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

FORM 10-K

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

For the fiscal year ended December 31, 2019

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

Commission File Number 001-36818

TRACON Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**34-2037594**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
4350 La Jolla Village Drive, Suite 800, San Diego, CA	**92122**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 550-0780
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TCON	The Nasdaq Stock Market LLC

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $14.7 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market on June 28, 2019 of $6.80 per share.

The number of outstanding shares of the registrant's common stock as of February 14, 2020 was 5,397,938.

TRACON Pharmaceuticals, Inc.

FORM 10-K — ANNUAL REPORT
For the Fiscal Year Ended December 31, 2019

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K, or this Annual Report, including the sections entitled “Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements. We may, in some cases, use words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes, to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the success, cost and timing of results of our and our collaborators’ ongoing clinical trials;
- our and our collaborators’ plans to develop and commercialize our product candidates;
- the potential benefits of our collaboration arrangements and our ability to enter into additional collaboration arrangements;
- our development and regulatory strategy and potential benefits associated therewith;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- the impact of competing products that are or may become available;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources, and our need for additional financing; and
- our ability to realize the anticipated benefits associated with our capital efficiency focused initiatives.

These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report and are subject to risks and uncertainties. We discuss many of these risks in greater detail under “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

We qualify all of the forward-looking statements in this Annual Report by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. Business.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration, or wet AMD, through our license to Santen Pharmaceutical Co. Ltd. (Santen), and utilizing our product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the United States.

In December 2019, we entered into a collaboration and clinical trial agreement (the Envafolimab Collaboration Agreement) with 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) for the development of envafolimab, also known as KN035, an investigational PD-L1 single-domain antibody (sdAb) administered by subcutaneous injection for the treatment of soft tissue sarcoma in North America. We intend to file an investigational new drug (IND) application and apply for orphan drug status in the first half of 2020, and initiate a registration enabling study of envafolimab in the sarcoma subtype of undifferentiated pleomorphic sarcoma (UPS) and other select soft tissue sarcoma (STS) subtypes in the second half of 2020. Subject to input from the U.S. Food and Drug Administration (FDA), we expect that the trial will include one cohort of approximately 80 patients who will receive single agent treatment with envafolimab and a second cohort of approximately 80 patients who will receive

envafolimab in combination with Yervoy® (ipilimumab), a checkpoint inhibitor marketed by Bristol-Meyers Squib (BMS), with the primary endpoint in each of the cohorts being overall response rate (ORR), which could be the basis for accelerated approval of envafolimab by the FDA as a single agent and/or in combination with Yervoy. We estimate disclosing a summary of the independent data monitoring committee decisions following reviews of interim data in 2021, having a final response assessment in early 2022, and, assuming positive data, submitting a biologics license application (BLA) for accelerated approval in early 2023. Additionally, assuming positive data from the initial UPS trial, we plan to initiate a randomized trial for multiple soft tissue sarcoma subtypes, which could include biomarker directed enrollment, to expand the target patient population.

We continue to support Santen's development of the ophthalmic formulation of carotuximab, called DE-122, for the treatment of wet AMD, the leading cause of blindness in the Western world. In March 2014, Santen licensed from us exclusive worldwide rights to develop and commercialize our endoglin antibodies for ophthalmology indications and in July 2017, Santen initiated dosing in the randomized Phase 2a AVANTE study of DE-122, which is a randomized controlled trial assessing the efficacy and safety of repeated intravitreal injections of DE-122 in combination with Lucentis® (ranibizumab) compared to Lucentis single agent therapy in patients with wet AMD. Santen completed enrollment in the randomized Phase 2a AVANTE study in 2019 and we expect top-line data in the first half of 2020.

Other clinical stage oncology product candidates include TRC102, which is a small molecule that is in Phase 1 and Phase 2 clinical development for the treatment of mesothelioma, lung cancer and solid tumors, TRC253, which is a small molecule that is in a Phase 1/2 clinical trial for the treatment of metastatic castration-resistant prostate cancer, that we licensed from Janssen Pharmaceutica N.V. (Janssen) in September 2016, and TJ004309, which is a CD73 antibody in Phase 1 clinical development for the treatment of solid tumors, that we licensed from I-Mab Biopharma (I-Mab) in November 2018.

TRC102 is designed to reverse resistance to specific chemotherapeutics by inhibiting base excision repair, or BER. In initial clinical trials of more than 100 patients, TRC102 has shown good tolerability and promising anti-tumor activity in combination with alkylating and antimetabolite chemotherapy in the treatment of cancer patients. TRC102 began Phase 2 testing in mesothelioma in combination with the approved chemotherapeutic Alimta in 2015. TRC102 is also being studied in three Phase 1 clinical trials: in combination with Alimta and cisplatin in solid tumor patients, in combination with chemoradiation in lung cancer patients, and in combination with Temodar in ovarian, lung and colorectal cancer patients. All current TRC102 trials are sponsored and funded by the National Cancer Institute (NCI). We retain global rights to develop and commercialize TRC102 in all indications.

TRC253 is being developed for the treatment of men with prostate cancer and is a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR) and multiple AR mutant receptors containing point mutations that cause drug resistance to currently approved treatments. In November 2019, following review of available Phase 2 data indicating a lower than expected initial response rate and prevalence of the F877L mutation, we agreed with Janssen that the more than 70 currently enrolled patients in the Phase 1/2 trial of TRC253 are sufficient to determine the risk-benefit profile of the drug in three cohorts of metastatic castrate resistant prostate cancer patients: those with a F877L mutation, those with another undisclosed androgen receptor point mutation, and those with another basis for resistance to Xtandi or Erleada. We expect to provide Phase 2 proof of concept data to Janssen in the first half of 2020. Until 90 days after receiving Phase 2 proof of concept data, Janssen has an exclusive option to reacquire full rights to TRC253 for an upfront payment of $45.0 million to us, and obligations to make regulatory and commercialization milestone payments totaling up to $137.5 million upon achievement of specified events and a low single-digit royalty. If Janssen does not exercise its exclusive option to reacquire the program, we would then have the ability to retain worldwide development and commercialization rights, in which case we would be obligated to pay Janssen a total of up to $45.0 million in development and regulatory milestones upon achievement of specified events, in addition to a low single digit royalty.

TJ004309, also known as TJD5, is a novel humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to the immunosuppressive metabolite adenosine. We are developing TJ004309 in collaboration with I-Mab under a strategic collaboration and clinical trial agreement that we entered into in November 2018 (the TJ004309 Agreement). In July 2019, we began enrollment in a Phase 1 clinical study to assess safety and preliminary efficacy of TJ004309 as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® in patients with advanced solid tumors. We also entered into a separate strategic collaboration and clinical trial agreement (the Bispecific Agreement) which allows for the development of up to five of I-Mab's proprietary bispecific antibody product candidates to be nominated within a five-year period for development and commercialization in North America, with the option to opt-in and acquire product rights outside of Greater China and Korea prior to completing the first pivotal clinical study for any bispecific product candidate.

In April 2019, we announced the termination of enrollment in trials of carotuximab in oncology following the Independent Data Monitoring Committee (IDMC) recommendation that the Phase 3 TAPPAS trial be terminated for futility. We have terminated activities related to carotuximab development in oncology.

The following table summarizes key information regarding ongoing and planned development of clinical stage product candidates:

	Phase	Data Expected
Envafolimab (3D Medicines and Alphamab)		
Soft Tissue Sarcoma	Planned Pivotal	Final data - 2022
DE-122 (Santen)		
Wet AMD	Randomized Phase 2	2020
TRC253		
Prostate Cancer	Phase 2	2020
TJ004309 (I-Mab)		
Solid Tumors	Phase 1	2020
TRC102		
Mesothelioma	Phase 2	2020
Solid tumors	Phase 1	2020
Solid tumors and Lymphomas	Phase 1/2	2021
Lung Cancer	Phase 1	2020

We utilize a product development platform that emphasizes capital efficiency. Our experienced clinical operations, data management, quality assurance, product development and regulatory affairs groups manage significant aspects of our clinical trials with internal resources. We use these internal resources to minimize the costs associated with utilizing contract research organizations, or CROs, to conduct clinical trials. In our experience, this model has resulted in capital efficiencies and improved communication with clinical trial sites, which expedites patient enrollment and improves the quality of patient data as compared to a CRO-managed model. We have leveraged this platform in all of our sponsored clinical trials. We have also leveraged our product development platform to diversify our product pipeline without payment of upfront license fees through license agreements with 3D Medicines and Alphamab, I-Mab, and Janssen. We continue to evaluate ex-U.S. companies who would benefit from a rapid and capital-efficient U.S. drug development solution that includes U.S. and European Union (EU) clinical development expertise. We believe we will continue to be recognized as a preferred U.S. clinical development partner through a cost- and risk-sharing partnership structure which may include U.S. commercialization.

Our goal is to be a leader in the development of targeted therapies for patients with cancer and other diseases of high unmet medical need.

Our Lead Clinical Stage Product Candidate – Envafolimab

Overview of PD-L1

PD-L1 is an immune-inhibitory checkpoint molecule expressed on epithelial and vascular endothelial cells, as well as by a number of immune cells, that is utilized by tumor cells as an immune escape mechanism. Numerous preclinical and clinical studies of PD-1/PD-L1 products have demonstrated that antibodies that block the interaction of PD-1 with its ligands, PD-L1 and PD-L2, or those that block only the interaction of PD-L1 with PD-1, can augment anti-tumor T-cell responses and lead to complete and durable tumor eradication in a certain proportion of patients. Potent therapeutic anti-tumor responses due to blocking of PD-1/PD-L1 interaction has been demonstrated by these approved products in patients with various solid tumors including, but not limited to, non-small cell lung cancer (NSCLC), melanoma, renal cell carcinoma (RCC), head and neck cancer, cutaneous squamous cell carcinoma (cSCC) and urothelial carcinoma.

About Envafolimab and Preclinical Studies

Envafolimab is an investigational sdAb that binds selectively to PD-L1 and is administered by subcutaneous injection without an adjuvant. Envafolimab is being developed by 3D Medicines for the treatment of various cancer indications, including in two ongoing pivotal trials in China.

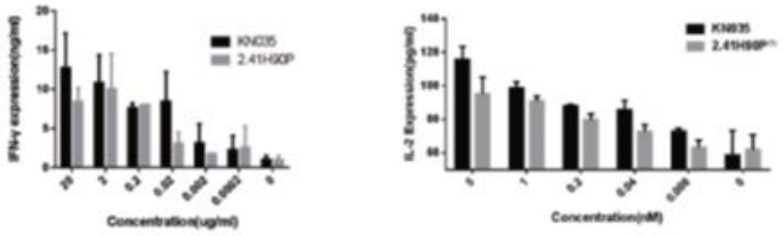
Single-domain antibodies are a novel class of therapeutic protein that contain the unique structural and functional properties of naturally-occurring heavy chains and lack light chains. On February 6, 2019, the FDA approved the first sdAb, Cablivi® (caplacizumab), for adults with acquired thrombotic thrombocytopenic purpura.

Envafolimab is a camelid IgG4 sdAb with single digit nanomolar affinity to PD-L1. Benefitting from the sdAb format, envafolimab has half the molecular weight as compared to a full antibody with better stability and high solubility, which enables the development of high concentration formulation injections suitable for subcutaneous injection. In addition, the effector functions are muted in envafolimab to help limit its exposure to the immune system and avoid unwanted adverse immune responses. As a result, compared with approved PD-(L)1 inhibitors, envafolimab potentially has the following advantages:

- *Better patient compliance with increased convenience*. Subcutaneous formulation enables more rapid administration and the potential for self-injection, which enables better patient compliance with the treatment regimen;
- *Relatively stable plasma-drug concentration*. The plasma-drug concentration of envafolimab is relatively stable without significant fluctuations due to the nature of subcutaneous administration. This unique pharmacokinetic (PK) profile compared with intravenous formulations may result in lower risks to patients; and
- *Potential for improved tumor penetration*. Envafolimab is approximately half the size of a full length standard monoclonal antibody, which may provide for improved tumor penetration in cancer patients as was observed in pre-clinical experiments. This unique tumor penetration compared with full length standard monoclonal antibodies may improve efficacy.

In pre-clinical studies in human cell models and a humanized mouse model, envafolimab was compared with 2.41H90P, an antibody with a sequence that is identical to durvalumab, the only approved PD-L1 inhibitor at the time, and envafolimab showed the following potential advantages:

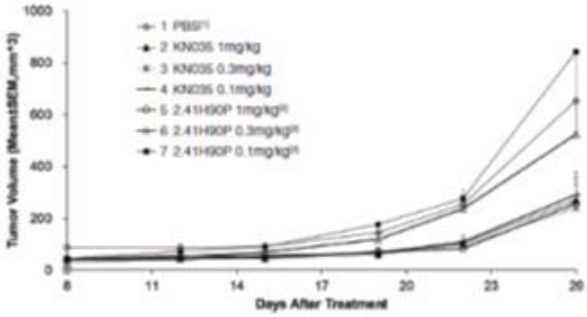
- *Stronger T-cell activation effect*. The level of T-cell activation can be measured by the secretion levels of IFN- and IL-2. Higher secretion levels are generally associated with stronger T-cell activation. In pre-clinical studies, envafolimab (KN035) demonstrated higher potency and a higher maximal stimulatory effect on IFN- and IL-2 secretion compared to 2.41H90P, as illustrated in the following figure.



(1) 2.41H90P was an in-house produced durvalumab with the same amino acid sequence as MedImmune's Imfinzi (durvalumab), and cloned using the 2.14H9 method.

Source: Investigator's Brochure (v.4.0) on KN035

- *Higher anti-tumor efficacy*. Envafolimab and 2.41H90P were each injected intraperitoneally in mice at 0.1 mg/kg, 0.3 mg/kg and 1.0 mg/kg dose levels. As illustrated in the following graph, envafolimab showed more potent tumor growth inhibition effects with maximum inhibition demonstrated at a ten-fold lower dose.



(1) The control group was given PBS alone.

(2) 2.41H90P was an in-house produced durvalumab with the same amino acid sequence as MedImmune's Imfinzi (durvalumab), and cloned using the 2.14H9 method.

Source: Investigator's Brochure (v.4.0) on KN035

- *More rapid tumor penetration.* After injection of envafolimab and 2.4H90P in tumor bearing nude mice, the tumor radioactivity signal was consistently higher in the envafolimab group up to 52 hours post injection. The tumor radioactivity signal in the envafolimab group between 1 hour to 2.5 hours was statistically significantly higher, which suggests potentially better distribution of envafolimab into the tumor.

Clinical Trials of Envafolimab

As of December 31, 2019, envafolimab had been dosed in more than 650 patients in a total of 6 ongoing clinical trials in the United States, China or Japan, including a pivotal Phase 2 trial in microsatellite instability-high (MSI-H) cancer patients in China, a Phase 2 trial of envafolimab plus chemotherapy in gastric cancer, a Phase 3 randomized trial of envafolimab plus chemotherapy versus chemotherapy alone in biliary tract cancer (BTC) in China, a Phase 1 dose escalation and dose exploration trial in the United States, a Phase 1 dose escalation and dose exploration trial in China, and a Phase 1 dose escalation and dose exploration trial in Japan.

Phase 1 Dose Escalation Clinical Trial in China

An open-label, single-arm Phase 1 dose escalation and exploration clinical trial of envafolimab has completed enrollment in China. The safety and efficacy data from this trial were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2019. Based on the data presented in the ASCO Annual Meeting (ASCO Presentation), 17 subjects were enrolled in the dose escalation phase in this trial as of May 1, 2019. A total of 287 subjects were enrolled in this Phase 1 study at dose levels shown to be tolerable during dose escalation.

Study purpose. The primary objectives of the Phase 1 dose escalation were to assess the safety and tolerability profile and maximum tolerated dose (MTD) of single agent envafolimab administered subcutaneously in subjects with advanced solid tumors. The secondary objectives were to evaluate the PK profile, immunogenicity and anti-tumor activity.

Study design of the dose escalation phase. This trial adopted a modified "3+3" design with a dose limiting toxicity (DLT) evaluation period of 28 days. Subjects received envafolimab in six cohorts at 0.1 mg/kg, 0.3 mg/kg, 1.0 mg/kg, 2.5 mg/kg, 5.0 mg/kg and 10.0 mg/kg once every week (QW) subcutaneously. Starting from the 1.0 mg/kg cohort, a traditional "3+3" design was followed. Safety and tolerability were assessed by monitoring treatment emergent adverse events (TEAEs). Tumor assessments were performed based on RECIST version 1.1.

Safety of dose escalation phase. The majority of the subjects received two or more prior systemic oncology treatments. According to the ASCO Presentation, 16 of the subjects discontinued treatment due to disease progression (n=15) or consent withdrawal (n=1). All of the enrolled subjects experienced TEAEs. 13 (76.5%) experienced treatment-related TEAEs. Three (17.6%) subjects experienced serious TEAEs, although none were determined to be treatment-related. A TEAE led to treatment discontinuation in one subject and was also determined to be not treatment-related. No DLT was reported and the MTD was not reached. Details of the TEAEs observed from the 17 subjects enrolled in the Phase 1 dose escalation study are summarized in the following table.

TEAE categories[1]	n (%) (N=17)
AE	17 (100%)
Any TEAE	17 (100%)
TEAE, Grade ≥ 3	7 (41.2%)
Treatment-related TEAE[2]	13 (76.5%)
Treatment-related TEAE, Grade ≥ 3[3]	1 (5.9%)
SAEs	3 (17.6%)
Treatment-related SAEs	0
IrAEs	1 (5.9%)
IrAEs, Grade ≥ 3[3]	1 (5.9%)
TEAE leading to permanent treatment discontinuation	1 (5.9%)
Treatment-related TEAE leading to permanent treatment discontinuation	0
TEAE leading to death	0
Treatment-related TEAE leading to death	0

(1) Reported under National Cancer Institute Common Terminology Criteria for Adverse Events v. 4.03.
(2) The most frequent treatment-related TEAEs (all grades ≥ 10%) included increased alanine aminotransferase (n=6, 35.3%), increased aspartate aminotransferase (n=6, 35.3%), dermatitis/rash (n=3, 17.6%), blood bilirubin increased (n=3, 17.6%), injection site reaction (n=2, 11.8%).
(3) An immune-related dermatitis that occurred in the 0.3 mg/kg cohort. The subject recovered completely after the study drug was withheld.

Source: Phase I Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Patients with Advanced Solid Tumors in China, Abstract No. 2608, Poster No. 252, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

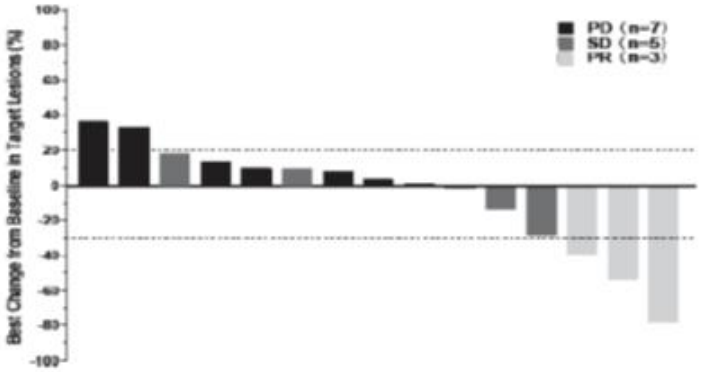
Efficacy. According to the ASCO Presentation, 15 out of 17 subjects were evaluable for the efficacy analysis. Three subjects had confirmed partial response (PR), including one renal cell carcinoma (RCC) subject in the 2.5 mg/kg cohort, one intrahepatic cholangiocarcinoma subject from the 5.0 mg/kg cohort and one BTC subject from the 10.0 mg/kg cohort. In addition, five subjects achieved stable disease (SD). All 15 subjects completed at least one post-baseline tumor assessment, according to the ASCO Presentation. Two enrolled subjects who had not reached the first post-baseline tumor assessment were excluded. The table below summarizes the best overall response in the efficacy analysis of this trial, according to the ASCO Presentation.

Response	0.1 mg/kg (N=1)	0.3 mg/kg (N=2)	1.0 mg/kg (N=3)	2.5 mg/kg (N=3)	5.0 mg/kg (N=3)	10.0 mg/kg (N=3)	Total (N=15)
				n (%)			
CR	0	0	0	0	0	0	0
PR	0	0	0	1	1	1	3 (20.0%)
SD	0	0	2	2	1	0	5 (33.3%)
PD	1	2	1	0	1	2	7 (46.7%)
CR+PR	0	0	0	1	1	1	3 (20.0%)
DCR (CR+PR+SD)	0	0	2	3	2	1	8 (53.3%)

Abbreviations: CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease, DCR=disease control rate.

Source: Phase I Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Patients with Advanced Solid Tumors in China, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

The following waterfall plot shows the best overall response of the 15 evaluable subjects receiving envafolimab as measured by percentage of change of target lesions from baseline, according to the ASCO Presentation.



Abbreviations: PD=progressive disease, SD=stable disease, PR=partial response.

Source: Phase I Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Patients with Advanced Solid Tumors in China, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

Conclusion. According to the ASCO Presentation, envafolimab exhibited a tolerable safety profile and preliminary efficacy in patients with advanced malignancies in the Phase 1 dose escalation trial in China.

Phase 1 Dose Escalation Clinical Trial in the United States

An open-label Phase 1 dose escalation and dose exploration clinical trial of envafolimab is being conducted in the United States. Safety and efficacy data from the dose escalation phase of the trial were presented at the 2018 Annual Congress of the European Society for Medical Oncology (ESMO) in October 2018. Based on the data presented at ESMO (the ESMO Presentation), 18 subjects were enrolled in the dose escalation phase of this trial as of July 5, 2018.

Study purpose of the dose escalation phase. The primary objectives of the Phase 1 dose escalation clinical trial were to evaluate and characterize the tolerability and safety profile of single agent envafolimab in subjects with locally advanced or metastatic solid tumors. The secondary objectives were to characterize the PK profile, determine MTD and to evaluate anti-tumor activity.

Study design of the dose escalation phase. This trial adopted a modified "3+3" design with a DLT evaluation period of 28 days. Subjects received envafolimab across eight cohorts at 0.01 mg/kg, 0.03 mg/kg, 0.1 mg/kg, 0.3 mg/kg, 1.0 mg/kg, 2.5 mg/kg, 5.0 mg/kg and 10.0 mg/kg QW subcutaneously. Starting from the 0.3 mg/kg cohort, a traditional "3+3" design was followed. Safety and tolerability were assessed by monitoring TEAEs. Tumor assessments were performed based on RECIST version 1.1.

Safety of dose escalation phase. The median duration of exposure to envafolimab was 9 weeks with a range of 6 to 32 weeks. As of July 5, 2018, two of the subjects (11.1%) remained in the study, 11 subjects had discontinued treatment due to disease progression, three subjects had discontinued treatment due to TEAEs, and two subjects had discontinued treatment due to the opinion of the investigator that no more clinical benefit could be obtained or for other reasons. All of the 18 enrolled subjects experienced TEAEs. Treatment-related TEAEs at grade 3 or above included increased aspartate aminotransferase (10.5%), increased alanine aminotransferase (10.5%) and lymphopenia (10.5%). No DLT was observed and the planned maximum dose of 10.0 mg/kg was reached.

Efficacy of dose escalation phase. According to the ESMO Presentation, 17 out of 18 subjects were evaluable for the efficacy analysis. Two subjects had confirmed PR, including one NSCLC subject from the 0.3 mg/kg QW cohort (response duration of 9 months) and one MSI-H prostate cancer subject from the 2.5 mg/kg QW cohort. In addition, five subjects achieved SD. All 17 evaluable subjects completed at least one post-baseline tumor assessment according to the ESMO Presentation. One enrolled subject who had not reached the first post-baseline tumor assessment was excluded. The table below summarizes the best overall response in the efficacy analysis of this trial according to the ESMO Presentation.

	0.01 mg/kg weekly (N=1)	0.03 mg/kg weekly (N=1)	0.1 mg/kg weekly (N=1)	0.3 mg/kg weekly (N=3)	1.0 mg/kg weekly (N=3)	2.5 mg/kg weekly (N=3)	5.0 mg/kg weekly (N=3)	10.0 mg/kg weekly (N=3)	Total (N=18)
	n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)
CR	0	0	0	0	0	0	0	0	0
PR	0	0	0	1 (33.3)	0	1 (33.3)	0	0	2 (11.1)
SD	0	1 (100)	0	1 (33.3)	1 (33.3)	0	1 (33.3)	1 (33.3)	5 (27.8)
PD	1 (100)	0	1 (100)	0	2 (66.7)	2 (66.7)	2 (66.7)	1 (33.3)	9 (50.0)
NE	0	0	0	0	0	0	0	1 (33.3)	1 (5.6)
CR+PR	0	0	0	1 (33.3)	0	1 (33.3)	0	0	2 (11.1)
DCR: (CR+PR+SD)	0	1 (100)	0	2 (66.7)	1 (33.3)	1 (33.3)	1 (33.3)	1 (33.3)	7 (38.9)

Abbreviations: CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease, NE=not evaluable, DCR=disease control rate.

Source: *Phase I Study of KN035, A Novel Fusion Anti-PD-L1 Antibody Administered Subcutaneously in Patients with Advanced Solid Tumors in the USA, 2018 Annual Congress of the European Society for Medical Oncology (ESMO)*

PK profile of dose escalation phase. This study showed that the exposure to envafolimab was dose-dependent and increased proportionally across all eight dose levels. Mean half-life of envafolimab was approximately 200 hours.

Conclusion. According to the ESMO Presentation, envafolimab exhibited a favorable safety profile in subjects with advanced solid tumors and preliminary efficacy results demonstrated encouraging anti-tumor activity. Based on the PK profile, patients in the trial were treated with envafolimab at 300 mg every 4 weeks by subcutaneous injection.

Phase 1 Clinical Trial in Japan

An open-label Phase 1 dose escalation and dose exploration clinical trial of envafolimab is being conducted in Japan. The safety, efficacy and PK data of this trial as of May 5, 2019 were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2019. Based on the data presented in the ASCO Annual Meeting (the Japan Trial ASCO Presentation), 26 subjects were enrolled in this trial as of May 5, 2019.

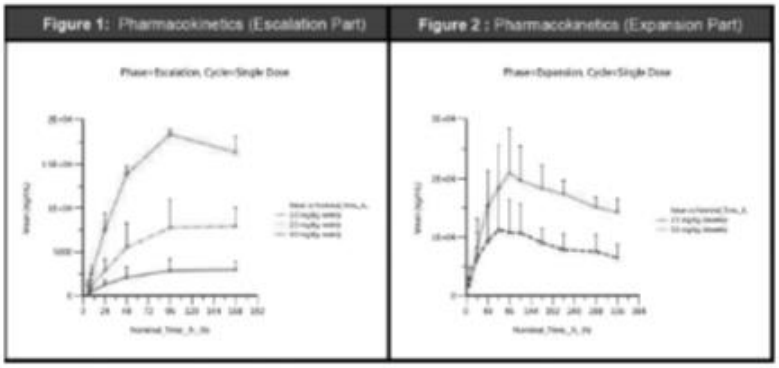
Study purpose. The primary objectives of the Phase 1 clinical trial are to assess the safety and tolerability profile of single agent envafolimab in Japanese subjects with previously treated advanced solid tumors. The secondary objectives are to characterize the PK profile, determine MTD and evaluate the anti-tumor activity.

Study design. This Phase 1 trial consists of a multi-dose escalation phase followed by a dose exploration phase. Subjects will receive envafolimab across five cohorts at 1.0 mg/kg, 2.5 mg/kg and 5.0 mg/kg QW subcutaneously, and 2.5 mg/kg and 5.0 mg/kg Q2W subcutaneously. The QW schedule adopted a traditional "3+3" design. For the Q2W schedule, six patients were planned for each cohort. Safety and tolerability are being assessed by monitoring TEAEs under common terminology criteria for adverse events (CTCAE) version 4.0. Tumor assessments are being performed based on RECIST version 1.1. Full PK sampling is performed after the first dose of cycle 1 (28 days) and sparse PK samples are collected at pre-dose and around Cmax during the subsequent cycles.

Safety. According to the Japan Trial ASCO Presentation, as of May 5, 2019, no MTD had been reached. As of the same date, three subjects had remained in the study. 21 subjects had discontinued treatment due to disease progression and two subjects had discontinued treatment due to TEAEs. All of the enrolled subjects experienced TEAEs, 17 subjects (65.4%) experienced treatment-related TEAEs, and only one grade 3 treatment-related TEAE (cerebral infraction) was reported. There were no grade 4/5 treatment-related TEAEs. There were a total of four SAEs, two of which were treatment-related. No DLT was reported.

Efficacy. According to the Japan Trial ASCO Presentation, nine out of 26 patients were evaluable for the efficacy analysis as of May 5, 2019. Two subjects had confirmed PR and two subjects had unconfirmed PR. The other five evaluable subjects had achieved SD. 17 enrolled subjects who did not reach the first post-baseline tumor assessment were excluded.

PK profile. In the dose escalation phase, the exposure to envafolimab was dose-dependent and increased proportionally. Tmax varied from 96 to 168 hours after a single dose as shown in Figure 1 below. In the dose exploration phase, the exposure to envafolimab was dose-dependent and increased proportionally. Preliminary PK suggested a prolonged half-life that may support a less frequent dosing schedule than once every 2 weeks.



Source: Phase I Study and Pharmacokinetic Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Japanese Patients with Advanced Solid Tumors, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

Conclusion. Envafolimab exhibited a favorable safety profile in patients with advanced malignancies and preliminary efficacy results demonstrated promising anti-tumor activity in the Phase 1 clinical trial in Japan. Based on the PK profile, patients in the trial are currently being treated with envafolimab at 300 mg every 4 weeks by subcutaneous injection.

Other Ongoing Clinical Trials

A pivotal clinical trial of envafolimab dosed as a single agent for the treatment of MSI-H tumors was initiated in August 2018. The trial is a non-randomized trial enrolling approximately 110 patients in China, including colorectal cancer patients who are required to have been previously treated with standard therapies, which must include fluoropyrimidine, oxaliplatin or irinotecan, and other solid tumor patients, who are required to have been previously treated with at least one line of systemic standard of care therapy. Patients will receive 150mg of envafolimab subcutaneously dosed weekly. Top-line data from the trial are expected in 2020 with ORR as the primary endpoint defined by RECIST version 1.1. 3D Medicines is planning to file a BLA in China for envafolimab in 2020. The filing will be based on the principle that the response rate required for approval in China is similar to the response rate demonstrated by products approved in the United States for the treatment of MSI-H cancer patients. Data from this trial may be presented by our partner 3D Medicines at ASCO 2020.

