Privacy Rights Act of 2020, or the CPRA, expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states (such as Colorado, Utah, Connecticut and Virginia) have also passed comprehensive data privacy laws.

Outside the United States, there are an increasing number of laws, regulations, and industry standards related to data privacy and security with which we, our collaborators, service providers (including our CROs, and contractors) may need to comply, including in connection with our clinical trial activities. For example, the EU's General Data Protection Regulation, or GDPR, and the United Kingdom's GDPR, or UK GDPR, include strict requirements for processing the personal information of individuals (including clinical trial data), respectively, located within the European Economic Area, or EEA, and the United Kingdom, or UK. The processing of sensitive personal information, such as health information, may impose heightened compliance burdens under the GDPR and the UK GDPR. For example, under the GDPR, government regulators may impose temporary and definitive bans on personal information processing as well as fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater.

Certain jurisdictions have enacted data localization laws and cross-border personal information transfer laws, which could make it more difficult for us to transfer personal information across jurisdictions (such as transferring or receiving personal information that originates in the EU or UK). Existing mechanisms that facilitate cross-border personal information transfers may change or be invalidated. Inability to import personal information from Europe or elsewhere to the United States may limit our ability to conduct clinical trials activities in Europe or elsewhere, limit our ability to collaborate with CROs, service providers, contractors and others, and require us to increase our data processing capabilities in Europe or elsewhere at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly frequent fashion. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparation for and compliance with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems, and practices, and to any third parties that process personal information on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations. If we or our third party collaborators or service providers fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; reputational harm; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business and financial condition, including, but not limited to: interruptions or stoppages in business operations (including, clinical trials); inability to process personal information; limited ability to develop or commercialize or products; expenditure of time and resources to defend any claim, inquiry or similar request; adverse publicity; and revision or restructuring of our operations.

Risks Related to Our Business Operations

Our recent corporate restructuring undertaken to reduce operating expenses, focus our resources on our clinical pipeline and extend our cash runway may not be successful.

In November 2022, we announced a corporate restructuring designed to reduce operating expenses and focus our resources on our clinical pipeline. In connection with the restructuring plan, our workforce will be reduced by approximately 45%, with the majority of the reductions having taken place at the end of 2022 and remainder to occur in the first half of 2023. We estimate that we will incur costs up to approximately $1.8 million in charges for termination benefits related to the restructuring plan. Also, as a part of the restructuring, we have initiated activities to reduce our corporate facilities footprint by subletting all of our research labs and associated office and relocating to a smaller facility.

These restructuring activities may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reduction-in-force, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our results of operations or financial condition. In addition, while positions have been eliminated, certain functions necessary to our reduced operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. We may also discover that the reductions in workforce and cost cutting measures will make it difficult for us to pursue new opportunities, hire new employees, complete initiatives and require us to hire qualified replacement personnel, which may result in us incurring additional and unanticipated costs and expenses. Moreover, there is no assurance that we will be able to fully realize the value from our restructuring measures, such as reduced costs from our current facility obligations. Our failure to successfully accomplish any of the above activities and goals may have a material adverse impact on our business, financial condition, results of operations and ability to successfully develop our focused clinical programs.

Manufacturing our TriTAC, ProTriTAC and TriTAC-XR 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, ProTriTACs and TriTAC-XRs 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, ProTriTAC and TriTAC-XR, 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. 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.

Unstable market and economic conditions, including adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, may have serious adverse consequences on our business, financial condition, results of operations and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, increased interest rates, inflationary pressures, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

In addition, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

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 any effects from a local or global recession or depression that may depress economic conditions for a prolonged period;

- 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;
- the impact of public health epidemics, such the COVID-19 pandemic; and
- business interruptions resulting from political instability and geo-political actions, particularly in foreign economies and markets (such as the conflict between Russia and Ukraine), and other instances of war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires.

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.

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 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.

In November 2021, we appointed a new President and Chief Executive Officer and, in October 2022, we appointed a new Chief Medical Officer. Our Chief Financial Officer resigned, effective August 31, 2022, and we are in the process of recruiting a replacement. Resignations of executive officers and changes in management may cause disruption in our business, strategic and employee relationships, which may delay or prevent the achievement of our business objectives. In particular, the loss of key managers and senior scientists could delay our research and development activities. Transitions may also cause uncertainty among investors, employees and others concerning our future direction and performance.

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 need to expand our development, regulatory and, in the future, sales and marketing capabilities, and may encounter difficulties in managing and growing our operations, particularly in light of recent cost-containment activities.

As of February 28, 2023, we had 50 full-time employees, which includes the reduction in our workforce actions. In order to progress our development, regulatory and sale and marketing capabilities, we expect to need to, over the long-term, significantly grow 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 any anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to efficiently utilize, recruit and train qualified personnel. Due to our limited financial resources, including recent cost-containment objectives, and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage any expansion of our operations or efficiently utilize, recruit and train qualified personnel. Any future expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage our operations and any growth of our operations could delay the execution of our business plans or disrupt our operations.

In addition, managing our operations requires significant involvement from members of management, including in: 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 operations, and our management may at times also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage operating 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 also 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.

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 Commercialization of Our Product Candidates

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

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

further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

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

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

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

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

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

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

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

Cancer therapies are sometimes characterized by line of therapy (first, second, third, fourth, etc.), and the FDA often initially approves new therapies only for use in a particular line or lines of therapy. When cancer is detected early enough, first line therapy is sometimes adequate to provide a cure or prolong life without a cure. Whenever first line therapy (typically chemotherapy, hormone therapy, surgery or a combination of these) proves unsuccessful, second line therapy (typically more chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these) may be administered. Third or fourth line therapies can include antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. We may initially seek approval of our product candidates as a third line therapy for patients who have failed other approved treatments. Subsequently, for product candidates that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second and first line therapy. However, there is no guarantee that our product candidates, even if initially approved, would be subsequently approved as a second or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval as a second or first line therapy. Because the potentially addressable patient target population for our product candidates may be limited to patients who are

ineligible for or have failed prior treatments, even if we obtain significant market share for our product candidates, we may never achieve profitability.

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

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

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

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

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

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

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

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

To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or

in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with

applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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

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

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

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Therefore, for some of our product candidates, we may decide to enter into new collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those product candidates. For instance, we have a discovery collaboration and license agreement with AbbVie, pursuant to which we have licensed the development and commercialization of certain of our product candidates, as well as a Development and Option Agreement with AbbVie, pursuant to which we granted to AbbVie an option to a worldwide, exclusive license with respect to HPN217.

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. In addition, pursuant to the terms of our Series A Preferred Stock, we will be required to use a portion of the proceeds generated from certain collaboration or licensing agreements to redeem shares of our Series A Preferred Stock. Accordingly, we may not be able to realize the full benefit of payments made pursuant to any such agreements to further fund our operations.

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 work with third-party contract manufacturers to produce sufficient quantities 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. As an example, we have in the past, as a result of the COVID-19 pandemic, experienced some minor disruptions in our manufacturing supply chain that affected our drug supply and patient enrollment in some of our clinical trials.

Our TriTAC, ProTriTAC and TriTAC-XR platforms rely on third parties for the biological materials used in testing and qualifying our products. 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 quality assurance, volume and timing of 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. 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 third-party suppliers, 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 an irreparable delay in our development or commercialization timeline.

To date, we have primarily relied on single-source suppliers per product for bulk drug substance. The loss of any of our suppliers or their failure to supply us with bulk drug substance, or BDS, on a timely basis could cause a delay in our ability to develop the impacted product candidates and adversely affect our business.

We depend on one single-source supplier per product for BDS for our HPN217 and HPN601 programs. We have several suppliers for our HPN328 program, however 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 suppliers, and cannot ensure that our suppliers will deliver to us the BDS we order on time, or at all. The loss of BDS provided by our suppliers could require us to change the design of the product candidate development process for the impacted product(s) 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 for any product. 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 a single-source supplier per product exposes us to certain risks, including the following:

- our suppliers may cease or reduce production or deliveries, raise prices or renegotiate terms which would impact those products produced;
- 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 any 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 clinical trial sites 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 suppliers upon which we rely, per product, 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 suppliers may need to increase manufacturing capacity, which could involve significant challenges. This may require us and our suppliers to invest substantial additional funds and hire and retain the technical personnel who have the necessary experience. Neither we nor our suppliers 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 CMOs for the supply of 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 commercial products must be approved by the FDA or other global regulatory authorities pursuant to inspections that will be conducted after we submit our marketing authorization application or BLA to the relevant agency. 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 global regulatory authorities, 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 delay the manufacturing of our product candidates or approved products, 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 service provider 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 would prevent the sale of these products to global markets. The inability to sell our 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 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 that we may enter into with these third parties, we may not own, or may have to share, these intellectual property rights to improvements.

We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on our manufacturers to purchase the raw 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 our manufacturers may qualify second-source suppliers of critical raw materials to prevent a possible disruption of the supply 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. We cannot be sure that the third-party raw material suppliers will remain in business, or that they will not be purchased by a company that is not interested in continuing to produce these materials. In addition, the lead time needed to qualify a new raw material supplier can be lengthy, and we may experience delays in meeting demand for our product in the event a new supplier must be used. The time and effort to qualify a new raw material supplier could result in additional costs, diversion of resources or inability to produce a comparable product candidate, any of which would negatively impact our operating results. Any significant delay in the supply of a product candidate for an ongoing clinical trial due to the need to replace a third-party raw material manufacturer, or the ability of our third-party manufacturers to obtain raw materials timely, could considerably slow our enrollment or delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. For example, in 2021, due to the impact of the COVID-19 pandemic on our supply chain components, the start of our manufacturing run to resupply the HPN328 trial was delayed until early 2022. As a result, enrollment of new patients in the HPN328 study was temporarily slower until the resupply was delivered in October 2022. 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.

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, ProTriTAC and TriTAC-XR 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, ProTriTAC and TriTAC-XR 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, ProTriTAC and TriTAC-XR 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, ProTriTAC and TriTAC-XR 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, ProTriTAC and TriTAC-XR 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, ProTriTAC and TriTAC-XR 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 patents relating to our TriTAC, ProTriTAC and TriTAC-XR 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, ProTriTAC and TriTAC-XR 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, ProTriTAC and TriTAC-XR 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, ProTriTAC and TriTAC-XR 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 have and may from time to time become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. For example, from 2018 through 2021, we were involved in a suit that involved claims for misappropriation of trade secrets and for alleged breach of a contractual non-compete provision, brought against us by Maverick Therapeutics, Inc., which had the potential to impair the development of our ProTriTAC platform. The court ultimately ruled in our favor on these claims, but we may be subject to similar litigation in the future.

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, ProTriTAC and TriTAC-XR 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.

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 2019 at a price of $14.00 per share, the reported low and high sales prices of our common stock through February 28, 2023 has ranged from $0.59 to $25.24, respectively.

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 effects of the recent and other potential corporate restructurings;
- the anticipated results of our Phase 1 trial of HPN217, Phase 1/2 trial of HPN328, and 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;
- our cash position and the methods by which we seek financing;
- changes in laws or regulations, including but not limited to preclinical study or clinical trial requirements for approvals;
- any adverse changes to our relationship with manufacturers or suppliers;
- manufacturing, supply or distribution shortages;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- variations in our results of operations;
- our 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 ability to establish collaborations, including a partnership arrangement for the further development of our HPN536 program;
- our ability to effectively manage our growth;
- the size of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- changes in the market valuations of similar companies;
- press reports, whether or not true, about our business;

- sales or perceived potential sales of our common stock by us or our stockholders in the future;
- overall fluctuations in the equity markets;
- ineffectiveness of our internal controls;
- changes in accounting practices or principles;
- changes or developments in the global regulatory environment;
- general political and economic conditions, such as the geopolitical instability resulting from the conflict between Russia and Ukraine or historically high inflation;
- ongoing effects of the COVID-19 pandemic;
- effects from a local or global recession or depression that may depress economic conditions for a prolonged period; 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.

We have in the past and may in the future fail to continue to meet the listing standards of Nasdaq, and as a result our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.

Our common stock currently trades on The Nasdaq Global Select Market. The Nasdaq Stock Market LLC, or Nasdaq, has requirements that a company must meet in order to remain listed on Nasdaq. For example, Nasdaq rules require us to maintain a minimum closing bid price of $1.00 per share of our common stock.

On November 29, 2022, we received a letter from the Listing Qualifications Staff, or the "Nasdaq Staff" of Nasdaq notifying us that for the last 30 consecutive business days, the bid price of our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5450(a)(1). The notification received had no immediate effect on the listing of our common stock on the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days to regain compliance with the minimum bid price requirement by having shares of our common stock maintain a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive trading days. On February 10, 2023, we received a letter from the Nasdaq Staff notifying us that the closing bid price of our common stock had been at $1.00 per share or greater for 10 consecutive business days, from January 27, 2023 to February 9, 2023, and accordingly, we had regained compliance with Nasdaq Listing Rule 5450(a)(1).

There can be no assurance that we will continue to meet the minimum bid price requirement, or any other Nasdaq requirements, in the future. Of note, from February 14, 2023 to March 24, 2023, the closing price of our common stock was below $1.00 per share. Since the closing bid price of our common stock has fallen below $1.00 per share for 30 consecutive trading days, Nasdaq may initiate another delisting process with a notification letter indicating that we are not in compliance with Nasdaq's listing standards.