A Phase 3 randomized clinical trial in BTC was initiated in April 2018. This trial is an open-label study to assess the safety and efficacy of envafolimab plus standard of care gemcitabine-based chemotherapy compared to gemcitabine-based chemotherapy alone with overall survival (OS) as the primary endpoint. In the envafolimab arm, envafolimab will be dosed at 2.5 mg/kg subcutaneously weekly, along with gemcitabine and oxaliplatin at recommended doses. The trial is expected to enroll over 390 patients in China and data are expected in 2022.

A Phase 2 study of envafolimab in combination with chemotherapy (FOLFOX) in first line treatment of advanced gastric cancer was fully enrolled (n=15) as of January 15, 2019. Data have not been presented publicly.

Clinical Development in UPS

We intend to file an IND application, apply for orphan drug status, and initiate a registration enabling study of envafolimab in UPS and select STS subtypes in 2020. Subject to input from the FDA, we expect that the trial will include one cohort of approximately 80 patients who will receive single agent treatment with envafolimab and a second cohort of approximately 80 patients who will receive envafolimab in combination with Yervoy (ipilimumab) with the primary endpoint in each of the cohorts being ORR, which could be the basis for accelerated approval of envafolimab by the FDA as a single agent and in combination with Yervoy. We estimate disclosing a summary of the independent data monitoring committee decisions following reviews of interim data in 2021, having a final response assessment in early 2022, and, assuming positive data, submitting a BLA for accelerated approval in early 2023. Additionally, assuming positive data from the initial UPS trial, we plan to initiate a randomized trial for multiple soft tissue sarcoma subtypes, which could include biomarker directed enrollment, to expand the target patient population.

UPS has an incidence of 0.8 to 1.0 cases per 100,000 patients in the western world and accounts for 10% of new cases of soft tissue sarcoma in the United States, with prevalence rates estimated at approximately 1.5 to 2.0 times incidence. We estimate that refractory UPS could generate net sales of up to $200 million in the United States without considering a price premium to the reference PD-1 inhibitors Opdivo® (nivolumab) or Keytruda® (pembrolizumab) that are administered intravenously.

Our Second Clinical Stage Product Candidate – DE-122

Overview of AMD

AMD is a major public health problem that has a devastating effect on patients. AMD distorts central vision, which is necessary for daily activities such as reading, face recognition, watching television and driving and can lead to loss of central vision and blindness. According to a 2010 study sponsored by AMD Alliance International, the annual direct healthcare system cost of visual impairment worldwide due to AMD was estimated at approximately $255 billion.

According to the Macular Degeneration Partnership, approximately 15 million people in the United States and 30 million people worldwide suffer from some form of AMD. There are two forms of AMD: dry AMD and wet AMD. It is reported that wet AMD represents approximately 10% of all cases of AMD, but is responsible for 90% of the severe vision loss associated with the disease. Wet AMD is the leading cause of blindness in the Western world.

In a subset of AMD patients, dry AMD progresses to wet AMD as a result of abnormal angiogenesis in the choroid layer beneath the retina, which is referred to as choroidal neovascularization, or CNV. In the context of wet AMD, CNV is associated with the accumulation of other cell types and altered tissue. The new blood vessels associated with this abnormal angiogenesis tend to be fragile and often bleed and leak fluid into the macula, the central-most portion of the retina responsible for central vision and color perception. If left untreated, the blood vessel growth and associated leakage typically lead to retinal distortion and eventual retinal scarring, with irreversible destruction of the macula and loss of vision. This visual loss occurs rapidly with a progressive course.

Currently Available Therapies for Wet AMD

The current standard of care for wet AMD is administration by intraocular injection of VEGF inhibitors as single agents. VEGF inhibitors have been reported to be effective in treating wet AMD because of their ability to inhibit the effects of abnormal angiogenesis that defines CNV. The FDA has approved the VEGF inhibitors Lucentis (ranibizumab), Eylea® (aflibercept), Beovu® (brolucizumab) and Macugen® (pegaptanib sodium) for the treatment of wet AMD. Lucentis is an antibody fragment derived from the same full length antibody from which Avastin was derived. In 2018, annual worldwide sales of Lucentis and Eylea for all indications totaled more than $10.0 billion. This sales number does not include Avastin, which is commonly used off-label to treat wet AMD in the United States and, to a lesser extent, in the European Union.

The availability of VEGF inhibitors has significantly improved visual outcomes for many patients with wet AMD. A retrospective study published in 2012 confirmed that the prevalence of both legal blindness and moderate visual impairment in patients two years after being diagnosed with wet AMD has decreased substantially following the introduction of VEGF inhibitor therapy. Nonetheless, the condition of many patients with wet AMD treated with VEGF inhibitors does not improve significantly and in many cases deteriorates.

VEGF inhibitors prevent VEGF from binding to its natural receptor on endothelial cells in the abnormal new blood vessels, thereby inhibiting further CNV and leakage associated with wet AMD. However, VEGF inhibitor therapy may be limited in its ability to improve CNV. Results of third-party clinical trials suggest that visual outcomes for wet AMD patients receiving treatment with a VEGF inhibitor worsen over time and are often associated with the development of subretinal fibrosis and the growth of CNV over time. At the present time, the development of agents that effectively complement approved treatment in wet AMD remains an unmet need.

As is the case with angiogenesis that drives tumor growth, we believe that the endoglin pathway serves as an escape pathway that allows continued CNV despite inhibition of the VEGF pathway. In addition, the impact of VEGF inhibitors may be limited by the activity of pericytes, which are the cells that cover the outside of blood vessels and support and stabilize newly formed vessels. Pericytes are not targeted by VEGF inhibitor therapies, but because they express endoglin, they are an additional target for endoglin antibodies such as TRC105. These facts provide the rationale for treating wet AMD with a combination of endoglin antibodies and VEGF inhibitors.

DE-122 for Wet AMD

Our endoglin antibodies for ophthalmology indications are being developed in collaboration with Santen. We have produced a formulation of carotuximab for development in ophthalmology that Santen is developing under the name DE-122.

In June 2015, Santen filed an IND with the FDA for the initiation of clinical studies for DE-122 in patients with wet AMD and began enrollment into the Phase 1/2 PAVE trial. Safety and bioactivity data from the Phase 1/2 PAVE trial were reported at the Bascom Palmer conference on Angiogenesis, Exudation and Regeneration on February 10, 2018.

The open-label, dose-escalation, sequential-cohort Phase 1/2 study assessed the safety, tolerability, and bioactivity of a single intravitreal injection of DE-122 at four dose levels in 12 subjects (n=3 per dose) with wet AMD refractory to vascular endothelial growth factor (VEGF) inhibitors. Subjects were followed up to 90 days. No serious adverse events were reported. One adverse event of yellowish deposits in the vitreous was reported to be related to DE-122 in cohort 2 of 4, that spontaneously resolved. Eight of twelve refractory wet AMD patients demonstrated signs of bioactivity, as evidenced by improved visual acuity, decreased macular edema or decreased fluorescein leak by angiography, after treatment with DE-122 followed by a single dose of the VEGF inhibitor treatment used prior to study entry.

In July 2017, Santen initiated the Phase 2a AVANTE clinical study of DE-122 for the treatment of patients with wet AMD. The Phase 2a AVANTE study is a randomized controlled trial assessing the efficacy and safety of repeated intravitreal injections of DE-122 in combination with Lucentis compared to Lucentis monotherapy in patients with wet AMD. Santen completed enrollment of the Phase 2a AVANTE study of DE-122 in wet AMD patients in 2019 and top-line data are expected in the first half of 2020.

Our Third Clinical Stage Product Candidate – TRC102

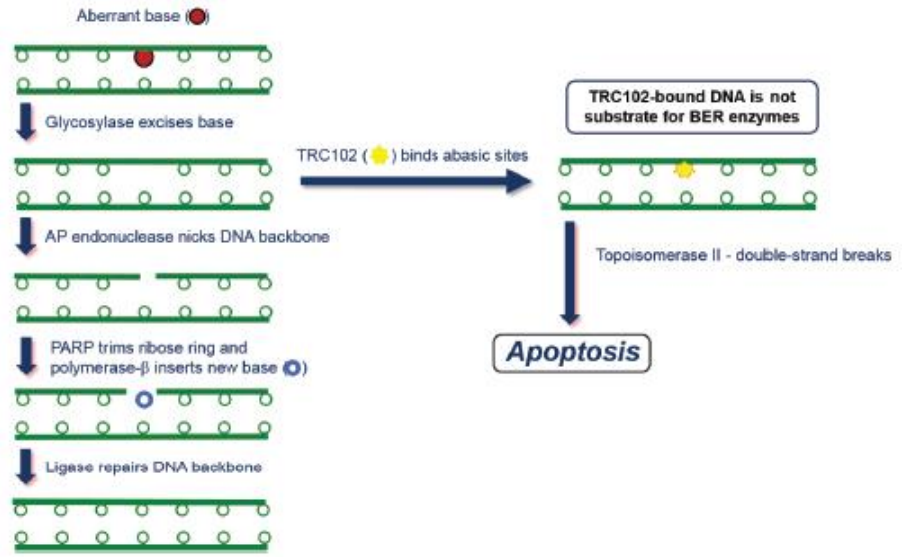
Overview of Base Excision Repair and the Mechanism of Action of TRC102

Base-excision repair, or BER, is a complex and fundamental cellular process used by cancer cells to repair the DNA damage caused by chemotherapeutics, especially the classes of chemotherapeutics known as alkylating agents, including Temodar, dacarbazine and bis-dichloroethyl-nitrosourea, or BCNU, and anti-metabolite agents, including Fludara and Alimta. The process of BER removes DNA bases damaged by chemotherapy, resulting in the formation of gaps in the DNA strand called apurinic and

apyrimidinic, or AP, sites. The appropriate base is then inserted in this gap to restore the proper tumor DNA sequence. By this process, cancer cells can circumvent the anti-tumor effects of chemotherapy.

Inhibition of BER has been proposed as a way to improve the efficacy of chemotherapeutics; however, to our knowledge, no inhibitors of BER have been tested in clinical trials. We are developing TRC102 (methoxyamine hydrochloride) to reverse resistance to specific chemotherapeutics by inhibiting BER. TRC102 interrupts BER by rapidly and covalently binding within AP sites, converting the AP site to a substrate for the enzyme topoisomerase II, which cleaves TRC102-bound DNA, resulting in an accumulation of DNA strand breaks that trigger cellular apoptosis, or programmed cell death, as illustrated in the figure below:

TRC102 binding results in apoptosis



The induction of apoptosis by TRC102 is relatively selective for cancer cells, which typically overexpress topoisomerase II. In nonmalignant cells with low topoisomerase II expression, TRC102-bound DNA is excised and replaced by a separate DNA repair system.

TRC102 Development in Oncology

TRC102 is being developed to reverse resistance to Temodar, an alkylating chemotherapeutic, as well as to Alimta and Fludara, two antimetabolite chemotherapeutics. We consider it advantageous to combine TRC102 with Alimta because Alimta is approved in one large market indication (lung cancer) and one orphan drug indication (mesothelioma). Temodar is an approved chemotherapeutic used as a standard of care agent to treat glioblastoma, and Fludara is an approved chemotherapeutic used as a standard of care agent to treat lymphoma and leukemia. In initial clinical trials of more than 100 patients, TRC102 has shown good tolerability and promising anti-tumor activity in combination with alkylating and antimetabolite chemotherapy.

We filed an IND for TRC102 in March 2008, Case Western filed an IND for TRC102 in March 2006, and NCI filed an IND for TRC102 in March 2013, all for the treatment of patients with advanced solid tumors. The IND filed by NCI cross references our IND.

Phase 1 ascending dose clinical trials evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and anti-tumor activity of TRC102 were completed with Alimta in patients with advanced solid tumors, with Fludara in patients with hematologic malignancy and with Temodar in patients with solid tumors. In each trial, TRC102 was tolerable with the companion chemotherapeutic, and demonstrated signs of activity. One patient treated with TRC102 and Alimta had a partial response as assessed by RECIST 1.1 and remained in our clinical trial without cancer progression for 14 months. In addition, 14 patients had SD including patients with squamous cell lung cancer (three patients), epithelial ovarian cancer (three patients), colorectal cancer (two patients), non-squamous non-small cell lung cancer (one patient), pancreatic cancer (one patient), prostate cancer (one patient), endometrial cancer (one patient), head and neck cancer (one patient) and breast cancer (one patient). These data were published in *Investigational New Drugs* in 2012. Case Western reported data from a trial of intravenous TRC102 given in combination with Fludara in a Phase 1

clinical trial that were published in *Oncotarget* in 2017. Anti-tumor activity, including partial response, was noted in patients with lymphoma and chronic lymphocytic leukemia, including patients treated previously with Fludara. TRC102 combined with Fludara was safe and well tolerated. Hematologic toxicity was comparable to single agent Fludara and activity appeared to correlate with increased levels of DNA damage. Case Western reported data from a trial of TRC102 given intravenously in combination with Temodar in a Phase 1 clinical trial at the ASCO annual meeting in June 2015. Anti-tumor activity was noted in patients with ovarian cancer and neuroendocrine tumors.

The following table summarizes certain key information regarding ongoing clinical trials of TRC102 in cancer patients:

Phase	Indication	Sponsor	Companion Treatment	Design (Number of Patients)
2	Mesothelioma	NCI	Alimta	Single arm Phase 2 portion (14 total)
1	Solid Tumors	NCI	Almita + Cisplatin	Dose escalation (44)
1	Solid Tumors and Lymphomas	NCI	Temodar	Dose escalation (65)
1	Lung Cancer	NCI	Chemoradiation	Dose escalation (15)

The NCI reported data from the Phase 1 study of TRC102 in combination with Temodar in relapsed solid tumors and lymphoma patients at ASCO in 2017. There were no pharmacologic interactions between the two drugs and TRC102 target concentrations were achieved. Based on partial responses in patients with ovarian cancer, non-small cell lung cancer, and KRAS-positive colorectal cancer, the NCI decided to enroll expansion cohorts in each of these tumor types at the recommended Phase 2 oral dose of TRC102. The authors concluded that the combination of Temodar and TRC102 is active, and DNA damage response markers (Rad51, ϒ-H2AX and/or pNbs1) were induced in four of five paired colonic biopsies, indicating DNA damage following treatment. Updated data in the cohort of patients with colorectal cancer reported by the NCI at AACR in 2019 indicated a low response rate in patients with colorectal cancer treated with Temodar and TRC102.

The combination of TRC102 and Temodar was assessed in a Phase 2 trial of patients with recurrent glioblastoma that was reported at the Society for Neuro-Oncology annual meeting in November 2018. The combination of Temodar and TRC102 was tolerable, but did not meet the primary efficacy endpoint of demonstrating objective responses by Response Assessment in Neuro-Oncology criteria in the 19 enrolled patients, most of whom were treated at Cleveland Clinic. Two patients (10.5%) demonstrated evidence of clinical benefit and met the secondary endpoint of progression free survival (PFS) beyond 6 months. Both patients who demonstrated PFS for more than 11 months were alive over 30 months following treatment initiation with TRC102 and Temodar for recurrent glioblastoma. PFS of greater than 11 months was associated with N-methylpurine DNA glycosylase expression, a biomarker that initiates the BER pathway of resistance that is inhibited by TRC102. Efforts to identify whether DNA glycosylase expression or other biomarkers can be used as a predictive biomarker of TRC102 activity are expected to continue in ongoing TRC102 trials in 2020. Data from multiple trials of TRC102 may be presented by investigators associated with the NCI Cancer Therapeutics Evaluation Program at ASCO 2020

Our Fourth Clinical Stage Product Candidate – TRC253

TRC253 Development

TRC253 (formerly JNJ-63576253) is a novel, orally bioavailable small molecule discovered and developed by Janssen that is a potent, high affinity competitive inhibitor of the wild type androgen receptor (AR) and multiple AR mutations, including the F877L mutation, and is under development for the treatment of men with prostate cancer. The AR F877L mutation results in an alteration in the ligand binding domain that confers resistance to current AR inhibitors, including Xtandi® (enzalutamide) and Erleada® (apalutamide). TRC253 also potently inhibits signaling through the wild type AR and may also be developed in earlier lines of treatment as a single agent or in combination with drugs approved in prostate cancer.

Activation of the AR is crucial for the growth of prostate cancer at all stages of the disease. Therapies targeting the AR have demonstrated clinical efficacy by extending time to disease progression, and in some cases, the survival of patients with metastatic castration-resistant prostate cancer. However, resistance to these agents is often observed and several molecular mechanisms of resistance have been identified, including amplification, overexpression, alternative splicing, or mutation of the AR.

We filed an IND in December 2016, which was cleared by the FDA in January 2017. We initiated a Phase 1/2 clinical trial of TRC253 in March 2017 and the recommended Phase 2 dose was established in July 2018, allowing dosing to commence in the Phase 2 portion of the Phase 1/2 trial. In November 2019, following review of available Phase 2 data indicating a lower than expected initial response rate and prevalence of the F877L mutation, we agreed with Janssen that the more than 70 currently enrolled patients in the Phase 1/2 trial of TRC253 are sufficient to determine the risk-benefit profile of the drug in three cohorts of metastatic castrate resistant prostate cancer patients: those with a F877L mutation, those with another undisclosed androgen receptor point mutation, and those with another basis for resistance to Xtandi or Erleada. We expect to provide Phase 2 proof of concept data to Janssen in the first half of 2020.

Our Fifth Clinical Stage Product Candidate – TJ004309

TJ004309, is a novel, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular AMP to the immunosuppressive metabolite adenosine. In December 2018, we submitted an IND application with the FDA for the initiation of a Phase 1 clinical study in patients with advanced solid tumors, which was cleared by the FDA in January 2019. In July 2019, we began enrollment in a Phase 1 clinical study to assess safety and preliminary efficacy of TJ004309 as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® (atezolizumab) in patients with advanced solid tumors. We expect Phase 1 data in 2020.

Collaboration and License Agreements

Collaboration Agreement with 3D Medicines and Alphamab

In December 2019, we, 3D Medicines, and Alphamab entered into the Envafolimab Collaboration Agreement for the development of envafolimab.

Pursuant to the Envafolimab Collaboration Agreement, we were granted an exclusive license to develop and commercialize envafolimab for the treatment of sarcoma in North America. We are responsible for conducting, and will bear the costs of any Phase 1, Phase 2, Phase 3, or post-approval clinical trial in North America for envafolimab in the indications of refractory and first line treatment of soft tissue sarcoma. 3D Medicines and Alphamab are responsible for conducting, and will bear the costs of IND-enabling studies (other than those specific to the sarcoma indication) and the preparation of CMC activities sections of an IND application for envafolimab. 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply envafolimab to us at pre-negotiated prices that vary based on clinical or commercial use. 3D Medicines and Alphamab retained the right to develop envafolimab in all territories outside of North America as well as within North America for all indications other than soft tissue sarcoma.

We will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue, unless (a) envafolimab is first approved in North America for an indication other than soft tissue sarcoma and launched in North America, or (b) envafolimab is first approved in North America for soft tissue sarcoma and subsequently approved in North America for an additional non-orphan indication and sold commercially by 3D Medicines and/or Alphamab, in which case 3D Medicines and Alphamab will be responsible for commercializing envafolimab for soft tissue sarcoma in North America, including booking of sales revenue. If 3D Medicines and Alphamab become responsible for commercialization under the Envafolimab Collaboration Agreement, we have the option to co-market envafolimab for sarcoma in North America. In the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace us as the party responsible for commercialization, and we elect and 3D Medicines and Alphamab agree for us to not co-market envafolimab for sarcoma in North America, then 3D Medicine and Alphamab will be required to compensate us for our costs associated with preparing for and conducting commercial activities.

If we have the responsibility for commercialization under the Envafolimab Collaboration Agreement, we will owe 3D Medicines and Alphamab tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits. If 3D Medicines and Alphamab have responsibility for commercialization under the Envafolimab Collaboration Agreement, we will be entitled to (a) tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if we have elected to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if we have chosen to co-market envafolimab in sarcoma. Payment obligations under the Envafolimab Collaboration Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

3D Medicines and Alphamab retain the right to reacquire the rights to envafolimab for sarcoma in North America in connection with an arm’s length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications, provided that the sale may not occur prior to completion of a pivotal trial of envafolimab in sarcoma without our written consent and the parties must negotiate in good faith and agree to fair compensation be paid to us for the value of and opportunity represented by the reacquired rights.

Each party agreed that during the term of the Envafolimab Collaboration Agreement, it would not develop or license from any third party a monospecific inhibitor to PD-L1 or PD-1.

The term of the Envafolimab Collaboration Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in North America or the expiration of all payment obligations. The Envafolimab Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab. In the event we elect, or a joint steering committee determines, to cease further development or commercialization of envafolimab, or if we fail to use commercially reasonable efforts to develop (including progress in clinical trials) and commercialize envafolimab and do not cure such failure within a specified time period, then our rights and obligations under the Envafolimab Collaboration Agreement will revert to 3D Medicines and Alphamab.

Collaboration Agreements with I-Mab Biopharma

In November 2018, we entered into separate strategic collaboration and clinical trial agreements (the Collaboration Agreements) with I-Mab for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 (the TJ4309 Agreement) as well as up to five proprietary bispecific antibodies currently under development by I-Mab (the Bispecific Agreement).

In the TJ004309 Agreement, we are collaborating with I-Mab on developing TJ004309, also known as TJD5, and will bear the costs of filing an IND and for Phase 1 clinical trials, share costs equally for Phase 2 clinical trials, and we will bear 40% and I-Mab 60% of the costs for pivotal clinical trials. I-Mab will also be responsible for the cost of certain non-clinical activities and the supply of TJ004309 and any reference drugs used in the development activities. We also agreed with I-Mab for a specified period of time to not develop or license to or from a third party any monoclonal antibody targeting CD73 or any other biologic for certain indications that a joint steering committee (JSC), as set up under the TJ004309 Agreement, selects for TJ004309 development.

In the event that I-Mab licenses rights to TJ004309 to a third party, we would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to territories outside of Greater China. In the event that I-Mab commercializes TJ004309, we would be entitled to receive a royalty on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the EU and Japan in the mid-single digits. The portions of certain third party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which we would be entitled escalate based on the phase of development and relevant clinical trial obligations we complete under the TJ004309 Agreement, ranging from a high-single digit to a mid-teen percentage of non-royalty consideration as well as a double digit percentage of royalty consideration.

The TJ004309 Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to TJ004309. I-Mab may also terminate the TJ004309 Agreement if we cause certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJ004309 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical trial, in which case we would be entitled to a minimum termination fee of $9.0 million, or following the completion of the first Phase 2 clinical trial, in which case we would be entitled to a pre-specified termination fee of $15.0 million and either a percentage of non-royalty consideration I-Mab may receive as part of a license to a third party or an additional payment if TJ004309 is approved for marketing outside Greater China before a third party license is executed, in addition to a double digit percentage of royalty consideration.

Pursuant to the Bispecific Agreement, we and I-Mab may mutually select through a joint steering committee (JSC) up to five of I-Mab's bispecific antibody product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, we will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical trials, and we will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical trials, in each case within North America. Subject to I-Mab's right to co-promote an approved product candidate, we will be responsible for commercializing any approved product candidates in North America, and we will share profits and losses equally with I-Mab in North America. We would also be entitled to receive tiered low single digit royalties on net sales of product candidates in the EU and Japan.

At any time prior to completing the first pivotal clinical study for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical trials costs for a product candidate or the JSC decides to cease development over our objections after initiating Phase 3 clinical trials, we will have an option to obtain an exclusive license to such product candidate in all territories except Greater China and Korea and any other territories in which I-Mab previously licensed rights to a third party subject to our right of first refusal for any licenses I-Mab may grant to third-parties.

If we exercise our licensing option, we would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, we would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time we obtained the exclusive license as follows: (i) if before IND-enabling studies and the preparation of the chemistry-manufacturing-controls activities of the collaborative product, we

would owe I-Mab a one-time upfront payment of $10.0 million, development and regulatory based milestone payments totaling up to $90.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the mid-single digits on annual net sales; (ii) if after IND submission but before completion of a Phase 1a clinical trial of the collaborative product, we would owe I-Mab a one-time upfront payment of $25.0 million, development and regulatory based milestone payments totaling up to $125.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high single digits on annual net sales; (iii) if after completion of a Phase 1a clinical trial but before completion of a Phase 2 proof of concept study for the collaborative product, we would owe I-Mab a one-time upfront payment of $50.0 million, development and regulatory based milestone payments totaling up to $250.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the low double digits on annual net sales; and (iv) if after completion of a Phase 2 proof of concept study and before completion of a pivotal study for the collaborative product, we would owe I-Mab a one-time upfront payment of $80.0 million, development and regulatory based milestone payments totaling up to $420.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high-teens on annual net sales.

Each party agreed that for a specified period of time, it would not develop or license to or from any third party any bispecific monoclonal antibody targeting the same two biological targets as those of any selected product candidates under the Bispecific Agreement.

If development of any selected product candidates is terminated by a decision of the JSC, all rights to the product candidate will revert to I-Mab, subject to our rights to obtain an exclusive license in certain circumstances. If development is terminated after submission of an IND and prior to initiating Phase 3 clinical studies or after initiating Phase 3 clinical studies and with our concurrence, we would be entitled to tiered low single digit royalties on net sales of the product candidate in North America, the EU and Japan.

The Bispecific Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or with respect to any selected product candidate, for safety reasons related to that product candidate.

License Agreement with Janssen Pharmaceutica N.V.

In September 2016, we entered into a strategic licensing collaboration with Janssen for two novel oncology assets from Janssen's early oncology development portfolio. The agreement, as amended, grants us the rights to develop TRC253 (formerly JNJ-63576253), a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR Mutant Program) and multiple AR mutant receptors which display drug resistance to approved treatments, which is intended for the treatment of men with prostate cancer. The other oncology asset licensed from Janssen, TRC694, the Company determined the compound did not warrant further development and, in February 2019, issued written notice to terminate the licensing collaboration with respect to the TRC694 program and returned TRC694 and all rights thereto to Janssen.

Janssen maintains an option, which is exercisable until 90 days after we demonstrate clinical proof of concept with respect to the AR Mutant Program, to regain the rights to the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the AR Mutant Program. If Janssen exercises the option, Janssen will be obligated to pay us (i) a one-time option exercise fee of $45.0 million; (ii) regulatory and commercial based milestone payments totaling up to $137.5 million upon achievement of specified events; and (iii) royalties in the low single digits on annual net sales of AR Mutant Program products. If Janssen does not exercise the option, we would then have the right to retain worldwide development and commercialization rights to the AR Mutant Program, in which case, we would be obligated to pay to Janssen (x) development and regulatory based milestone payments totaling up to $45.0 million upon achievement of specified events, and (y) royalties in the low single digits based on annual net sales of AR Mutant Program products, subject to certain specified reductions.

The license agreement may be terminated for uncured breach (including failure to satisfy specified development and spending obligations we have in relation to the AR Mutant Program), bankruptcy, or the failure or inability to demonstrate clinical proof of concept with respect to the AR Mutant Program during specified timeframes. In addition, the license and agreement will automatically terminate with respect to the AR Mutant Program, upon Janssen exercising its option in respect of the AR Mutant Program and making payment of the option exercise fee to us or, if Janssen does not exercise the option, upon the expiration of all our payment obligations to Janssen with respect of the AR Mutant Program. We may also terminate the agreement in its entirety without cause, subject to specified conditions.

License Agreement with Santen

In March 2014, we entered into a license agreement with Santen, under which we granted Santen an exclusive, worldwide license to certain patents, information and know-how related to carotuximab, or the Carotuximab Technology. Under the agreement, as amended, Santen is permitted to use, develop, manufacture and commercialize carotuximab products for ophthalmology indications, excluding systemic treatment of ocular tumors. Santen also has the right to grant sublicenses to affiliates and third party collaborators, provided such sublicenses are consistent with the terms of our agreement. In the event Santen sublicenses any of its

rights under the agreement relating to the Carotuximab Technology, Santen will be obligated to pay us a portion of any upfront and certain milestone payments received under such sublicense.

Santen has sole responsibility for funding, developing, seeking regulatory approval for and commercializing carotuximab products in the field of ophthalmology. In the event that Santen fails to meet certain commercial diligence obligations, we will have the option to co-promote carotuximab products in the field of ophthalmology in the United States with Santen. If we exercise this option, we will pay Santen a percentage of certain development expenses, and we will receive a percentage of profits from sales of the licensed products in the ophthalmology field in the United States, but will not also receive royalties on such sales.

We will own any and all discoveries and inventions made solely by us under the agreement, and Santen will own any and all discoveries and inventions made solely by Santen under the agreement. We will jointly own discoveries and inventions made jointly by us and Santen. We have the first right, but not the obligation, to enforce the patents licensed to Santen under the agreement, and Santen has the first right, but not the obligation, to enforce the patents it controls that are related to carotuximab and the patents owned jointly by us and Santen. Subject to certain limitations, if the party with the first right to enforce a patent fails to timely do so, the other party will have the right to enforce such patent.

In consideration of the rights granted to Santen under the agreement, we received a one-time upfront fee of $10.0 million. In addition, we are eligible to receive up to a total of $155.0 million in milestone payments upon the achievement of certain milestones, of which $20.0 million relates to the initiation of certain development activities, $52.5 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals, and $82.5 million relates to commercialization activities and the achievement of specified levels of product sales. If carotuximab products are successfully commercialized in the field of ophthalmology, Santen will be required to pay us tiered royalties on net sales ranging from high single digits to low teens, depending on the volume of sales, subject to adjustments in certain circumstances. In addition, Santen will reimburse us for all royalties due by us under certain third party agreements with respect to the use, manufacture or commercialization of carotuximab products in the field of ophthalmology by Santen and its affiliates and sublicensees. Royalties will continue on a country-by-country basis through the later of the expiration of our patent rights applicable to the carotuximab products in a given country or 12 years after the first commercial sale of the first carotuximab product commercially launched in such country.

Santen may unilaterally terminate this agreement in its entirety, or on a country-by-country basis, for any reason or for no reason upon at least 90 days' notice to us (or 30 days' notice if after a change in control). Either party may terminate the agreement in the event of the other party's bankruptcy or dissolution or for the other party's material breach of the agreement that remains uncured 90 days (or 30 days with respect to a payment breach) after receiving notice from the non-breaching party. Unless earlier terminated, the agreement continues in effect until the termination of Santen's payment obligations.

License Agreement with Roswell Park Cancer Institute and Health Research Inc.

In November 2005, we entered into a license agreement with Health Research Inc. and Roswell Park Cancer Institute, referred to collectively as RPCI. Under the agreement, as amended, we obtained an exclusive, worldwide license to certain patents and other intellectual property rights controlled by RPCI related to endoglin antibodies, including carotuximab, and their therapeutic uses, which we refer to as the RPCI Technology, and a non-exclusive, worldwide license to certain know-how controlled by RPCI related to the RPCI Technology. Under the agreement, we are permitted to use, manufacture, develop and commercialize products utilizing the RPCI Technology in all fields of use. In addition, we are permitted to sublicense our rights under the agreement to third parties.

Under the agreement, we are responsible for development and commercialization activities for products utilizing the RPCI Technology, and we are obligated to use all commercially reasonable efforts to bring a product utilizing the RPCI Technology to market timely and efficiently.

In consideration of the rights granted to us under the agreement, we paid a one-time upfront fee to RPCI. In addition, we may be required to pay up to an aggregate of approximately $6.4 million upon the achievement of certain milestones for products utilizing the RPCI Technology, including carotuximab, of which approximately $1.4 million relates to the initiation of certain development activities and $5.0 million relates to certain regulatory filings and approvals. Pursuant to an amendment entered into in November 2009, we may also be required to pay up to an aggregate of approximately $6.4 million upon the achievement of certain milestones for products utilizing a patent owned by us covering humanized endoglin antibodies, including TRC205, a humanized and deimmunized endoglin antibody, of which approximately $1.4 million relates to the initiation of certain development activities and $5.0 million relates to certain regulatory filings and approvals. Upon commercialization, we will be required to pay RPCI mid-single-digit royalties based on net sales of products utilizing the RPCI Technology in each calendar quarter, subject to adjustments in certain circumstances. In addition, pursuant to the amendment entered into in November 2009, we will be required to pay RPCI low single-digit royalties based on net sales in each calendar quarter of products utilizing our patent covering humanized endoglin antibodies. Our royalty obligations continue until the expiration of the last valid claim in a patent subject to the agreement, which we expect to occur in 2029, based on the patents currently subject to the agreement.

We may unilaterally terminate this agreement in whole or in part, for any reason or no reason, upon at least 60 days' notice to RPCI. RPCI may terminate the agreement if we fail to pay any amount due under the agreement or materially breach the agreement and the breach remains uncured 90 days after receiving notice. In the event of our bankruptcy, the agreement will automatically terminate. Unless otherwise terminated, the agreement will remain in effect on a country-by-country basis until the expiration of the last valid claim under the patents subject to the agreement.

License Agreement with Case Western

In August 2006, we entered into a license agreement with Case Western, under which we obtained an exclusive, worldwide license to certain patents, know-how and other intellectual property controlled by Case Western related to methoxyamine, which we refer to as the TRC102 Technology. Under the agreement, as amended, we have the right to use, manufacture and commercialize products utilizing the TRC102 Technology for all mammalian therapeutic uses, and to sublicense these rights.

Under the agreement, we are generally obligated to use our best efforts to commercialize the TRC102 Technology as soon as possible. We are also required to meet specified diligence milestones, and if we fail to do so and do not cure such failure, Case Western may convert our license into a non-exclusive license or terminate the agreement.

In consideration of the rights granted to us under the agreement, we paid a one-time upfront fee to Case Western. In addition, we may be required to pay up to an aggregate of approximately $9.8 million in milestone payments, of which $650,000 relates to the initiation of certain development activities and approximately $9.1 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals. If products utilizing the TRC102 Technology are successfully commercialized, we will be required to pay Case Western a single-digit royalty on net sales, subject to adjustments in certain circumstances. Beginning on the earlier of a specified number of years from the effective date of the agreement and the anniversary of the effective date following the occurrence of a specified event, we will be required to make a minimum annual royalty payment of $75,000, which will be credited against our royalty obligations. In the event we sublicense any of our rights under the agreement relating to the TRC102 Technology, we will be obligated to pay Case Western a portion of certain fees we may receive under the sublicense. Our royalty obligations will continue through the later of (i) the expiration of any orphan drug marketing exclusivity for a product utilizing the TRC102 Technology, (ii) August 2026, or (iii) on a country-by-country basis upon the expiration of the last valid claim under the TRC102 Technology or any patent we receive that is a derivative of the TRC102 Technology.

We may unilaterally terminate this agreement in its entirety, for any reason or for no reason, upon at least 30 days' notice to Case Western. If we do so, we will be required to pay Case Western a termination fee. If we fail to pay any amount required under the agreement and do not cure the default within 90 days of receiving notice, Case Western will have the right to convert our exclusive license to a non-exclusive license or to terminate the agreement entirely. Either party may terminate the agreement in the event of the other party's material breach of the agreement that remains uncured 60 days after receiving notice of the breach.

License Agreement with Lonza Sales AG

In June 2009, we entered into a license agreement with Lonza Sales AG, or Lonza, under which we obtained a world-wide non-exclusive license to Lonza's glutamine synthetase gene expression system consisting of cell lines into which TRC105 may be transfected and corresponding patents and applications, which we refer to as the Lonza Technology. Under the agreement, we are permitted to use, develop, manufacture and commercialize TRC105 obtained through use of the Lonza Technology.

In consideration for the rights granted to us under the agreement, we are required to pay Lonza a low single-digit percentage royalty on the net selling price of TRC105 product manufactured by Lonza. In the event that we or a strategic partner or collaborator manufactures the product, we will be required to pay Lonza an annual lump sum payment of £75,000, along with a low single-digit percentage royalty on the net selling price of the manufactured TRC105 product. In the event that we sublicense our manufacturing rights under the agreement (other than to a strategic partner or collaborator), we will be obligated to pay Lonza an annual lump sum payment of £300,000 per sublicense, along with a low single-digit percentage royalty on the net selling price of the manufactured TRC105 product. If, on a country-by-country basis, the manufacture or sale of the TRC105 product is not protected by a valid claim in a licensed patent, our royalty obligations in such country will decrease and will expire 12 years after the first commercial sale of the product.

We may unilaterally terminate this agreement for any reason upon at least 60 days' written notice to Lonza. Either party may terminate the agreement by written notice if the other party commits a breach and, if the breach is curable, does not cure the breach within 30 days of receiving notice from the non-breaching party. In addition, either party may terminate the agreement with written notice in the event of the other party's liquidation or appointment of a receiver. Unless earlier terminated, the agreement continues in

effect until the later of the expiration of the last valid claim in a licensed patent or for so long as the know-how subject to the agreement is identified and remains secret and substantial.

Cooperative Research and Development Agreements with NCI

We are a party to a Cooperative Research and Development Agreement, or CRADA, with the U.S. Department of Health and Human Services, as represented by NCI, for the development of TRC102 for the treatment of cancer. We entered into the CRADA governing the development of TRC102 (TRC102 CRADA) in August 2012 with NCI's Center for Cancer Research.

Under the CRADA, as amended, NCI conducts clinical trials and non-clinical studies of TRC102. Pursuant the TRC102 CRADA, we are required to pay NCI $20,000 per year per Phase 1 clinical trial and $25,000 per year per Phase 2 clinical trial, as well as expenses incurred by NCI in connection with carrying out its responsibilities under the TRC102 CRADA, up to an aggregate maximum per year of $200,000. We may also provide funding to support assays and other studies, and if NCI supplies TRC102 for additional mutually approved clinical trials beyond the planned trials, we will reimburse NCI for costs associated with manufacturing TRC102. In addition, we made a one-time payment of $20,000 for the initial IND filing and may be required to make additional one-time payments of $10,000 each for additional IND filings. Funding for clinical trials beyond those contemplated by the TRC102 CRADA will be determined in an amendment to the applicable CRADA.

Under the CRADA, each party individually owns all inventions, data and materials produced solely by its employees in the course of performing research activities pursuant to the CRADA. The parties jointly own any inventions and materials that are jointly produced by employees of both parties. Subject to certain conditions, we have the option under the CRADA to negotiate commercialization licenses from the government to intellectual property conceived or first reduced to practice in performance of the CRADA research plan that was developed solely by NCI employees or jointly by us and NCI employees.

The TRC102 CRADA had an original five-year term expiring on August 7, 2020. The CRADA may be terminated at any time by mutual written consent, and we or NCI may unilaterally terminate the CRADA for any reason or no reason by providing written notice at least 60 days before the desired termination date.

Manufacturing

We do not own or operate, nor do we expect to own or operate, facilities for product manufacturing, storage, distribution or testing. We therefore rely on various third-party manufacturers and corporate partners for the production of our product candidates.

Envafolimab is manufactured by AlphaMab in China and fill finish is performed by a contract manufacturer in the United States. Pursuant to the Envafolimab Collaboration Agreement, 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to us at pre-negotiated prices that vary based on clinical or commercial use.

TRC102 drug substance is manufactured through a standard chemical synthesis and may be obtained from multiple manufacturers.

TRC253 drug substance is manufactured through a standard chemical synthesis by an experienced contract manufacturer and is currently being produced at clinical scale.

TJ004309 is supplied to us from a contract manufacturer contracted by I-Mab as I-Mab is responsible for the supply of TJ004309 and all related drug supply activities under the terms of the TJ004309 Agreement.

Competition

The development and commercialization of new drugs is highly competitive, and we and our collaborators face competition with respect to each of our product candidates in their target indications. Many of the entities developing and marketing potentially competing products have significantly greater financial, technical and human resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

If our product candidates are approved, they will compete with currently marketed drugs and therapies used for treatment of the following indications, and potentially with drug candidates currently in development for the same indications.

The key competitive factors affecting the success of any approved product will include its efficacy, safety profile, price, method of administration and level of promotional activity.

Oncology Therapies

There is no PD-1 or PD-L1 therapy approved by the FDA for the treatment of soft tissue sarcoma. Keytruda (marketed by Merck) has a compendia listing for the treatment of UPS, and is used off-label for the treatment of patients with UPS. If envafolimab is approved, it may nevertheless compete with currently marketed PD-1 and PD-L1 inhibitors, including Opdivo (marketed by Bristol-Meyers Squibb), Keytruda (marketed by Merck), Imfinzi (marketed by AstraZeneca), and Tecentriq (marketed by Roche) which are approved by the FDA in multiple indications other than soft tissue sarcoma. PD-1 and PD-L1 inhibitors collectively sold over $14 billion in 2018.

We are developing TRC102 to be used in combination with alkylating chemotherapeutics (including Temodar) and antimetabolite chemotherapeutics (including Alimta and Fludara) for the treatment of cancer. If TRC102 is approved, it could compete with other inhibitors of DNA repair. Tesaro, Inc. (now GSK), Clovis Oncology and Astra Zeneca each market inhibitors of DNA repair that work by a mechanism of action that is distinct from that of TRC102. In addition to the therapies mentioned above, there are many generic chemotherapeutics and other regimens commonly used to treat various types of cancer, including soft tissue sarcoma and glioblastoma.

We are developing TRC253 for the treatment of castration-resistant prostate cancer. If TRC253 is approved, it could compete with other androgen receptor inhibitors such as Xtandi, Nubeqa (darolutamide) and Erleada. In addition to the therapies mentioned above, there are many generic chemotherapeutics and other agents commonly used to treat prostate cancer.

We are developing TJ004309 for the treatment of solid tumors, including bladder cancer. If TJ004309 is approved, it could compete with other anti-CD73 immunotherapies including CD73 antibodies as well as adenosine receptor inhibitors already in clinical development sponsored by Bristol-Meyers Squibb, AstraZeneca, Arcus Biosciences and Corvus Pharmaceuticals.

Wet AMD Therapies

Our partner, Santen, is developing DE-122 for the treatment of wet AMD and other eye diseases. If DE-122 is approved as a single agent, it would compete with currently marketed VEGF inhibitors, including Avastin and Lucentis (marketed by Genentech in the United States), and Eylea (marketed by Regeneron in the United States), Beovu (marketed by Novartis) which are well established therapies and are widely accepted by physicians, patients and third-party payors as the standard of care for the treatment of wet AMD. In addition, DE-122 could face competition from other VEGF inhibitors in development in wet AMD, including gene therapy products.

Commercialization

We hold North America commercialization rights in the field of sarcoma for envafolimab (subject to certain rights held by 3D Medicines and Alphamab) and worldwide commercialization rights for our other oncology product candidates (subject to certain rights held by Janssen for TRC253 and I-Mab for TJ004309), while Santen holds worldwide commercialization rights for our endoglin antibodies, including TRC105, in the field of ophthalmology. If any of our product candidates are approved in oncology indications, our plan is to build an oncology-focused specialty sales force in the U.S. to support their commercialization and seek a partner(s) to support commercialization outside the U.S. to the extent we have commercial rights in other territories. We believe that a specialty sales force will be sufficient to target key prescribing physicians in oncology. We currently do not have any sales or marketing capabilities or experience as a company. We plan to establish the required capabilities within an appropriate time frame ahead of any product approval and commercialization to support a product launch.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our protein therapeutics, novel biological discoveries, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and

implementation of our business. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we expect to benefit from a variety of statutory frameworks in the United States, Europe, Japan and other countries that relate to the regulation of biosimilar molecules and orphan drug status. These statutory frameworks provide periods of non-patent-based exclusivity for qualifying molecules. See "Government Regulation."

Our patenting strategy is focused on our protein therapeutics. We seek composition of matter and method of treatment patents for each such protein in key therapeutic areas. We also seek patent protection with respect to companion diagnostic methods and compositions and treatments for targeted patient populations. We have sought patent protection alone or jointly with our collaborators, as dictated by our collaboration agreements.

Our patent estate as of December 31, 2019, on a worldwide basis, includes sixteen (16) issued patents/allowed applications and ten (10) pending patent applications in the United States; and includes one hundred eleven (111) issued patents/allowed applications and sixty-five (65) pending patent applications outside the United States with pending and issued claims relating to our product candidates. These figures exclude development rights we have acquired through our licensing and collaboration agreements, including TRC253, TJ004309, and envafolimab.

Individual patents extend for varying periods of time depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued from applications filed in the United States are effective for twenty years from the earliest non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, however, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also twenty years from the earliest international filing date. Our issued patents and pending applications with respect to our protein therapeutic candidates will expire on dates ranging from 2023 to 2038, exclusive of possible patent term extensions. However, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of extensions of patent term, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

National and international patent laws concerning protein therapeutics remain highly unsettled. No consistent policy regarding the patent-eligibility or the breadth of claims allowed in such patents has emerged to date in the United States, Europe or other countries. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries can diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that may be granted in our patents or in third-party patents. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our drugs and technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own or may receive in the future, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. The patent positions for our most advanced programs are summarized below:

Carotuximab/TRC205 Patent Coverage

We hold issued patents covering methods for inhibiting breast cancer or colon cancer with a combination of carotuximab and cyclophosphamide (CPA) or doxorubicin in the United States. The expected expiration date for these method-of-use patents is 2034, exclusive of possible patent term extensions.

We are co-owners with Health Research, Inc., to issued patents covering the combination therapy of cancer with carotuximab and VEGF inhibitors in Australia, Canada, China, Europe, Eurasia, Israel, South Korea, and Japan and pending patent applications in Europe, Hong Kong, and the United States. We also have an exclusive license from Health Research, Inc., to these issued patents and pending applications. The expected expiration date for these method-of-use patents is 2030, exclusive of any possible patent term extensions.

We hold issued patents and allowed applications covering formulations of endoglin antibodies in Australia, Eurasia, Georgia, Japan, Mexico, New Zealand, the Philippines, Singapore, South Korea, Ukraine, Uzbekistan, and the United States; and patent

applications are pending in Brazil, Canada, China, Europe, Hong Kong, India, Indonesia, Israel, Malaysia, Singapore, Thailand, the United States, and Vietnam. The expected expiration date for any patent that may issue from this application is 2033, exclusive of possible patent term extensions.

We hold issued patents and allowed applications covering our humanized and deimmunized anti-endoglin antibodies, including TRC205, in Australia, Canada, China, Eurasia, Europe, India, Israel, Japan, South Korea, and the United States, and similar applications are pending in many other major jurisdictions worldwide, including the United States, and Brazil. The expected expiration date for these composition of matter and methods of use patents is 2029, exclusive of possible patent term extensions.

We hold issued patents covering methods of treating fibrosis with our anti-endoglin antibodies in the United States and have pending patent applications in Australia, Canada, Israel, Japan, and the United States. The expected expiration date for any patent that may arise from these applications is 2035, exclusive of possible patent term extensions.

Envafolimab Patent Coverage

Specific to the development of envafoloimab for the treatment of soft tissue sarcoma in North America, we hold an exclusive license from 3D Medicines and Alphamab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering envafoloimab. We also hold a non-exclusive license for the conduct of clinical trials in the European Union in support of the development of envafoloimab for the treatment of soft tissue sarcoma in North America. 3D Medicines and Alphamab retain ownership of any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering any pharmaceutical composition or preparation comprising envafoloimab.

TRC102 Patent Coverage

We hold issued patents directed to combination of TRC102 and pemetrexed in the United States, Australia, Canada, Europe, Japan, Mexico, Norway, Russia, Singapore, South Africa, South Korea, Ukraine, and the United Kingdom. We also have pending applications in other jurisdictions, including Brazil, China, Hong Kong, and India. The expected expiration date for these patents is 2027, exclusive of possible patent term extensions.

We hold an issued patent on further combinations of TRC102 in Europe and have a pending patent application in the United States. The expected expiration date for these patents is 2031, exclusive of possible patent term extensions.

TRC253 Patent Coverage

We hold an exclusive license to a patent in the United States covering TRC253 and methods of using TRC253. The expected expiration date for the US case and any patents issuing from the PCT application is 2037, exclusive of possible patent term extensions.

We also hold an exclusive license to patents in Australia, Eurasia, Europe, Japan, Ukraine, and the United States; and to patent applications in Armenia, Azerbaijan, Brazil, Belarus, Canada, Chile, China, Columbia, Costa Rica, Ecuador, Egypt, El Salvador, Europe, Guatemala, Hong Kong, Honduras, Indonesia, Israel, India, Kazakhstan, Kyrgyz Republic, Malaysia, Mexico, Moldova, New Zealand, Nicaragua, Nigeria, Panama, Peru, Philippines, Russian Federation, Singapore, South Africa, South Korea, Sri Lanka, Tajikistan, Thailand, Turkmenistan, United States, and Vietnam, which are directed to methods for determining resistance to androgen receptor therapy. The expected expiration date for patents issuing from these applications is 2033, exclusive of possible patent term extensions.

TJ004309 Patent Coverage

Specific to the development of TJ004309 in North America, we hold a non-exclusive license from I-Mab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering any pharmaceutical composition or preparation comprising or containing TJ004309. I-Mab retains ownership of any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering any pharmaceutical composition or preparation comprising or containing TJ004309.

Trade Secrets, Trademarks and Know-How

In addition to patents, we rely upon unpatented trade secrets, trademarks and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These

agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. In addition, we seek trademark protection in the United States and internationally where available and when we deem appropriate. Furthermore, we are a party to a number of license agreements under which we are granted intellectual property rights to know-how that are important to our business.

U.S. Government Regulation

The preclinical studies and clinical testing, manufacture, labeling, storage, record keeping, advertising, promotion, export, marketing and sales, among other things, of our product candidates and future products, are subject to extensive regulation by governmental authorities in the United States and other countries. In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA), and other laws, including, in the case of biologics, the Public Health Service Act (PHSA), in addition to the FDA's implementing regulations. We expect envafolimab to be regulated by the FDA as a biologic, which requires the submission of a BLA and approval by the FDA prior to being marketed in the United States. We expect our small molecule product candidate TRC102 to be regulated as a drug and subject to New Drug Application, or NDA, requirements, which are substantially similar to the BLA requirements discussed below. Manufacturers of our product candidates may also be subject to state regulation. Failure to comply with FDA requirements, both before and after product approval, may subject us or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA refusal to approve applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines and/or criminal prosecution.

The steps required before a biologic may be approved for marketing of an indication in the United States generally include:

- completion of preclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices, or GLPs, and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may commence;
- completion of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices, or GCPs, to establish that the biological product is "safe, pure and potent," which is analogous to the safety and efficacy approval standard for a chemical drug product for its intended use;
- submission to the FDA of a marketing application;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with applicable current Good Manufacturing Practice requirements, or cGMPs; and
- FDA review of the marketing application and issuance of a biologics license which is the approval necessary to market a biologic therapeutic product.

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation as well as animal studies to assess the potential safety and efficacy of the biologic candidate. Preclinical studies must be conducted in compliance with FDA regulations regarding GLPs. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Nonclinical testing may continue after the IND is submitted. In addition to including the results of the preclinical testing, the IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase or phases of the clinical trial lends themselves to an efficacy determination. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA within the 30-day time period places the IND on clinical hold because of its concerns about the drug candidate or the conduct of the trial described in the clinical protocol included in the IND. The FDA can also place the IND on clinical hold at any time during drug development for safety concerns related to the investigational drug or to the class of products to which it belongs. The IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

All clinical trials must be conducted under the supervision of one or more qualified principal investigators in accordance with GCPs. They must be conducted under protocols detailing the objectives of the applicable phase of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to the FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that

institution, approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, and monitor the study until completed.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations. Phase 1 clinical trials may be conducted in a limited number of patients, but are usually conducted in healthy volunteer subjects for indications other than oncology. The drug candidate is initially tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics.

Phase 2 usually involves trials in a larger, but still limited, patient population to evaluate preliminarily the efficacy of the drug candidate for specific, targeted indications to determine dosage tolerance and optimal dosage and to identify possible short-term adverse effects and safety risks.

Phase 3 trials are undertaken to further evaluate clinical efficacy of a specific endpoint and to test further for safety within an expanded patient population at geographically dispersed clinical trial sites. Phase 1, Phase 2, or Phase 3 testing might not be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Results from one trial are not necessarily predictive of results from later trials. Furthermore, the FDA or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug candidate has been associated with unexpected serious harm to patients.

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a marketing application requesting approval to market the drug candidate for a proposed indication. Under the PDUFA, the fees payable to the FDA for reviewing a marketing application, as well as annual program fees for approved products, can be substantial. The fees typically increase each year. Each marketing application submitted to the FDA for approval is reviewed for administrative completeness and reviewability within 60 days following receipt by the FDA of the application. If the application is found complete, the FDA will file the marketing application, triggering a full review of the application. The FDA may refuse to file any marketing application that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goal is to review 90% of priority marketing applications within six months after the application is accepted for filing and 90% of standard marketing applications within 10 months of the acceptance date, whereupon a review decision is to be made. The FDA, however, may not approve a drug candidate within these established goals and its review goals are subject to change from time to time. Further, the outcome of the review, even if generally favorable, may not be an actual approval but a "complete response letter" that describes additional work that must be done before the application can be approved. Before approving a marketing application, the FDA may inspect the facility or facilities at which the product is manufactured and will not approve the product unless the facility complies with cGMPs. The FDA may deny approval of a marketing application if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can extend the review process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval may impose limitations on the uses for which the product may be marketed, may require that warning statements be included in the product labeling, may require that additional studies be conducted following approval as a condition of the approval, and may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a Risk Evaluation and Mitigation Strategy, or REMS, or otherwise limit the scope of any approval. The FDA must approve a marketing application supplement or a new marketing application before a product may be marketed for other uses or before certain manufacturing or other changes may be made. Further post-marketing testing and surveillance to monitor the safety or efficacy of a product is required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

The Biologics Price Competition and Innovation Act of 2009, or the BPCIA, created a pathway for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, earlier biological products licensed under the PHSA. Also under the BPCIA, innovator manufacturers of original reference biological products are granted 12 years of exclusivity before biosimilars can be approved for marketing in the United States.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the marketing application for the product are subject to comprehensive regulatory oversight. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance.

Additionally, the FDA strictly regulates marketing, labeling, advertising and promotion of products. 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 liability. However, physicians may, in their independent medical judgment,

prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

Other Healthcare Laws

Although we currently do not have any products on the market, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal, fraud and abuse, including anti-kickback and false claims, privacy and security and physician sunshine laws and regulations, many of which may become more applicable if our product candidates are approved and we begin commercialization. For additional details regarding the federal, state and foreign healthcare laws that may affect our ability to operate, see "Risk Factors—Risks Related to Our Business and Industry— "We are subject to extensive federal, state, and foreign regulation, and our failure to comply with these laws could harm our business." If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, significant civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, imprisonment, and additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results.

Orphan Drug Act

The United States Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. Orphan drug designation must be requested before submitting a BLA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and 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 holder of the approval is entitled to a seven-year exclusive marketing period in the United States for that product except in very limited circumstances. For example, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug.

Legislation similar to the Orphan Drug Act has been enacted outside the United States, including in the European Union and Japan. The orphan legislation in the European Union is available for therapies addressing chronic debilitating or life-threatening conditions that affect five or fewer out of 10,000 persons or are financially not viable to develop. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity. The market exclusivity may be extended to 12 years if sponsors complete a pediatric investigation plan agreed upon with the relevant committee of the European Medicines Agency. Orphan legislation in Japan similarly provides for ten years of marketing exclusivity for drugs that are approved for the treatment of rare diseases and conditions.

Exclusivity

New biological products will benefit, if approved, from the data exclusivity provisions legislated in the United States, the European Union and Japan. All three regions effectively provide a period of data exclusivity to innovator biologic products. U.S. legislation provides a 12-year period of data exclusivity from the date of first licensure of a reference biologic product. EU legislation provides a period of 10 to 11 years and Japan legislation provides a period of 8 years during which companies cannot be granted approval as generic drugs to approved biologic therapies. Protection from generic competition is also available for new chemical entities, including potentially the small molecule TRC102, in the United States for 5 years, in the European Union for 10 to 11 years and in Japan for 8 years.

Exclusivity in the European Union

The European Union has led the way among the International Council for Harmonisation regions in establishing a regulatory framework for biosimilar products. The marketing authorization of generic medicinal products and similar biological medicinal products are governed in the European Union by Article 10(1) of Directive 2001/83/EC (2001). Unlike generic medicinal products, which only need to demonstrate bioequivalence to an authorized reference product, similar biological medicinal products are required to submit preclinical and clinical data, the type and quantity of which is dictated by class and product specific guidelines. In order to submit a marketing authorization for a similar biological medicinal product, the reference product must have been authorized for marketing in the European Union for at least 8 years. Biosimilars can only be authorized for use once the period of data exclusivity on the biological reference medicine has expired. In general, this means that the biological reference medicine must have been authorized

for at least 10 years before a similar biological medicine can be made available by another company. The 10-year period can be extended to a maximum of 11 if, during the first 8 years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization are held to bring a significant clinical benefit in comparison to existing therapies.

Many EU countries have banned interchangeability of biosimilars with their reference products to ensure adequate characterization of the safety profile of the biosimilar and to enable comparison to that of reference product.

Exclusivity in Japan

In 2009, Japan's Ministry of Health, Labour and Welfare, or MHLW, and Pharmaceuticals and Medical Device Agency, or PMDA, issued the first Japanese guidance on biosimilars. The guideline (currently available only in Japanese), which shares common key features to EU guidelines, outlines the nonclinical, clinical and CMC requirements for biosimilar applications and describes the review process, naming conventions and application fees.

Japan does not grant exclusivity to pharmaceutical products; however, the country does have a Post Marketing Surveillance, or PMS, system that affects the timing of generic entry and, in effect, provides a period of market exclusivity to innovator products. This system allows safety data to be acquired for each product. A PMS period is set for most of new drug approvals, and until this period is over, generic companies cannot submit their applications for drug approvals as generic drugs. Recently, this period was extended to 8 years for all new drug approvals. Japan's regulations do not allow currently for interchangeability of biosimilars with their reference products.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs and biologics, and/or provide for the approval of a drug or biologic on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a drug candidate receiving accelerated approval perform post-marketing clinical trials to confirm the clinically meaningful outcome as predicted by the surrogate marker trial.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA, or a Written Request, relating to the use of the active moiety of the drug in children. The FDA may decline to issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

We have not received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under

PREA, original NDAs, BLAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must include the evaluation of the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In both domestic and foreign markets, sales and reimbursement of any approved products will depend, in part, on the extent to which third-party payors, such as government health programs, commercial insurance and managed healthcare organizations provide coverage, and establish adequate reimbursement levels, for such products. Third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Additionally, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products after approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

The containment of healthcare costs also has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

Outside the United States, ensuring adequate coverage and payment for our products will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. Recent budgetary pressures in many European Union countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

Healthcare Reform

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the healthcare system of the United States. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for medical goods and services may take in response to any healthcare reform proposals or legislation. Adoption of new legislation at the federal or state level could further limit reimbursement for pharmaceuticals, including our product candidates if approved. We cannot predict the effect medical or healthcare reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect. For additional details regarding health reform activity, see “Risk Factors—Risks Related to Commercialization of Product Candidates — “Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.”

Foreign Regulation

In addition to regulations in the United States, we and our collaborators will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates. Whether or not we or our collaborators obtain FDA approval for a product candidate, we or our collaborators must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we or our collaborators may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product

licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be approved by the competent national health authority and by independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country. In all cases, the clinical trials must be conducted in accordance with good clinical practices, or GCPs and other applicable regulatory requirements.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use. A favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure provides for approval by one or more "concerned" member states based on an assessment of an application performed by one member state, known as the "reference" member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

In China, the China Food and Drug Administration (CFDA) monitors and supervises the administration of pharmaceutical products, as well as medical devices and equipment. In order to conduct clinical trials in China a clinical trial application must be submitted and approved by the CFDA. When clinical trials have been completed, an applicant must apply to the CFDA for approval of a new drug application. The CFDA, the Center for Drug Evaluation (CDE), and the Drug Inspection Institution will then conduct reviews and on-site inspections. The CFDA determines whether to approve the application according to the comprehensive evaluation opinions produced by the reviews and on-site inspections. We or our collaborators must obtain approval of new drug applications before our product candidates can be manufactured and sold in the Chinese market. In addition, all facilities and techniques used in the manufacture of products for clinical use or for sale in China must be operated in conformity with good manufacturing practice guidelines as established by the CFDA. Failure to comply with applicable requirements could result in the termination of manufacturing and significant fines.

Additional Regulation

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involves the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Employees

As of December 31, 2019, we had 19 full-time employees, 12 of whom are involved in research, development or manufacturing, and two of whom have Ph.D., Pharm.D. or M.D. degrees. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Corporate and Other Information

We were incorporated in the state of Delaware in October 2004 as Lexington Pharmaceuticals, Inc. and we subsequently changed our name to TRACON Pharmaceuticals, Inc. in March 2005, at which time we relocated to San Diego, California. Our principal executive offices are located at 4350 La Jolla Village Dr., Suite 800, San Diego, CA 92122, and our telephone number is (858) 550-0780. Our corporate website address is www.traconpharma.com and we regularly post copies of our press releases as well

as additional information about us on our website. Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

This Annual Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Item 1A. Risk Factors.

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report as well as our other public filings with the Securities and Exchange Commission.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred losses from operations since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability.

We are a clinical stage company with limited operating history. All of the product candidates we are developing will require substantial additional development time and resources before we or our partners would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred losses from operations in each year since our inception, including net losses of $22.7 million and $35.0 million for the years ended December 31, 2019 and 2018, respectively. At December 31, 2019, we had an accumulated deficit of $162.3 million.