In addition, we may be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, in which case our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

Holders of our preferred stock may have interests and rights that are different from our common stockholders.

We are permitted under our certificate of incorporation to issue up to 10,000,000 shares of preferred stock. We can issue shares of our preferred stock in one or more series and can set the terms of the preferred stock without seeking any further approval from our common stockholders. Any preferred stock that we issue may rank ahead of our common stock in terms of dividend priority or liquidation premiums and may have greater voting rights than our common stock, which could dilute the value of our common stock to current stockholders and could adversely affect the market price of our common stock.

In March 2023, we raised additional capital through a Private Placement pursuant to which we sold 25,000 shares of Series A Preferred Stock and warrants to purchase up to an aggregate of 7,485,762 shares of common stock to investors. We are required to

redeem the Series A Preferred Stock at certain specified times and upon the occurrence of certain specified events, including upon the receipt of proceeds in connection with certain strategic transactions, at the applicable redemption price set forth in the certificate of designation of the Series A Preferred Stock, or the Certificates of Designation. Upon liquidation, dissolution or winding up of our company, the holders of Series A Preferred Stock will be entitled to receive, in preference to the holders of any other capital stock, an amount per share equal to the greater of (i) $1,000 multiplied by 3.5 (or 4.5 from and after the 18 month anniversary of the closing of the Private Placement) plus accrued and unpaid dividends thereon, if any, and (ii) the amount a holder of Series A Preferred Stock would have been entitled to receive had such holder exchanged the share of Series A Preferred Stock for a number of shares of common stock equal to (x) 1,000 plus all accrued but unpaid dividends, divided by (y) the "Minimum Price" as defined in Nasdaq Rule 5635(d). Additionally, as long as there is at least 2,500 shares of Series A Preferred Stock outstanding, unless we have received the consent of the Requisite Holders (as defined in the Certificate of Designation), we are prohibited from taking certain actions, including, among other things, subject to certain exceptions, authorizing or issuing any securities senior to the Series A Preferred Stock, actions that would impede our ability to make required redemptions of the Series A Preferred Stock, incur indebtedness, transfer or license certain assets, and redeem or repurchase shares of our capital stock. In addition, holders of the Series A Preferred Stock are entitled to receive, when, as, and if declared by our board of directors, dividends that accrue on a day-to-day basis until paid at a rate of 8.000% per year on the stated value of $1,000 per share of Series A Preferred Stock, and unless full cumulative dividends have been paid, we may not declare or pay any dividends on any junior securities, including our common stock.

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, 2023, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates owned approximately 38.2% of our outstanding voting common stock, and as of March 23, 2023, approximately 70% of our outstanding Series A Preferred Stock. While these stockholders collectively own less than a majority of our voting stock, these stockholders will nevertheless continue to have significant influence over matters requiring stockholder approval. Therefore, these stockholders will have the ability to influence us through this ownership position. For example, these stockholders may be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. Additionally, holders of our Series A Preferred Stock have consent rights with respect to certain actions, limiting our ability to enter into certain change in control, liquidation or licensing transactions, or incur indebtedness without their approval. 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.

Sales of substantial amounts of our outstanding 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.

In addition, in connection with the Private Placement, we issued warrants to purchase up to 7,485,762 shares of common stock. To the extent these warrants are exercised, our stockholders would be diluted, and the price of our common stock may decline.

In addition, in the future, we may issue 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, including pursuant to the Sales Agreement with Cantor Fitzgerald, could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

If we are unable to maintain effective internal control over financial reporting, it 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 are 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 requires annual management assessment of the effectiveness of our internal control over financial reporting. 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 a smaller reporting company, and any decision on our part to comply only with applicable reduced reporting and disclosure requirements could make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or 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 $1.235 billion in gross 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, which is December 31, 2024.

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 are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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; however, the holders of the Series A Preferred Stock are entitled to receive, when, as, and if declared by our board of directors, 8.000% annual dividends payments. We do not intend to

declare or pay any cash dividends on our common 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. Furthermore, while we currently intend to retain all our available funds and any future earnings to support operations and to finance the growth and development of our business, the holders of the Series A Preferred Stock are entitled to certain redemption rights upon the receipt of proceeds in connection with certain strategic and licensing transactions. As a result of this and of the liquidation and dividend preferences of the Series A Preferred Stock, any investment return on our common stock may be diminished.

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

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

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

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

Our amended and restated certificate of incorporation provides 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. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring

a claim in a venue other than those designated in the exclusive forum provision. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provision will be enforced by a court in those other jurisdictions.

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. If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

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 carryforwards arising in taxable years beginning prior to 2018 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. Our U.S. NOL carryforwards arising in taxable years beginning after 2017 carry forward indefinitely but are subject to limitations in taxable years beginning after 2020. 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 by certain stockholders 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.

General Risk Factors

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

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

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

The SEC, and the Department of Justice continue to view FCPA enforcement activities as a high priority. There is no certainty that all of our employees, agents, contractors or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, cessation of business activities in

sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could materially damage our reputation, our brand, our international operations, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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.

If our information technology systems or data, or those of third parties upon whom we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential and sensitive data, including personal information (such as health-related data), intellectual property, and trade secrets. We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business, particularly since the COVID-19 pandemic. We also rely on third-party service providers and technologies to operate our business. parties and their information technology systems. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Any of the previously identified or similar threats could cause a security incident or other interruption, which could result in the unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data, including clinical trial data. We may be unable to anticipate or there is a risk that an attack may remain undetected for a period of time. As the cyber-threat landscape evolves, these threats are increasing in frequency, sophistication and intensity and are likely to become increasingly difficult to detect. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents and other interruptions. However, there can be no assurance that these measures will be effective.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. Furthermore, if we (or a third party upon whom we rely) experience a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting

requirements and/or oversight; restrictions on processing data (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (for example, due to data integrity, availability or confidentiality issues); financial loss; diverted management attention; and other similar harms.

A security incident may cause us to breach our contracts. Furthermore, there can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages.

We cannot be sure that our insurance coverage will be adequate to protect us from or to mitigate liabilities arising out of our privacy and cybersecurity practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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 is 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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties.

We currently lease approximately 34,988 square feet of office and laboratory space in South San Francisco, California under an eight-year lease agreement that expires in June 2027. 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.

In October 2021, we entered into a lease agreement for approximately 24,770 rentable square feet of office space in South San Francisco, California, or the Gateway Lease. Under the lease agreement we have an initial lease term of 5 years.

We believe that our existing facilities are 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.

We are not currently a party to any 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, 2023, there were approximately 17 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.

In addition, holders of the Series A Preferred Stock are entitled to receive, when, as, and if declared by our board of directors, dividends that accrue on a day-to-day basis until paid at a rate of 8.000% per year on the stated value of $1,000 per share on the Series A Preferred Stock, and unless full cumulative dividends have been paid, we may not declare or pay any dividends on any junior securities, including our common stock. See Note 12 *Subsequent Events* to our financial statements included elsewhere in this report for further details.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during the period covered by this Annual Report on Form 10-K.

Registrant Purchases of Equity Securities

None.

Item 6. [Reserved.]

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. In addition, the section of this Management's Discussion and Analysis of Financial Condition and Results of Operations generally discusses 2022 and 2021 items and year-to-year comparisons between 2022 and 2021. Discussions of 2020 items and year-to-year comparisons between 2021 and 2020 that are not included in this Annual Report on Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 10, 2022.

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. We are developing a pipeline of novel T cell engagers initially focused on the treatment of solid tumors and hematologic malignancies. In addition to our product candidates utilizing our TriTAC technology, we have also nominated our first clinical candidate using our proprietary ProTriTAC platform, a prodrug version of our TriTAC platform, designed to expand the target space for T cell engagers and bring the benefits of TriTACs to a broader number of patients.

TriTAC

Our TriTAC product candidates in ongoing clinical development include HPN217 a Phase 1 clinical trial targeting B-cell maturation antigen, or BCMA, for the treatment of multiple myeloma, and HPN328 a Phase 1/2 clinical trial targeting Delta-like canonical Notch ligand 3, or DLL3, for the treatment of small cell lung cancer, or SCLC, and other DLL3-expressing tumors. As of March 10, 2022, we have discontinued further development of HPN424 as a treatment of metastatic castration-resistant prostate cancer, or mCRPC, and as of August 2022 we have discontinued further enrollment in our HPN536 Phase 1/2a clinical trial for the treatment of ovarian cancer and other mesothelin-, or MSLN-, expressing solid tumors, as we seek a partner for further development.

TriTAC Pipeline Update

HPN217

In December 2022, we announced the interim results of ongoing Phase 1 clinical trial of HPN217. As of the October 17, 2022 data cut-off date, 62 patients had been treated across fixed and step doses up to 2.86 mg/week in fixed dosing cohorts and 24 mg/week target dose in step dosing cohorts. Premedication to minimize CRS includes dexamethasone and other standard therapies. Enrolled patients had a median of 6 prior therapies. The most frequent treatment-emergent adverse events, or TEAEs, occurring in greater than 15% were anemia (44%), fatigue (32%), and transient CRS (27%), No grade 3 or higher CRS was reported in this patient population as of the October 17, 2022 data cut-off date. Two DLTs, of reversible transaminitis were reported at a fixed dose of 2.86 mg was reported. An MTD has not been reached at the target dose in step dosing regimens. Following our results announced at ASH in December 2022, one patient experienced Grade 3 CRS and Grade 1 Immune Effector Cell Associated Neurotoxicity (ICANS), which was followed by a post-traumatic Grade 5 subdural hematoma. Overall, a well-tolerated safety profile continues to emerge, with low incidence of CRS across the patient population studied to date.

HPN217 was active across a wide dose range (2.15 to 24 mg), with 77% (10/13) ORR observed across the highest step doses (12 and 24 mg). Additionally, 86% (18/21) of responders remain on study treatment with sustained response, with many responders on treatment for over a year. Three patients in the study were evaluated for minimal residual disease (MRD), and all three were MRD negative ($<10^5$).

HPN217 demonstrated a dose proportional increase in Cmax and area under the curve, or AUC, with a median serum half-life of 66 hours, confirming half-life extension. Half-life, clearance rate, and volume of distribution were dose-independent, suggesting linear PK kinetics. Pharmacodynamic analysis shows a trend of attenuation in cytokine and chemokine (IL-6, IL-8, TNFα) spikes upon administration of target doses compared to step doses.

In January 2021, HPN217 received orphan drug designation for the treatment of multiple myeloma. In March 2022, HPN217 was granted fast track designation for the treatment of relapsed, refractory and multiple myeloma.

Dose exploration is continuing with ongoing patient enrollment in the escalation phase of the Phase 1 trial expected to reach completion in the first half of 2023 and identification of a recommended Phase 2 dose by the end of 2023.

HPN217 is covered by a global Development and Option Agreement with AbbVie, and treatment of the first patient in the clinical trial triggered a $50 million milestone payment, which we received in June 2020. HPN217 targets B-cell maturation antigen, or BCMA, a well-validated target expressed on multiple myeloma cells. Harpoon is responsible for conducting the Phase 1 trial, and we are actively enrolling patients in the dose escalation portion of the multi-country trial. Under the agreement with AbbVie, we are eligible to receive future payments totaling up to $430 million upon AbbVie's exercise of an exclusive license option and achievement of certain development, regulatory, and commercial milestones, in addition to royalties on commercial sales.

HPN328

We are currently enrolling patients in a Phase 1/2 clinical trial, HPN328, for the treatment of small cell lung cancer, or SCLC, and other tumors associated with DLL3 expression. Dose escalation is ongoing with the addition of dose regimens to determine the maximum tolerated dose, or MTD, which has not yet been reached.

In March 2022, we received orphan drug designation for the treatment of SCLC.

In April 2022, we entered into a Master Clinical Supply Agreement with F. Hoffmann-La Roche Ltd, or Roche, for the supply of atezolizumab (Tecentriq®). We plan to enroll additional cohorts in our ongoing Phase 1/2 clinical trial evaluating HPN328, a DLL3 targeting TriTAC®, in combination with atezolizumab for the treatment of patients with SCLC in the first half of 2023. Under this agreement, we are the sponsor of the anticipated clinical trials, and Roche will supply atezolizumab.

In June 2022, we provided a clinical update on our ongoing Phase 1/2 clinical trial. As of the April 21, 2022, data-cutoff date, 18 patients had been enrolled in dose cohorts ranging from 15 µg to 1200 µg per week in both fixed and step dose cohorts administered once weekly by intravenous infusion. Eighteen patients with a median of 2 lines (range 1 to 5) of prior therapy have been enrolled and eligible patients include small cell lung cancer patients who have relapsed after platinum chemotherapy and patients with other malignancies with high grade neuroendocrine tumors associated with DLL3 expression. HPN328 has been well tolerated with Grade 1-2 CRS reported in 27% of patients. No dose-limiting toxicities, or DLTs, were observed and a maximum tolerated dose, or MTD, has not been reached. Seven of 18 patients (39%) had a decrease in sum of target lesion diameters, with 3 of 11 patients (27%) with SCLC across all dose cohorts experiencing a greater than 30% decrease in sum of target lesion diameters. Additionally, 4 of 6 patients (67%) with SCLC treated at greater than or equal to 1215 µg per week experienced a decrease in sum of target lesion diameters, including one confirmed Partial Response (cPR) per RECIST criteria. The patient with a cPR experienced a target lesion reduction of 53% at week 10.

In November 2022, we reported two events of Grade 3 cytokine release syndrome (CRS) following an initial 2mg priming dose of HPN328 during the dose escalation portion of the study. CRS in one patient resolved with treatment. CRS in a second patient was complicated by a requirement for oxygen prior to dosing and other complications that led to an additional event of respiratory failure, which led to the patient's death.

In December 2022 we lowered the priming dose to 1mg and excluded patients requiring oxygen prior to dosing and dose escalation enrollment continued.

In February 2023, we confirmed a second SCLC patient had a partial response per RECIST criteria.

Patient enrollment is on track with monotherapy cohorts at the 12mg target dose. We plan to enroll additional cohorts in our ongoing Phase 1/2 clinical trial evaluating HPN328 in combination with atezolizumab for the treatment of patients with SCLC in the second half of 2023.

We plan to present interim data in the second half of 2023 with the goal of identifying a recommended Phase 2 dose in the monotherapy setting by the end of 2023.

HPN536

In August 2022, we announced that, based on our decision to prioritize assets in our portfolio, we intend to seek a partner to further develop HPN536 in monotherapy or combination studies. No further enrollment in the current study is planned, and winddown is expected to be completed by end of 2023.

HPN424

In March 2022, we announced the discontinuation of further clinical development for HPN424, our PSMA-targeting TriTAC, and winddown is expected to be completed by end of 2023.

ProTriTAC

In December 2021, as a part of our pipeline update, we also presented advancements in our second platform, ProTriTAC, which was designed to expand the universe of addressable targets and indications for T cell engagers. We have nominated the first ProTriTAC clinical candidate, HPN601, with Investigational New Drug application, or IND, enabling studies underway, and we expect to provide additional development updates later this year. 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. If active molecules leave the tumor tissue, they are rapidly eliminated from the body, therefore further limiting the potential side effects in normal tissues.

Two new candidates for IND-enabling studies from the ProTriTAC platform have been identified against the targets trophoblast cell surface antigen 2 (TROP2) and Integrin-β6 (ITGB6). TROP2 is a glycoprotein that spans the epithelial membrane surface and plays a role in cell self-renewal, proliferation, and transformation. ITGB6 is a protein that is encoded by the ITGB6 gene and are adhesion receptors that function in signaling from the extracellular matrix to the cell.

HPN601

Our first ProTriTAC candidate is currently in preclinical development. HPN601 targets the epithelial cell adhesion molecule, or EPCAM, which is expressed on variety of solid tumors. IND filing timeline to enable a Phase 1 dose exploration study will be dependent on available resources.

TriTAC-XR

In April 2022, we presented preclinical data on TriTAC-XR at the Society for Immunotherapy of Cancer (SITC) American Association for Cancer Research (AACR) annual meeting. The poster presentation demonstrated that TriTAC-XR and its underlying extended-release mechanism represents a new approach to managing CRS, either alone or in combination with other existing CRS-mitigation approaches. The expected safety improvements would enable T cell engagers targeting immune cells to broaden its adoption from oncology to autoimmune and other non-oncology diseases.

Business Operations

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 proceeds from the issuance of convertible notes, the sale of redeemable convertible preferred stock and warrants, the sale of common stock and payments received under our discovery collaboration agreement with AbbVie.

Since our inception, we have incurred significant net 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. In November 2022, we announced a corporate restructuring and a reduction in workforce of approximately 45% of our headcount to focus our resources on our clinical pipeline, including HPN217, HPN328, HPN601. We currently estimate that we will incur costs up to approximately $1.8 million in charges for termination benefits related to the restructuring plan. We paid $0.5 million for termination benefits in 2022. The estimates of the expenses we expect to incur are subject to a number of assumptions, risks and uncertainties, and actual results may differ from our estimates. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the corporate restructuring. Also, as a part of the restructuring, we plan to initiate activities to reduce our corporate facilities footprint by subletting all of our research labs and associated office and relocating to a smaller facility.

Our net losses were $67.7 million, $116.8 million, and $49.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we had an accumulated deficit of $352.5 million. Our primary use of cash is to fund net losses, 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 HPN217, HPN328, and HPN601, as well as any 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, ProTriTAC and TriTAC-XR;

- 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.

From October 2020 through the period ended December 31, 2022, pursuant to our Sales Agreement with Cantor Fitzgerald, we received an aggregate of approximately $11.2 million in net proceeds from the sale of shares of our common stock. In 2023, we received an aggregate of approximately $1.5 million in net proceeds from the sale of shares of our common stock under such Sales Agreement.

In March 2023, we entered into a Securities Purchase Agreement, or Purchase Agreement. Pursuant to the Purchase Agreement, we sold and issued (i) 25,000 shares of Series A Preferred Stock and (ii) warrants to purchase up to an aggregate of 7,485,762 shares of our Common Stock, or the Warrants. The shares of Series A Preferred Stock and accompanying Warrants were sold at a purchase price of $1,000 per share of Series A Preferred Stock. The total gross proceeds we received from the sale of the Series A Preferred Stock and Warrants in the Private Placement were approximately $25.0 million, which does not include any proceeds that may be received upon exercise of the Warrants.

COVID-19

We are continuing to monitor the overall impact of the COVID-19 pandemic on our business. Our assessment to date continues to support that we have not experienced any material delays or significant financial impacts directly related to the pandemic other than some minor disruptions to clinical operations, including some disruptions in our manufacturing supply chain that affected and may continue to affect our drug supply, disruptions in patient enrollment in some of our clinical trials and delays in collecting, receiving and analyzing data from patients enrolled in our clinical trials due to limited staff at our clinical trial sites. We will continue to monitor any potential impacts of the COVID-19 pandemic on our third-party contract manufacturers, contract research organizations and other third parties that assist us with clinical trials and our clinical trial sites. See “Part II Item 1A—Risk Factors” for more information regarding the potential impact of the COVID-19 pandemic on our business and operations. We continue to actively monitor this situation and the possible effects on our business and operations.

Collaborations with AbbVie

Development and Option Agreement

On November 20, 2019, we entered into a Development and Option Agreement, which we refer to, as amended, as the Development and Option Agreement, with AbbVie in connection with our HPN217 program, which targets B cell maturation antigen, or BCMA. Pursuant to such agreement, we granted to AbbVie an option to a worldwide, exclusive license to our patents and know-how applicable to the HPN217 program to develop, manufacture, and commercialize products arising from the HPN217 program and targeting BCMA, or HPN217 Products. Under the Development and Option Agreement, we filed an IND for HPN217 and are responsible for conducting clinical development activities pursuant to a mutually agreed upon development plan, including conducting a Phase 1 trial of HPN217, in order for AbbVie to determine whether it wishes to exercise its option to a worldwide, exclusive license to such HPN217 program. We initiated a Phase 1 clinical trial in April 2020.

Under the Development and Option Agreement, AbbVie may exercise its license option at any time during a period commencing on the effective date of the agreement and expiring after a specified period following delivery by us of a specified data package arising from the first Phase 1 trial for the HPN217 Products. Following AbbVie’s exercise of its option, and except for completion of certain development activities by us under the development plan, AbbVie will be solely responsible, at its cost, for the development, manufacture and commercialization of HPN217 and any other HPN217 Products. AbbVie is required to use commercially reasonable efforts to develop and obtain regulatory approval for one HPN217 Product, for at least one indication, for use in each Major Market (as defined in the Development and Option Agreement).

AbbVie paid an upfront payment of $30.0 million and, in June 2020, a development milestone payment of $50.0 million, as we dosed our first patient in the Phase 1 trial of HPN217 in April 2020. If AbbVie exercises its option, AbbVie will pay us an option exercise fee of $200.0 million. Following option exercise, AbbVie will be required to make further payments to us of up to $230.0 million in the aggregate for the achievement of specified development, regulatory and commercial sales milestones for HPN217 Products. We will also receive tiered royalties on net sales by AbbVie, its affiliates and sublicensees of HPN217 Products at percentages ranging from the high single digits to the very low double digits, subject to specified offsets and reductions. Royalties will be payable under the Development and Option Agreement on a product-by-product and country-by-country basis commencing on the date of first commercial sale of HPN217 and other HPN217 Products, and ending on the later of expiration of all valid claims of

specified licensed patents in such country, expiration of regulatory exclusivity in such country, or ten years following first commercial sale of such HPN217 Product in such country.

We will recognize revenue under the Development and Option Agreement as the initial development activities are performed using an input method, according to the costs incurred as related to the estimated costs for the development and regulatory activities to be performed through the completion of a Phase 1 trial of HPN217. Accordingly, of the $30.0 million upfront payment received in 2019 and $50.0 million development milestone received in 2020, $24.4 million and $18.4 million of revenue was recognized for the year ended 2022 and 2021, respectively, and as of December 31, 2022, we had $21.7 million of deferred revenue under the Development and Option Agreement.

Amended and Restated Discovery Collaboration Agreement

On August 16, 2021, we entered into Amendment No. 1 to the Amended and Restated Discovery Collaboration and License Agreement, or the First Amendment, with AbbVie, which amends the Amended and Restated Discovery Collaboration and License Agreement, or, as amended by the First Amendment, the Restated Collaboration Agreement, entered on November 20, 2019, between us and AbbVie, which agreement amends and restates the Discovery Collaboration and License Agreement entered into between us and AbbVie, dated October 20, 2017 and amended April 3, 2019, or the Original Collaboration Agreement. Pursuant to the First Amendment, we and AbbVie agreed to include the ProTriTAC technology within the Restated Collaboration Agreement. Pursuant to the Original 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 Original Collaboration Agreement, AbbVie was granted the right to designate up to two targets for development of TriTAC constructs, which it selected in 2017 and 2019, respectively. Pursuant to the Restated Collaboration Agreement, AbbVie is permitted to designate two further targets, with an option to select up to four additional targets, selected during a specified period following the effective date, to be the subject of activities under the collaboration, and is granted a worldwide, exclusive license to develop and commercialize products that incorporate either our proprietary TriTAC platform technology, or (as a result of and pursuant to the First Amendment) our ProTriTAC platform technology, together with soluble T cell receptors, or TCRs. Such products may incorporate antibodies provided by AbbVie or by us. During a period of up to four years following the date of AbbVie's designation of each target for the products, and subject to 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 or ProTriTAC technologies, in conjunction with the soluble TCR or antibody sequences directed at the agreed upon targets of interest. We may not, including through any third party, develop or commercialize any competing product that binds to any of the included targets. As was the case under the Original Collaboration Agreement, 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 each Major Market (as defined in the Restated Collaboration Agreement).

In addition to the upfront payment of $17.0 million already paid under the Original Collaboration Agreement, we received an upfront payment of $20.0 million under the Restated Collaboration Agreement for AbbVie's right to select two further targets and an option to select up to four further targets. AbbVie will be required to make payments to us, upon target selection, of $10.0 million for each target, for up to four additional targets selected by AbbVie. For each of the up to eight targets selected, we are eligible to receive up to $300.0 million in the aggregate for the achievement of specified development, regulatory and commercial sales milestones for licensed products indicated for human therapeutic or prophylactic use. We will also be eligible to 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. Royalties will be payable under the Restated Collaboration Agreement on a product-by-product and country-by-country basis commencing on the date of first commercial sale of each product, and ending on the later of expiration of all valid claims of specified licensed patents in such country, expiration of regulatory exclusivity in such country or ten years following first commercial sale of such product in such country. 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 recognized revenue under the Original Collaboration Agreement over a period in which related research and development activities occur. As of December 31, 2021, we had recognized the full $17.0 million upfront payment related to the initial two targets.

We will recognize revenue under the Restated Collaboration Agreement over a period in which related research and development activities occur. Accordingly, of the $20.0 million upfront payment received in 2019, $7.5 million and $0.9 million of revenue was recognized during the years ended 2022 and 2021. As of December 31, 2022, we had $11.6 million of deferred revenue under the Restated Collaboration Agreement.

The Restated Collaboration Agreement will terminate upon the date of the expiration of all AbbVie's royalty payment obligations in all countries. The Restated 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 such agreement by the other party. AbbVie may also terminate the Restated 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 Restated 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.

Financial Operations Overview

Revenue

We have no products approved for commercial sale and have not generated any revenue from product sales. Our collaboration and license revenue to date is related to work performed by us under the Restated Collaboration Agreement and Development and Option Agreement, and is recognized when designated research and development services are performed. To date, we have received upfront payments under the Original Collaboration Agreement and Restated Collaboration Agreement, and Development and Option Agreement and milestone payments under the Development and Option Agreement. We expect that any collaboration and license revenue we generate from the Restated Collaboration Agreement and the Development and Option 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. Additionally, for research and development services that we recognize over time, we measure our progress using an input method. The input methods we use are based on the effort we expend or costs we incur toward the satisfaction of our performance obligation. We estimate the amount of effort we expend, including the time we estimate it will take us to complete the activities, or costs we incur in a given period, relative to the estimated total effort or costs to satisfy the performance obligation. This results in a percentage that we multiply by the transaction price to determine the amount of revenue we recognize each period. This approach requires us to make numerous estimates and use significant judgement. If our estimates or judgements change over the course of the collaboration, they may affect the timing and amount of revenue that we recognize in the current and future periods.