We expect to continue to incur substantial expenses as we expand our development activities and advance our clinical programs. To become and remain profitable, we or our partners must succeed in developing product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we or our partners may obtain regulatory approval. We or they may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any product candidates. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations.

We will require substantial additional financing to achieve our goals, and failure to obtain additional financing when needed could force us to delay, limit, reduce or terminate our drug development efforts. There is substantial doubt as to our ability to continue as a going concern.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our current level of research and development expenses to decrease slightly due to the termination of carotuximab development in oncology as we expect to initiate a registration enabling study of envafolimab in UPS.

At December 31, 2019, we had cash and cash equivalents totaling $16.4 million. Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital requirements into early 2021, presuming our payment obligations under the 2018 Amended SVB Loan continue to follow the contractual maturity schedule. We will need additional funding to complete the development and commercialization of product candidates, including envafolimab. In addition, in 2016 we licensed TRC253 from Janssen Pharmaceutica N.V., or Janssen, and are subject to obligations to develop the program through clinical proof of concept. To the extent we retain the program, we will need additional funds to advance the program through later stages of development. In November 2018, we entered into separate collaboration and clinical trial agreements with I-Mab for the development of multiple immuno-oncology programs. Under the agreements, we are responsible for various portions of the costs to conduct clinical trials, among other development obligations. We will need additional funds to advance the development of these programs and meet our cost-sharing obligations, and these requirements may be substantial depending on how many programs are selected for development and the stage of development each program reaches. As more fully discussed in Note 1 to the consolidated financial statements included in this report, the uncertainties around our ability to obtain additional funding raise

substantial doubt regarding our ability to continue as a going concern for a period of one year following the date that these financial statements were issued.

Regardless of our expectations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties or we could encounter difficulties obtaining clinical trial material that could increase our development costs more than we expect. In any event, we will require additional capital prior to completing clinical development, filing for regulatory approval, or commercializing any product candidates.

In September 2018, we entered into a Capital on Demand™ Sales Agreement, or the JonesTrading Agreement, as amended in February 2019, with JonesTrading Institutional Services LLC, or JonesTrading, pursuant to which we could sell from time to time, at our option, up to an aggregate of $11.6 million of shares of our common stock through JonesTrading, as sales agent, subject to limitations on the amount of securities we may sell under our effective registration statement on Form S-3 within any 12 month period. In October 2019, we entered into a Common Stock Purchase Agreement, or the 2019 Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which, upon the terms and subject to the conditions and limitations set forth in the 2019 Purchase Agreement, Aspire Capital committed to purchase up to an aggregate of $15.0 million of shares of our common stock at our request from time to time. As of the date of this report, we have sold approximately $5.3 million under the JonesTrading Agreement and we have sold $0.8 million under the 2019 Purchase Agreement with Aspire Capital. While the JonesTrading Agreement and 2019 Purchase Agreement provide us with additional options to raise capital through sales of our common stock, there can be no guarantee that we will be able to sell shares under either agreement in the future, or that any sales will generate sufficient proceeds to meet our capital requirements. In particular, JonesTrading is under no obligation to sell any shares of our common stock that we may request to be sold under the JonesTrading Agreement from time to time, and while Aspire Capital is obligated to purchase shares of our common stock under the 2019 Purchase Agreement, the obligation is subject to our satisfaction of various conditions which we may not be able to meet in the future. If sales are made under either the JonesTrading Agreement or the 2019 Purchase Agreement, our existing stockholders may experience dilution and such sales, or the perception that such sales are or will be occurring, may cause the trading price of our common stock to decline.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of product candidates or otherwise significantly curtail, or cease, operations. If we are unable to pursue or are forced to delay our planned drug development efforts due to lack of financing, it would have a material adverse effect on our business, operating results and prospects.

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

We may seek additional capital through a variety of means, including through equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to product candidates, or grant licenses on terms that are not favorable to us.

Our loan and security agreement with Silicon Valley Bank, or SVB, contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.

On May 3, 2018, we entered into an amended loan and security agreement with SVB to borrow $7.0 million, all of which was used to refinance amounts outstanding under prior credit facilities with SVB. The agreement, as amended, contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- convey, sell, lease or otherwise dispose of certain parts of our business or property;
- change the nature of our business;
- liquidate or dissolve;
- enter into certain change in control or acquisition transactions;
- incur or assume certain debt;

- grant certain types of liens on our assets;
- maintain certain collateral accounts;
- pay dividends or make certain distributions to our stockholders;
- make certain investments;
- enter into material transactions with affiliates;
- make or permit certain payments on subordinate debt; and
- become an "investment company" as defined under the Investment Company Act of 1940, as amended.

The restrictive covenants of the agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include negative results in clinical trials, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the agreement occurs. In the case of a continuing event of default under the agreement, SVB could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted SVB a security interest under the agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the agreement are secured by all of our existing and future assets, excluding intellectual property, which is subject to a negative pledge arrangement.

Risks Related to Clinical Development and Regulatory Approval of Product Candidates

If the response rate of envafolimab as a single agent or in combination with ipilimumab in UPS is not significantly higher than existing therapies, our strategy of basing the initial accelerated approval of envafolimab on overall response rate as the primary endpoint could delay or prevent the approval of envafolimab in UPS.

Envafolimab will be initially developed in refractory UPS, where the PD-(L)1 inhibitors given as single agents or in combination with ipilimumab demonstrated response rates which were significantly higher than the response rate demonstrated by the approved treatment Votrient or chemotherapy in UPS. We believe that the response rate of envafolimab as a single agent or in combination with ipilimumab has the potential to exceed that of other PD-(L)1 inhibitors given as single agents and when combined with ipilimumab. However, if the response rate of envafolimab as a single agent or in combination with ipilimumab in UPS is not significantly higher than Votrient or other chemotherapy, our strategy of basing the initial accelerated approval of envafolimab on overall response rate as the primary endpoint will be unlikely to succeed, which could delay or prevent the approval of envafolimab in UPS.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.

Clinical development 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. For example, we announced in April 2019 that the Phase 3 TAPPAS trial evaluating carotuximab in combination with Votrient (pazopanib) in patients with advanced or metastatic angiosarcoma was terminated for futility based on the recommendation of the Independent Data Monitoring Committee following its review of interim unblinded safety and efficacy data from more than 120 patients enrolled in the trial at the time of the analysis. Given these data, we terminated further enrollment in trials of carotuximab in oncology. It is possible that the failure of carotuximab to show efficacy in late-stage oncology clinical trials makes it less likely that it will be effective in wet AMD due to the same mechanism of action and strategy to combine it with VEGF inhibitors. In addition, favorable results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of subsequent clinical trials.

Even if product candidates demonstrate favorable results in ongoing or planned Phase 1 and 2 clinical trials, many product candidates fail to show desired safety and efficacy traits in late-stage clinical trials despite having progressed through earlier trials. In addition to the potential lack of safety or efficacy of product candidates, clinical trial failures may result from a multitude of factors including flaws in trial design, manufacture of clinical trial material, dose selection and patient enrollment criteria, or differences in determination of progression events by investigators compared to central radiographic reviewers. With respect to envafolimab, while results of trials conducted by others outside of the United States have been promising, they may not be predictive of results in U.S. trials due to differences in study design, target indications, patient populations, availability of alternative treatments and other factors. 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. Based upon negative or inconclusive results, we or our partners may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data

obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our stock price would be materially and adversely affected.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of product candidates. Our ongoing and planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- adverse findings in toxicology studies, including chronic toxicology studies;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in enrollment caused by the availability of alternative treatments;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays in our ability to acquire sufficient supply of clinical trial materials.

If initiation or completion of our ongoing or planned clinical trials are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize product candidates could be materially harmed, which could have a material adverse effect on our business. For example, we had experienced slower than anticipated enrollment in our ongoing Phase 2 clinical trial of TRC253 resulting from a lower than expected frequency of a specific tumor mutation targeted by TRC253 among metastatic prostate cancer patients.

Our product candidates or those of our partners may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events, or AEs, caused by product candidates or other potentially harmful characteristics of product candidates could cause us, our partners, including the National Cancer Institute, or NCI, or other third party clinical trial sponsors, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval.

Phase 1 or Phase 2 clinical trials of TRC102 conducted to date have generated AEs related to the study drug, some of which have been serious. The most common AE identified in our clinical trials of TRC102 has been anemia. TRC253 is currently being tested in a Phase 2 clinical trial and the most common AE identified has been QTcF prolongation. It is possible that the AE profile in our Phase 2 study of TRC253 could preclude further development or cause Janssen to not exercise its option to regain rights to the program. There can be no assurance that adverse events associated with product candidates will not be observed. As is typical in drug development, we have a program of ongoing toxicology studies in animals for clinical stage product candidates and cannot provide assurance that the findings from such studies or any ongoing or future clinical trials will not adversely affect our clinical development activities.

Further, if any approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for product candidates, our business will be substantially harmed.

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. For example, we cannot guarantee that for certain oncology indications where the FDA has traditionally granted approval to therapies that can demonstrate progression-free survival, the agency will not later require us to demonstrate overall survival, which would greatly extend the time and increase the capital required to complete clinical development. 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.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of product candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, or a New Drug Application, or NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- 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; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

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

In addition, even if we were to obtain approval, regulatory authorities may approve any 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 harm the commercial prospects for our product candidates or those of our partners.

We are also targeting specific patient populations with TRC253 and if we continue development beyond the current Phase 2 clinical trial we expect to continue to develop companion diagnostic tests in prostate cancer to improve selection of patients that would respond to treatment. If we are unable to establish a companion diagnostic for TRC253, our ability to successfully identify target patient populations for future clinical development may be limited. In addition, as the actual patient population with the specific genetic mutation targeted by TRC253 is lower than originally expected, the commercial opportunity for TRC253 may be limited.

We have not previously submitted a marketing application, or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any product candidates will be successful in clinical trials or receive regulatory approval. Further, product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

We may not receive Fast Track designation for additional product candidates from the FDA, or Fast Track designation may not actually lead to a faster development or regulatory review or approval process.

Fast track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for the disease or condition. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA will grant it. The FDA may also withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may be unsuccessful in our efforts to obtain orphan drug designations from the FDA for product candidates or may not ultimately realize the potential benefits of orphan drug designation.

We intend to seek orphan drug designation for envafolimab for the treatment of UPS and may seek orphan drug designations for other product candidates and indications. The FDA grants orphan designation to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Orphan drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and may be eligible for a market exclusivity period of seven years. We cannot guarantee that we will be able to receive orphan drug status from the FDA for any product candidates or indications. If we are unable to secure orphan drug designation for product candidates or indications, our regulatory and commercial prospects may be negatively impacted.

Despite orphan drug exclusivity, the FDA can still approve another drug containing the same active ingredient and used for the same orphan indication if it determines that a subsequent drug is safer, more effective or makes a major contribution to patient care, and orphan exclusivity can be lost if the orphan drug manufacturer is unable to assure that a sufficient quantity of the orphan drug is available to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs for the same or similar indication containing a different active ingredient. If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering our eligible product candidates, we could be subject to generic competition earlier than we anticipate. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as any product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity.

Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as studies or trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it

can be approved for sale in that jurisdiction. In some cases, the price that we would intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates or those of our partners will be harmed.

Even if we receive regulatory approval of product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with product candidates.

Any product candidates for which we receive regulatory approvals will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, in order to approve product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing, as well as continued compliance with regulatory requirements for current good manufacturing practices, or cGMPs, and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Although physicians, in the practice of medicine, may prescribe an approved drug for unapproved indications, pharmaceutical companies are prohibited from promoting uses that are not approved by the FDA as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses of approved pharmaceutical products, and a company that is found to have improperly promoted off-label may be subject to significant liability. Later discovery of previously unknown problems with product candidates, including adverse events of unanticipated severity or frequency, or with our third party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of existing approvals;
- product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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.

Risks Related to Our Reliance on Third Parties

We and our partners rely on third party manufacturers to make product candidates, and any failure by a third party manufacturer may delay or impair our ability to complete clinical trials or commercialize our product candidates.

Manufacturing drugs and biologics is complicated and is tightly regulated by regulatory authorities, including the FDA and foreign equivalents. We currently rely on third party manufacturers to supply us with drug substance for preclinical and clinical trials. Moreover, the market for contract manufacturing services for drug products, including small molecules such as TRC253, is highly cyclical, with periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide tight capacity, we may not be able to access the required capacity on a timely basis or on commercially viable terms, which could result in delays in initiating or completing clinical trials or our ability to apply for or receive regulatory approvals.

We rely on other third parties for drug substance and to perform additional steps in the manufacturing process, including filling into vials, shipping and storage. For our clinical stage pipeline programs, there can be no guarantee that lack of clinical supplies will not force us or our partners to delay or terminate any ongoing or planned clinical trials. For example, DE-122 had been supplied to us from Lonza, which we then provided to Santen under our collaboration. In April 2019, we exercised our right to terminate the supply and manufacturing agreement with Lonza following our decision to stop further development of TRC105 in oncology, and cannot be certain that Santen will be able to procure additional supplies of DE-122 from Lonza or any other third party.

We also expect to continue to rely on third party manufacturers for any drug required for commercial supply and do not intend to build our own manufacturing capability. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is costly, time consuming and subject to potential difficulties and delays.

We do not have any long-term supply agreements for the manufacture of product candidates and cannot guarantee that any third party manufacturer would be willing to continue supplying drug product for clinical trials or commercial sale at a reasonable cost or at all. In addition, manufacturing agreements are often subject to early termination by the third party manufacturer under certain circumstances.

The facilities used by our current or future third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA or an NDA to the FDA. While we work closely with our third party manufacturers on the manufacturing process for product candidates, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our third party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both drug substances and finished drug products. If our third party manufacturers or those of our collaborators cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we may experience delays in initiating planned clinical trials and we may not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third party 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 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 commercialize product candidates.

We depend in part on NCI and other third party sponsors to advance clinical development of TRC102.

NCI is currently sponsoring and funding multiple clinical trials involving TRC102. In addition, Case Western has sponsored and funded two separate clinical trials involving TRC102. The advancement of TRC102 depends in part on the continued sponsorship and funding of clinical trials by these organizations, as our resources and capital would not be sufficient to conduct these trials on our own. None of these third party sponsors are obligated to continue sponsorship or funding of any clinical trials involving our product candidates and could stop their support at any time. If these third party sponsors ceased their support for our product candidates, our ability to advance clinical development of product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued.

Even if these third party sponsors continue to sponsor and fund clinical trials of our product candidates, our reliance on their support subjects us to numerous risks. For example, we have limited control over the design, execution or timing of their clinical trials and limited visibility into their day-to-day activities, including with respect to how they are providing and administering our product candidates. If a clinical trial sponsored by a third party has a failure due to poor design of the trial, errors in the way the clinical trial is executed or for any other reason, or if the sponsor fails to comply with applicable regulatory requirements or if there are errors in the reported data, it could represent a major set-back for the development and approval of our product candidates, even if we were not directly involved in the trial and even if the clinical trial failure was not related to the underlying safety or efficacy of the product candidate. In addition, these third party sponsors could decide to de-prioritize clinical development of our product candidates in relation to other projects, which could adversely affect the timing of further clinical development. We are also subject to various confidentiality obligations with respect to the clinical trials sponsored by third party sponsors, which could prevent us from disclosing current information about the progress or results from these trials until the applicable sponsor publicly discloses such information or permits us to do so. This may make it more difficult to evaluate our business and prospects at any given point in time and could also impair our ability to raise capital on our desired timelines.

We are dependent on 3D Medicines and Alphamab with respect to certain aspects of our development of envafolimab for soft tissue sarcoma in North America. The failure to maintain the collaboration and clinical trial agreement, the failure of 3D Medicines or Alphamab to perform their obligations under the agreement, or the actions of 3D Medicines or Alphamab or their other partners with respect to envafolimab in other indications or outside North America could negatively impact our business.

Pursuant to the terms of our collaboration and clinical trial agreement with 3D Medicines and Alphamab, we were granted an exclusive license to develop and commercialize envafolimab for soft tissue sarcoma in North America. While we are generally

responsible for clinical development, 3D Medicines and Alphamab are responsible for certain critical activities, including the manufacture and supply of envafolimab, CMC activities and prosecution and enforcement of intellectual property rights. We have limited control over the amount and timing of resources that 3D Medicines and Alphamab will dedicate to their respective efforts, and their failure to perform their obligations would impair our ability to develop envafolimab for soft tissue sarcoma in North America. In addition, we very limited influence or control over 3D Medicines' or Alphamab's (or their respective other partners') activities with respect to the development and commercialization of evnafolimab in indications outside of soft tissue sarcoma or outside of North America, even though these activities could have a significant impact on the development and commercialization of envafolimab for soft tissue sarcoma in North America. For example, adverse events in clinical trials outside of the United States could cause the FDA to put clinical trials of envafolimab in the United States on hold, and negative results of clinical trials of envafolimab in other indications may cast doubt as to the likelihood of positive results of clinical trials in UPS or other soft tissue sarcoma indications.

We are subject to a number of other risks associated with our collaboration and clinical trial agreement with 3D Medicines and Alphamab, including:

- we and 3D Medicines and Alphamab could disagree as to future development plans which could delay initiation of clinical trials or stop a future clinical trial;
- there may be disputes between us and 3D Medicines and Alphamab, including disagreements regarding the terms of the collaboration and clinical trial agreement, that may result in the delay of or failure to achieve development, regulatory and commercial objectives and/or costly litigation or arbitration that diverts our management's attention and resources;
- 3D Medicines and Alphamab may not provide us with timely and accurate information regarding development progress and activities outside of soft tissue sarcoma and North America, which could adversely impact our ability to report progress to our investors and may cause us to make ill-informed decisions with respect to our own development efforts; and
- 3D Medicines and Alphamab may not properly maintain or defend the intellectual property rights licensed to us in North America or may undertake activities that invite litigation that could jeopardize or invalidate the intellectual property rights licensed to us or expose us to potential litigation.

If we have disagreements with 3D Medicines or Alphamab, if they do not perform their obligations under the collaboration and clinical trial agreement or there are negative events with respect to envafolimab outside of soft tissue sarcoma or North America, there could be material adverse consequences to our ability to successfully develop and commercialize envafolimab in soft tissue sarcoma in North America or to the value of envafolimab to us.

We are dependent on our license agreement with Santen to develop and commercialize our endoglin antibodies, including DE-122, in the field of ophthalmology and may enter into additional license agreements with third parties. The failure to maintain our license agreements or the failure of our licensees to perform their obligations under the agreements, could negatively impact our business.

Pursuant to the terms of our license agreement with Santen, we granted Santen an exclusive, worldwide license to certain patents, information and know-how related to our endoglin antibodies, including carotuximab, which is referred to by Santen as DE-122, for development and commercialization in ophthalmology indications, excluding systemic treatment of ocular tumors. Consequently, our ability to realize value or generate any revenues from our endoglin antibodies in the field of ophthalmology depends on Santen's willingness and ability to develop and obtain regulatory approvals for and successfully commercialize product candidates using our technology for these indications. We have limited control over the amount and timing of resources that Santen or any other licensees will dedicate to their respective efforts. In particular, we will not be entitled to receive additional milestone or royalty payments from Santen absent further development and eventual commercialization of endoglin antibodies in ophthalmology indications.

We are subject to a number of other risks associated with our dependence on our license agreement with Santen and will be subject to similar risks with respect to any other license agreement, including:

- our licensees may not comply with applicable regulatory requirements with respect to developing or commercializing products under the license agreements, which could adversely impact development, regulatory approval and eventual commercialization of such products;
- we and our licensees could disagree as to future development plans and our licensees may delay initiation of clinical trials or stop a future clinical trial;
- there may be disputes between us and our licensees, including disagreements regarding the terms of the license agreement, that may result in the delay of or failure to achieve development, regulatory and commercial objectives that would result in milestone or royalty payments to us, the delay or termination of any future development or commercialization of licensed products using our technology, and/or costly litigation or arbitration that diverts our management's attention and resources;

- our licensees may not provide us with timely and accurate information regarding development progress and activities under the license agreement, which could adversely impact our ability to report progress to our investors;
- our licensees may fail to meet expected timelines, which could result in the delay of or failure to achieve development, regulatory and commercial objectives;
- business combinations or significant changes in a licensee's business strategy may adversely affect the licensee's ability or willingness to perform its obligations under the applicable license agreement;
- our license partners and potential license partners may not properly maintain or defend our intellectual property rights in their licensed fields or territories or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation; and
- the royalties we are eligible to receive from Santen or other licensees may be reduced or eliminated based upon their and our ability to maintain or defend our intellectual property rights.

The license agreement with Santen is subject to early termination, including through Santen's right to terminate without cause upon advance notice to us. If our license agreements are terminated early, we may not be able to find another collaborator for the commercialization and further development of our product candidates, on acceptable terms, or at all, and we may otherwise be unable to pursue continued development on our own in the applicable territories or indications.

To the extent we enter into additional agreements for the development and commercialization of our product candidates we would likely be similarly dependent on the performance of those third parties and subject to similar risks. For example, if Janssen exercises its option to reacquire rights to TRC253, we would be entitled to receive a pre-negotiated, up-front fee from Janssen, but we would be dependent on Janssen to further develop the program in order to receive any further value in the form of milestone payments or royalties.

Our ability to realize value from any product candidates developed under our agreements with I-Mab will depend in part on I-Mab's activities and willingness to fund future development.

Pursuant to the terms of our strategic collaboration and clinical trial agreements with I-Mab, we are largely responsible for clinical development activities and I-Mab is responsible for pre-clinical development and manufacturing activities. Consequently, our ability to realize value or generate any revenues from the development of product candidates in collaboration with I-Mab will depend in part of I-Mab's willingness and ability to successfully complete pre-clinical development and manufacturing activities, in addition to funding agreed-upon portions of the costs of clinical development. We have limited control over the amount and timing of resources that I-Mab will dedicate to its respective efforts, and have limited rights in the event that I-Mab determines to cease development or manufacturing activities or funding for any product candidate under the collaboration. We could also encounter disagreements with I-Mab over the timing and scope of development or manufacturing of any product candidates under the collaboration or which, if any, bispecific antibody product candidates are selected for development.

We may not be successful in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize our existing product candidates or to leverage our clinical development capabilities.

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional licensing and collaboration agreements, including potentially with major biotechnology or pharmaceutical companies. In particular, we are actively seeking additional corporate partnerships in which we would share in the cost and risk of clinical development and commercialization of innovative product candidates of third parties. We face significant competition in seeking appropriate partners, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as having the requisite potential to demonstrate safety and efficacy and as being economically valuable in light of the terms that we are seeking and other available products for licensing by other companies. With respect to additional partnerships whereby we would develop third party product candidates, we will need to identify promising product candidates where the owner of the development and commercial rights could benefit from our clinical development capabilities. Due to our existing license agreement with Santen, we may find it more difficult to secure additional collaborations for our endoglin antibodies if major biotechnology or pharmaceutical companies would prefer to have exclusive control over development for all indications and in all territories. In addition, under our collaboration and clinical trial agreement with I-Mab for TJ004309, we are prohibited from developing other biologic product candidates targeting the same indications for which TJ004309 is being developed, which increases our reliance on the success of I-Mab's activities with respect to TJ004309 and could limit our ability to collaborate with others with respect to biologic product candidates in certain indications. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any inability or delay in entering into new collaboration agreements related to our product candidates, in particular in foreign countries where we do not have and do not intend to establish significant capabilities, could delay the development and commercialization of our product candidates

and reduce their market potential. If we are unable to enter into additional collaborations that leverage our clinical development capabilities, we may be forced to reduce these capabilities, which could lower the value of our company and make it less likely that third parties will seek to collaborate with us to develop their product candidates.

We rely on third parties to conduct preclinical studies and clinical trials of product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for product candidates.

We do not have our own capabilities to perform preclinical testing of product candidates, and therefore rely entirely on third party contractors and laboratories to conduct these studies for us. In addition, while we intend to continue designing, monitoring and managing our clinical trials of product candidates using our clinical operations and regulatory team, we still depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials at their sites under agreements with us. We will compete with many other companies for the resources of these third party contractors, laboratories, investigators and collaborators, and the initiation and completion of our preclinical studies and clinical trials may be delayed if we encounter difficulties in engaging these third parties or need to change service providers during a study or trial.

We control only certain aspects of the activities conducted for us by the third parties on which we currently rely and on which we will rely in the future for our preclinical studies and clinical trials. Nevertheless, we are responsible for ensuring that each of our clinical trials and certain of our preclinical studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. With respect to clinical trials, we and these third parties are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, 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, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with product candidates produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state health care laws, including, among others, fraud and abuse, false claims, privacy and security, and physician payment transparency laws. Any third parties conducting our preclinical studies and clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical development programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties 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 protocols or regulatory requirements or for other reasons, our preclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize product candidates. As a result, our financial results and the commercial prospects for our product candidates or those of our partners would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies which could do harm to our business and affect our ability to be profitable. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. Additionally, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Any disclosure or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market.

The patent position of biotechnology companies is generally uncertain because it involves complex legal and factual considerations in a legal framework that is constantly evolving. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. There is a substantial amount of prior art in the biotechnology and pharmaceutical fields, including scientific publications, patents and patent applications. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. Several patent applications covering our product candidates have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop. Since patent applications in the United States and most other countries 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 a product candidate.

For applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the claims of our applications and patents. As of March 16, 2013, the United States transitioned 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. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear, what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Furthermore, due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all our product candidates or methods involving these product candidates in the parent patent application.

In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords is limited. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. 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 generic and biosimilar products.

Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products.

As of December 31, 2019, we own ten (10) U.S. Patents, four (4) pending U.S. patent applications, fifty-two (52) issued non-U.S patents and twenty-two (22) pending non-U.S. patent applications relating to "Antifolate Agent Combinations in the Treatment Of Cancer," "Humanized Endoglin Antibodies," "Potentiation of Anti-Cancer Activity Through Combination Therapy with BER Pathway Inhibitors," "Antibody Formulations and Uses Thereof," and "Anti-Endoglin Antibodies and Uses Thereof".

We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.

As of December 31, 2019, we are the exclusive licensee of two (2) issued U.S. patents, two (2) pending U.S. patent applications, sixteen (16) issued non-U.S patents and two (2) pending non-U.S. patent applications relating to "Anti-Endoglin Monoclonal Antibodies and their use in Antiangiogenic Therapy," "Method For Increasing the Efficacy of Anti-Tumor Agents by Anti-Endoglin Antibody," and "Combination Therapy of Cancer with Anti-Endoglin Antibodies and Anti-VEGF Agents." We are also the exclusive licensee of two (2) issued U.S. patents, forty-three (43) issued non-U.S. patents, one (1) pending U.S. patent application, and thirty-nine (39) pending non-U.S. applications related to TRC253. Specific to the development of TJ004309 in North America, we hold a non-exclusive license from I-Mab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering any pharmaceutical composition or preparation comprising or containing TJ004309. Specific to the development of envafoloimab for the treatment of soft tissue sarcoma in North America, we hold an exclusive license from 3D Medicines and Alphamab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering envafoloimab. We also hold a non-exclusive license for the conduct of clinical trials in the European Union in support of the development of envafoloimab for the treatment of soft tissue sarcoma in North America.

As a licensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

Third party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination and review proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we and our partners are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product candidates or methods of use of our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use or manufacture of our product candidates.

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, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit

were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If any third party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we or our partner obtain a license. These licenses may not be available on acceptable terms, if at all. Even if we or our partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we or our partner could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our partner are unable to enter into licenses on acceptable terms.

Parties making claims against us or our partner may obtain injunctive or other equitable relief, which could effectively block our or our partner's ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Third parties may submit applications for patent term extensions in the United States and/or supplementary protection certificates in the European Union member states seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our products.

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patent of our licensors, which could be expensive and time consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. In addition, one or more of our third party collaborators may have submitted, or may in the future submit, a patent application to the USPTO without naming a lawful inventor that developed the subject matter in whole or in part while under an obligation to execute an assignment of rights to us. As a result, we may be required to file infringement or inventorship claims to stop third party infringement, unauthorized use, or to correct inventorship. This can be expensive, particularly for a company of our size, and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation or other proceedings brought at the USPTO or any foreign patent authority may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our trade secrets, confidential information or proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We have in-licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. Carotuximab is protected, in part, by patents exclusively in-licensed from Roswell Park Cancer Institute. TRC102 is protected, in part, by patents exclusively licensed from Case Western University. TRC253 and associated intellectual property have been licensed from Janssen Pharmaceutica NV, Envafolimab and associated intellectual property have been licensed from 3D Medicines and Alphamab, and TJ004309 and associated intellectual property have been licensed from I-Mab.

Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment or diligence obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partners' ability to utilize the affected intellectual property in our drug development efforts, and our ability to enter into collaboration or marketing agreements for a product candidate, may be adversely affected.

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

Filing, prosecuting and defending patents on 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, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. 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 a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our development processes that involve proprietary know-how or information that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business.

Risks Related to Commercialization of Product Candidates

Even if we obtain regulatory approval of product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors and others in the medical community.

Factors that will influence whether product candidates are accepted in the market include:

- the clinical indications for which product candidates are approved, if any;
- physicians, hospitals, cancer treatment centers and patients considering product candidates as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by governmental and commercial third party payors;
- the willingness of patients to pay out-of-pocket in the absence of coverage by governmental and commercial third party payors;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If, for any of these or other reasons, product candidates fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Off-label use of approved drugs could adversely impact a product candidate's peak sales, including Keytruda's off-label use in UPS if we are able to successfully commercialize envafolimab in the U.S.

While no PD-(L)1 treatments are currently approved in UPS or any other sarcoma subtype, Keytruda has a compendia listing in UPS and is reimbursed for off-label use in UPS. The off-label use of Keytruda in UPS may adversely affect the peak net sales of envafolimab in UPS and other sarcoma subtypes, if envafolimab is approved by the U.S. FDA and successfully commercialized in the U.S.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize product candidates.

We face competition both in the United States and internationally, including from major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. 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. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing product candidates against competitors.

Under the terms of our license agreement with Case Western, we obtained an exclusive, worldwide license to certain patents, know-how and other intellectual property controlled by Case Western related to TRC102. Despite our exclusive license, Case Western retained the right to grant non-exclusive licenses to third parties in the same field of use as our exclusive license as a means to settle any intellectual property disputes Case Western may have in the future with such third parties. While Case Western has not made us aware of any present intent to exercise this right, there can be no guarantee that Case Western will not do so in the future or that it would not grant such a non-exclusive license to a competitor of ours seeking to develop and commercialize a product that is identical to TRC102 in the same field of use that we are pursuing. If this were to occur, and we did not have other intellectual property outside of the Case Western license agreement to prevent competitive products for the same indications, we may face competition much earlier than we currently anticipate and the value of TRC102 may decline substantially.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from “biosimilars” due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar,” or “biosimilar,” to or “interchangeable” with an FDA-approved biological product. This pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. Future FDA standards or criteria for determining biosimilarity and interchangeability, and FDA discretion to determine the nature and extent of product characterization, non-clinical testing and clinical testing on a product-by-product basis, may further facilitate the approval of biosimilar products and their ability to compete with our product candidates or those of our partners. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Any such event or further changes in the law could decrease the period for which we have exclusivity and consequently negatively impact our business and competitive position. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and/or scope of patents relating to our competitors’ products. The availability of our competitors’ products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Coverage and reimbursement may be limited or unavailable in certain market segments for product candidates, which could make it difficult for us to sell product candidates profitably.