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 continue 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 continue to incur expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or the SEC, Nasdaq and any other securities exchange on which our securities are traded, insurance expenses, investor relations activities and other administrative and professional services.

Litigation Settlement

Litigation settlement related to the damages settlement resulting from the Maverick Litigation described in Note 6 *Commitments and Contingencies* to our financial statements included elsewhere in this report.

Interest Income, net

Interest income, net is primarily comprised of interest income and gains or losses realized on cash and cash equivalents and marketable securities.

Other Expense, net

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

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021

	Year Ended December 31,			
	2022	2021	Change ($)	Change (%)
	(dollars in thousands)			
Revenue:				
Collaboration and license revenue	$ 31,915	$ 23,654	$ 8,261	35%
Total revenue	31,915	23,654	8,261	35%
Operating expenses:				
Research and development	81,393	72,124	9,269	13%
General and administrative	18,847	18,327	520	3%
Litigation settlement	—	49,954	(49,954)	*
Total operating expenses	100,240	140,405	(40,165)	-29%
Loss from operations	(68,325)	(116,751)	(48,426)	-41%
Interest income	776	240	536	223%
Other expense	(182)	(210)	(28)	-13%
Net loss	$ (67,731)	$ (116,721)	$ (48,990)	-42%

* Not meaningful.

Revenue

Collaboration and license revenue increased by $8.3 million, or 35%, for the year ended December 31, 2022 compared to the year ended December 31, 2021. The increase was primarily due to a $6.0 million increase in revenue recognized related to the Development and Option Agreement, for research and development services performed, and a $2.3 million increase in revenue recognized for research and development services performed on the third and fourth targets under the Restated Collaboration Agreement.

Research and Development

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

	Year Ended December 31,	
	2022	2021
	(In thousands)	
Product and clinical development	$ 36,289	$ 29,070
Research and technology services	3,799	4,530
Laboratory supplies and equipment	2,271	2,585
Pharmacology services	543	2,255
Personnel-related	26,674	23,092
Facility and other allocated expenses	8,095	6,996
Consulting	3,722	3,596
Total research and development expenses	$ 81,393	$ 72,124

Research and development expenses increased by $9.3 million to $81.4 million, or 13%, in 2022 compared to 2021. The increase was primarily due to a $7.2 million increase in product and clinical development expense due to continued development of our lead product candidates which included conducting clinical studies and manufacturing runs to support ongoing clinical development, a $3.6 million increase in personnel-related expenses primarily due to charges related to the corporate restructuring

implemented in the fourth quarter of 2022, a $1.1 million increase in facility and other allocated expenses, a $0.1 million increase in consulting expenses which was offset by a $2.4 million decrease in pharmacology services and research and technology services due to the termination and winddown of HPN424 and HPN536 studies, and a $0.3 million decrease in laboratory supplies and equipment as a result of winddown in research activities associated with the corporate restructuring.

General and Administrative

General and administrative expenses increased by $0.5 million to $18.8 million, or 3%, in 2022 compared to 2021. The increase was primarily due to a $0.9 million increase in legal fees related to corporate legal services, a $0.5 million increase in consulting expenses, a $0.4 million in other professional services, offset by a $1.4 million decrease in personnel-related expenses.

Litigation Settlement

Litigation settlement decreased by $50.0 million in 2022 compared to 2021. The decrease was due to the litigation settlement incurred in the first quarter of 2021. See Note 6 *Commitments and Contingencies* to our financial statements included elsewhere in this report.

Interest Income, net

Interest income increased by $0.5 million to $0.8 million, or 223%, in 2022 compared to 2021. The increase was primarily due to higher interest yields on our cash, money-market and marketable securities balances.

Liquidity and Capital Resources

Liquidity

Since our inception and through December 31, 2022, we have financed our operations primarily through proceeds from the issuance of convertible notes, the sale of redeemable convertible preferred stock and warrants, the sale of common stock, and upfront payments received by us from our collaboration and license agreements. As of December 31, 2022, we had $53.1 million in cash and cash equivalents and marketable securities, an accumulated deficit of $352.5 million and working capital of $2.3 million.

In March 2023, we sold and issued (i) 25,000 shares of Series A Preferred Stock and (ii) Warrants to purchase up to an aggregate of 7,485,762 shares of the Company's Common Stock. The shares of Series A Preferred Stock and accompanying Warrants were sold at a purchase price of $1,000 per share of Series A Preferred Stock. The total gross proceeds we received from the sale of the Series A Preferred Stock and Warrants in the Private Placement was approximately $25.0 million, which does not include any proceeds that may be received upon exercise of the Warrants.

In January 2021, we sold an aggregate 6,764,704 shares of our common stock for $107.6 million in net proceeds after deducting underwriting discounts and commissions and offering costs.

From October 2020 through December 31, 2022 pursuant to our Sales Agreement with Cantor Fitzgerald, we received an aggregate of approximately $11.2 million in net proceeds from the sale of shares of our common stock. In 2023, we received an aggregate of approximately $1.5 million in net proceeds from the sale of shares of our common stock under such Sales Agreement..

With respect to the Maverick Litigation described above and in Note 6 *Commitments and Contingencies* to our financial statements included elsewhere in this report, on May 5, 2021, we paid the full amount of damages awarded by the Court, equal to $50.0 million, consisting of $38.2 million in damages plus $11.8 million in pre-judgment interest through May 5, 2021.

In November 2022, we announced a corporate restructuring and a reduction in workforce of approximately 45% of our headcount, to focus our resources on our clinical pipeline, which includes HPN217 (BCMA), HPN328 (DLL3), HPN601 (EpCAM). We currently estimate that we will incur costs up to approximately $1.8 million in charges for termination benefits related to the restructuring plan, of which $0.5 million in cash was paid in 2022. The estimates of the expenses we expect to incur are subject to a number of assumptions, risks and uncertainties, and actual results may differ from our estimates. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the corporate restructuring. We are also initiating activities to reduce our corporate facilities footprint by subletting all of our research labs and associated office and relocating to a smaller facility. We are currently evaluating the impact of the restructuring plan on certain of our assets and whether any related impairment charge will need to be recorded. We expect that our existing cash and marketable securities, including the additional funds from the recently completed offering of preferred stock and warrants, combined with cost-saving efforts, which include the impact of the restructuring and planned facility expense reduction, will result in an extension of our cash runway for at least 12 months from the date of issuance of these financial statements.

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 will likely be

required to further reduce our operations, which could involve significantly reducing operating expenses and delaying, reducing the scope of or eliminating some of the development programs or commercialization efforts, out-licensing intellectual property rights to our product candidates and selling 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.

The effect and extent of the impact of the COVID-19 pandemic on our employees, patients, communities and business operations, as well as the U.S. economy and financial markets continues to be uncertain and difficult to predict. While we have seen recovery from the initial economic effects of the pandemic, the duration and impact of the COVID-19 pandemic (including variants) may continue to affect our results of operation. The extent to which COVID-19 (including any variants) continues to impact our results and financial position will depend on future developments, which are uncertain and difficult to predict.

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.

In March 2020, we entered into a Controlled Equity Offering[SM] Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which we may offer and sell, from time to time at our sole discretion through Cantor Fitzgerald, as our sales agent, shares of our common stock having an aggregate offering price of up to $75.0 million. Cantor Fitzgerald may sell the common stock by any method permitted by law deemed to be an “at the market offering”, or ATM, as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including sales made directly on or through The Nasdaq Global Select Market or on any other existing trading market for our common stock. We will pay Cantor Fitzgerald a commission up to 3.0% of the gross sales proceeds of any shares of our common stock sold through Cantor Fitzgerald under the Sales Agreement. From October 2020 through December 31, 2022, we had sold a total of 2,884,335 shares of our common stock under the Sales Agreement, resulting in aggregate net proceeds of $11.2 million. In 2023, we have sold a total of 1,593,278 shares of our common stock under the Sales Agreement, resulting in aggregate net proceeds of $1.5 million. As of December 31, 2022 and at the date of this report, there was approximately $63.8 million and $62.3 million, respectively, remaining available to be sold under the terms of the Sales Agreement.

Based on our current business plans, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our planned operations for at least the next 12 months from the issuance date of the audited financial statements included in this report. However, we will require additional capital 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, or we may seek to control expenses by delaying certain candidates in our portfolio and reducing internal expenditures. 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 expect to 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, operating and capital leases, 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,	
	2022	2021
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (89,182)	$ (122,154)
Investing activities	89,737	34,354
Financing activities	6,372	111,523
Net increase in cash, cash equivalents, and restricted cash	$ 6,927	$ 23,723

Cash Flows from Operating Activities

In 2022, cash used in operating activities was $89.2 million, which consisted of a net loss of $67.7 million and a net change of $33.6 million in our net operating assets and liabilities, partially offset by $12.1 million in non-cash charges. The non-cash charges consisted of stock-based compensation of $8.6 million, depreciation and amortization of $2.4 million, net amortization of premiums and accretion of discounts on marketable securities of $0.4 million and amortization of operating right-of-use lease asset of $0.7 million. The change in operating assets and liabilities was primarily due to a decrease in deferred revenue of $31.9 million resulting from the recognition of revenue related to the AbbVie Restated Collaboration Agreement and the Development Option Agreement, a decrease of $1.7 million in operating lease obligations, and a decrease in accrued liabilities of $3.0 million related to timing for research and development activities, and a decrease in other assets of $0.1 million which was offset by an increase in accounts payable of $2.1 million and an increase in prepaid expenses of $1.0 million resulting from the timing of payments made for ongoing research and development activities and operating costs to support our operations as a public company.

In 2021, cash used in operating activities was $122.2 million, which consisted of a net loss of $116.7 million and a net change of $19.9 million in our net operating assets and liabilities, partially offset by $14.5 million in non-cash charges. The non-cash charges consisted of stock-based compensation of $9.5 million, depreciation and amortization of $2.2 million, amortization operating right-of-use lease asset of $0.5 million and net amortization of premiums and discounts on marketable securities of $2.4 million. The change in operating assets and liabilities was primarily due to a decrease in deferred revenue of $23.7 million resulting from the recognition of revenue related to the AbbVie Restated Collaboration Agreement and the Development Option Agreement, a decrease of $1.6 million in prepaid expenses and other assets, a net decrease of $1.3 million in operating lease obligations which was offset by an increase in accrued liabilities of $2.9 million primarily related to timing for ongoing research and development activities, and an increase of $0.5 million in accounts payable resulting from the timing of payments made for operating costs.

Cash Flows from Investing Activities

In 2022, cash provided by investing activities of $89.7 million was primarily related to $90.1 million of net maturities and sales and purchases of marketable securities, offset by purchases of lab equipment of $0.4 million.

In 2021, cash provided by investing activities of $34.4 million primarily related to net maturities and purchases of marketable securities.

Cash Flows from Financing Activities

In 2022, cash provided by financing activities of $6.4 million was primarily from $5.4 million in net proceeds from the sale of our common stock pursuant to our Sales Agreement with Cantor Fitzgerald and $1.0 million from purchases of our common stock under our 2019 employee stock purchase plan.

In 2021, cash provided by financing activities of $111.5 million was primarily from $107.6 million in net proceeds from the follow-on offering completed in January 2021, $2.8 million in net proceeds from the sale of our common stock pursuant to our Sales Agreement with Cantor Fitzgerald through December 31, 2021, $0.6 million in proceeds from the exercise of common stock options and $0.6 million from purchases of our common stock under our 2019 employee stock purchase plan.

Contractual Obligations and Other Commitments

Contractual obligations as of December 31, 2022 represent operating lease obligations related to our currently occupied lab and office space at 131 Oyster Point Blvd in South San Francisco, California that commenced in July 2019 and expires in June 2027 and additional office space located at 611 Gateway Blvd in South San Francisco, California. The initial annual base rents 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 maintain a letter of credit for the benefit of the landlord in the amount of $0.5 million. Under the lease agreement, we have an option to extend the lease for an additional period of eight years. As of December 31, 2022, we have determined not to exercise our option to extend the lease term.

In November 2022, we announced a corporate restructuring designed to reduce operating expenses and focus our resources on our clinical pipeline. We estimate that in first half of 2023 we will incur cash payments up to approximately $1.1 million for termination benefits related to the restructuring plan.

In October 2021, we entered into a lease agreement for approximately 24,770 rentable square feet of office space in South San Francisco, California. The initial annual base rents are approximately $1.3 million and such amount will increase by 3.0% annually on each anniversary of the commencement date, equaling approximately $6.6 million over the five-year lease term. Upon the execution of the lease agreement, we provided the landlord with a security deposit of $0.2 million, which is included in other assets on the balance sheet. The lease commencement date was December 19, 2022, at which time we obtained control, gained physical access and took occupancy. The lease does not contain a renewal option.

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.

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—Collaboration and License 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.

If we raise additional funds through licensing or collaboration arrangements with third parties, pursuant to the terms of our Series A Preferred Stock, we will be required to use a portion of the net proceeds from certain licensing or collaboration arrangements to redeem shares of Series A Preferred Stock as described above and in Note 12 *Subsequent Events* to our financial statements included elsewhere in this report.

Critical Accounting 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

To date, all of our revenue has been derived from our collaboration and license agreements entered into with AbbVie and Werewolf Therapeutics. The terms of these arrangements include payments to us for the following: non-refundable, upfront license fees; development, regulatory and commercial milestone payments, and royalties on net sales of licensed products.