Successful sales of product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third party payors. In addition, because our product candidates and those of our partners represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from these product candidates.

Patients who are provided medical treatment for their conditions generally rely on third party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and other third party payors, such as commercial health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third party payor may depend upon a number of factors, including, but not limited to, the third party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Obtaining coverage and reimbursement approval of a product from a government or other third party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data to each payor separately for the use of our products, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of product candidates.

We intend to seek approval to market product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of product candidates will depend significantly on the availability of coverage and adequate reimbursement from third party payors for product candidates.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Third party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, was enacted in the United States. There remain judicial and Congressional challenges to certain aspects of the ACA. Since January 2017, the current U.S. President has signed two Executive Orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA. For example, the Tax Cuts and Jobs Act of 2017 (Tax Act) includes a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative changes to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2029 unless additional Congressional action is taken. In January 2013, the former U.S. President signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently there has been heightened governmental scrutiny over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent 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 products. At the federal level, the current U.S. President’s budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to

eliminate cost sharing for generic drugs for low-income patients. Further, the current U.S. President's administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services (HHS) solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the current U.S. President's administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain market acceptance in the medical community;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any product candidates are approved for commercialization, we expect that we or our partners will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- different payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If we or our partners outside of the Unites States are unable to successfully manage these risks associated with international operations, the market potential for our product candidates or those of our partners outside the Unites States will be limited and our results of operations may be harmed.

Risks Related to Our Business and Industry

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

We do not have internal new drug discovery capabilities or a technology platform with which to develop novel product candidates. Unless we develop or acquire these capabilities or a technology platform, our only means of expanding our product pipeline will be to acquire or in-license product candidates that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. In addition, part of our corporate strategy is to leverage our existing internal clinical development and regulatory capabilities by entering into collaborations where we conduct development activities related to third party product candidates in exchange for commercialization and payment rights, such as our collaboration with Janssen with respect to TRC253, our collaboration with 3D Medicines and Alphamab with respect to envafolimab, and our collaboration with I-Mab with respect to I-Mab's proprietary CD73 antibody, TJ004309, and potential bispecific antibody candidates. Identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources. Efforts to do so may not result in the actual development, acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. With respect to TRC253, Janssen has an option to reacquire the intellectual property rights to the program on pre-negotiated terms until a certain period of time following the completion of clinical proof of concept. If Janssen exercises this right, while we would be entitled to receive an up-front payment and would have the opportunity to receive future milestone and royalty payments from Janssen, we would have no further rights to develop, commercialize or realize value from TRC253. With respect to TJ004309, if I-Mab licenses rights to TJ004309 to a third party, while we would be entitled to receive varying portions of royalty and non-royalty payments from I-Mab, we would have no further rights to develop, commercialize or realize value from TJ004309. With respect to envafolimab, 3D Medicines and Alphamab retain certain rights to reacquire the rights for sarcoma in North America in connection with an arm's length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications. While we and 3D Medicines and Alphamab must negotiate in good faith and agree to fair compensation be paid to us for the value of and opportunity represented by the reacquired rights, we cannot guarantee that any compensation paid to us would adequately cover our investments in the program, the present value of the rights to us or our opportunity costs as a result of having advanced the program prior to reacquisition. Also, in the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace us as the party responsible for commercialization, and we do not co-market envafolimab for sarcoma in North America, then 3D Medicine and Alphamab will be required to compensate us for our costs associated with preparing for and conducting commercial activities. However, we may not be able to agree with 3D Medicines and Alphamab on adequate compensation and cannot guarantee that any agreed-upon compensation would adequately cover our investments in commercializing envafolimab in North America or our lost opportunity costs in pursuing commercialization. If we are unable to retain existing product candidates and add additional product candidates to our pipeline, we may not be able to execute on an important part of our business strategy and our long-term business and prospects will be limited.

If we fail to attract and keep senior management and key clinical operations and regulatory personnel, we may be unable to successfully develop product candidates and execute our business strategy.

We are highly dependent on members of our senior management, including Charles Theuer, M.D., Ph.D., our President and Chief Executive Officer. Our clinical development strategy and ability to directly manage or oversee our on-going and planned clinical trials are also dependent on the members of our clinical operations and regulatory team. The loss of the services of any of these persons could impede the development of product candidates and our ability to execute our business strategy. We may be particularly impacted by the unexpected loss of employees due to our small employee base and limited ability to quickly shift responsibilities to other employees in our organization. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining other qualified employees for our business, including scientific, quality assurance and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense, particularly in the San Diego, California area, and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our development and strategic objectives.

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

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate:

- FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;

- federal and state fraud and abuse laws and other healthcare laws;
- laws governing the conduct of business abroad; or
- laws that require the reporting of true and accurate financial information or data.

Additionally, these parties may fail to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. 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 misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, integrity oversight and reporting obligations, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with additional third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with partners, consultants, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management, including having to divert a disproportionate amount of its attention away from day-to-day operating activities to implement and manage future growth. Our future financial performance and our ability to commercialize product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

We are subject to extensive federal, state, and foreign regulation, and our failure to comply with these laws could harm our business.

Although we do not currently have any products on the market, we are subject to healthcare regulation and enforcement by the federal government and the states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the federal anti-kickback statute, which applies to our business activities, including our research, marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs;
- federal civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalty laws that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other governmental healthcare programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, imposes certain regulatory and contractual requirements on covered entities and their business associates that create, receive, maintain or transmit individually identifiable health information for or on their behalf regarding the privacy, security and transmission of individually identifiable health information;

- federal “sunshine” requirements imposed by the ACA on certain drug manufacturers regarding any transfers of value provided to physicians, as defined by such law, and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members; and
- state or foreign law equivalents of each of the above federal laws that may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information relating to drug and biologic pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

It is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened certain of these laws. For example, the ACA, among other things, amended the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

We are also subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and/or may in the future, be subject. For example, the collection and use of personal health data in the European Union is governed by the General Data Protection Regulation, or the GDPR. The GDPR, which is wide-ranging in scope, 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. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The GDPR requirements apply not only to third party transactions, but also to transfers of information within our company, including employee information. The GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third party vendors process, including in clinical trials conducted in the United States and European Union. In addition, 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 European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, significant administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, imprisonment, exclusion from governmental health care programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates or those of our partners. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;

- substantial monetary awards to patients or other claimants;
- the inability to commercialize product candidates; and
- decreased demand for product candidates, if approved for commercial sale.

We currently carry product liability insurance covering our clinical trials with limits we believe are customary for other companies in our field and stage of development. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If our third party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' 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 medical or hazardous materials. As a result of any such contamination or injury, we may incur liability, including through obligations to indemnify our third party manufacturers, 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. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our development and production efforts or those of our third party manufacturers, which could harm our business, prospects, financial condition or results of operations.

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

As of December 31, 2019, we had federal and California net operating loss carryforwards, or NOLs, of approximately $137.1 million and $117.7 million, respectively, which expire in various years beginning in 2030, if not utilized. Under the Tax Act, federal NOLs generated after 2017 may be carried forward indefinitely and be available to offset up to 80% of future taxable income each year. As of December 31, 2019, we had federal and California research and development and Orphan Drug tax credit carryforwards of approximately $10.0 million and $2.3 million, respectively. The federal research and development and Orphan Drug tax credit carryforwards expire in various years beginning in 2031, if not utilized. The California research and development credit will carry forward indefinitely under current law. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We believe we have experienced certain ownership changes in the past and have reduced our deferred tax assets related to NOLs and research and development tax credit carryforwards accordingly. In the event we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

We are dependent upon our own or third party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may make them vulnerable to service interruption or destruction, malicious intrusion, or random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our clinical trial data, intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Third party sites that take part in clinical trials we sponsor or third parties that are also sponsoring clinical trials involving our product

candidates or those of our partners, such as NCI and Case Western, face similar risks and any security breach of their systems could adversely affect us. A security breach or privacy violation that leads to disclosure or modification of, or prevents access to, patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to litigation or other liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Any of these events could be particularly harmful to our business due to our reliance on internal clinical development functions and systems to conduct our clinical trials. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our contractors, consultants and collaborators, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. For example, the ongoing coronavirus outbreak emanating from China at the beginning of 2020 has resulted in increased travel restrictions and the shutdown or delay of business activities in the region, including certain development activities of our collaborators in China. To the extent our collaborators are unable to comply with their obligations under our agreements with them or they are otherwise unable to complete or are delayed in completing development activities in China due to the coronavirus outbreak, our ability to advance development in the United States may become impaired. Travel restrictions and shutdowns in business operations in China as a result of the outbreak may also limit our ability to pursue our business development strategy with respect to China-based biopharmaceutical companies seeking U.S. drug development expertise. In addition, NCI may be affected by government shutdowns in the United States or withdrawn funding, which may lead to suspension or termination of ongoing NCI-sponsored clinical development of our product candidates. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. In addition, our ability and the ability of our partners to obtain clinical supplies of product candidates could be disrupted if the operations of our third party manufacturers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are located in San Diego, California near major earthquake faults and fire zones. The ultimate impact on us and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Risks Related to Our Common Stock

The market price of our common stock may be highly volatile, and our stockholders may not be able to resell their shares at a desired market price and could lose all or part of their investment.

Even though our common stock trades on the Nasdaq Capital Market, we cannot assure you that an active, liquid trading market for our shares will develop or persist. Our stockholders may not be able to sell their shares quickly or at a recently reported market price if trading in our common stock is not active. The trading price of our common stock has been, and is likely to continue to be, volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in clinical trials;
- inability to obtain additional funding;
- any delay in submitting a BLA or an NDA for any product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that marketing application;
- failure to successfully develop and commercialize product candidates;
- changes in laws or regulations applicable to product candidates;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;

- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future, in particular any sales by significant stockholders or our affiliates; and
- trading volume of our common stock.

In addition, the stock market in general, and the Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from the Nasdaq Capital Market, which could have an adverse impact on the liquidity and market price of our common stock.

Our common stock is currently listed on the Nasdaq Capital Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the Nasdaq listing requirements in the future, including, for example, if the closing bid price for our common stock falls below $1.00 per share for 30 consecutive trading days, or if we are unable to maintain at least $2.5 million in stockholders' equity, Nasdaq could determine to delist our common stock.

A delisting of our common stock could adversely affect the market liquidity of our common stock, decrease the market price of our common stock, adversely affect our ability to obtain financing for the continuation of our operations and result in the loss of confidence in our company.

In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Quarterly Report and our other periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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 have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Additionally, our credit agreement with SVB contains covenants that restrict our ability to pay dividends. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our principal executive offices are located at 4350 La Jolla Village Drive, Suite 800, San Diego, California 92122, in a facility we lease encompassing 10,458 square feet of office space. Our lease expires in April 2022 with an option for an additional five-year term.

Item 3. Legal Proceedings.

We are not currently a party to any legal proceedings. From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is listed on The Nasdaq Capital Market under the ticker symbol "TCON".

Holders of Common Stock

On January 31, 2020, there were approximately 121 holders of record of our common stock.

Dividend Policy

We have never declared or paid any dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. In addition, pursuant to our credit and security agreement with Silicon Valley Bank, we are prohibited from paying cash dividends without the prior consent of Silicon Valley Bank. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities.

None.

Item 6. Selected Financial Data.

The following selected financial data has been derived from our audited consolidated financial statements and should be read together with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this Annual Report. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year.

	Years Ended December 31,		
	2019	2018	2017
	(in thousands, except share and per share data)		
Statements of Operations Data:			
Collaboration revenue	$ —	$ 3,000	$ 8,755
Operating expenses:			
Research and development	14,530	30,460	19,355
General and administrative	7,766	7,280	7,610
Total operating expenses	22,296	37,740	26,965
Loss from operations	(22,296)	(34,740)	(18,210)
Other expense	(378)	(219)	(893)
Net loss	$ (22,674)	$ (34,959)	$ (19,103)
Net loss per share, basic and diluted	$ (7.47)	$ (12.97)	$ (11.37)
Weighted-average shares outstanding, basic and diluted	3,034,299	2,694,624	1,680,667

	As of December 31,	
	2019	2018
	(in thousands)	
Balance Sheets Data:		
Cash and cash equivalents	$ 16,412	$ 25,136
Short-term investments	—	13,968
Working capital	5,426	27,108
Total assets	18,121	40,648
Long-term debt, less current portion	2,739	5,343
Accumulated deficit	(162,334)	(139,660)
Total stockholders’ equity	2,698	21,442

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 "Selected Financial Data" and our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report. 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 and future financial performance, includes forward-looking statements that are based upon current beliefs, plans and expectations and involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause our actual results and the timing of selected events to differ materially from those described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also see the section within Part I of this Annual Report entitled "Forward-Looking Statements."

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration, or wet AMD, through our license to Santen Pharmaceutical Co. Ltd. (Santen), and utilizing our product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the United States.

In December 2019, we entered into a collaboration and clinical trial agreement (the Envafolimab Collaboration Agreement) with 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) for the development of envafolimab, also known as KN035, an investigational PD-L1 single-domain antibody (sdAb) administered by subcutaneous injection for the treatment of soft tissue sarcoma in North America. We intend to file an investigational new drug (IND) application and apply for orphan drug status in the first half of 2020, and initiate a registration-enabling study of envafolimab in the sarcoma subtype of undifferentiated pleomorphic sarcoma (UPS) and other select soft tissue sarcoma (STS) subtypes in the second half of 2020. Subject to input from the U.S. Food and Drug Administration (FDA), we expect that the trial will include one cohort of approximately 80 patients who will receive single agent treatment with envafolimab and a second cohort of approximately 80 patients who will receive envafolimab in combination with Yervoy® (ipilimumab), a checkpoint inhibitor marketed by Bristol-Meyers Squib (BMS), with the primary endpoint in each of the cohorts being overall response rate (ORR), which could be the basis for accelerated approval of envafolimab by the FDA as a single agent and/or in combination with Yervoy. We estimate disclosing a summary of the independent data monitoring committee decisions following reviews of interim data in 2021, having a final response assessment in early 2022, and, assuming positive data, submitting a biologics license application (BLA) for accelerated approval in early 2023. Additionally, assuming positive data from the initial UPS trial, we plan to initiate a randomized trial for multiple soft tissue sarcoma subtypes, which could include biomarker directed enrollment, to expand the target patient population.

We continue to support Santen's development of the ophthalmic formulation of carotuximab, called DE-122, for the treatment of wet AMD, the leading cause of blindness in the Western world. In March 2014, Santen licensed from us exclusive worldwide rights to develop and commercialize our endoglin antibodies for ophthalmology indications and in July 2017, Santen initiated dosing in the randomized Phase 2a AVANTE study of DE-122, which is a randomized controlled trial assessing the efficacy and safety of repeated intravitreal injections of DE-122 in combination with Lucentis® (ranibizumab) compared to Lucentis single agent therapy in patients with wet AMD. Santen completed enrollment in the randomized Phase 2a AVANTE study in 2019 and we expect top-line data in the first half of 2020.

Other clinical stage oncology product candidates include TRC102, which is a small molecule that is in Phase 1 and Phase 2 clinical development for the treatment of mesothelioma, lung cancer and solid tumors, TRC253, which is a small molecule that is in a Phase 1/2 clinical trial for the treatment of metastatic castration-resistant prostate cancer, that we licensed from Janssen Pharmaceutica N.V. (Janssen) in September 2016, and TJ004309, which is a CD73 antibody in Phase 1 clinical development for the treatment of solid tumors, that we licensed from I-Mab Biopharma (I-Mab) in November 2018.

TRC102 is a small molecule in clinical development to reverse resistance to specific chemotherapeutics by inhibiting base excision repair, or BER. In initial clinical trials of more than 100 patients, TRC102 has shown good tolerability and promising anti-tumor activity in combination with alkylating and antimetabolite chemotherapy in the treatment of cancer patients. TRC102 began Phase 2 testing in mesothelioma in combination with the approved chemotherapeutic Alimta in 2015. TRC102 is also being studied in three Phase 1 clinical trials: in combination with Alimta and cisplatin in solid tumor patients, in combination with chemoradiation in lung cancer patients, and in combination with Temodar in ovarian, lung and colorectal cancer patients. All current TRC102 trials are sponsored and funded by the National Cancer Institute (NCI). We retain global rights to develop and commercialize TRC102 in all indications.

TRC253 is being developed for the treatment of men with prostate cancer and is a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR) and multiple AR mutant receptors containing point mutations that cause drug resistance

to currently approved treatments. In November 2019, following review of available Phase 2 data indicating a lower than expected initial response rate and prevalence of the F877L mutation, we agreed with Janssen that the more than 70 currently enrolled patients in the Phase 1/2 clinical trial of TRC253 are sufficient to determine the risk-benefit profile of the drug in three cohorts of metastatic castrate resistant prostate cancer patients: those with a F877L mutation, those with another undisclosed androgen receptor point mutation, and those with another basis for resistance to Xtandi or Erleada. We expect to provide Phase 2 proof of concept data to Janssen in the first half of 2020. Until 90 days after receiving Phase 2 proof of concept data, Janssen has an exclusive option to reacquire full rights to TRC253 for an upfront payment of $45.0 million to us, and obligations to make regulatory and commercialization milestone payments totaling up to $137.5 million upon achievement of specified events and a low single-digit royalty. If Janssen does not exercise its exclusive option to reacquire the program, we would then have the ability to retain worldwide development and commercialization rights, in which case we would be obligated to pay Janssen a total of up to $45.0 million in development and regulatory milestones upon achievement of specified events, in addition to a low single digit royalty.

TJ004309, also known as TJD5, is a novel humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to the immunosuppressive metabolite adenosine. We are developing TJ004309 in collaboration with I-Mab under a strategic collaboration and clinical trial agreement that we entered into in November 2018 (the TJ004309 Agreement). In July 2019, we began enrollment in a Phase 1 clinical trial to assess safety and preliminary efficacy of TJ004309 as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® in patients with advanced solid tumors. We also entered into a separate strategic collaboration and clinical trial agreement (the Bispecific Agreement) which allows for the development of up to five of I-Mab's proprietary bispecific antibody product candidates to be nominated within a five-year period for development and commercialization in North America, with the option to opt-in and acquire product rights outside of Greater China and Korea prior to completing the first pivotal clinical trial for any bispecific product candidate.

In April 2019, we announced the termination of enrollment in trials of carotuximab in oncology following the Independent Data Monitoring Committee (IDMC) recommendation that the Phase 3 TAPPAS trial be terminated for futility. We have terminated activities related to carotuximab development in oncology.

The following table summarizes key information regarding ongoing and planned development of clinical stage product candidates:

	Phase	Data Expected
Envafolimab (3D Medicines and Alphamab)		
Soft Tissue Sarcoma	Planned Pivotal	Final data - 2022
DE-122 (Santen)		
Wet AMD	Randomized Phase 2	2020
TRC253		
Prostate Cancer	Phase 2	2020
TJ004309 (I-Mab)		
Solid Tumors	Phase 1	2020
TRC102		
Mesothelioma	Phase 2	2020
Solid tumors	Phase 1	2020
Solid tumors and Lymphomas	Phase 1/2	2021
Lung Cancer	Phase 1	2020

We utilize a product development platform that emphasizes capital efficiency. Our experienced clinical operations, data management, quality assurance, product development and regulatory affairs groups manage significant aspects of our clinical trials with internal resources. We use these internal resources to minimize the costs associated with utilizing contract research organizations, or CROs, to conduct clinical trials. In our experience, this model has resulted in capital efficiencies and improved communication with clinical trial sites, which expedites patient enrollment and improves the quality of patient data as compared to a CRO-managed model. We have leveraged this platform in all of our sponsored clinical trials. We have also leveraged our product development platform to diversify our product pipeline without payment of upfront license fees through license agreements with 3D Medicines and Alphamab, I-Mab, and Janssen. We continue to evaluate ex-U.S. companies who would benefit from a rapid and capital-efficient U.S. drug development solution that includes U.S. and European Union (EU) clinical development expertise. We believe we will continue to be recognized as a preferred U.S. clinical development partner through a cost- and risk-sharing partnership structure which may include U.S. commercialization.

Since our inception in 2004, we have devoted substantially all of our resources to research and development efforts relating to our product candidates, including conducting clinical trials and developing manufacturing capabilities, in-licensing related intellectual property, providing general and administrative support for these operations, and protecting our intellectual property. To date, we have not generated any revenue from product sales and instead, have funded our operations from the sales of equity securities, payments received in connection with our collaboration agreements, and commercial bank debt under our credit facilities with Silicon Valley Bank (SVB). At December 31, 2019, we had cash and cash equivalents totaling $16.4 million.

We do not own or operate, nor do we expect to own or operate, facilitates for product manufacturing, storage, distribution or testing. We contract with third parties or our collaboration partners for the manufacture of our product candidates and we intend to continue to do so in the future.

We have incurred losses from operations in each year since our inception. Our net losses were $22.7 million and $35.0 million for the years ended December 31, 2019 and 2018, respectively. At December 31, 2019, we had an accumulated deficit of $162.3 million.

We expect to continue to incur significant expenses and operating losses for at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses to decrease slightly due to the termination of carotuximab development in oncology as we expect to initiate a registration enabling study of envafolimab in UPS and as we:

- continue to conduct clinical trials of product candidates;
- continue our research and development efforts;
- maintain, expand and protect our intellectual property portfolio; and
- seek regulatory approvals for product candidates that successfully complete clinical trials.

We do not expect to generate any revenues from product sales until we successfully complete development and obtain regulatory approval for one or more product candidates, which we expect will take a number of years. If we obtain regulatory approval for any product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to raise substantial additional capital. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts and the timing and nature of the regulatory approval process for product candidates. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Further, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and ability to develop product candidates.

Collaboration and License Agreements

Collaboration Agreement with 3D Medicines and Alphamab

In December 2019, we, 3D Medicines, and Alphamab entered into the Envafolimab Collaboration Agreement for the development of envafolimab, an investigational PD-L1 sdAb, or nanobody, administered by subcutaneous injection, for the treatment of soft tissue sarcoma in North America.

Pursuant to the Envafolimab Collaboration Agreement, we were granted an exclusive license to develop and commercialize envafolimab for the treatment of sarcoma in North America. We are responsible for conducting and will bear the costs of any Phase 1, Phase 2, Phase 3, or post-approval clinical trial in North America for envafolimab in the indications of refractory and first line treatment of soft tissue sarcoma. 3D Medicines and Alphamab are responsible for conducting and will bear the costs of investigational new drug (IND)-enabling studies (other than those specific to the sarcoma indication) and the preparation of chemical, manufacturing and controls (CMC) activities sections of an IND application for envafolimab. 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to us at pre-negotiated prices that vary based on clinical or commercial use. 3D Medicines and Alphamab retained the right to develop envafolimab in all territories outside of North America as well as within North America for all indications other than soft tissue sarcoma.

We will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue, unless (a) envafolimab is first approved in North America for an indication other than soft tissue sarcoma and launched in North America, or (b) envafolimab is first approved in North America for soft tissue sarcoma and subsequently approved in North America for an additional non-orphan indication and sold commercially by 3D Medicines and/or Alphamab, in which case 3D Medicines and Alphamab will be responsible for commercializing envafolimab for soft tissue sarcoma in North America, including booking of sales

revenue. If 3D Medicines and Alphamab become responsible for commercialization under the Envafolimab Collaboration Agreement, we have the option to co-market envafolimab for sarcoma in North America. In the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace us as the party responsible for commercialization, and we elect and 3D Medicines and Alphamab agree for us to not co-market envafolimab for sarcoma in North America, then 3D Medicines and Alphamab will be required to compensate us for our costs associated with preparing for and conducting commercial activities.

If we have the responsibility for commercialization under the Envafolimab Collaboration Agreement, we will owe 3D Medicines and Alphamab tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits. If 3D Medicines and Alphamab have responsibility for commercialization under the Envafolimab Collaboration Agreement, we will be entitled to (a) tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if we have elected to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if we have chosen to co-market envafolimab in sarcoma. Payment obligations under the Envafolimab Collaboration Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

3D Medicines and Alphamab retain the right to reacquire the rights to envafolimab for sarcoma in North America in connection with an arm's length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications, provided that the sale may not occur prior to completion of a pivotal trial of envafolimab in sarcoma without our written consent and the parties must negotiate in good faith and agree to fair compensation be paid to us for the value of and opportunity represented by the reacquired rights.

Each party agreed that during the term of the Envafolimab Collaboration Agreement, it would not develop or license from any third party a monospecific inhibitor to PD-L1 or PD-1.

The term of the Envafolimab Collaboration Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in North America or the expiration of all payment obligations. The Envafolimab Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab. In the event we elect, or a joint steering committee (JSC) determines, to cease further development or commercialization of envafolimab, or if we fail to use commercially reasonable efforts to develop (including progress in clinical trials) and commercialize envafolimab and do not cure such failure within a specified time period, then our rights and obligations under the Envafolimab Collaboration Agreement will revert to 3D Medicines and Alphamab.

Collaboration Agreements with I-Mab Biopharma

In November 2018, we entered into separate strategic collaboration and clinical trial agreements (the Collaboration Agreements) with I-Mab for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 (the TJ4309 Agreement) as well as up to five proprietary bispecific antibodies currently under development by I-Mab (the Bispecific Agreement).

In the TJ004309 Agreement, we are collaborating with I-Mab on developing TJ004309, also known as TJD5, and will bear the costs of filing an IND and for Phase 1 clinical trials, share costs equally for Phase 2 clinical trials, and we will bear 40% and I-Mab 60% of the costs for pivotal clinical trials. I-Mab will also be responsible for the cost of certain non-clinical activities and the supply of TJ004309 and any reference drugs used in the development activities.

In the event that I-Mab licenses rights to TJ004309 to a third party, we would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to territories outside of Greater China. In the event that I-Mab commercializes TJ004309, we would be entitled to receive a royalty on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the EU and Japan in the mid-single digits. The portions of certain third party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which we would be entitled escalate based on the phase of development and relevant clinical trial obligations we complete under the TJ004309 Agreement, ranging from a high-single digit to a mid-teen percentage of non-royalty consideration as well as a double digit percentage of royalty consideration.

The TJ004309 Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to TJ004309. I-Mab may also terminate the TJ004309 Agreement if we cause certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJ004309 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical trial, in which case we would be entitled to a minimum termination fee of $9.0 million, or following the completion of the first Phase 2 clinical trial, in which case we would be entitled to a pre-specified termination fee of $15.0 million and either a percentage of non-royalty consideration I-Mab may receive as part of a license to a third party or an additional payment if TJ004309 is approved for marketing outside Greater China before a third party license is executed, in addition to a double digit percentage of royalty consideration.

Pursuant to the Bispecific Agreement, we and I-Mab may mutually select through a JSC up to five of I-Mab's bispecific antibody product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, we will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical trials, and we will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical trials, in each case within North America. Subject to I-Mab's right to co-promote an approved product candidate, we will be responsible for commercializing any approved product candidates in North America, and we will share profits and losses equally with I-Mab in North America. We would also be entitled to receive tiered low single digit royalties on net sales of product candidates in the EU and Japan.

At any time prior to completing the first pivotal clinical study for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical trial costs for a product candidate or the JSC decides to cease development over our objections after initiating Phase 3 clinical trials, we will have an option to obtain an exclusive license to such product candidate in all territories except Greater China and Korea and any other territories in which I-Mab previously licensed rights to a third party subject to our right of first refusal for any licenses I-Mab may grant to third-parties.

If we exercise our licensing option, we would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, we would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time we obtained the exclusive license as follows: (i) if before IND-enabling studies and the preparation of the CMC activities of the collaborative product, we would owe I-Mab a one-time upfront payment of $10.0 million, development and regulatory based milestone payments totaling up to $90.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the mid-single digits on annual net sales; (ii) if after IND submission but before completion of a Phase 1a clinical trial of the collaborative product, we would owe I-Mab a one-time upfront payment of $25.0 million, development and regulatory based milestone payments totaling up to $125.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high single digits on annual net sales; (iii) if after completion of a Phase 1a clinical trial but before completion of a Phase 2 proof of concept clinical trial for the collaborative product, we would owe I-Mab a one-time upfront payment of $50.0 million, development and regulatory based milestone payments totaling up to $250.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the low double digits on annual net sales; and (iv) if after completion of a Phase 2 proof of concept clinical trial and before completion of a pivotal study for the collaborative product, we would owe I-Mab a one-time upfront payment of $80.0 million, development and regulatory based milestone payments totaling up to $420.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high-teens on annual net sales.

License Agreement with Janssen Pharmaceutica N.V.

In September 2016, we entered into a strategic licensing collaboration with Janssen for two novel oncology assets from Janssen's early oncology development portfolio. The agreement, as amended, grants us the right to develop TRC253 (formerly JNJ-63576253), a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR Mutant Program) and multiple AR mutant receptors which display drug resistance to approved treatments, which is intended for the treatment of men with prostate cancer.

Janssen maintains an option, which is exercisable until 90 days after we demonstrate clinical proof of concept with respect to the AR Mutant Program, to regain the rights to the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the AR Mutant Program. If Janssen exercises the option, Janssen will be obligated to pay us (i) a one-time option exercise fee of $45.0 million; (ii) regulatory and commercial based milestone payments totaling up to $137.5 million upon achievement of specified events; and (iii) royalties in the low single digits on annual net sales of AR Mutant Program products. If Janssen does not exercise the option, we would then have the right to retain worldwide development and commercialization rights to the AR Mutant Program, in which case, we would be obligated to pay to Janssen (x) development and regulatory based milestone payments totaling up to $45.0 million upon achievement of specified events, and (y) royalties in the low single digits based on annual net sales of AR Mutant Program products, subject to certain specified reductions.

License Agreement with Santen

In March 2014, we entered into a license agreement with Santen, under which we granted Santen an exclusive, worldwide license to certain patents, information and know-how related to carotuximab, or the Carotuximab Technology. Under the agreement, as amended, Santen is permitted to use, develop, manufacture and commercialize carotuximab products for ophthalmology indications, excluding systemic treatment of ocular tumors. Santen also has the right to grant sublicenses to affiliates and third party

collaborators, provided such sublicenses are consistent with the terms of our agreement. In the event Santen sublicenses any of its rights under the agreement relating to the Carotuximab Technology, Santen will be obligated to pay us a portion of any upfront and certain milestone payments received under such sublicense.

Santen has sole responsibility for funding, developing, seeking regulatory approval for and commercializing carotuximab products in the field of ophthalmology. In the event that Santen fails to meet certain commercial diligence obligations, we will have the option to co-promote carotuximab products in the field of ophthalmology in the United States with Santen. If we exercise this option, we will pay Santen a percentage of certain development expenses, and we will receive a percentage of profits from sales of the licensed products in the ophthalmology field in the United States, but will not also receive royalties on such sales.

In consideration of the rights granted to Santen under the agreement, we received a one-time upfront fee of $10.0 million. In addition, we are eligible to receive up to a total of $155.0 million in milestone payments upon the achievement of certain milestones, of which $20.0 million relates to the initiation of certain development activities, $52.5 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals and $82.5 million relates to commercialization activities and the achievement of specified levels of product sales. If carotuximab products are successfully commercialized in the field of ophthalmology, Santen will be required to pay us tiered royalties on net sales ranging from high single digits to low teens, depending on the volume of sales, subject to adjustments in certain circumstances. In addition, Santen will reimburse us for all royalties due by us under certain third party agreements with respect to the use, manufacture or commercialization of carotuximab products in the field of ophthalmology by Santen and its affiliates and sublicensees. Royalties will continue on a country-by-country basis through the later of the expiration of our patent rights applicable to the carotuximab products in a given country or 12 years after the first commercial sale of the first carotuximab product commercially launched in such country. As of December 31, 2019, $10.0 million of the development milestones have been achieved and received in accordance with the agreement.

Other License Agreements

As further described in the “Contractual Obligations and Commitments” section below, certain of our other license agreements have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones, and we may be required to make milestone payments and royalty payments in connection with the sale of products developed under these agreements. We do not currently have any significant ongoing annual payment obligations under these agreements.

Financial Operations Overview

Revenue

Our revenue to date has been derived from our March 2014 collaboration with Santen and our December 2017 collaboration with Ambrx. In February 2019, Ambrx notified us that it had elected to terminate the agreement, which became effective 90 days after the notice. The terms of these arrangements contain multiple promised goods and services. The license agreements provide for the receipt of multiple types of payments, including a non-refundable upfront payment, payment for various technical and regulatory support, payments for delivery of drug substance and drug product, reimbursement of certain development costs, milestone payments, and royalties on net product sales. In accordance with our revenue recognition policy, we have identified one performance obligation for all the promised goods or services under the agreements and recognized revenue for the fixed or determinable collaboration consideration on a straight-line basis over the estimated development period for the Santen license, and at a point in time for the Ambrx license.

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing of any future achievement of milestones, the timing of any additional collaboration agreements and recognition of associated upfront and milestone payments, such as from our license with Santen, whether and when Janssen reacquires rights to the AR Mutant Program, and the extent to which any of our products are approved and successfully commercialized by us or our partners. If we or our partners fail to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues, our results of operations and our financial position could be adversely affected.

Research and Development Expenses

Research and development expenses consist of costs associated with the preclinical and clinical development of product candidates. These costs consist primarily of:

- salaries and employee-related expenses, including stock-based compensation and benefits for personnel in research and development functions;
- costs incurred under clinical trial agreements with investigative sites;

- costs to acquire, develop and manufacture preclinical study and clinical trial materials;
- costs associated with conducting our preclinical, development and regulatory activities, including fees paid to third party professional consultants, service providers and our scientific advisory board;
- payments related to licensed products and technologies; and
- facilities, depreciation and other expenses, including allocated expenses for rent and maintenance of facilities.

Research and development costs, including third party costs reimbursed by Santen and I-Mab as part of such collaborations, are expensed as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received.

The following table summarizes our research and development expenses by product candidate for the periods indicated:

	Years Ended December 31,		
	2019	2018	2017
	(in thousands)		
Third-party research and development expenses:			
TRC105	$ 4,596	$ 18,732	$ 10,684
TRC253	3,752	3,573	1,494
TRC102	161	164	87
TRC694	115	1,401	355
TRC205	—	—	16
TJ004309	517	21	—
Envafolimab	4	—	—
Total third-party research and development expenses	9,145	23,891	12,636
Unallocated expenses	5,385	6,569	6,719
Total research and development expenses	$ 14,530	$ 30,460	$ 19,355

Unallocated expenses consist primarily of our internal personnel related and facility costs.

We expect our current level of research and development expenses to decrease slightly due to the termination of carotuximab development in oncology as we expect to initiate a registration enabling study of envafolimab in UPS.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

The costs of clinical trials to us may vary significantly based on factors such as:

- the extent to which costs for comparator drugs are borne by third parties;
- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;

- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate;
- the efficacy and safety profile of the product candidate; and
- the extent to which costs are borne by third parties such as NCI.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance and administration, corporate development and administrative support functions, including stock-based compensation expenses and benefits. Other significant general and administrative expenses include legal services, including those associated with obtaining and maintaining patents, insurance, occupancy costs, accounting services, and the cost of various consultants.

We anticipate that our general and administrative expenses will remain relatively constant in the near term.

Other Income (Expense)

Other income (expense) primarily consists of interest related to our loan agreement with SVB offset in part by interest income from our short-term investments and cash equivalents.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, as well as the reported revenues and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience and on various other factors that we believe to be 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. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies related to revenue recognition, expense accruals, and stock-based compensation are most critical to understanding and evaluating our reported financial results.

Revenue Recognition

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which supersedes all existing revenue recognition requirements, which we adopted January 1, 2018, using the modified retrospective approach. This new standard requires a company to recognize revenues when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. We did not identify any accounting changes that impacted the amount of historically reported retained earnings, therefore no adjustment to retained earnings was required upon adoption.

To date, substantially all of our revenue has been derived from our license agreements with Santen and Ambrx as described in Note 7 to the consolidated financial statements. The terms of these arrangements include payments to us for the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services we may provide through our contract manufacturers; and royalties on net sales of licensed products. In accordance with ASU 2014-09, 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 contract(s) with a customer; (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 or services transferred to the customer. Once a contract is determined to be within the scope of Accounting Standards Codification 606, Revenue from Contracts with Customers, at contract inception, we assess the goods or services promised within the contract to determine those that are performance obligations and assess whether each promised good 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.

As part of the accounting for these arrangements, we develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

Licenses of intellectual property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment 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 progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, we evaluate whether the achievement of the milestones is considered probable and estimate the amount to be included in the transaction price using the most likely amount method. Performance milestone payments represent a form of variable consideration. If it is probable that a significant revenue reversal would not occur, the associated milestone payment is included in the transaction price. Achievement of milestones that are not within our control or the licensee, such as regulatory approvals, are not considered probable until the approvals are achieved. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achieving such development milestones and any related constraint, and if necessary, adjust our estimate 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.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the outset of the arrangement.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our out-licensing arrangements.

We receive payments from our collaborators based on billing schedules established in each contract. Up-front payments and fees may require deferral of revenue recognition to a future period until we perform our obligations under the collaboration arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Clinical Trial Expense Accruals

As part of the process of preparing our financial statements, we are required to estimate expenses resulting from our obligations under contracts with vendors, contract research organizations, or CROs, and consultants and under clinical site agreements in

connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

Our objective is to reflect the appropriate trial expenses in our financial statements by recording those expenses in the period in which services are performed and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials. During the course of a clinical trial, we adjust the clinical expense recognition if actual results differ from our estimates. We make estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical accruals are dependent upon accurate reporting by CROs or other third-party vendors. Although we do not expect our estimates to differ materially from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period. For the three years in the period ended December 31, 2019, there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of employee stock option and award grants recognized as expense over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of actual forfeitures. We estimate the fair value of stock option grants using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of subjective assumptions, including the risk-free interest rate, the expected dividend yield of our common stock, the expected volatility of the price of our common stock and the expected term of the option. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our employee stock options granted for all periods presented.

The following table summarizes the stock-based compensation expense recognized in our consolidated financial statements:

	Years Ended December 31,		
	2019	2018	2017
	(in thousands)		
Research and development	$ 776	$ 1,462	$ 1,482
General and administrative	848	1,205	1,712
Total stock-based compensation expense	$ 1,624	$ 2,667	$ 3,194

As of December 31, 2019, the unrecognized stock-based compensation expense related to outstanding time-based stock options was $1.6 million and is expected to be recognized as expense over a weighted-average period of approximately 2.6 years.

Other Company Information

Net Operating Loss and Research and Development Tax Credit Carryforwards

At December 31, 2019, we had federal and California net operating loss, or NOL, carryforwards, of approximately $137.1 million and $117.7 million, respectively. The federal and California NOL carryforwards will begin expiring in 2030, unless previously utilized. The federal NOL generated after 2017 of $53.9 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year. At December 31, 2019, we had federal and California research and development and Orphan Drug credit carryforwards of approximately $10.0 million and $2.3 million, respectively. The federal research and development and Orphan Drug credit carryforwards will begin expiring in 2031, unless previously utilized. The California research and development credit carryforwards do not expire.

Pursuant to Sections 382 and 383 of the Internal Revenue Code (Code), our annual use of our NOL and research and development credit carryforwards may be limited in the event that a cumulative change in ownership of more than 50% occurs within a three-year period. We completed a Section 382/383 analysis regarding the limitation of our NOL and research and development credit carryforwards as of December 31, 2018 and did not identify a cumulative change in ownership of more than 50% within the proceeding three-year period. Future ownership changes, including changes during the year ended December 31, 2019, may limit our ability to utilize our remaining NOL and research and development tax credit carryforwards. As of December 31, 2019, we had a full valuation allowance against our deferred tax assets.

JOBS Act

On April 5, 2012, the Jumpstart our Business Startups Act of 2012 (JOBS Act) was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering (which is fiscal year 2020), (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Recently Adopted Accounting Standards

In February 2016, the FASB issued ASU 2016-02, Leases, which outlines a comprehensive lease accounting model and supersedes the then current lease guidance. The new accounting standard requires lessees to recognize lease liabilities and corresponding right-of-use (ROU) assets for all leases with lease terms of greater than twelve months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. We adopted ASU 2016-02 on January 1, 2019, using the modified retrospective method. Under this approach, financial information and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. We elected the "package of practical expedients" upon adoption, which permits it to not reassess under the new standard prior conclusions about lease identification, lease classification and initial direct costs. We did not elect the use of hindsight or the practical expedient pertaining to land easements, the latter of which not being applicable. Upon adoption, we (i) recognized a ROU asset and lease liability on our balance sheet for our corporate office operating lease and (ii) derecognized the deferred rent balance as of December 31, 2018 under the superseded lease guidance. The ROU asset has been recorded in other assets and the short-term and long-term lease liability has been recorded in accounts payable and accrued expenses and other long-term liabilities, respectively, within the consolidated balance sheet. There was no impact on retained earnings or other components of equity, nor was there any impact on the statement of operations, upon adoption.

In June 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, which expands the scope of Accounting Standards Codification 718, Compensation-Stock Compensation, to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. We adopted ASU 2018-07 on January 1, 2019, which did not have a material impact on our consolidated financial statements and notes thereto.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Years Ended December 31,		
	2019	2018	Change
	(in thousands)		
Collaboration revenue	$ -	$ 3,000	$ (3,000)
Research and development expenses	14,530	30,460	(15,930)
General and administrative expenses	7,766	7,280	486
Other expense	378	219	159

Collaboration revenue. Collaboration revenue was $0 and $3.0 million for the years ended December 31, 2019 and 2018, respectively. The decrease of $3.0 million was due to revenue recognized under the Ambrx license agreement in the year ended December 31, 2018 with no corresponding revenue in the comparable period in 2019.

Research and development expenses. Research and development expenses were $14.5 million and $30.5 million for the years ended December 31, 2019 and 2018, respectively. The decrease of $15.9 million was primarily due to lower drug manufacturing expenses and direct clinical trial expenses following the termination of further enrollment in company sponsored clinical trials of carotuximab.

General and administrative expenses. General and administrative expenses were $7.8 million and $7.3 million for the years ended December 31, 2019 and 2018, respectively.

Other expense, net. Other expense, net was $0.4 million and $0.2 million for the years ended December 31, 2019 and 2018, respectively.

Comparison of the Years Ended December 31, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017:

	Years Ended December 31,		
	2018	2017	Change
	(in thousands)		
Collaboration revenue	$ 3,000	$ 8,755	$ (5,755)
Research and development expenses	30,460	19,355	11,105
General and administrative expenses	7,280	7,610	(330)
Other expense	219	893	(674)

Collaboration revenue. Collaboration revenue was $3.0 million and $8.8 million for the years ended December 31, 2018 and 2017, respectively. The decrease of $5.8 million was due to the $3.0 million non-refundable upfront payment received in connection with the Ambrx agreement recorded as revenue in the year ended December 31, 2018, compared to $8.8 million recognized under the Santen license agreement in the year ended December 31, 2017.

Research and development expenses. Research and development expenses were $30.5 million and $19.4 million for the years ended December 31, 2018 and 2017, respectively. The increase of $11.1 million was primarily due to increased drug manufacturing expenses and direct clinical trial expenses for TRC105 and TRC253.

General and administrative expenses. General and administrative expenses were $7.3 million and $7.6 million for the years ended December 31, 2018 and 2017, respectively.

Other expense, net. Other expense, net was $0.2 million and $0.9 million for the years ended December 31, 2018 and 2017, respectively. The decrease in other expense was primarily due to additional interest income earned related to a higher short-term investments balances.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception. As of December 31, 2019, we had an accumulated deficit of $162.3 million, and we expect to continue to incur net losses for the foreseeable future. We expect our current level of research and development expenses to decrease slightly due to the termination of carotuximab development in oncology as we expect to initiate a registration enabling study of envafolimab in UPS. Given we do not anticipate any revenues from product sales in the foreseeable future, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third party funding, and licensing or collaboration arrangements.

On February 4, 2015, we completed our initial public offering and a concurrent private placement of our common stock, which resulted in net proceeds to us of approximately $35.0 million. In September 2016, we sold shares of our common stock in a private placement for net proceeds of approximately $5.0 million and in November 2016, we completed an underwritten public offering which resulted in net proceeds of approximately $16.1 million. In March 2017, we sold shares of our common stock to Aspire Capital for net proceeds of approximately $0.9 million, and throughout 2017, we sold shares through our previous At-the-market (ATM) facility with Stifel, Nicolaus & Company, Incorporated (Stifel) for net proceeds of approximately $3.4 million. In March and April 2018, we sold shares of our common stock and common warrants in a private placement for net proceeds of approximately $36.5 million. In December 2019 and January 2020, we sold shares of our common stock for gross proceeds of approximately $2.4 million and $2.9 million, respectively, through our Capital on Demand agreement with JonesTrading. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation. We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements into early 2021, presuming our payment

obligations under the 2018 Amended SVB Loan continue to follow the contractual maturity schedule. Based on our current business plan, we believe that there is substantial doubt as to whether our existing cash and cash equivalents will be sufficient to meet our obligations as they become due within one year from the date the financial statements are issued.

Credit Facility with SVB

In May 2018, we entered into a third amendment to our Amended and Restated Loan and Security Agreement with SVB (the 2018 Amended SVB Loan) under which we borrowed $7.0 million, all of which was used to refinance previously outstanding amounts under the loan and security agreement. In connection with the 2018 Amended SVB Loan, we issued warrants to purchase up to 5,363 shares of common stock at an exercise price of $26.10 per share. The warrants are fully exercisable and expire on May 3, 2025.

The 2018 Amended SVB Loan provides for interest to be paid at a rate of 9.0% per annum, with interest-only payments due monthly through June 30, 2019. Thereafter, in addition to interest accrued during such period, the monthly payments will include an amount equal to the outstanding principal at June 30, 2019 divided by 30 months. At maturity (or earlier prepayment), we are also required to make a final payment equal to 4.0% of the original principal amount of the amounts borrowed. The 2018 Amended SVB Loan provides for prepayment fees of 2.0% of the amount prepaid if the prepayment occurs after May 3, 2019 but prior to May 3, 2020 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The 2018 Amended SVB Loan is collateralized by substantially all of our assets, other than our intellectual property, and contains customary conditions of borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of our capital stock. Should an event of default occur, including the occurrence of a material adverse change, we could be required to immediately repay all obligations under the 2018 Amended SVB Loan. As of December 31, 2019, we were in compliance with all covenants and conditions of the 2018 Amended SVB Loan.

Private Placement of Common Shares and Warrants

In March 2018, we entered into a securities purchase agreement with new and certain existing investors for the purchase of $38.7 million of our common stock and warrants. We sold approximately 1.2 million shares of common stock at a purchase price of $27.00 per share, pre-funded warrants to purchase approximately 0.2 million shares of common stock at a purchase price of $26.90 per share and an exercise price of $0.10 per share, and warrants to purchase approximately 1.4 million shares of common stock at a purchase price of $1.25 per share and an exercise price of $27.00 per share. We received total gross proceeds of $38.7 million.

Common Stock Purchase Agreement with Aspire Capital

In October 2019, we entered into the 2019 Purchase Agreement with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations of the 2019 Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of our common stock at our request from time to time during the 30 month term of the 2019 Purchase Agreement and at prices based on the market price of our common stock at the time of each sale. In consideration for entering into the 2019 Purchase Agreement and concurrently with the execution of the 2019 Purchase Agreement, we issued to Aspire Capital 142,658 shares of our common stock. As of December 31, 2019, we had not sold any shares of common stock to Aspire Capital under the 2019 Purchase Agreement. As of the date of this report, we have sold 0.2 million shares of common stock under the 2019 Purchase Agreement with Aspire Capital for gross proceeds of $0.8 million.

In March 2017, we entered into a common stock purchase agreement (the 2017 Purchase Agreement) with Aspire Capital which provided that, upon the terms and subject to the conditions and limitations of the 2017 Purchase Agreement, Aspire Capital was committed to purchase up to an aggregate of $21.0 million of shares of common stock. Upon execution of the 2017 Purchase Agreement, we sold to Aspire Capital 22,222 shares of common stock at $45.00 per share for proceeds of $1.0 million and Aspire Capital was committed to purchase up to $20.0 million of additional shares of our common stock at our request from time to time during a 30 month period that began on May 1, 2017 and at prices based on the market price of our common stock at the time of each sale, subject to certain conditions. In consideration for entering into the 2017 Purchase Agreement and concurrently with the execution of the 2017 Purchase Agreement, we issued to Aspire Capital 19,573 shares of our common stock. As of December 31, 2019, we had issued 41,795 shares of common stock to Aspire Capital under the 2017 Purchase Agreement for net proceeds of approximately $0.9 million after offering expenses. Upon execution of the 2019 Purchase Agreement, the 2017 Purchase Agreement was terminated in its entirety and no further sales of our common stock will occur under the 2017 Purchase Agreement.

ATM Facility

In September 2018, as amended in February 2019, we entered into a Sales Agreement with JonesTrading pursuant to which we may sell from time to time, at our option, up to an aggregate of $11.6 million of shares of our common stock through JonesTrading, as sales agent, subject to limitations on the amount of securities we may sell under our effective registration statement on Form S-3 within any 12 month period. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made on the Nasdaq Capital Market under our effective registration statement on Form S-3, by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, we may also sell shares of our common stock through JonesTrading, on the Nasdaq Capital Market or otherwise, at negotiated prices or at prices related to the prevailing market price. JonesTrading will use its commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are required to pay JonesTrading 2.5% of gross proceeds from the common stock sold through the Sales Agreement. As of December 31, 2019, we had sold 0.9 million shares of common stock through the Sales Agreement with JonesTrading for gross proceeds of $2.4 million and $9.2 million of common stock remained available for sale under the Sales Agreement as of December 31, 2019. As of the date of this report, we have sold 2.1 million shares of common stock through the Sales Agreement with JonesTrading for gross proceeds of $5.3 million.

In September 2018, we terminated a similar at-the-market sales agreement we had entered into with Stifel. We had sold approximately 103,700 shares of common stock for aggregate proceeds of approximately $3.5 million under the Stifel agreement prior to it being terminated.

Cash Flows

The following table summarizes our net cash flow activity for each of the periods set forth below:

	Years Ended December 31,		
	2019	2018	2017
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ (23,650)	$ (30,783)	$ (13,243)
Investing activities	14,020	(8,869)	3,674
Financing activities	906	35,321	3,326
Decrease in cash and cash equivalents	$ (8,724)	$ (4,331)	$ (6,243)

Operating activities. Net cash used in operating activities was $23.7 million, $30.8 million, and $13.2 million for the years ended December 31, 2019, 2018 and 2017, respectively, and was primarily due to our net loss for the respective year, adjusted for noncash items and offset by changes in our working capital.

Investing activities. Net cash provided by investing activities was $14.0 million for the year ended December 31, 2019 and was due to maturities of short-term investments partially offset by purchases of these investments. Net cash used in investing activities was $8.9 million for the year ended December 31, 2018 and was related to purchases of short-term investments, partially offset by proceeds from investments. Net cash provided by investing activities was $3.7 million for the year ended December 31, 2017 and was related to proceeds from the maturities of short-term investments, offset by the purchases of investments.

Financing activities. Net cash provided by financing activities was $0.9 million for the year ended December 31, 2019 and primarily resulted from $2.3 million in net proceeds received from the issuance of common stock through our ATM facility with JonesTrading, offset by $1.4 million in net repayments on borrowings under our SVB loan agreement. Net cash provided by financing activities was $35.3 million for the year ended December 31, 2018 and primarily resulted from $36.5 million in net proceeds received from the issuance of common stock and warrants, offset by $1.3 million in net repayments on borrowings under our SVB loan agreement. Net cash provided by financing activities was $3.3 million for the year ended December 31, 2017 and resulted from net proceeds received totaling $4.1 million from sales of shares of common stock to Aspire Capital and through our ATM facility, partially offset by repayments of our loan under our credit facility with SVB.

Funding Requirements

At December 31, 2019, we had cash and cash equivalents totaling $16.4 million. We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements into early 2021, presuming our payment obligations under the 2018 Amended SVB Loan continue to follow the contractual maturity schedule. We will need additional funding to complete the development and commercialization of our product candidates or those of our partners. In addition, we may evaluate in-licensing and acquisition opportunities to gain access to new product candidates that fit with our strategy. Any such transaction will likely increase

our future funding requirements. These uncertainties raise substantial doubt about our ability to continue as a going concern for a period of one year following the date that the accompanying financial statements were issued.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- our ability to initiate, and the progress and results of, our planned clinical trials;
- the ability and willingness of our collaboration partners and licensees to continue clinical development of product candidates;
- our ability to enter into and maintain our collaborations, including our collaborations with 3D Medicines and Alphamab, Santen, Janssen, and I-Mab;
- our ability to achieve, and our obligations to make, milestone payments under our collaboration and license agreements;
- the costs and timing of procuring supplies of product candidates for clinical trials and regulatory submissions;
- the scope, progress, results and costs of preclinical development, and clinical trials of product candidates;
- whether and when Janssen reacquires the rights to the AR Mutant Program;
- the costs, timing and outcome of regulatory review of product candidates;
- the revenue, if any, received from commercial sales of product candidates for which we or any of our partners, including Santen or I-Mab, may receive marketing approval;
- 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;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidates for which we receive marketing approval and do not partner for commercialization; and
- the extent to which we acquire or in-license other products and technologies.

Until we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and licensing arrangements. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans or programs which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve our intended business objectives. Any of these actions could materially harm our business, results of operations and future prospects.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2019:

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
		(in thousands)			
Long-term debt obligations, including interest and final payment (1)	$ 6,413	$ 3,195	$ 3,218	$ —	$ —
Operating lease obligations (2)	1,059	442	617	—	—
Total	$ 7,472	$ 3,637	$ 3,835	$ —	$ —

(1) We will make principal and interest payments to SVB in accordance with the required payment schedule.
(2) Our operating lease obligations relate to our corporate headquarters in San Diego, California. We lease 10,458 square feet of office space under an operating lease that expires in April 2022.

Under each of our license agreements we may have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. We do not have any

significant ongoing annual payment obligations under these license agreements. As of December 31, 2019, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above. These commitments include the following:

- Under our license agreement with Health Research Inc. and Roswell Park Cancer Institute, referred to collectively as RPCI, we may be required to pay up to an aggregate of approximately $6.4 million upon the achievement of certain milestones for products utilizing a patent owned by us covering humanized endoglin antibodies, including TRC205, of which approximately $1.4 million relates to the initiation of certain development activities and $5.0 million relates to certain regulatory filings and approvals. Upon commercialization, we will be required to pay RPCI mid-single-digit royalties based on net sales of products utilizing the RPCI Technology in each calendar quarter, subject to adjustments in certain circumstances. In addition, we will be required to pay RPCI low single-digit royalties based on net sales in each calendar quarter of products utilizing our patent covering humanized endoglin antibodies. Our royalty obligations continue until the expiration of the last valid claim in a patent subject to the agreement, which we expect to occur in 2029, based on the patents currently subject to the agreement.
- Under our license agreement with Case Western, we may be required to pay up to an aggregate of approximately $9.8 million in milestone payments, of which $0.7 million relates to the initiation of certain development activities ($0.2 million of which has been paid) and approximately $9.1 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals. If products utilizing certain intellectual property licensed from Case Western, or the TRC102 Technology, are successfully commercialized, we will be required to pay Case Western a single-digit royalty on net sales, subject to adjustments in certain circumstances. Beginning on the earlier of a specified number of years from the effective date of the agreement and the anniversary of the effective date following the occurrence of a specified event, we will be required to make a minimum annual royalty payment of $75,000, which will be credited against our royalty obligations. In the event we sublicense any of our rights under the agreement relating to the TRC102 Technology, we will be obligated to pay Case Western a portion of certain fees we may receive under the sublicense. Our royalty obligations will continue on a country-by-country basis through the later of the expiration of the last valid claim under the TRC102 Technology or 14 years after the first commercial sale of a product utilizing the TRC102 Technology in a given country.
- Under our license agreement with Janssen for TRC253, as amended, we may be required to pay up to an aggregate of $45.0 million in milestone payments, of which $15.0 million relates to the initiation of certain development activities and $30.0 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals. If TRC253 is successfully commercialized, we will be required to pay Janssen a low single-digit royalty on net sales, subject to reductions in certain circumstances.

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturing organizations and with vendors for preclinical safety and research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the applicable rules of the Securities and Exchange Commission (SEC).

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

At December 31, 2019, our cash and cash equivalents consist of cash and money market funds. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes. Our long-term debt bears interest at a fixed rate.

Foreign Currency Exchange Risk

We incur expenses for patients enrolled in our clinical studies and for the manufacture of clinical trial materials outside the United States based on contractual obligations denominated in currencies other than the U.S. dollar, primarily Pounds Sterling and Euros. At the end of each reporting period, these liabilities are converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies. We do not enter into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. However, to date, these fluctuations have not been significant. Based on our purchase commitments for our 2019 fiscal year, a movement of 1% in the U.S. dollar to Pounds Sterling exchange rate would not have a material effect on our results of operations or financial condition.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations or financial condition during the periods presented.

Item 8. Financial Statement and Other Supplementary Information.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of
TRACON Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TRACON Pharmaceuticals, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2011.
San Diego, California
February 27, 2020

TRACON Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 16,412	$ 25,136
Short-term investments	-	13,968
Prepaid and other assets	848	1,499
Total current assets	17,260	40,603
Property and equipment, net	23	45
Other assets	838	—
Total assets	$ 18,121	$ 40,648
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,875	$ 10,947
Accrued compensation and related expenses	1,355	1,464
Long-term debt, current portion	2,604	1,084
Total current liabilities	11,834	13,495
Other long-term liabilities	850	368
Long-term debt, less current portion	2,739	5,343
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value, authorized shares — 10,000,000 at December 31, 2019 and December 31, 2018; issued and outstanding shares — none	—	—
Common stock, $0.001 par value; authorized shares — 20,000,000 at December 31, 2019 and December 31, 2018; issued and outstanding shares — 4,051,187 and 2,987,182 at December 31, 2019 and December 31, 2018, respectively	4	3
Additional paid-in capital	165,028	161,099
Accumulated deficit	(162,334)	(139,660)
Total stockholders' equity	2,698	21,442
Total liabilities and stockholders' equity	$ 18,121	$ 40,648

See accompanying notes.

TRACON Pharmaceuticals, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Years Ended December 31,		
	2019	2018	2017
Collaboration revenue	$ —	$ 3,000	$ 8,755
Operating expenses:			
Research and development	14,530	30,460	19,355
General and administrative	7,766	7,280	7,610
Total operating expenses	22,296	37,740	26,965
Loss from operations	(22,296)	(34,740)	(18,210)
Other income (expense):			
Interest expense, net	(386)	(231)	(886)
Other income (expense), net	8	12	(7)
Total other income (expense)	(378)	(219)	(893)
Net loss	$ (22,674)	$ (34,959)	$ (19,103)
Net loss per share, basic and diluted	$ (7.47)	$ (12.97)	$ (11.37)
Weighted-average shares outstanding, basic and diluted	3,034,299	2,694,624	1,680,667

See accompanying notes.

TRACON Pharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2016	1,608,515	$ 2	$ 113,932	$ (85,598)	$ 28,336
Issuance of common stock under equity plans	17,218	—	35	—	35
Stock-based compensation expense	—	—	3,194	—	3,194
Vested shares related to repurchase liability	—	—	14	—	14
Issuances of common stock, net of offering costs	145,509	—	4,308	—	4,308
Issuance of common stock in exchange for services	—	—	29	—	29
Issuance of common stock warrants in connection with debt financing	—	—	174	—	174
Net loss	—	—	—	(19,103)	(19,103)
Balance at December 31, 2017	1,771,242	2	121,686	(104,701)	16,987
Issuance of common stock under equity plans	22,881	—	185	—	185
Stock-based compensation expense	—	—	2,667	—	2,667
Vested shares related to repurchase liability	—	—	8	—	8
Issuances of common stock and warrants, net of offering costs	1,193,059	1	36,455	—	36,456
Issuance of common stock warrants in connection with debt financing	—	—	98	—	98
Net loss	—	—	—	(34,959)	(34,959)
Balance at December 31, 2018	2,987,182	3	161,099	(139,660)	21,442
Issuance of common stock under equity plans	9,270	—	12	—	12
Stock-based compensation expense	—	—	1,624	—	1,624
Issuances of common stock, net of offering costs	1,054,735	1	2,293	—	2,294
Net loss	—	—	—	(22,674)	(22,674)
Balance at December 31, 2019	4,051,187	$ 4	$ 165,028	$ (162,334)	$ 2,698

See accompanying notes.