Revenue is recognized in accordance with 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 Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers,* or Topic 606, we perform the following five steps in determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of these agreements: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, we satisfy each performance obligation.

We only apply the five-step model to contracts when it is probable that we will collect 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 allocate the transaction price to each performance obligation on a relative stand-alone selling price basis. The stand-alone selling price may be, but is not presumed to be, the contract price. In determining the allocation, we maximize the use of observable inputs. When the stand-alone selling price of a good or service is not directly observable, we estimate the stand-alone selling price for each performance obligation using assumptions that require judgment. Acceptable estimation methods include, but are not limited to: (i) the adjusted market assessment approach, (ii) the expected cost plus margin approach, and (iii) the residual approach (when the stand-alone selling price is not directly observable and is either highly variable or uncertain). In order for the residual approach to be used, we must demonstrate that (a) there are observable stand-alone selling prices for one or more of the performance obligations and (b) one of the two criteria in ASC 606-10- 32-34(c)(1) and (2) is met. The residual approach cannot be used if it would result in a stand-alone selling price of zero for a performance obligation, as a performance obligation, by definition, has value on a stand-alone basis.

An option in a contract to acquire additional goods or services gives rise to a performance obligation only if the option provides a material right to the customer that it would not receive without entering into that contract. Factors that we consider in evaluating whether an option represents a material right include, but are not limited to: (i) the overall objective of the arrangement, (ii) the benefit the collaborator might obtain from the arrangement without exercising the option, (iii) the cost to exercise the option (e.g. priced at a significant and incremental discount) and (iv) the likelihood that the option will be exercised. With respect to options determined to be performance obligations, we recognize revenue when those future goods or services are transferred or when the options expire.

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.

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.

See Note 7 *Collaboration & License Agreements* to our financial statements included elsewhere in this report for additional details regarding our collaboration arrangements with AbbVie.

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, production of materials for clinical trials, 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 measure and recognize compensation expense for all stock-based awards made to employees, directors and non-employees, based on estimated fair values of the awards on the grant date and recognized using the straight-line method over the requisite service period.

The fair value of options is estimated on the grant date using the Option Pricing Model (OPM) Black-Scholes model. The calculation of stock-based compensation expense requires that we make certain 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.

Changes in these assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. 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.

We estimate the fair value of stock options granted to our employees on the grant date, and rights to acquire stock granted under our Employee Stock Purchase Plan, or ESPP, and the resulting stock-based compensation expense, using the OPM Black-Scholes model.

Recent Accounting Pronouncements

See Note 2 *Summary of Significant Accounting Policies* 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 Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. 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,* ASU No. 2016-02, *(Topic 842), Leases*, 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. We expect to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least $1.235 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.

As a smaller reporting company, we are not required to provide the information in this section.

Item 8. Financial Statements and Supplemental Data

The information required to be filed in this item appears under "Exhibits and 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-27.

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 Annual Report on Form 10-K.

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 Principal Financial and Accounting 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 Principal Financial and Accounting 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 Principal Financial and Accounting Officer as appropriate, to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our management, under the supervision and with the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022 based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on the results of its evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2022 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.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item is incorporated by reference to the information set forth in the sections titled "Proposal 1—Elections of Directors," "Information Regarding the Board and Corporate Governance" and "Information About Our Executive Officers" in our definitive proxy statement to be filed with the SEC on Schedule 14A in connection with our 2023 Annual Meeting of Shareholders, or the Proxy Statement, which is expected to be filed not later than 120 days after December 31, 2022.

Item 11. Executive Compensation

Information required by this item is incorporated by reference to the information set forth in the sections titled "Information about Our Executive Officers," "Executive Officer and Director Compensation" and "Equity Compensation Plan Information" in the Proxy Statement.

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

Information required by this item is incorporated by reference to the information set forth in the sections titled "Equity Compensation Plan Information" and "Security Ownership of Certain Beneficial Owners and Management" in the Proxy Statement.

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

Information required by this item is incorporated by reference to the information set forth in the sections titled "Information Regarding the Board and Corporate Governance – Board of Directors Independence" and "Transactions With Related Persons" in the Proxy Statement.

Item 14. Principal Accountant Fees and Services.

Information required by this item is incorporated by reference to the information set forth in the section titled "Independent Registered Public Accounting Firm Fees and Services" in the Proxy Statement.

PART IV

Item 15. Exhibits and 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:

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
3.1	Amended and Restated Certificate of Incorporation of the Registrant	10-Q	001-38800	3.1	8/5/2019	
3.2	Certificate of Designation	8-K	001-38800	3.1	3/27/2023	
3.3	Amended and Restated Bylaws of the Registrant	8-K	001-38800	3.2	2/13/2019	
4.1	Form of Common Stock Certificate.	S-1	333-229040	4.1	1/29/2019	
4.2	Form of Common Stock Purchase Warrant	8-K	001-38800	3.1	3/27/2023	
4.3	Registration Rights Agreement by and between the Registrant and the purchasers named therein, dated March 22, 2023	8-K	001-38800	3.1	3/27/2023	
4.4	Description of Registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934					x
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 Holger Wesche and the Registrant, dated as of March 17, 2015, as amended	S-1	333-229040	10.6	12/27/2018	
10.6+	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	
10.7	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	
10.8¥	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	
10.9¥	CHEF 1 Collaboration and License Agreement between the Registrant and CMC ICOS Biologics, Inc., dated as of October 26, 2015	S-1	333-229040	10.15	12/27/2018	
10.10¥	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	
10.11¥	Development and Manufacturing Services Agreement between the Registrant and CMC ICOS Biologics, Inc., dated as of July 5, 2016	S-1	333-229040	10.16	12/27/2018	
10.12	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	
10.13+	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	
10.14¥	Amended and Restated Discovery Collaboration and License Agreement between the Registrant and AbbVie Biotechnology Ltd., dated as of November 20, 2019	10-K	001-38800	10.17	3/12/2020	
10.15¥	Development and Option Agreement between the Registrant and AbbVie Biotechnology Ltd., dated as of November 20, 2019	10-K	001-38800	10.18	3/12/2020	
10.16¥	Second Amended and Restated Assignment and License Agreement between the Registrant and Werewolf Therapeutics, Inc., dated as of December 20, 2019	10-K	001-38800	10.19	3/12/2020	
10.17	Controlled Equity Offering℠ Sales Agreement between Cantor Fitzgerald & co. and the Registrant, dated as of March 13, 2020.	S-3	333-237175	1.1	3/13/2020	
10.18¥*	First Amendment to the Development and Option Agreement between the Registrant and AbbVie Biotechnology Ltd., dated as of April 21, 2020	10-Q	001-38800	10.1	8/05/2020	
10.19*	Side Letter Amendment to Development and Option Agreement between the Registrant and AbbVie Biotechnology Ltd., dated as of April 15, 2020	10-Q	001-38800	10.2	8/05/2020	
10.20+	Amended and Restated Non-Employee Director Compensation Policy	10-Q	001-38800	10.1	5/12/2022	
10.21#	Amendment No. 1 to Amended and Restated Discovery Collaboration and License Agreement by and between the Registrant and AbbVie, Inc., dated as of August 16, 2021	10-Q	001-38800	10/1	11/10/2021	

10.22+	Employment Offer Letter by and between Julie Eastland and the Registrant, dated as of October 25, 2021	10-Q	001-38800	10.1	5/12/2022	
10.23+	Harpoon Therapeutics, Inc. 2022 Inducement Award Plan and related form agreements	8-K	001-38800	10.1	6/28/2022	
10.24+	Employment Offer Letter by and between Luke Walker and the Registrant dated as of September 17, 2022					x
10.25+	Separation Agreement by and between Holger Wesche and the Registrant, dated as of January 31, 2023					x
10.26	Securities Purchase Agreement by and between the Registrant and the purchasers named therein, dated March 22, 2023	8-K	001-38800	3.1	3/27/2023	
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
24.1	Power of Attorney (included on signature page to this Form 10-K)					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 Principal 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 Principal Financial and Accounting 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	Inline XBRL Instance Document					
101.SCH	Inline XBRL Taxonomy Schema Linkbase Document					
101.CAL	Inline XBRL Taxonomy Definition Linkbase Document					
101.DEF	Inline XBRL Taxonomy Calculation Linkbase Document					
101.LAB	Inline XBRL Taxonomy Labels Linkbase Document					
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document					
104	The cover page for this Annual Report on Form 10-K has been formatted in Inline XBRL					

†	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.
**	Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulation S-K.

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 Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 27, 2023

HARPOON THERAPEUTICS, INC.
By: /s/ Julie Eastland
Julie Eastland
President and Chief Executive Officer

HARPOON THERAPEUTICS, INC.
By: /s/ Frank Lanza
Frank Lanza
Principal Financial and Accounting Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Julie Eastland and Frank Lanza, and each of them, as her and his true and lawful attorneys-in-fact and agents, with full power of substitution for her and his, and in her and his 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 she or he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and either of them, her or his 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 Annual Report on Form 10-K 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/ Julie Eastland Julie Eastland	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 27, 2023
/s/ Frank Lanza Frank Lanza	Corporate Controller *(Principal Financial & Accounting Officer)*	March 27, 2023
/s/ Scott Myers Scott Myers	Chairman of the Board of Directors	March 27, 2023
/s/ Joseph Bailes Joseph Bailes	Director	March 27, 2023
/s/ Mark Chin Mark Chin	Director	March 27, 2023
/s/ Alan Colowick Alan Colowick	Director	March 27, 2023
/s/ Jonathan Drachman, M.D. Jonathan Drachman, M.D.	Director	March 27, 2023
/s/ Ron Hunt Ron Hunt	Director	March 27, 2023
/s/ Andrew Robbins	Director	

Andrew Robbins		March 27, 2023
/s/ Lauren Silvernail Lauren Silvernail	Director	March 27, 2023
/s/ Joanne Viney Joanne Viney	Director	March 27, 2023

HARPOON THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

Auditor Firm Id: 42 Auditor Name: Ernst & Young LLP Auditor Location: Redwood City, California

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, 2022 and 2021, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, 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 as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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 these 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 Mateo, California

March 27, 2023

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

	December 31,	
	2022	2021
Assets		
Current assets		
Cash and cash equivalents	$ 51,614	$ 44,687
Short-term marketable securities	1,498	90,411
Prepaid expenses and other current assets	1,615	2,597
Total current assets	54,727	137,695
Property and equipment, net	7,237	9,248
Long-term marketable securities	-	1,522
Operating lease right-of-use asset	10,854	6,127
Other assets	911	860
Total assets	$ 73,729	$ 155,452
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 4,712	$ 2,666
Accrued liabilities	14,361	17,362
Deferred revenue, current	30,937	37,462
Operating lease liabilities, current	2,423	1,649
Total current liabilities	52,433	59,139
Deferred revenue, noncurrent	2,314	27,705
Operating lease liabilities, net of current portion	13,583	10,538
Total liabilities	68,330	97,382
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; zero shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized at December 31, 2022 and 2021; 35,786,684 shares and 32,765,788 shares issued and outstanding at December 31, 2022 and 2021, respectively	4	4
Additional paid-in capital	357,921	342,905
Accumulated other comprehensive loss	(3)	(47)
Accumulated deficit	(352,523)	(284,792)
Total stockholders' equity	5,399	58,070
Total liabilities and stockholders' equity	$ 73,729	$ 155,452

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,		
	2022	2021	2020
Revenue			
Collaboration and license revenue	$ 31,915	$ 23,654	$ 17,444
Total revenue	31,915	23,654	17,444
Operating expenses			
Research and development	81,393	72,124	52,565
General and administrative	18,847	18,327	16,210
Litigation settlement	—	49,954	—
Total operating expenses	100,240	140,405	68,775
Loss from operations	(68,325)	(116,751)	(51,331)
Interest income	776	240	1,449
Other expense	(182)	(210)	(26)
Net loss	(67,731)	(116,721)	(49,908)
Other comprehensive loss:			
Net unrealized gain (loss) on marketable securities	44	(50)	(38)
Comprehensive loss	$ (67,687)	$ (116,771)	$ (49,946)
Net loss per share, basic and diluted	$ (2.04)	$ (3.62)	$ (1.99)
Weighted-average common shares used in computing net loss per share, basic and diluted	33,167,435	32,274,362	25,034,947