TRACON Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2019	**2018**	**2017**
Cash flows from operating activities			
Net loss	$ (22,674)	$ (34,959)	$ (19,103)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,624	2,667	3,194
Common stock issued for services	—	—	29
Depreciation and amortization	22	28	48
Noncash interest	234	272	354
Amortization of debt discount	81	94	117
Amortization of premium/discount on short-term investments	(52)	(100)	(9)
Lease asset amortization and liability accretion, net	(6)	—	—
Deferred rent	—	11	60
Deferred revenue	—	(3,000)	1,741
Changes in assets and liabilities:			
Prepaid expenses and other assets	651	92	(356)
Accounts payable and accrued expenses	(3,421)	4,142	776
Accrued compensation and related expenses	(109)	(30)	(94)
Net cash used in operating activities	(23,650)	(30,783)	(13,243)
Cash flows from investing activities			
Purchase of property and equipment	—	—	(39)
Purchases of available-for-sale short-term investments	(4,980)	(32,869)	(13,992)
Proceeds from the maturity of available-for-sale short-term investments	19,000	24,000	17,705
Net cash provided by (used in) investing activities	14,020	(8,869)	3,674
Cash flows from financing activities			
Proceeds from long-term debt	—	7,000	8,000
Repayment of long-term debt	(1,400)	(8,320)	(8,850)
Proceeds from sale of common stock and warrants, net of offering costs	2,294	36,456	4,141
Proceeds from issuance of common stock under equity plans	32	263	172
Payment of tax withholdings related to net share settlements of vested restricted stock awards	(20)	(78)	(137)
Net cash provided by financing activities	906	35,321	3,326
Decrease in cash and cash equivalents	(8,724)	(4,331)	(6,243)
Cash and cash equivalents at beginning of period	25,136	29,467	35,710
Cash and cash equivalents at end of period	$ 16,412	$ 25,136	$ 29,467
Supplemental disclosure of cash flow information			
Interest paid	$ 612	$ 642	$ 664
Supplemental schedule of noncash investing and financing activities			
Issuance of common stock warrants in connection with long-term debt	$ —	$ 98	$ 174
Issuance of common stock in connection with common stock purchase agreement	$ 450	$ —	$ 793

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Organization and Business

TRACON Pharmaceuticals, Inc. (formerly Lexington Pharmaceuticals, Inc.) (TRACON or the Company) was incorporated in the state of Delaware on October 28, 2004. TRACON is a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer and, through its license to Santen Pharmaceutical Co. Ltd. (Santen), wet age-related macular degeneration, or wet AMD. The Company's product development platform, which emphasizes capital efficiency, also provides to ex-U.S. companies a rapid and capital-efficient U.S. drug development solution that includes U.S. and European Union (EU) clinical development expertise and U.S. commercialization expertise.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, TRACON Pharma Limited and TRACON Pharma International Limited, which were formed in September 2015 and January 2019, respectively, and are currently inactive. All significant intercompany accounts and transactions have been eliminated.

Basis of Presentation

As of December 31, 2019, the Company has devoted substantially all of its efforts to product development, raising capital, and building infrastructure and has not realized revenues from its planned principal operations. The Company has incurred operating losses since inception. As of December 31, 2019, the Company had an accumulated deficit of $162.3 million. The Company anticipates that it will continue to incur net losses into the foreseeable future as it continues the development and commercialization of its product candidates and works to develop additional product candidates through research and development programs. At December 31, 2019, the Company had cash and cash equivalents of $16.4 million. Based on the Company's current business plan, management believes that there is substantial doubt as to whether existing cash and cash equivalents will be sufficient to meet its obligations as they become due within one year from the date the financial statements are issued. The Company's ability to execute its operating plan into early 2021 and beyond depends on its ability to obtain additional funding through equity offerings, debt financings, or potential licensing and collaboration arrangements. The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. However, the Company's current working capital, anticipated operating expenses and net losses, and the uncertainties surrounding its ability to raise additional capital as needed, as discussed below, raise substantial doubt about its ability to continue as a going concern for a period of one year following the date that these financial statements are issued. The consolidated financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company plans to continue to fund its losses from operations through cash, cash equivalents, and investments on hand, as well as through future equity offerings, debt financings, other third party funding, and potential licensing or collaboration arrangements, including equity financing through the common stock purchase agreement (the 2019 Purchase Agreement) the Company entered into with Aspire Capital Fund, LLC (Aspire Capital) in October 2019 for the purchase of up to $15.0 million of the Company's common stock over a 30 month period, all of which remains available for sale as of December 31, 2019, and/or the Capital on Demand™ Sales Agreement (the Sales Agreement) the Company entered into with JonesTrading Institutional Services LLC (JonesTrading) in September 2018, as amended in February 2019, pursuant to which the Company could sell, at its option, up to an aggregate of $11.6 million of the Company's common stock, $9.2 million of which remains available for sale as of December 31, 2019. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to the Company. Even if the Company raises additional capital, it may also be required to modify, delay or abandon some of its plans which could have a material adverse effect on the Company's business, operating results and financial condition, and the Company's ability to achieve its intended business objectives. Any of these actions could materially harm the Company's business, results of operations, and future prospects.

Reverse Stock Split

On November 7, 2019, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-10 reverse stock split of its common stock (the reverse stock split). The reverse stock split applied to all of the Company's outstanding shares of common stock and therefore did not affect any stockholder's relative ownership percentage. In connection with the reverse stock split, the number of authorized shares of common stock was reduced from 200,000,000 shares to 20,000,000 shares. The number of authorized shares of preferred stock remained (and remains) unchanged at 10,000,000 shares. The par value of the common stock was not adjusted as a result of the reverse stock split. All of the Company's stock options, warrants and restricted stock units outstanding immediately prior to the reverse stock split were proportionately adjusted. All share and price per

share data for all periods presented in these consolidated financial statements and notes thereto have been adjusted to give effect to the reverse stock split, including retrospectively where applicable.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenue, and expenses. The most significant estimates in the Company's financial statements relate to revenue recognition and expenses incurred for clinical trials. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less at the date of purchase. The carrying amounts approximate fair value due to the short maturities of these investments. Cash and cash equivalents include cash in readily available checking and money market funds.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property and Equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful life of the related assets, which is generally five years. Leasehold improvements are amortized over the shorter of the lease term or estimated useful life of the related assets. Repairs and maintenance costs are charged to expense as incurred.

Leases

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, operating leases are recorded as other assets, accounts payable and accrued expenses, and other long-term liabilities within the consolidated balance sheet. The Company currently does not have any finance leases.

Operating lease right-of-use (ROU) assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. Lease terms may include options to extend or terminate when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term.

Revenue Recognition

To date, substantially all of the Company's revenue has been derived from its license agreements with Santen and Ambrx, Inc. (Ambrx) as described in Note 7. The terms of these arrangements include payments to the Company for the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. In accordance with ASU 2014-09, the Company performs the following five steps in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of these agreements: (i) identification of the contract(s) with a customer; (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, the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services transferred to the customer. Once a contract is determined to be within the scope of Accounting Standards Codification 606, Revenue from Contracts with Customers, at contract inception, the Company assesses the goods or services promised within the contract to determine those that are performance obligations and assesses whether each promised good 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.

As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

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 revenues 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 promised goods or services, the Company utilizes judgment 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 progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, the Company evaluates whether the achievement of the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. Performance milestone payments represent a form of variable consideration. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Achievement of milestones that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable until the approvals are achieved. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis and 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 of achieving such milestones and any related constraint, and if necessary, adjusts its estimate 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.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the outset of the arrangement.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its out-licensing arrangements.

The Company receives payments from its collaborators based on billing schedules established in each contract. Up-front and other payments may require deferral of revenue recognition to a future period until the Company performs its obligations under its collaboration arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Clinical Trial Expense Accruals

As part of the process of preparing the Company's financial statements, the Company is required to estimate expenses resulting from its obligations under contracts with vendors, clinical sites, contract research organizations (CROs), and consultants in connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

The Company's objective is to reflect the appropriate trial expenses in its financial statements by recording those expenses in the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with the clinical sites and applicable personnel and outside service providers as to the progress or state of consummation of trials. During the course of a clinical trial, the Company adjusts the clinical expense recognition if actual results differ from its estimates. The Company makes estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company's clinical trial accruals are dependent upon accurate reporting by clinical sites, CROs, and other third-party vendors. Although the Company does not expect its estimates to differ materially from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period. For each of the three years ended December 31, 2019, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Research and Development Costs

Research and development costs, including license fees, are expensed as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of employee stock option grants, employee restricted stock unit grants (RSUs), and employee stock purchase plan (ESPP) rights recognized as expense over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The Company estimates the fair value of stock option grants and ESPP rights using the Black-Scholes option pricing model. The fair value of RSUs is based on the closing sales price for such stock on the date of grant. Equity award forfeitures are recorded as they occur.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized as income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and comprehensive loss were the same for all periods presented.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average shares of common stock outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted-average number of common shares outstanding that are subject to repurchase. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	December 31,		
	2019	2018	2017
Warrants to purchase common stock	1,561,903	1,561,903	10,384
Common stock options and restricted stock units	370,391	300,738	251,574
ESPP shares	1,322	1,275	365
	1,933,616	1,863,916	262,323

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Recently Adopted Accounting Standards

In February 2016, the FASB issued ASU 2016-02, Leases, which outlines a comprehensive lease accounting model and supersedes the then current lease guidance. The new accounting standard requires lessees to recognize lease liabilities and corresponding ROU assets for all leases with lease terms of greater than twelve months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The Company adopted ASU 2016-02 on January 1, 2019 using the modified retrospective method. Under this approach, financial information and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. The Company elected the "package of practical expedients" upon adoption, which permits it to not reassess under the new standard prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the use of hindsight or the practical expedient pertaining to land easements, the latter of which not being applicable. Upon adoption, the Company (i) recognized a ROU asset and lease liability on its balance sheet for its corporate office operating lease and (ii) derecognized the deferred rent balance as of December 31, 2018 under the superseded lease guidance. The ROU asset in the amount of $1.1 million has been recorded in other assets and the short-term and long-term lease liability in the amount of $0.3 million and $0.9 million, respectively, have been recorded in accounts payable and accrued expenses and other long-term liabilities, respectively, within the consolidated balance sheet. There was no impact on retained earnings or other components of equity, nor was there any impact on the statement of operations, upon adoption.

In June 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, which expands the scope of Accounting Standards Codification 718, Compensation-Stock Compensation, to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. The Company adopted ASU 2018-07 on January 1, 2019, which did not have a material impact on the consolidated financial statements and notes thereto.

2. Short-Term Investments, Cash Equivalents and Fair Value Measurements

At December 31, 2019, the Company had no short-term investments and at December 31, 2018, short-term investments consisted of U.S. treasury securities. The Company classifies all investments as available-for-sale securities, as the sale of such investments may be required prior to maturity to implement management strategies. These investments are carried at amortized cost which approximates fair value. A decline in the market value of any short-term investment below cost that is determined to be other-than-temporary will result in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented.

Realized gains and losses from the sale of short-term investments, if any, are determined on a specific identification basis. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense on the consolidated statements of operations. Realized and unrealized gains and losses during the periods presented were immaterial. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method and are included in interest income on the consolidated statements of operations. Interest and dividends on securities classified as available-for-sale are included in interest income on the consolidated statements of operations.

The carrying amounts of cash and cash equivalents, prepaid and other assets, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, which is considered a Level 2 input, the Company believes that the fair value of long-term debt approximates its carrying value.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements.

None of the Company’s non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

Cash equivalents, which are classified as equity securities, and short-term investments, which are classified as available-for-sale securities, consisted of the following (in thousands):

	December 31, 2018			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	$ 5,832	$ —	$ —	$ 5,832
U.S. treasury securities	13,968	—	—	13,968
	$ 19,800	$ —	$ —	$ 19,800
Classified as:				
Cash equivalents				$ 5,832
Short-term investments				13,968
Total cash equivalents and short-term investments				$ 19,800

The fair values of the Company’s assets and liabilities, which are measured at fair value on a recurring basis, were determined using the following inputs (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At December 31, 2018				
Money market funds and U.S. treasury securities, included in cash equivalents and short-term investments	$ 19,800	$ —	$ 19,800	$ —

3. Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2019	2018
Computer and office equipment	$ 133	$ 133
Furniture and fixtures	19	19
Leasehold improvements	21	21
	173	173
Less: accumulated depreciation and amortization	(150)	(128)
	$ 23	$ 45

Depreciation expense related to property and equipment totaled approximately $22,000, $28,000 and $48,000 for the years ended December 31, 2019, 2018 and 2017, respectively.

4. Long-Term Debt

Long-term debt and unamortized debt discount balances were as follows (in thousands):

	December 31,	
	2019	2018
Long-term debt	$ 5,600	$ 7,000
Less debt discount, net of current portion	(61)	(257)
Long-term debt, net of debt discount	5,539	6,743
Less current portion of long-term debt	(2,800)	(1,400)
Long-term debt, less current portion	$ 2,739	$ 5,343
Current portion of long-term debt	$ 2,800	$ 1,400
Current portion of debt discount	(196)	(316)
Current portion of long-term debt, net	$ 2,604	$ 1,084

In May 2018, the Company entered into a third amendment to its Amended and Restated Loan and Security Agreement (the 2018 Amended SVB Loan) with Silicon Valley Bank (SVB) under which the Company borrowed $7.0 million, all of which was immediately used to repay the Company's existing loan with SVB (the 2017 Amended SVB Loan). In accordance with the terms of the 2017 Amended SVB Loan, the Company paid a final payment of $0.3 million associated with the payoff of the 2017 Amended SVB Loan. The transaction was accounted for as a debt modification.

The 2018 Amended SVB Loan provides for interest to be paid at a rate of 9.0% per annum. Interest-only payments were due monthly through June 30, 2019. Thereafter, in addition to interest accrued during such period, the monthly payments will include an amount equal to the outstanding principal at June 30, 2019 divided by 30 months. At maturity (or earlier prepayment), the Company is also required to make a final payment equal to 4.0% of the original principal amount borrowed.

The 2018 Amended SVB Loan provides for prepayment fees of 2.0% of the amount prepaid if the prepayment occurs after May 3, 2019 but prior to May 3, 2020 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The 2018 Amended SVB Loan is collateralized by substantially all of the Company's assets, other than the Company's intellectual property, and contains customary conditions of borrowing, events of default and covenants, including covenants that restrict the Company's ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of the Company's capital stock. Should an event of default occur, including the occurrence of a material adverse change, the Company could be liable for immediate repayment of all obligations under the 2018 Amended SVB Loan. As of December 31, 2019, the Company was in compliance with all covenants and conditions of the 2018 Amended SVB Loan.

In connection with the 2018 Amended SVB Loan, the Company issued SVB a warrant to purchase 5,363 shares of its common stock at an exercise price of $26.10 per share. The warrant is fully exercisable and expires on May 3, 2025. The fair value of the warrant and the final payment related to the 2018 Amended SVB Loan were recorded as debt discounts and are being amortized to interest expense using the effective interest method over the term of the debt, in addition to the remaining unamortized discounts related to the 2017 Amended SVB Loan.

At December 31, 2019, the Company had the following exercisable outstanding warrants for the purchase of common stock issued in connection with the Company's loan agreements with SVB:

Expiration	Number of shares	Exercise price
May 13, 2022	1,841	$ 108.60
November 14, 2023 through June 4, 2024	3,874	$ 77.40
January 25, 2024	4,669	$ 51.40
May 3, 2025	5,363	$ 26.10
	15,747	

Future minimum principal and interest payments under the 2018 Amended SVB Loan, including the final payment, as of December 31, 2019 are as follows (in thousands):

2020	$ 3,195
2021	3,218
	6,413
Less interest and final payment	(813)
Long-term debt	$ 5,600

5. Commitments and Contingencies

Lonza Biologics Tuas Pte Ltd (Lonza)

On February 22, 2017, the Company entered into a long-term manufacturing agreement (Manufacturing Agreement) with Lonza for the long term manufacture and supply of registration and commercial batches of TRC105. Under the Manufacturing Agreement, Lonza agreed to manufacture TRC105 pursuant to purchase orders and in accordance with the manufacturing specifications agreed upon between the Company and Lonza. Following the announcement of the TAPPAS interim unblinded safety and efficacy data in April 2019, the Company exercised its right to terminate the Manufacturing Agreement as a result of its decision to terminate further TRC105 development in oncology.

License Agreements

The Company has entered into various license agreements pursuant to which the Company acquired licenses to certain intellectual property. The agreements generally required an upfront license fee and, in some cases, reimbursement of patent costs. Additionally, under each agreement, the Company may be required to pay annual maintenance fees, royalties, milestone payments and sublicensing fees. Each of the license agreements is generally cancelable by the Company, given appropriate prior written notice. At December 31, 2019, potential future milestone payments under these agreements, including future milestone payments associated with TRC253 acquired from Janssen Pharmaceutica N.V. (Janssen) should they not exercise their option to regain their rights to certain assets as discussed in Note 7, totaled an aggregate of approximately $66.0 million.

6. Stockholders' Equity

Sales of Common Stock

In October 2019, the Company entered into the 2019 Purchase Agreement with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth in the 2019 Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of the Company's common stock solely at the Company's request from time to time during a 30 month period and at prices based on the market price at the time of each sale. In consideration for entering into the 2019 Purchase Agreement and concurrently with the execution of the 2019 Purchase Agreement, the Company issued 142,658 shares of its common stock to Aspire Capital. As of December 31, 2019, the Company had not sold any shares of common stock to Aspire Capital under the 2019 Purchase Agreement. As of the date of this report, the Company has sold 0.2 million shares of common stock under the 2019 Purchase Agreement with Aspire Capital for gross proceeds of $0.8 million.

In March 2017, the Company entered into a common stock purchase agreement (the 2017 Purchase Agreement) with Aspire Capital which provided that, upon the terms and subject to the conditions and limitations of the 2017 Purchase Agreement, Aspire Capital was committed to purchase up to an aggregate of $21.0 million of shares of its common stock. As of December 31, 2019, the

Company had issued 41,795 shares of common stock to Aspire Capital under the 2017 Purchase Agreement for net proceeds of approximately $0.9 million. Upon execution of the 2019 Purchase Agreement, the 2017 Purchase Agreement with Aspire Capital was terminated in its entirety and no further sales of the Company's common stock will occur under the 2017 Purchase Agreement.

In March and April 2018, the Company sold 1,193,059 shares of its common stock at a purchase price of $27.00 per share, warrants to purchase 176,554 shares of its common stock at a purchase price of $26.90 per share and an exercise price of $0.10 per share (the Pre-Funded Warrants) and warrants to purchase 1,369,602 shares of its common stock at a purchase price of $1.25 per share and an exercise price of $27.00 per share (the Common Warrants) for net proceeds of approximately $36.5 million in a private placement to new and certain existing accredited investors. In accordance with their terms, the Pre-Funded Warrants and the Common Warrants may not be exercised if the holder's ownership of the Company's common stock would exceed 9.99% or 19.99% of the Company's total shares outstanding following such exercise, depending on the investor. Both the Pre-Funded Warrants and the Common Warrants were recorded as a component of stockholders' equity within additional paid-in capital. In April 2018, in connection with this transaction, the Company paid Angel Pond Capital, an affiliate of a holder of more than 5% of the Company's common stock and an affiliate of a member of the Company's Board of the Directors at that time, a fee totaling approximately $1.9 million as consideration for acting as a nonexclusive placement agent for this financing.

At-The-Market Issuance Sales Agreement

In September 2018, as amended February 2019, the Company entered into the Sales Agreement with JonesTrading, pursuant to which it could sell from time to time, at its option, up to an aggregate of $11.6 million of the Company's shares of its common stock through JonesTrading, as sales agent, subject to limitations on the amount of securities the Company may sell pursuant to its effective registration statement on Form S-3 within any 12 month period. The Company is required to pay JonesTrading 2.5% of gross proceeds for the common stock sold through the Sales Agreement. During the year ended December 31, 2019, the Company sold 0.9 million shares of common stock through the Sales Agreement with JonesTrading for gross proceeds of $2.4 million and $9.2 million remains available for sale under the Sales Agreement as of December 31, 2019. As of the date of this report, the Company has sold 2.1 million shares of common stock through the Sales Agreement with JonesTrading for gross proceeds of $5.3 million.

In September 2018, the Company terminated its At-the-Market Equity Offering Sales Agreement (Stifel Sales Agreement) with Stifel, Nicolaus & Company, Incorporated (Stifel). The Company had sold an aggregate of approximately $3.5 million of common stock through Stifel pursuant to the Stifel Sales Agreement prior to termination.

Common Stock Warrants

As of December 31, 2019, the Company had the following outstanding warrants for the purchase of common stock:

Expiration	Number of shares	Exercise price
May 13, 2022	1,841	$ 108.60
November 14, 2023 through June 4, 2024	3,874	$ 77.40
January 25, 2024	4,669	$ 51.40
March 27, 2024	1,369,602	$ 27.00
March 27, 2025	176,554	$ 0.10
May 3, 2025	5,363	$ 26.10
	1,561,903	

During the year ended December 31, 2019, no warrants were exercised.

Stock Compensation Plans

2011 Equity Incentive Plan

The Company granted awards under the TRACON Pharmaceuticals, Inc. 2011 Equity Incentive Plan (the 2011 Plan) until January 2015. The 2011 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights (SARs), restricted stock grants and restricted stock units to eligible recipients. Recipients of incentive stock options are eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2011 Plan is no more than ten years. Grants made under the 2011 Plan generally vest on the last day of each month over 48 months from the vesting commencement date subject to continuous service. In connection with the adoption of the 2015 Equity Incentive Plan (the 2015 Plan), the Company terminated the 2011 Plan and no additional awards will be or have been granted under the 2011 Plan.

2015 Equity Incentive Plan

Effective January 1, 2015, the Company's board of directors adopted the 2015 Plan. Under the 2015 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. Initially, a total of 80,103 shares of common stock were reserved for issuance under the 2015 Plan. In addition, the number of shares of common stock available for issuance under the 2015 Plan will be annually increased on the first day of each fiscal year during the term of the 2015 Plan, beginning with the 2016 fiscal year, by an amount equal to 4% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year or such other amount as the Company's board of directors may determine. The maximum term of the options granted under the 2015 Plan is no more than ten years. Grants generally vest at 25% one year from the vesting commencement date and ratably each month thereafter for a period of 36 months, subject to continuous service. In December 2015, the 2015 Plan was amended to allow an additional 50,000 shares of common stock to be used exclusively for the grant of equity awards as a material inducement for individuals to commence employment at the Company in compliance with Nasdaq Listing Rule 5635(c)(4).

Restricted Stock Units

In 2016, the Company issued RSUs to employees and members of the Company's board of directors under the 2015 Plan. The total grant-date fair value of RSUs that vested during the years ended December 31, 2019 and 2018 was $0.4 million and $0.5 million, respectively. The aggregate intrinsic value of outstanding RSUs at December 31, 2019 was $8,000 and is based on the Company's closing market price per share on December 31, 2019 of $2.34. As of December 31, 2019, there was approximately $16,000 of unrecognized compensation costs related to outstanding RSUs, which is expected to be recognized over a weighted average remaining period of 0.05 years.

Restricted stock unit activity under the 2015 Plan is summarized as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	9,254	$ 79.20
Granted	—	—
Vested	(4,629)	79.20
Forfeited	(1,105)	79.20
Outstanding at December 31, 2019	3,520	$ 79.20

Stock Options

Stock option activity under all Plans is summarized as follows:

	Number of Options	Weighted-Average Exercise Price
Balance at December 31, 2018	291,484	$ 52.78
Granted	163,297	$ 7.79
Exercised	—	$ —
Forfeited	(87,910)	$ 36.65
Balance at December 31, 2019	366,871	$ 36.62

Information about the Company's outstanding stock options as of December 31, 2019 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding	366,871	$ 36.62	7.25	$ —
Options vested and expected to vest	366,871	$ 36.62	7.25	$ —
Options exercisable	185,629	$ 58.61	5.73	$ —

The weighted-average grant date fair value per share of employee option grants during the years ended December 31, 2019, 2018 and 2017 was $5.55, $16.69 and $34.68, respectively. The aggregate intrinsic value used in the above table of options at December 31, 2019 is based on the Company's closing market price per common share on December 31, 2019 of $2.34. The Company received approximately $0.2 million and $44,900 in proceeds from the exercise of stock options during the years ended December 31, 2018 and 2017, respectively. The total intrinsic value of options exercised was approximately $0.2 million and $0.2 million during the years ended December 31, 2018 and 2017, respectively. No stock options were exercised during the year ended December 31, 2019. The total grant-date fair value of options that vested during the years ended December 31, 2019, 2018 and 2017 was $1.5 million, $2.6 million and $1.9 million, respectively.

Employee Stock Purchase Plan (ESPP)

On January 1, 2015, the Company's board of directors adopted the ESPP, which became effective upon the pricing of the Company's initial public offering on January 29, 2015. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. Initially, a total of 18,346 shares of common stock was reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP will be annually increased on the first day of each fiscal year during the term of the ESPP, beginning with the 2016 fiscal year, by an amount equal to the lessor of: (i) 36,692 shares; (ii) 1% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year; or (iii) such other amount as the Company's board of directors may determine. Stock compensation expense for the years ended December 31, 2019, 2018 and 2017 related to the ESPP was immaterial.

Stock-Based Compensation Expense

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	Years Ended December 31,		
	2019	2018	2017
Risk-free interest rate	2.6%	2.8%	2.1%
Expected volatility	81.1%	79.6%	83.0%
Expected term (in years)	6.2	6.2	6.2
Expected dividend yield	—	—	—

Risk-free interest rate. The Company bases the risk-free interest rate assumption on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

Expected volatility. The expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

The allocation of stock-based compensation expense was as follows (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Research and development	$ 776	$ 1,462	$ 1,482
General and administrative	848	1,205	1,712
	$ 1,624	$ 2,667	$ 3,194

As of December 31, 2019 and 2018, the unrecognized compensation cost related to outstanding time-based options was $1.6 million and $2.6 million, respectively, and is expected to be recognized as expense over approximately 2.6 years and 2.6 years, respectively.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance was as follows:

	December 31,	
	2019	2018
Common stock warrants	1,561,903	1,561,903
Common stock options and restricted stock units granted and outstanding	370,391	300,738
Awards available under the 2015 Plan	128,589	81,495
Shares available under the ESPP	73,472	50,135
	2,134,355	1,994,271

7. Collaborations

3D Medicines and Alphamab

In December 2019, the Company, 3D Medicines Co., Ltd. (3D Medicines), and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) entered into the Envafolimab Collaboration Agreement for the development of envafolimab, also known as KN035, an investigational PD-L1 sdAb, or nanobody, administered by subcutaneous injection, for the treatment of soft tissue sarcoma in North America. No consideration was exchanged in the Envafolimab Collaboration Agreement. Given no consideration was exchanged, no value was assigned to the Envafolimab Collaboration Agreement in the accompanying consolidated balance sheet.

Pursuant to the Envafolimab Collaboration Agreement, the Company was granted an exclusive license to develop and commercialize envafolimab for the treatment of sarcoma in North America. The Company is responsible for conducting, and will bear the costs of Phase 1, Phase 2, Phase 3, or post-approval clinical trials in North America for envafolimab in the indications of refractory and first line treatment of soft tissue sarcoma. 3D Medicines and Alphamab are responsible for conducting, and will bear the costs of, investigational new drug (IND)-enabling studies (other than those specific to the sarcoma indication) and the preparation of chemistry, manufacturing and controls (CMC) activities sections of an IND application for envafolimab. 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to the Company at pre-negotiated prices that vary based on clinical or commercial use. 3D Medicines and Alphamab retained the right to develop envafolimab in all territories outside of North America as well as within North America for all indications other than soft tissue sarcoma.

The Company will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue, unless (a) envafolimab is first approved in North America for an indication other than soft tissue sarcoma and launched in North America, or (b) envafolimab is first approved in North America for soft tissue sarcoma and subsequently approved in North America for an additional non-orphan indication and sold commercially by 3D Medicines and/or Alphamab, in which case 3D Medicines and Alphamab will be responsible for commercializing envafolimab for soft tissue sarcoma in North America, including booking of sales revenue. If 3D Medicines and Alphamab become responsible for commercialization under the Envafolimab Collaboration Agreement, the Company has the option to co-market envafolimab for sarcoma in North America. In the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace the Company as the party responsible for commercialization, and the Company elects and 3D Medicines and Alphamab agree for the Company to not co-market envafolimab for sarcoma in North America, then 3D Medicine and Alphamab will be required to compensate the Company for its costs associated with preparing for and conducting commercial activities.

If the Company has the responsibility for commercialization under the Envafolimab Collaboration Agreement, the Company will owe 3D Medicines and Alphamab tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits. If 3D Medicines and Alphamab have responsibility for commercialization under the Collaboration Agreement, the Company will be entitled to (a) escalating double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if the Company has chosen to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if the Company has chosen to co-market envafolimab in sarcoma. Payment obligations under the Envafolimab Collaboration Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

3D Medicines and Alphamab retain the right to reacquire the rights to envafolimab for sarcoma in North America in connection with an arm’s length sale to a third party, provided that the sale may not occur prior to completion of a pivotal trial of envafolimab in sarcoma without the Company’s written consent and the parties must negotiate in good faith and agree to fair compensation to be paid to the Company for the value of and opportunity represented by the required rights.

Each party agreed that during the term of the Envafolimab Collaboration Agreement, it would not develop or license from any third party a monospecific inhibitor to PD-L1 or PD-1.

The term of the Envafolimab Collaboration Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in North America or the expiration of all payment obligations. The Envafolimab

Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab. In the event the Company elects, or a joint steering committee determines, to cease further development or commercialization of envafolimab, or if the Company fails to use commercially reasonable efforts to develop (including progress in clinical trials) and commercialize envafolimab and does not cure such failure within a specified time period, then the Company's rights and obligations under the Envafolimab Collaboration Agreement will revert to 3D Medicines and Alphamab.

I-Mab

In November 2018, the Company and I-Mab Biopharma (I-Mab) entered into separate strategic collaboration and clinical trial agreements (the Collaboration Agreements) for the development of programs for multiple immuno-oncology product candidates, including I-Mab's proprietary CD73 antibody TJ004309 (the TJ004309 Agreement) as well as up to five proprietary bispecific antibodies currently under development by I-Mab (the Bispecific Agreement).

No consideration was exchanged in the Collaboration Agreements. Given the early preclinical stage of development of these assets as of the agreement date, no value was assigned to the Collaboration Agreements in the accompanying consolidated balance sheet.

TJ004309 Agreement

Pursuant to the TJ004309 Agreement, the Company and I-Mab are collaborating on developing the TJ004309 antibody, with the Company bearing the costs of filing an IND and for Phase 1 clinical trials, with the parties sharing costs equally for Phase 2 clinical trials, and with the Company and I-Mab bearing 40% and 60%, respectively, of the costs for pivotal clinical trials. I-Mab will be responsible for the cost of certain non-clinical activities, the drug supply of TJ004309, and any reference drugs used in the clinical trials. Each of the parties also agreed for a specified period of time to not develop or license to or from a third party any monoclonal antibody targeting CD73 or any other biologic for certain indications that a joint steering committee (JSC), as set up under the TJ004309 Agreement, selects for TJ004309 development.