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

HARPOON THERAPEUTICS, INC.
Statements of Stockholders' Equity
(in thousands, except share and per share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	24,850,064	$ 3	$ 212,339	$ 41	$ (118,163)	$ 94,220
Issuance of common stock pursuant to ATM facility, net of offering costs of $113	192,069	—	3,032	—	—	3,032
Issuance of common stock under equity incentive plans including exercise of stock options	475,667	—	1,644	—	—	1,644
Vesting of early exercised stock options	35,372	—	29	—	—	29
Stock-based compensation		—	4,860	—	—	4,860
Net loss	—	—	—	—	(49,908)	(49,908)
Other comprehensive loss	—	—	—	(38)	-	(38)
Balances at December 31, 2020	25,553,172	3	221,904	3	(168,071)	53,839
Issuance of common stock in follow-on offering, net of underwriter discounts, commissions and issuance costs of $7,400	6,764,704	1	107,578			107,579
Issuance of common stock pursuant to ATM facility, net of offering costs of $100	138,153	—	2,769	—	—	2,769
Issuance of common stock under equity incentive plans including exercise of stock options	293,528	—	1,174	—	—	1,174
Vesting of early exercised stock options	16,231	—	18	—	—	18
Stock-based compensation		—	9,462	—	—	9,462
Net loss	—	—	-	—	(116,721)	(116,721)
Other comprehensive loss	—	—	-	(50)	-	(50)
Balances at December 31, 2021	32,765,788	4	342,905	(47)	(284,792)	58,070
Issuance of common stock pursuant to ATM facility, net of offering costs of $180	2,554,113	—	5,382	—	—	5,382
Issuance of common stock under equity incentive plans including exercise of stock options	462,175	—	990	—	—	990
Vesting of early exercised stock options	4,608	—	8	—	—	8
Stock-based compensation	—	—	8,636	—	—	8,636
Net loss	—	—	—	—	(67,731)	(67,731)
Other comprehensive income	—	—	—	44	—	44
Balances at December 31, 2022	**35,786,684**	**$ 4**	**$ 357,921**	**$ (3)**	**$ (352,523)**	**$ 5,399**

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,		
	2022	**2021**	**2020**
Cash flows from operating activities			
Net loss	$ (67,731)	$ (116,721)	$ (49,908)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities			
Stock-based compensation expense	8,636	9,462	4,860
Depreciation and amortization	2,357	2,190	2,082
Non-cash lease expense	740	456	432
Net amortization of discounts on marketable securities	394	2,369	491
Changes in operating assets and liabilities			
Prepaid expenses and other assets	982	1,125	(1,179)
Other assets	(50)	468	(359)
Accounts payable	2,047	542	(1,228)
Accrued liabilities	(2,993)	2,937	6,151
Deferred revenue	(31,915)	(23,654)	31,470
Operating lease liabilities	(1,649)	(1,328)	(1,428)
Net cash used in operating activities	(89,182)	(122,154)	(8,616)
Cash flows from investing activities			
Purchases of property and equipment	(347)	(100)	(683)
Purchases of marketable securities	(24,426)	(151,965)	(202,182)
Maturities of marketable securities	114,510	186,419	139,239
Net cash (used in) provided by investing activities	89,737	34,354	(63,626)
Cash flows from financing activities			
Proceeds from follow-on offering, net of issuance costs	—	107,580	3,032
Proceeds from ATM, net of commissions and underwriting discounts	5,382	2,769	—
Proceeds from issuance of common stock in connection with employee benefit plans	990	1,174	1,644
Net cash provided by financing activities	6,372	111,523	4,676
Net increase (decrease) in cash, cash equivalents, and restricted cash	6,927	23,723	(67,566)
Cash, cash equivalents, and restricted cash at beginning of period	45,360	21,637	89,203
Cash, cash equivalents, and restricted cash at end of period	$ 52,287	$ 45,360	$ 21,637
Supplemental disclosures of non-cash investing and financing information			
Deferred follow on offering costs included in accrued liabilities	$ —	$ —	$ 229
Purchases of property and equipment included in accounts payable	$ —	$ 1,149	$ 204
Reclassification of employee stock liability to equity upon vesting	$ 8	$ 18	$ 29
Right-of-use asset obtained in exchange for lease obligation	$ 5,468	$ —	$ —

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 ("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 is also developing its ProTriTAC platform, which builds upon the core elements of the TriTAC platform by utilizing a prodrug approach designed to allow T cell engagers to address cancer targets that would otherwise be limited by on-target toxicities. The Company's third proprietary technology platform, extended release TriTAC-XR, is designed to mitigate cytokine release syndrome. The Company was incorporated in Delaware in March 2015 and is headquartered in South San Francisco, California.

Liquidity

Since its inception, the Company has incurred significant losses and has negative cash flows from operations. As of December 31, 2022, the Company had an accumulated deficit of $352.5 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, 2022, the Company had cash, cash equivalents, and marketable securities of $53.1 million, which is available to fund future operations. The Company believes that its cash, cash equivalents and marketable securities as of December 31, 2022, and including the proceeds from the issuance of Series A Preferred Stock in March 2023 (Note 12 *Subsequent Events)*, provide sufficient capital resources to continue its operations for at least 12 months from the issuance date of this Annual Report on Form 10-K. 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 accounting principles generally accepted in the United States of America ("GAAP").

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to, the fair value of stock options, the research period of the collaboration agreements with AbbVie Biotechnology Ltd. ("AbbVie"), operating lease asset and lease liabilities, income tax uncertainties and certain accruals. As of December 31, 2022, the Company has not experienced a significant financial impact directly related to the COVID-19 pandemic. See Note 1 *Organization – Liquidity* for more information

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. There are no significant unrealized gains or losses on the money market funds for the periods presented.

For each of the years ended December 31, 2022 and 2021, the Company classified $0.7 million, as restricted cash related to a letter of credit established for an operating lease entered into in August 2018 and collateral related to a deposit for an operating lease entered into in October 2021. The restricted cash is classified in "Other assets" in the balance sheets. See Note 6 *Commitments and Contingencies* for more information.

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,		
	2022	2021	2020
		(in thousands)	
Balance Sheets			
Cash and cash equivalents	$ 51,614	$ 44,687	$ 21,170
Restricted cash (included in other assets)	673	673	467
Cash, cash equivalents and restricted cash in Statements of Cash Flows	$ 52,287	$ 45,360	$ 21,637

Marketable Securities

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

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

Concentration of Credit Risk

The Company is subject to credit risk from its portfolio of cash equivalents and marketable securities. The Company invests in money market funds through a major U.S. bank and is exposed to credit risk in the event of default by the financial institution to the extent of amounts recorded on the consolidated balance sheets. The Company invests in money market funds and investment grade short- to intermediate-term fixed income securities. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. The Company is not exposed to any significant concentrations of credit risk from these financial instruments. The goals of the Company's investment policy, in order of priority, are as follows: preservation of principal, liquidity of investments, fiduciary control of cash and investments, prevention of inappropriate concentrations of investments, and obtaining the best yields. The Company minimizes the amount of credit exposure by investing cash that is not required for immediate operating needs in money market funds and marketable securities.

Leases

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

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

Fair Value Measurement

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

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

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and

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

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

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

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets, generally three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the assets' estimated useful lives or the remaining term of the lease. Depreciation and amortization begin at the time the asset is placed in service. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. There were no sales or retirement of assets for any of the periods presented.

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

In accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("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. The Company recognizes collaboration revenue by measuring the progress toward complete satisfaction of the performance obligation using an input measure. In order to recognize revenue over the research and development period, the Company measures actual costs incurred to date compared to the overall total expected costs to satisfy the performance obligation. Revenues are recognized as the program costs are incurred. The Company will re-evaluate the estimate of expected costs to satisfy the performance obligation each reporting period and make adjustments for any significant changes.

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 (i.e. research and development services) under these arrangements. Amounts due to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. Amounts recognized as revenue prior to receipt are recorded as contract assets included in prepaid expenses and other current assets on the balance sheet. If the Company expects to have an unconditional right to receive the consideration in the next twelve months, this will be classified in current assets.

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, production of materials for clinical trials, 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 and manufacturing organizations in connection with the production of materials for clinical trials 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 non-employees.

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, directors, consultants and nonemployees as of the grant date utilize the single-option award-valuation approach, and the Company uses the straight-line method for expense attribution. The valuation model used for calculating the estimated fair value of stock awards is the OPM Black-Scholes model. The OPM 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 yield. The Company has elected to recognize forfeitures of share-based payment awards as they occur.

Employee 401(k) Plan

The Company has a qualified contributory savings plan under Section 401(k) of the Internal Revenue Code (the "Code") covering substantially all U.S. employees of Harpoon. The 401(k) plan is designed to provide tax-deferred retirement benefits in accordance with the provisions of Section 401(k) of the Code. Eligible employees may defer up to 100% of their eligible compensation up to the annual maximum as determined by the Internal Revenue Service. The Company's contributions to the plan are discretionary. For the years ended December 31, 2022 and December 31, 2021, the Company made matching contributions of $0.6 million and $0.4 million, respectively.

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 10 *Net Loss Per Share*, 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 Loss

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

Emerging Growth Company Status

The Company is 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. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that the Company (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, the accompanying financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

Effective January 1, 2017, the Company early adopted ASU No. 2014-09, Revenue from Contracts with Customers (Accounting Standards Codification Topic 606), ASU No. 2016-09. Effective January 1, 2018, the Company early adopted ASU No. 2018-07 Stock Compensation—Improvements to Employee Share-Based Payment Accounting, ASU No. 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. Effective January 1, 2019, the Company early adopted ASU No. 2016-02, (Topic 842) Leases, using the alternative transition approach provided by ASU No. 2018-11, 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. 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 Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* and subsequent amendments to the initial guidance: *ASU 2018-19* and *ASU 2019-04* (collectively, Topic 326). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. The amendments apply to entities which hold financial assets that are not accounted for at fair value through net income as well as loans, debt securities, accounts receivables and any other financial assets not excluded from the scope that have the contractual right to receive cash. Topic 326 requires entities to record expected credit losses for certain financial instruments, including available-for-sale securities, as an allowance that reflect the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities in unrealized loss positions, ASU 2016-13 requires allowances to be recorded instead of reducing the amortized cost of the investment. Under ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, the effective date for ASU 2016-13 has been deferred for credit losses for SEC filers that are eligible as a smaller reporting company. As such, the amended effective date for ASU 2016-13 is January 1, 2023. The Company is currently evaluating the effect of the adoption of this guidance 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, 2022			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash Equivalents:				
Money market funds	$ 45,963	$ 45,963	$ —	$ —
Short-term marketable securities				
U.S. government securities	1,498	—	1,498	—
Total cash equivalents and marketable securities	$ 47,461	$ 45,963	$ 1,498	$ —

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash Equivalents:				
Money market funds	$ 42,867	$ 42,867	$ —	$ —
Short-term marketable securities				
U.S. government treasuries	9,999	9,999	—	—
U.S. government securities	45,241	45,241	—	—
Corporate debt securities	23,474	—	23,474	—
U.S. government agency securities	11,697	—	11,697	—
Long-term marketable securities				
U.S. government securities	1,522	—	1,522	—
Total cash equivalents and marketable securities	$ 134,800	$ 98,107	$ 36,693	$ —

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

The Company had no Level 3 assets or liabilities as of December 31, 2022 or 2021. There were no transfers between Level 1 and Level 2 during the years ended December 31, 2022 and 2021.

The Company did not have any financial liabilities subject to fair value measurements on a recurring basis as of December 31, 2022 and 2021.

4. Available-for-Sale Securities

All marketable securities were considered available-for-sale at December 31, 2022. The amortized cost, gross unrealized holding gains or losses and fair value of the Company's marketable securities by major security type are summarized in the tables below:

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
	(in thousands)			
Cash equivalents				
Money market funds	$ 45,963	$ —	$ —	$ 45,963
Total cash equivalents	45,963	—	—	45,963
Short-term marketable securities:				
U.S. government securities	1,501	—	(3)	1,498
Total short-term marketable securities	1,501	—	(3)	1,498
Total	$ 47,464	$ —	$ (3)	$ 47,461

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
	(in thousands)			
Cash equivalents				
Money market funds	$ 42,867	$ —	$ —	$ 42,867
Total cash equivalents	42,867	—	—	42,867
Short-term marketable securities:				
U.S. government treasuries	9,999	—	—	9,999
U.S. government agency securities	11,697	1	(1)	11,697
U.S. government securities	45,257	—	(16)	45,241
Corporate debt securities	23,495	—	(21)	23,474
Total short-term marketable securities	90,448	1	(38)	90,411
Long-term marketable securities:				
U.S. government securities	1,532	—	(10)	1,522
Total long-term marketable securities	1,532	—	(10)	1,522
Total	$ 134,847	$ 1	$ (48)	$ 134,800

As of December 31, 2022, some of the Company's marketable securities were in an unrealized loss position. The Company determined that it did have the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery, thus there has been no recognition of any other-than-temporary impairment in the year ended December 31, 2022. All marketable securities with unrealized losses at December 31, 2022 balance sheet date have been in a loss position for less than twelve months or the loss is not material.

All of the Company's marketable securities have an effective maturity within 12 months.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31,	
	2022	2021
	(in thousands)	
Laboratory equipment	$ 6,232	$ 5,886
Furniture and fixtures	585	585
Computer equipment and software	91	91
Leasehold improvements	8,872	8,872
	15,780	15,434
Less: Accumulated depreciation and amortization	(8,543)	(6,186)
Total property and equipment, net	$ 7,237	$ 9,248

Depreciation and amortization expense for property and equipment amounted to $2.4 million, $2.2 million and $2.1 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2022	2021
Accrued research and development	$ 8,569	$ 11,041
Accrued personnel costs	4,760	5,238
Accrued professional and consulting fees	896	200
Other	136	883
Total accrued liabilities	$ 14,361	$ 17,362

6. Commitments and Contingencies

Leases

In August 2018, the Company entered into a lease agreement for the office and laboratory space in South San Francisco, California (the “Cove Lease”). The lease commencement date was July 1, 2019, at which the Company took occupancy. The Cove Lease includes an option to renew, exercisable at the Company’s sole discretion, with a renewal term for an additional period of eight years. As of December 31, 2022, the Company has not determined whether it will exercise its option to extend the lease term. Therefore, the operating lease assets and lease liabilities only contemplate the initial lease terms. The Cove Lease qualifies as an operating lease.

In October 2021, the Company entered into a lease agreement for approximately 24,770 rentable square feet of office space in South San Francisco, California (the “Gateway Lease”). The Gateway Lease commencement date was December 19, 2022, at which time the Company obtained control, gained physical access and took occupancy. The Gateway Lease does not contain a renewal option. Therefore, the right-to-use asset and lease liabilities on the balance sheet only contemplate the initial lease term through March 31, 2028. The Gateway Lease qualifies as an operating lease.

The following table summarizes the presentation in the Company's balance sheet of its operating leases (in thousands):

	As of December 31, 2022
Assets:	
Operating lease right-of-use assets	$ 10,854
Liabilities	
Operating lease liabilities	$ 2,423
Operating lease liabilities, net of current portion	13,583
Total operating lease liabilities	$ 16,006

	As of December 31, 2021
Assets:	
Operating lease right-of-use assets	$ 6,127
Liabilities	
Operating lease liabilities	$ 1,649
Operating lease liabilities, net of current portion	10,538
Total operating lease liabilities	$ 12,187

The Company incurred $0.9 million, $0.9 million and $0.7 million in variable lease costs for each of the years ended December 31, 2022, 2021 and 2020, respectively.

Future minimum lease payments as of December 31, 2022 are as follows (in thousands):

As of December 31, 2022	Operating Lease Commitments
2023	$ 3,703
2024	4,087
2025	4,215
2026	4,347
2027	2,648
Thereafter	347
Total future minimum lease payments	19,347
Less: Present value adjustment for minimum lease commitments	(3,341)
Total	$ 16,006

As of December 31, 2022, the weighted average remaining lease term was 4.76 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 9.30%.

Rent expense was $1.8 million, $1.7 million and $1.7 million for the years ended December 31, 2022, 2021 and 2020, respectively. Amortization of the right-of-use lease assets was $0.7 million, $0.5 million and $0.4 million for the years ended December 31, 2022, 2021 and 2020, 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.

Maverick Litigation

On April 3, 2020, the Delaware Chancery Court (the "Court") issued a memorandum opinion, which related only to the Company's ProTriTAC platform. The Court ruled in favor of the Company on claims by Maverick Therapeutics, Inc. ("Maverick") for breach of contract and misappropriation of trade secrets and dismissed those claims. As part of that ruling, the Court determined that the Company's ProTriTAC technology is not in a field that is subject to a four year non-compete. The Court found in favor of Millennium Pharmaceuticals, Inc. ("Millennium") on its claim against the Company for fraud in inducing Millennium's January 2017 investment in Maverick. The Court found that Millennium had not proved its claims for tortious interference with contract and business relations or unfair competition, and those claims were dismissed. The Court held a one-day trial on Millennium's damages claim on September 22, 2020, and closing arguments were held December 8, 2020.

On April 23, 2021, following a damages phase, the Court issued a memorandum opinion awarding Millennium $38.2 million in damages, plus pre-judgment interest. The Court's opinion stated that pre-judgment interest would be calculated as set forth in 6 Del. Code Section 2301(a), which generally provides that the legal rate of interest shall be 5% over the Federal Reserve discount rate.

On May 5, 2021, the Company entered into a settlement agreement (the "Settlement Agreement") with Millennium and Maverick to resolve the parties' previously reported lawsuit. Pursuant to the terms of the Settlement Agreement, Millennium filed a proposed order and final judgment with the Court on May 5, 2021; the Company paid on May 5, 2021 the full amount of damages awarded by the Court, equal to $50.0 million, consisting of $38.2 million in damages plus $11.8 million in pre-judgment interest through May 5, 2021; and the Company, Millennium and Maverick each agreed to forego and waive its right to appeal the order and final judgment. Following execution of the Settlement Agreement, the Company is free to continue to develop its ProTriTAC platform and product candidates. The Court approved the proposed order and entered a final judgment on May 5, 2021. The $50.0 million litigation settlement payment is reflected in the statement of operations for year ended December 31, 2021.

7. Collaboration & License Agreements

Development and Option with AbbVie

On November 20, 2019, the Company entered into a Development and Option Agreement with AbbVie (as amended, the "Development and Option Agreement") in connection with the Company's HPN217 program, which targets B cell maturation antigen, ("BCMA"). Pursuant to such agreement, the Company granted to AbbVie an option to a worldwide, exclusive license under the Company's patents and know-how applicable to the HPN217 program to develop, manufacture, and commercialize products arising from the HPN217 program and targeting BCMA (the "HPN217 Products"). Under the Development and Option Agreement, the Company filed an Investigational New Drug Application for HPN217 and is responsible for conducting clinical development activities pursuant to a mutually agreed development plan, including conducting a Phase 1 trial of HPN217, in order for AbbVie to determine whether it wishes to exercise its option to take a worldwide, exclusive license to such HPN217 program.

Under the Development and Option Agreement, AbbVie may exercise its license option at any time during a period commencing on the effective date of the agreement and expiring after a specified period following delivery by the Company of a specified data package arising from the first Phase 1 trial for the HPN217 Products. Following AbbVie's exercise of its option, and except for completion of certain development activities by the Company under the development plan, AbbVie will be solely responsible, at its cost, for the development, manufacture and commercialization of HPN217 and any other HPN217 Products. AbbVie is required to use commercially reasonable efforts to develop and obtain regulatory approval for one HPN217 Product, for at least one indication, for use in each of the United States and specified European markets.

Upon execution of the Development and Option Agreement, the Company received an upfront payment of $30.0 million. Additionally, in June 2020, the Company received a development milestone payment of $50.0 million as a result of initiating its Phase 1 trial by dosing the first patient in trial in April 2020.

If AbbVie exercises its option to a worldwide, exclusive license, AbbVie will pay the Company an option exercise fee of $200.0 million. Following option exercise, AbbVie will be required to make further payments to the Company of up to $230.0 million in the aggregate for the achievement of specified development, regulatory and commercial sales milestones for HPN217 Products. The

Company will also receive tiered royalties on net sales by AbbVie, its affiliates and sublicensees of HPN217 Products at percentages ranging from the high single digits to the very low double digits, subject to specified offsets and reductions. Royalties will be payable under the Development and Option Agreement on a product-by-product and country-by-country basis commencing on the date of first commercial sale of HPN217 and other HPN217 Products, and ending on the later of expiration of all valid claims of specified licensed patents in such country, expiration of regulatory exclusivity in such country, or ten years following first commercial sale of such HPN217 Product in such country.

The Development and Option Agreement will terminate upon the date of the expiration of all AbbVie's royalty payment obligations in all countries, or upon expiration of the license option period and the failure of AbbVie to exercise its license option. The Development and Option 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 Development and Option Agreement by the other party. AbbVie may also terminate the Development and Option Agreement in its entirety or on a country-by-country basis for any reason on 90 days' written notice to the Company.

The Company assessed the Development and Option Agreement in accordance with Topic 606 and concluded that AbbVie is a customer under this agreement. The Company identified the following performance obligation at the inception of the Development and Option Agreement consisting of the initial development activities.

The Company evaluated AbbVie's option to obtain a worldwide exclusive license for HPN217 to determine whether it provides AbbVie with any material rights. The Company concluded that the option was not issued at a significant and incremental discount, and therefore do not provide material rights. As such, the option is excluded as a performance obligation at the outset of the agreement.

At the inception of the agreement, the transaction price included the $30.0 million up-front consideration received in December 2019 and a development milestone of up to $50.0 million to be received upon dosing of the first patient in the HPN217 Phase 1 trial within a specified time period, for a total transaction price of $80.0 million. In April 2020, the Company had achieved this development milestone as a result of dosing its first patient in the Phase 1 trial of HPN 217 and received $50.0 million in June 2020. The remaining development, commercialization, and sales milestones along with sales-based royalties were not included in the transaction price, as these milestone amounts were fully constrained on the probability of achievement. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

The transaction price of $80.0 million, relates to a single unit of accounting. The initial development activities are considered a single unit of accounting. The Company recognizes revenue associated with the performance obligation as the initial development activities are performed using an input method, according to the costs incurred as related to the estimated costs for the development and regulatory activities to be performed through the completion of a Phase 1 trial of HPN217. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. Such estimates are reviewed by the Company on a periodic basis and, if necessary, the Company will adjust the measure of performance and related revenue recognition. As of December 31, 2022, the Company had changes to the overall estimated costs to satisfy the performance obligation and as such, the Company adjusted revenue recognized relative to the measure of performance. As a result, the Company recorded $2.0 million of revenue in the fourth quarter of 2022.

As of December 31, 2022, the Company had recorded $21.7 million in short-term deferred revenue, in the accompanying balance sheet.

As of December 31, 2022, the Company will recognize royalty revenue in the period of sale of the related products, if any, based on the underlying contract terms. No such amounts were recognized during the year ended December 31, 2022.

Amended and Restated Discovery Collaboration Agreement with AbbVie

On August 16, 2021, the Company entered into Amendment No. 1 to the Amended and Restated Discovery Collaboration and License Agreement with AbbVie, or the First Amendment, which amends the Amended and Restated Discovery Collaboration and License Agreement entered on November 20, 2019, between the Company and AbbVie (such agreement, as amended by the First Amendment, the "Restated Collaboration Agreement"). The Restated Collaboration Agreement amends and restates the Discovery Collaboration and License Agreement entered into between the Company and AbbVie, dated October 20, 2017 and amended April 3, 2019, or the Original Collaboration Agreement. Pursuant to the First Amendment, the Company and AbbVie agreed to include the ProTriTAC technology within the Restated Collaboration Agreement. Pursuant to the Original Collaboration Agreement, the Company granted to AbbVie worldwide exclusive rights to develop and commercialize products that incorporate the Company's proprietary TriTAC technology together with soluble TCRs provided by AbbVie that bind to targets accepted by the parties. Under the terms of the Original Collaboration Agreement, AbbVie was granted the right to designate up to two targets for development of TriTAC constructs, which it selected in 2017 and 2019, respectively. Pursuant to the Restated Collaboration Agreement, AbbVie is permitted to designate two further targets, with an option to select up to four additional targets, selected during a specified period following the effective date, to be the subject of activities under the collaboration, and is granted a worldwide, exclusive license to

develop and commercialize products that incorporate either the Company's proprietary TriTAC platform technology, or (as a result of and pursuant to the First Amendment) its ProTriTAC platform technology, to pursue available T cell receptors, or TCRs and/or antibody targets. Such products may incorporate antibodies provided by AbbVie or by the Company. During a period of up to four years following the date of AbbVie's designation of each target for the products, and subject to 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 or ProTriTAC technologies, as applicable, in conjunction with the soluble TCR or antibody sequences directed at the agreed upon targets of interest. The Company may not, including through any third party, develop or commercialize any competing product that binds to any of the included targets. As was the case under the Original Collaboration Agreement, 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 each Major Market (as defined in the Restated Collaboration Agreement).

In addition to the upfront payment of $17.0 million already paid under the Original Collaboration Agreement, the Company received an upfront payment of $20.0 million under the Restated Collaboration Agreement for AbbVie's right to select two additional targets and an option to select up to four further targets. AbbVie will be required to make payments to the Company, upon target selection, of $10.0 million for each target, for up to four additional targets selected by AbbVie. For each of the up to eight targets selected, the Company is eligible to receive up to $300.0 million in the aggregate for the achievement of specified development, regulatory and commercial sales milestones for licensed products indicated for human therapeutic or prophylactic use. The Company will also be eligible to 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. Royalties will be payable under the First Amendment and Restated Collaboration Agreement on a product-by-product and country-by-country basis commencing on the date of first commercial sale of each product, and ending on the later of expiration of all valid claims of specified licensed patents in such country, expiration of regulatory exclusivity in such country or ten years following first commercial sale of such product in such country. 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 Restated Collaboration Agreement will terminate upon the date of the expiration of all AbbVie's royalty payment obligations in all countries. The Restated 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 such agreement by the other party. AbbVie may also terminate the Restated 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 Restated 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 Original Collaboration Agreement and Restated Collaboration Agreement including the First Amendment in accordance with Topic 606 and concluded that AbbVie is a customer under all agreements. The Company concluded that there are multiple promises under the Original Collaboration Agreement and Restated Collaboration Agreement including the First Amendment which include (1) research and development activities; (2) regulatory documentation and know-how; and (3) 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 under the Original Collaboration Agreement will be recognized over a period in which ongoing research and development activities are incurred 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 and, if necessary, the Company will adjust the measure of performance and related revenue recognition.

At the inception of the Original Collaboration Agreement, the Company determined that the transaction price was $17.0 million, which was all allocated to the two initial targets. The Company has evaluated the transaction price and has determined $17.0 million is still appropriate as of December 31, 2021. For the years ended December 31, 2021, 2020 and 2019, $4.3 million, $3.7 million and $4.0 million of revenue have been recognized in the accompanying statement of operations and comprehensive loss, respectively. As of December 31, 2021, the Company had recognized the full $17.0 million upfront payment related to the initial two targets.

At the inception of the Restated Collaboration Agreement, the Company determined that the transaction price included the $20.0 million upfront payment received in December 2019. The Company allocates $10.0 million to each additional target selected. The company estimates that the $20.0 million upfront payment under the Restated Collaboration Agreement will be recognized over a period in which ongoing research and development activities are incurred 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 and, if necessary, the Company will adjust the measure of performance and related revenue recognition. Accordingly, of the $20.0 million upfront payment received in 2019, $7.75 million and $0.9 million of revenue was recognized during the years ended 2022 and 2021, respectively.

As of December 31, 2022, the Company has recorded $11.6 million in deferred revenue, of which $2.3 million is classified as long-term and $9.3 million as short-term deferred revenue, in the accompanying balance sheet.

The Company determined that future contingent payments that may be received related to development and regulatory milestones under the Restated 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, 2022, the Company had not recognized or earned any milestone payments under the Original Collaboration or Restated Collaboration Agreement including the First Amendment. 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, 2022.

Collaboration and License Revenue

For the years ended December 31, 2022, 2021 and 2020, collaboration and license revenue in the accompanying statements of operations and comprehensive loss is comprised of the following:

Collaboration and License Revenue	2022	2021	2020
AbbVie Restated Collaboration Agreement	$ 7,496	$ 5,240	$ 3,667
AbbVie Development and Option Agreement	24,419	18,414	13,777
Total collaboration and license revenue	$ 31,915	$ 23,654	$ 17,444

8. Restructuring

In November 2022, the Company's Board approved a corporate restructuring and a reduction in workforce designed to reduce operating expenses and focus the Company’s resources on its clinical pipeline. This plan included a reduction of the Company’s full-time employees by 45% with the majority of the reductions that taking place at the end of 2022 and the remainder occurring in the first half of 2023. Affected employees have been offered separation benefits, including severance payments and in some cases payments to cover premiums for continuation of healthcare coverage for a limited period.

The activity in the restructuring liability, included within accrued liabilities on the balance sheets, was as follows for the year ended December 31, 2022 (in thousands):

	Restructuring liabilities at December 31, 2021	Charges	Cash Payments	Restructuring liabilities at December 31, 2022
Workforce Reduction	$ —	$ 1,586	$ (467)	$ 1,119

Workforce Reduction

Employees affected by the reduction in workforce under the Company's corporate restructuring plan obtained involuntary termination benefits that are provided pursuant to a one-time benefit arrangement. For employees who were notified of their

termination in November 2022 and have no requirements to provide future service, the Company recognized the liability for the termination benefits in full at fair value in the current period. For employees who are required to render services beyond a minimum retention period to receive their one-time termination benefits, the Company is recognizing the termination benefits ratably over their future service periods. The service periods began in November 2022 and all will end at various dates through March 31, 2023. The Company expects that it will incur approximately $1.8 million of employee termination benefits expense to implement the corporate restructuring plan. The termination benefits paid in 2022 was $0.5 million.

9. Equity

Stock Incentive Plans

2019 Equity Incentive Plan

The Board adopted, and the Company's stockholders approved the Company's 2019 Equity Incentive Plan (the "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. 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 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 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 the Board. 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.

2015 Equity Incentive Plan

In 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provided 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 have been 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 Board adopted and stockholders approved the Company's 2019 Plan (noted above), 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 award.

2022 Inducement Plan

In June 2022, the Board adopted the Harpoon Therapeutics, Inc. 2022 Inducement Award Plan, or the Inducement Plan. The Inducement Plan was adopted by the Board without stockholder approval pursuant to Nasdaq Marketplace Rule 5635(c)(4), or Rule 5635(c)(4). In accordance with Rule 5635(c)(4), awards made under the Inducement Plan may only be granted to newly hired employees as an inducement material to the employees entering into employment with the Company. Awards granted under the Inducement Plan expire no later than ten years from the date of grant. An aggregate of 1,000,000 shares of common stock were reserved for issuance under the Inducement Plan. As of December 31, 2022, there were 695,000 shares available for issuance under the Inducement Plan.

Stock Option Activity

The following summarizes option activity under the 2019 Plan and the 2015 Plan as combined:

	Number of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
		(in dollars)	(in years)	(in thousands)
Balance as of December 31, 2020	3,629,878	$ 6.38	7.88	$ 37,498
Options granted	2,293,225	13.72		
Options exercised	(216,834)	2.54		
Options cancelled	(235,452)	12.75		
Balance as of December 31, 2021	**5,470,817**	9.23	7.96	12,064
Options granted	4,353,735	2.98		
Options exercised	(234,377)	1.88		
Options cancelled	(3,159,229)	8.46		
Balance as of December 31, 2022	**6,430,946**	5.62	7.60	305,734
Vested and expected to vest as of December 31, 2022	6,430,946	5.62	7.60	305,734
Exercisable as of December 31, 2022	3,041,653	$ 7.58	5.67	$ 53,324

As of December 31, 2022, 2,254,423 shares were reserved by the Company to grant under the 2019 Plan. 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. The intrinsic value of options exercised for the years ended December 31, 2022, 2021 and 2020 was $1.0 million, $3.0 million and $5.6 million, respectively. There is no future tax benefit related to options exercised, as the Company has accumulated net operating losses at December 31, 2022, 2021 and 2020.

During the years ended December 31, 2022, 2021 and 2020, the estimated weighted-average grant-date fair value of the stock options vested was $5.31, $4.49 and $2.63 per share, respectively, and the estimated weighted-average grant-date fair value of stock options granted was $2.31, $9.69 and $9.63 per share, respectively.

Stock-Based Compensation

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

	Year Ended December 31,		
	2022	2021	2020
Expected term (years)	5.9	5.94	5.99
Expected volatility	83.21%	86.81%	78.86%
Risk-free interest rate	2.59%	0.95%	1.03%
Expected dividend	0%	0%	0%

Prior to our IPO in February 2019, and due to no public market for the Company's common stock, the fair value of the shares of common stock underlying stock options has historically been determined by the Board based on the 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. Subsequent to the completion of our IPO, the fair value of common stock underlying stock option is 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.

The OPM Black-Scholes 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— The Company uses an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company

does not have sufficient trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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,		
	2022	2021	2020
		(in thousands)	
Research and development	$ 4,586	$ 4,784	$ 1,980
General and administrative	4,050	4,678	2,880
Total stock-based compensation	$ 8,636	$ 9,462	$ 4,860

Stock-based compensation related to non-employee awards, which is included in the table above, was $0.1 million, $0.1 million, and $0.2 million for the years ended December 31, 2022, 2021 and 2020, respectively.

In addition to the stock-based compensation expense showing in the above table, as of December 31, 2022, there is an additional $8.8 million of unrecognized stock-based compensation related to unvested stock options that is expected to be recognized over a weighted-average period of 2.36 years.

2019 Employee Stock Purchase Plan

The Board 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 Company'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 Board prior to the first day of any calendar year. The Board 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.

The Company issued 227,798 shares under the 2019 ESPP during the year ended December 31, 2022. The Company has approximately 717,106 shares reserved for future issuance as of December 31, 2022.

	Year Ended December 31, 2022	Year Ended December 31, 2021
Expected term (years)	0.5	0.5
Expected volatility	94.25%	75.47%
Risk-free interest rate	2.48%	0.05%
Expected dividend	0%	0%

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, 2022 and 2021, there was zero and $8,200, 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, all shares have vested and no longer subject to repurchase at December 31, 2022.

10. Income Taxes

	December 31,		
	2022	2021	2020
		(in thousands)	
Computed expected tax benefit (at federal statutory income tax rate of 21%)	$ (14,173)	$ (24,511)	$ (10,481)
State tax	—	2,978	(4,231)
Stock compensation	2,630	534	321
Tax credits	966	2,222	1,552
Change in valuation allowance	10,477	18,800	12,540
Other	100	(23)	299
Total provision for income taxes	$ —	$ —	$ —

Since inception, the Company has only generated pretax losses. For the years ended December 31, 2022, 2021 and 2020, 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, 2022 and 2021 consisted of the following:

	December 31,	
	2022	2021
	(in thousands)	
Deferred tax assets:		
Net operating loss carry forwards	$ 50,863	$ 46,252
Stock-based compensation	470	1,325
Deferred revenue	6,932	13,685
Lease liability	3,373	2,568
Fixed assets	139	—
Capitalized R&D Cost Sec 174	13,832	—
Other	601	927
Total deferred tax assets	76,210	64,757
Less: valuation allowance	(73,931)	(63,462)
Net deferred tax assets	2,279	1,295
Fixed assets	-	(8)
Right-of-use asset	(2,279)	(1,287)
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 $10.5 million and $18.8 million during the years ended December 31, 2022 and 2021.

The Company has net operating carryforwards for federal and California income tax purposes of approximately $310.0 million and $288.1 million as of December 31, 2022 and 2021. The federal net operating loss carryforwards of $23.1 million, if not utilized, will expire beginning in 2035 and $185.3 million is carryforward indefinitely. The state net operating loss carryforwards of $101.6 million, if not utilized, will expire beginning in 2035.

The Company has research and development credit carryforwards for federal and California income tax purposes of approximately $22.2 million and $16.2 million as of December 31, 2022 and 2021. The federal credit carryforwards of $15.3 million, if not utilized, will expire beginning in 2035. The state credit carryforwards indefinitely.

Federal and California tax laws imposes 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.

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,		
	2022	2021	2020
		(in thousands)	
Unrecognized tax benefits at January 1	$ 15,100	$ 9,521	$ 5,844
Additions for tax positions taken in the current year	5,919	5,689	3,972
Reductions for tax positions taken in the prior year	(250)	(110)	(295)
Unrecognized tax benefits at December 31	$ 20,769	$ 15,100	$ 9,521

The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced and reflected as a reduction of the provision for income taxes in the period that such determination is made. Interest and penalties have not been accrued for 2022, 2021 and 2020.

The Company files income tax returns in the United States and California. The years 2015 through 2021 remain open to U.S. federal and state examination to the extent of the utilization of net operating loss and credit carryovers. As of December 31, 2022, the Company is not under examination by the Internal Revenue Services or any state tax jurisdiction.

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,		
	2022	2021	2020
Common stock options issued and outstanding	6,430,946	5,470,817	3,629,878
ESPP shares issuable and outstanding	198,617	37,586	11,881
Early exercised stock options subject to future vesting	—	4,608	20,839
Total	6,629,563	5,513,011	3,662,598

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,		
	2022	2021	2020
Net loss	$ (67,731)	$ (116,721)	$ (49,908)
Weighted-average shares used to compute basic and diluted net loss per share	33,167,435	32,274,362	25,034,947
Basic and diluted net loss per common share	$ (2.04)	$ (3.62)	$ (1.99)

12. Subsequent Events

Private Placement of Non-Voting 8.000% Series A Redeemable Preferred Stock and Warrants

On March 22, 2023, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) pursuant to which the Company agreed to sell and issue shares of the Company’s 8.000% Series A redeemable preferred stock, par value $0.0001 per share (the “Series A Preferred Stock”), and warrants (the “Warrants”) to purchase shares of the Company’s common stock, par value $0.0001 per share (“Common Stock”), in a Private Placement transaction.

At the closing of the Private Placement on March 23, 2023, (the "Closing") the Company sold and issued (i) 25,000 shares of Series A Preferred Stock and (ii) Warrants to purchase up to an aggregate of 7,485,762 shares of the Company’s common stock. The shares of Series A Preferred Stock and accompanying Warrants were sold at a purchase price of $1,000 per share of Series A Preferred Stock. The Warrants are exercisable immediately, will remain exercisable for a period of eight years following the date of issuance and have an exercise price of $0.978885 per share. The total gross proceeds to the Company from the sale of the Series A Preferred Stock and Warrants in the Private Placement were $25.0 million, which does not include any proceeds that may be received upon exercise of the Warrants.

The Series A Preferred Stock cannot be converted to common stock. The Series A Preferred Stock is non-voting stock. Some of the holders of the Series A Preferred Stock are considered related parties which the board of directors reviewed and approved in accordance with the Company's related-person transaction policy. Holders of Series A Preferred Stock shall be entitled to receive dividends that accrue on a day-to-day basis until paid at a rate of 8.000% per year on the stated value of $1,000 per share of Series A Preferred Stock. Such dividends shall be payable only when declared by the board of directors of the Company.

The Company may, at its option, redeem shares of Series A Preferred Stock from time to time at the Redemption Price Per Share, which is equal to the sum of (i) the product of (a) the Stated Value of $1,000 and (b) a Return Factor equal to 3.5 until the 18-month anniversary of the Closing and 4.5 thereafter and (ii) any accrued and unpaid dividends. In addition, the Series A Preferred Stock is mandatorily redeemable by the Company out of funds legally available therefor, at the Redemption Price Per Share, upon (i) receipt by the Company of certain amounts in connection with any HPN217 licensing transaction of which the maximum number of then-outstanding shares of Series A Preferred Stock that may be redeemed using up to 50% of the cash proceeds and fair market value of certain non-cash proceeds received by the Company, (ii) receipt by the Company of certain net proceeds in connection with certain strategic and licensing transactions and (iii) on the third anniversary of the Closing, unless extended by consent of the requisite holders. The Company is obligated to redeem all outstanding shares of Series A Preferred Stock at the Redemption Price Per Share on the third anniversary of the Closing, as that date may be extended up to an additional two years by consent of the requisite holders or for any period of time by consent of all holders.