In the event that I-Mab out-licenses the rights to TJ004309 to a third party, the Company would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to certain territories outside of Greater China. In the event that I-Mab commercializes TJ004309, the Company would be entitled to receive a royalty percentage on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the EU and Japan in the mid-single digits. The portions of certain third party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which the Company would be entitled will escalate based on the phase of development and relevant clinical trial obligations the Company completes under the TJ004309 Agreement, ranging from a high-single digit to a mid-teen percentage of non-royalty consideration as well as a double digit percentage of royalty consideration.

The TJ004309 Agreement may be terminated by either party in the event of an uncured material breach by the other party, bankruptcy of the other party, or for safety reasons related to TJ004309. I-Mab may also terminate the TJ004309Agreement if the Company causes certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJ004309 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical trial, in which case the Company would be entitled to a minimum termination fee of $9.0 million, or following the completion of the first Phase 2 clinical trial, in which case the Company would be entitled to a pre-specified termination fee of $15.0 million and either a low double-digit percentage of non-royalty consideration up to $35.0 million that I-Mab may receive as part of a license to a third party, or an additional payment of $35.0 million if TJ004309 is approved for marketing outside Greater China before a third party license is executed, in addition to a double digit percentage of royalty consideration.

Bispecific Agreement

Pursuant to the Bispecific Agreement, the Company and I-Mab may mutually select through a joint steering committee (JSC) up to five of I-Mab's bispecific antibody product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, while the Company will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical trials, and the Company will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical trials, in each case within North America. Subject to I-Mab's right to co-promote an approved product candidate, the Company will be responsible for commercializing any approved product candidates in North America and will share profits and losses equally with I-Mab in North

America. The Company would also be entitled to tiered low single digit royalties on net sales of product candidates in the EU and Japan.

At any time prior to completing the first pivotal clinical study for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical trial costs for a product candidate or the JSC decides to cease development over the Company's objections after initiating Phase 3 clinical trials, the Company will have an option to obtain an exclusive license to such product candidate in all territories except Greater China and Korea, and any other territories in which I-Mab previously licensed rights to a third party subject to the Company's right of first refusal for any licenses I-Mab may grant to third-parties.

If the Company exercises the option, it would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, the Company would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time the Company obtained the exclusive license: (i) if before IND-enabling studies and the preparation of the CMC activities of the collaborative product, the Company would owe I-Mab a one-time upfront payment of $10.0 million, development and regulatory based milestone payments totaling up to $90.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the mid-single digits on annual net sales; (ii) if after IND submission but before completion of a Phase 1a clinical trial of the collaborative product, the Company would owe I-Mab a one-time upfront payment of $25.0 million, development and regulatory based milestone payments totaling up to $125.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high single digits on annual net sales; (iii) if after completion of a Phase 1a clinical trial but before completion of Phase 2 proof of concept clinical trial for the collaborative product, the Company would owe I-Mab a one-time upfront payment of $50.0 million, development and regulatory based milestone payments totaling up to $250.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the low double digits on annual net sales; and (iv) if after completion of Phase 2 proof of concept clinical trial and before completion of pivotal study for the collaborative product, the Company would owe I-Mab a one-time upfront payment of $80.0 million, development and regulatory based milestone payments totaling up to $420.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high-teen double digits on annual net sales.

Each party agreed that for a specified period of time, it would not develop or license to or from any third party any bispecific monoclonal antibody targeting the same two biological targets as those of any selected product candidates under the Bispecific Agreement.

If development of any selected product candidates is terminated by a decision of the JSC, all rights to the product candidate will revert to I-Mab, subject to the Company's right to obtain an exclusive license in certain circumstances. If development is terminated after submission of an IND and prior to initiating Phase 3 clinical trials or after initiating Phase 3 clinical trials and with the Company's concurrence, the Company would be entitled to tiered low single digit royalties on net sales of the product candidate in North America, the EU, and Japan.

The Bispecific Agreement may be terminated by either party in the event of an uncured material breach by the other party, bankruptcy of the other party, or with respect to any selected product candidate, for safety reasons related to that product candidate.

Santen

In March 2014, the Company entered into a license agreement with Santen, under which the Company granted Santen an exclusive, worldwide license to certain patents, information and know-how related to TRC105. Under the agreement, Santen is permitted to use, develop, manufacture and commercialize TRC105 products for ophthalmology indications, excluding systemic treatment of ocular tumors. Santen also has the right to grant sublicenses to affiliates and third party collaborators. In the event Santen sublicenses any of its rights under the agreement, Santen will be obligated to pay the Company a portion of any upfront and certain milestone payments received under such sublicense.

Santen has sole responsibility for funding, developing, seeking regulatory approval for and commercializing TRC105 products in the field of ophthalmology. In the event that Santen fails to meet certain commercial diligence obligations, the Company will have the option to co-promote TRC105 products in the field of ophthalmology in the United States with Santen. If the Company exercises this option, the Company will pay Santen a percentage of certain development expenses, and the Company will receive a percentage of profits from sales of the licensed products in the ophthalmology field in the United States, but will not also receive royalties on such sales.

In consideration of the rights granted to Santen under the agreement, the Company received a one-time upfront fee of $10.0 million. In addition, the Company is eligible to receive up to a total of $155.0 million in milestone payments upon the achievement of certain milestones, of which $20.0 million relates to the initiation of certain development activities, $52.5 million

relates to the submission of certain regulatory filings and receipt of certain regulatory approvals and $82.5 million relates to commercialization activities and the achievement of specified levels of product sales. As of December 31, 2019, 2018 and 2017, two development milestones had been received totaling $10.0 million. If TRC105 products are successfully commercialized in the field of ophthalmology, Santen will be required to pay the Company tiered royalties on net sales ranging from high single digits to low teens, depending on the volume of sales, subject to adjustments in certain circumstances. In addition, Santen will reimburse the Company for all royalties due by the Company under certain third party agreements with respect to the use, manufacture or commercialization of TRC105 products in the field of ophthalmology by Santen and its affiliates and sublicensees. Royalties will continue on a country-by-country basis through the later of the expiration of the Company's patent rights applicable to the TRC105 products in a given country or 12 years after the first commercial sale of the first TRC105 product commercially launched in such country.

Santen may unilaterally terminate this agreement in its entirety, or on a country-by-country basis, upon written notice to the Company. Either party may terminate the agreement in the event of the other party's bankruptcy or dissolution or for the other party's material breach of the agreement that remains uncured 90 days (or 30 days with respect to a payment breach) after receiving notice from the non-breaching party. Unless earlier terminated, the agreement continues in effect until the termination of Santen's payment obligations.

Upon the adoption of ASU 2014-09, the Company assessed this agreement and identified multiple promised goods and services, which include at inception: (1) a license to patents, information and know-how related to TRC105, (2) a technology transfer, and (3) a collaboration, including technical and regulatory support provided by the Company. In addition, customer options were identified that include manufacturing and supply obligations and shared CMC development activities. All performance obligations were satisfied by the year ended December 31, 2017, which completed the Company's obligations.

Upon the adoption of ASC 2014-09 and as of December 31, 2019, the transaction price includes the $10.0 million upfront payment and the two development milestones received totaling $10.0 million, all of which had been fully recognized as revenue as of December 31, 2017. The remaining $52.5 million of potential development and regulatory milestone payments are not considered probable at December 31, 2019, and therefore no amounts have been included in the transaction price for these remaining milestones. In addition, in accordance with ASU 2014-09, any consideration related to the commercialization and sales-based milestones (including royalties) will be recognized when the related sales occur and have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company assessed this agreement upon the adoption of ASU 2014-09 and determined it had satisfied all of its performance obligations and recognized the full transaction price as of December 31, 2018, and accordingly, no adjustment was required to retained earnings under the modified retrospective approach used upon the adoption of ASC 2014-09. Revenue recognized related to this agreement totaled $0, $0, and $8.8 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Janssen

In September 2016, the Company entered into a license and option agreement with Janssen (the License and Option Agreement) under which Janssen granted the Company a license to technology and intellectual property to develop, manufacture and commercialize two compounds: a small molecule inhibitor of androgen receptor and androgen receptor mutations (the AR Mutant Program or TRC253), which is intended for the treatment of men with prostate cancer, and an inhibitor of NF-kB inducing kinase (the NIK Program or TRC694). Following completion of the pre-clinical development of TRC694, the Company determined the compound did not warrant further development and, in February 2019, issued written notice to terminate the License and Option Agreement with respect to the NIK Program and returned TRC694 and all rights thereto to Janssen.

With respect to the AR Mutant Program, the License and Option Agreement, as amended, provides Janssen with an option, which is exercisable until 90 days after the Company demonstrates clinical proof of concept of TRC253, to regain the rights to the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the AR Mutant Program. If Janssen exercises the option, Janssen will be obligated to pay the Company (i) a one-time option exercise fee of $45.0 million; (ii) regulatory and commercial based milestone payments totaling up to $137.5 million upon achievement of specified events; and (iii) royalties in the low single digits on annual net sales of AR Mutant Program products. If Janssen does not exercise the option, the Company would then have the right to retain worldwide development and commercialization rights to the AR Mutant Program, in which case, the Company would be obligated to pay to Janssen (x) development and regulatory based milestone payments totaling up to $45.0 million upon achievement of specified events, and (y) royalties in the low single digits based on annual net sales of AR Mutant Program products, subject to certain specified reductions.

No consideration was exchanged for these assets on the acquisition date. Given the early preclinical stage of development of these assets and the low likelihood of success of development through regulatory approval on the acquisition date, no value was assigned to these assets in the accompanying consolidated balance sheet.

The Company is obligated to use diligent efforts to develop the AR Mutant Program according to agreed upon development plans, timelines and budgets. The Company is further obligated as it relates to the AR Mutant Program to use commercially reasonable efforts to develop, obtain marketing approval for, and commercialize licensed products. Until the expiration or earlier termination of the development term of the AR Mutant Program, under the License and Option Agreement, subject to specified exceptions, the Company has agreed not to research, develop or commercialize any compounds or products related to the AR Mutant Program, other than pursuant to the collaboration with Janssen.

The License and Option Agreement may be terminated for uncured breach, bankruptcy, or the failure or inability to demonstrate clinical proof of concept with respect to a particular program during specified timeframes. In addition, the License and Option Agreement will automatically terminate with respect to the AR Mutant Program upon Janssen exercising its option in respect of the AR Mutant Program and making payment of the option exercise fee to the Company or, if Janssen does not exercise the option, upon the expiration of all payment obligations of the Company to Janssen with respect of the AR Mutant Program. The Company may also terminate a program or the License and Option Agreement in its entirety without cause, subject to specified conditions.

Ambrx, Inc.

In December 2017, the Company entered into a license agreement with Ambrx for the development and commercialization of the Company's endoglin antibodies, including TRC105, in Greater China. The license granted Ambrx the exclusive rights to use, develop, manufacture and commercialize the Company's endoglin antibodies in all indications (excluding ophthalmology which are held by Santen) in Greater China.

In February 2019, following discussions between the Company and Ambrx regarding Ambrx's progress towards initiating a Phase 1 clinical trial of TRC105 in China, Ambrx notified the Company that it had elected to terminate the license agreement, resulting in all rights to TRC105 in Greater China reverting to the Company.

In consideration of the rights granted to Ambrx under the agreement, the Company received a one-time upfront fee of $3.0 million, which was recorded as deferred revenue upon receipt and recognized as revenue in the first quarter of 2018 when the license and know-how related to TRC105 was delivered to Ambrx. No further revenue will be recognized associated with this agreement given Ambrx's decision to terminate the license agreement, resulting in all rights to TRC105 in Greater China reverting to the Company.

8. Leases

The Company leases its office space under a non-cancelable operating lease that expires in April 2022 and may be extended for an additional term of 60 months. The option to extend this lease has been excluded from the lease term as the Company is not reasonably certain that the option will be exercised. The lease is subject to base lease payments and additional charges for common area maintenance and other costs and includes certain lease incentives and tenant improvement allowances. Operating lease expense was $0.4 million, $0.4 million and $0.4 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, the Company does not have any finance leases, nor any other operating leases.

Supplemental cash flow information, as of December 31, 2019, related to operating leases was as follows (in thousands):

Cash paid within operating cash flows	$	423
ROU assets recognized in exchange for new lease obligations	$	1,143

Supplemental balance sheet information, as of December 31, 2019, related to operating leases was as follows (in thousands, except lease term and discount rate):

Reported as:	
Other assets (ROU asset)	$ 838
Accounts payable and accrued expenses (lease liability)	$ 355
Other long-term liabilities (lease liability)	570
Total lease liabilities	$ 925
Weighted average remaining lease term	2.30
Weighted average discount rate	11.3%

As of December 31, 2019, the maturities of the Company's operating lease liabilities are as follows (in thousands):

2020	$ 442
2021	461
2022	156
Total lease payments	1,059
Less imputed interest	(134)
Total operating lease liabilities	$ 925

Under the terms of the lease agreement, the Company provided the lessor with an irrevocable letter of credit in the amount of $175,000. The lessor is entitled to draw on the letter of credit in the event of any default by the Company under the terms of the lease.

ASC 840 Disclosures

The Company elected the alternative modified transition method and previously disclosed the following:

Future minimum payments under the non-cancelable operating lease as of December 31, 2018 were as follows (in thousands):

2019	$ 423
2020	442
2021	461
2022	156
	$ 1,482

9. Income Taxes

A reconciliation of the Company's effective tax rate and federal statutory tax rate is summarized as follows (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Federal income taxes	$ (4,761)	$ (7,341)	$ (6,686)
State income taxes, net of federal benefit	(1,381)	(2,340)	(1,404)
Permanent items	149	439	1,170
Uncertain tax positions	1,828	672	(1,158)
Research and development credits	(1,253)	(2,545)	(2,719)
California Net Operating Loss carryforwards	—	—	(2,208)
Rate change	—	629	—
Tax Cuts and Jobs Act	—	—	11,478
Other, net	(75)	—	(126)
Stock compensation	395	66	123
Change in valuation allowance	5,098	10,420	1,530
Provision for income taxes	$ —	$ —	$ —

Significant components of the Company's deferred tax assets and deferred tax liabilities are summarized as follows (in thousands):

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 36,850	$ 32,182
Research and development credits and Orphan Drug Credit	8,944	8,280
Depreciation and amortization	269	281
Right-of-use liability	194	—
Other, net	1,369	1,609
Total deferred tax assets	47,626	42,352
Right-of-use asset	(176)	—
Total deferred tax liabilities	(176)	—
Total net deferred	47,450	42,352
Valuation allowance	(47,450)	(42,352)
Net deferred tax assets	$ —	$ —

The Company has net deferred tax assets relating primarily to net operating loss (NOL) carryforwards, research and development and Orphan Drug tax credit carryforwards. Subject to certain limitations, the Company may use these deferred tax assets to offset taxable income in future periods. Due to the Company's history of losses and uncertainty regarding future earnings, a full valuation allowance has been recorded against the Company's deferred tax assets, as it is more likely than not that such assets will not be realized. The net change in the total valuation allowance for the years ended December 31, 2019, 2018 and 2017 was $5.1 million, $10.4 million and $1.5 million, respectively.

At December 31, 2019, the Company had federal and California NOL carryforwards of approximately $137.1 million and $117.7 million, respectively. The federal and California NOL carryforwards will begin to expire in 2030, unless previously utilized. The federal NOL generated after 2017 of $53.9 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year. At December 31, 2019, the Company also had federal and California research and development and Orphan Drug credit carryforwards of approximately $10.0 million and $2.3 million, respectively. The federal research and development and Orphan Drug credit carryforwards will begin expiring in 2031 unless previously utilized. The California research credit will carry forward indefinitely under current law.

Pursuant to Sections 382 and 383 of the Internal Revenue Code (Code), the annual use of the Company's NOL and research and development credit carryforwards may be limited in the event that a cumulative change in ownership of more than 50% occurs within a three-year period. The Company previously completed a Section 382/383 analysis regarding the limitation of NOL and research and development credit carryforwards as of December 31, 2018 and did not identify any change in ownership of more than 50% within the preceding three-year period since an ownership change was determined to have occurred at the time of the Company's initial public offering in January 2015. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since December 31, 2018. If the Company has experienced an ownership change at any time since December 31, 2018, utilization of the NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382 of the Code. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance with no net effect on income tax expense or the effective tax rate.

On December 22, 2017, the Tax Cuts and Jobs Act (TCJA) was enacted into law. The TCJA made significant changes to U.S. tax laws, including, but not limited to, the following: (a) reducing the federal corporate income tax rate from 35% to 21%, effective January 1, 2018; (b) eliminating the federal corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; and (c) eliminating several business deductions and credits, including deductions for certain executive compensation in excess of $1 million.

As a result of the rate reduction, as of December 31, 2017, the Company reduced the deferred tax asset balance by $11.5 million. Due to the Company's full valuation allowance position, the Company has also reduced the valuation allowance by the same amount.

The changes in the Company's unrecognized tax benefits are summarized as follows (in thousands):

Balance at December 31, 2016	$ 4,177
Change related to prior year positions	(2,701)
Increase related to current year positions	690
Balance at December 31, 2017	2,166
Change related to prior year positions	—
Increase related to current year positions	693
Balance at December 31, 2018	2,859
Change related to prior year positions	—
Increase related to current year positions	2,233
Balance at December 31, 2019	$ 5,092

The Company's policy is to include interest and penalties related to unrecognized income tax benefits as a component of income tax expense. The Company has no accruals for interest or penalties in the accompanying consolidated balance sheets as of December 31, 2019 and 2018 and has not recognized interest or penalties in the accompanying consolidated statements of operations for the three years in the period ended December 31, 2019.

Due to the valuation allowance recorded against the Company's deferred tax assets, future changes in unrecognized tax benefits will not impact the Company's effective tax rate. The Company does not expect its unrecognized tax benefits to change significantly in the next 12 months.

The Company is subject to taxation in the United States and California. Due to the net operating loss carryforwards, the U.S. federal and California returns are open to examination for all years since inception. The Company has not been, nor is it currently, under examination by the federal or any state tax authority.

10. 401(k) Plan

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company, at its discretion, may make certain matching contributions to the 401(k) plan. Matching contributions for the years ended December 31, 2019, 2018 and 2017 totaled approximately $173,000, $187,000 and $181,000, respectively.

11. Quarterly Financial Data (Unaudited)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for the years ended December 31, 2019 and 2018 are as follows (in thousands, except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2019				
Revenue	$ —	$ —	$ —	$ —
Total operating expenses	$ 7,163	$ 6,240	$ 5,081	$ 3,812
Consolidated net loss	$ (7,213)	$ (6,326)	$ (5,199)	$ (3,936)
Net loss per share, basic and diluted	$ (2.41)	$ (2.11)	$ (1.74)	$ (1.25)
2018				
Revenue	$ 3,000	$ —	$ —	$ —
Total operating expenses	$ 11,189	$ 9,737	$ 9,083	$ 7,731
Consolidated net loss	$ (8,364)	$ (9,754)	$ (9,085)	$ (7,756)
Net loss per share, basic and diluted	$ (4.59)	$ (3.28)	$ (3.04)	$ (2.60)

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

We maintain disclosure controls and procedures designed to provide reasonable assurance of achieving the objective that information in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified and pursuant to the requirements of the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer, to allow for timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, with the participation of our Management, including our Chief Executive Officer, of the effectiveness of our disclosure controls and procedures as of December 31, 2019, the end of the period covered by this report. Based upon the foregoing, our Chief Executive Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2019.

Management's Report on Internal Control Over Financial Reporting

Our Management is responsible for establishing and maintain adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

Our Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control — Integrated Framework.

Based on our assessment, our Management has concluded that, as of December 31, 2019, our internal control over financial reporting was effective based on those criteria.

Pursuant to Regulation S-K Item 308(b), this Annual Report on Form 10-K does not include an attestation report of our company's registered public accounting firm regarding internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes. During the quarter ended December 31, 2019, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers, Key Employees and Directors

The following table sets forth certain information regarding our current executive officers and key employees, including their ages as of February 14, 2020:

Name	Age	Position(s)
Executive Officers		
Charles P. Theuer, M.D., Ph.D.	56	President, Chief Executive Officer and Director
Mark C. Wiggins, M.B.A.	64	Chief Business Officer
Scott B. Brown, CPA, M.S.	39	Chief Accounting Officer
Key Employees		
Bonne Adams, M.B.A.	43	Executive Vice President of Clinical Operations
Suzy Benedict, M.S.	48	Executive Vice President, Regulatory Affairs

The name, age and certain other information of each member of the Board, as of February 14, 2020, is set forth below.

		Committee Memberships				
Name	**Age**	**Audit**	**Compensation**	**Nominating & Corporate Governance**	**Term Expires on Annual Meeting held in the Year**	**Director Class**
William R. LaRue	68	C	X		2021	III
Martin A. Mattingly, Pharm.D.	62		C	X	2020	II
J. Rainer Twiford, J.D., Ph.D.	67		X		2020	II
Paul Walker	45	X		C	2021	III
Stephen T. Worland, Ph.D.	62	X		X	2022	I

The following is a brief biography of each of our current executive officers, key employees and non-employee directors:

Charles P. Theuer, M.D., Ph.D. Dr. Theuer has served as our President, Chief Executive Officer and a member of our Board since July 2006. From 2004 to 2006, Dr. Theuer was the Chief Medical Officer and Vice President of Clinical Development at TargeGen, Inc., a biotechnology company. Prior to joining TargeGen, Inc., Dr. Theuer was Director of Clinical Oncology at Pfizer, Inc., a pharmaceutical corporation, from 2003 to 2004. Dr. Theuer has also held senior positions at IDEC Pharmaceuticals Corp. from 2002 to 2003 and at the National Cancer Institute from 1991 to 1993. In addition, he has held academic positions at the University of California, Irvine, where he was Assistant Professor in the Division of Surgical Oncology and Department of Medicine. Dr. Theuer received a B.S. from the Massachusetts Institute of Technology, an M.D. from the University of California, San Francisco, and a Ph.D. from the University of California, Irvine. He completed a general surgery residency program at Harbor-UCLA Medical Center and was board certified in general surgery in 1997. Dr. Theuer currently serves as a director at 4D Molecular Therapeutics, a position he has held since January 2016, and also serves as a director at Oncternal Therapeutics, Inc., a position he has held since 2018.

Our Board believes that Dr. Theuer's experience in the biotechnology industry, his medical training and his experience with our company provide him with the qualifications and skills to serve on our Board.

Mark C. Wiggins, M.B.A. Mr. Wiggins joined us as our Chief Business Officer in May 2018. Prior to joining us, Mr. Wiggins served as Chief Executive Officer at selectION Therapeutics, Inc., from 2017 to 2018, Senior Vice President of Corporate and Business Development at Elcelyx Therapeutics from 2012 to 2015, and Chief Business Officer at Mpex Pharmaceuticals from 2009 to 2011. Prior to this, he served as Executive Vice President of Corporate and Business Development at Biogen Idec, Inc. from 2003 to 2009 and Vice President of Marketing and Business Development at IDEC Pharmaceuticals from 1998 to 2003. Mr. Wiggins also previously served as Head of U.S. Business Development at Schering-Plough (now Merck), in addition to roles at Pfizer and Johnson & Johnson. Mr. Wiggins currently serves on the board of directors of Zogenix and SelectION. He received a B.S. in finance from Syracuse University and an M.B.A. from the University of Arizona.

Scott B. Brown, CPA, M.S. Mr. Brown joined us as Director, Finance and Controller in August 2015, was promoted to Sr. Director, Finance and Controller in January 2017, was promoted to Vice President, Finance in January 2019, and Chief Accounting Officer in September 2019. Prior to joining us, Mr. Brown was Associate Director, Finance at Ardea Biosciences (acquired by

AstraZeneca) where he led finance and accounting for Ardea Biosciences as a subsidiary of AstraZeneca from 2013 to 2015. Before that, from 2011 to 2013 Mr. Brown was Finance Manager at SciClone Pharmaceuticals, Inc., and Finance Manager at Exelixis, Inc. from 2009 to 2011. Prior to Exelixis, Mr. Brown held accounting positions of increasing responsibility at AcelRx, Inc., Spinal Elements, Inc., Stewart Title, and as an audit associate for KPMG, LLP. Mr. Brown received a B.S. from the University of California, Santa Barbara, a M.S. in Accountancy from San Diego State University, and is a Certified Public Accountant licensed in the state of California.

Key Employees

Bonne Adams, M.B.A. Ms. Adams joined us as our Vice President of Clinical Operations in August 2006, was promoted to Senior Vice President of Clinical Operations in July 2014, and to Executive Vice President of Clinical Operations in January 2019. Prior to joining us, Ms. Adams was a Manager of Clinical Operations at Pfizer, Inc., a pharmaceutical corporation, from 2004 to 2006 and at Biogen Idec, Inc., a biotechnology company, from 2002 to 2004. Ms. Adams has managed both early and late-stage oncology studies of small molecules as well as biologics in the areas of lymphoma, lung, colorectal, ovarian, kidney, sarcoma and breast cancers. From 2000 to 2002, she managed non-oncology programs at Quintiles Inc., a service provider for biopharmaceutical and health sciences companies, including studies in the areas of allergy and pulmonary disease. Ms. Adams received a B.A. in Kinesiology and Biology from the University of Colorado and an M.B.A. in Technology Management from The University of Phoenix.

Suzy Benedict, M.S. Ms. Benedict joined us as our Director of Regulatory Affairs in 2007, was promoted to Vice President of Regulatory Affairs in January 2014, was promoted to Senior Vice President of Regulatory Affairs in January 2019, and to Executive Vice President of Regulatory Affairs in January 2020. Ms. Benedict previously held positions in Regulatory Chemistry, Manufacturing and Controls (CMC) at Pfizer, Inc. and Amylin Pharmaceuticals, Inc. At Pfizer, she led the Regulatory CMC activities for the approval of Viracept® Tablets, 625 mg and played a key role in the global approvals for Macugen®. She began her pharmaceutical career at Agouron Pharmaceuticals in Medicinal Chemistry synthesizing VEGF inhibitors. Ms. Benedict has led the Regulatory CMC activities on chemical and pharmaceutical development teams from compound identification through commercialization and has experience with small molecule, peptide, oligonucleotide and protein products spanning a wide range of therapeutic areas and has led the regulatory strategy for all phases of clinical development in oncology. Ms. Benedict received a B.A. from the University of California, Santa Barbara and a M.S. in Chemistry from San Diego State University.

Non-Employee Directors

William R. LaRue

Mr. LaRue has served as a member of our Board since July 2014. He served as the Chief Financial Officer, Senior Vice President and Treasurer at Cadence Pharmaceuticals, Inc., a biopharmaceutical company, from June 2006 until its acquisition by Mallinckrodt plc in March 2014, and from April 2007 to March 2014, he served as the Assistant Secretary at Cadence. Prior to joining Cadence Pharmaceuticals, Inc., Mr. LaRue was the Senior Vice President and Chief Financial Officer of Micromet, Inc. (formerly CancerVax Corporation), a biotechnology company, from 2001 to 2006. From 2000 to 2001, Mr. LaRue served as the Executive Vice President and Chief Financial Officer of eHelp Corporation, a provider of user assistance software. Previously, he was the Vice President and Treasurer of Safeskin Corporation, a medical device company, from 1997 to 2000 and the Treasurer of GDE Systems, Inc., a high technology electronic systems company from 1993 to 1997. Mr. LaRue currently serves on the board of directors of Conatus Pharmaceuticals, Inc., a position he has held since February 2017. In addition, since December 2017 Mr. LaRue has served on the board of directors of Oncternal Therapeutics, Inc., a cancer therapeutics company that entered into a reverse merger agreement with GTx, Inc. in March 2019, and also serves on the board of directors of Alastin Skincare, Inc., a private innovative skincare company. Mr. LaRue received a B.S. in business administration and an M.B.A. from the University of Southern California.

Our Board believes that Mr. LaRue's extensive experience in finance, his experience as an executive officer of a public company in our industry and his educational background provide him with the qualifications and skills to serve on our Board.

Martin A. Mattingly, Pharm.D.

Dr. Mattingly has served as a member of our Board since December 2014. Previously, Dr. Mattingly served as the Chief Executive Officer of Trimeris, Inc., a biopharmaceutical company, from November 2007 until January 2012 following its merger with Synageva BioPharma Corp in November 2011. He also served on the board of directors of Trimeris, Inc. from November 2007 until November 2011. He has been a director of OncoGenex Pharmaceuticals, Inc., a biopharmaceutical company, since June 2010 and currently serves on the board of directors of Achieve Life Sciences, Inc. From 2005 to 2007, Dr. Mattingly served as President and Chief Executive Officer of Ambrx, Inc., a biopharmaceutical company. From 2003 to 2005, Dr. Mattingly served as Executive Vice President of CancerVax, Inc., a pharmaceutical company, and as Chief Operating Officer from June 2005 to September 2005. From 1996 to 2003, Dr. Mattingly provided senior leadership in various management positions at Agouron Pharmaceuticals, Inc. and

Pfizer, Inc., a pharmaceutical company. From 1983 to 1996, Dr. Mattingly held various positions in oncology marketing and sales management at Eli Lilly and Company, a biopharmaceutical company. Dr. Mattingly received a Doctor of Pharmacy degree from the University of Kentucky.

Our Board believes that Dr. Mattingly's experience in the biotechnology and pharmaceuticals industries, his educational background and his experience as a public company director provide him with the qualifications and skills to serve on our Board.

J. Rainer Twiford, J.D., Ph.D.

Dr. Twiford has served as a member of our Board since September 2008. Dr. Twiford has been President of Brookline Investments, Inc. (formerly Capital Strategies Advisors, Inc.), an investment advisory company he founded in 1994, since 1999. Dr. Twiford has been a member of the board of directors of Integrated Photonics, Inc., an optical device company, since November 1999. Prior to founding Brookline Partners, Dr. Twiford was a partner of Trammell Crow Company, a real estate development and investment company, from 1987 to 1991. From June 2007 to July 2013, Dr. Twiford was a member of the board of directors of Care Investment Trust Inc. (now Tiptree Financial Inc.), a real estate investment company. He also served as the Chairman of the Compensation, Nominating and Governance Committee of Care Investment Trust Inc. from September 2011 to July 2013. In addition, Dr. Twiford previously served on the board of a children's behavioral health company. Dr. Twiford received a B.A. and a Ph.D. from the University of Mississippi, an M.A. from the University of Akron and a J.D. from the University of Virginia.

Our Board believes that Dr. Twiford's extensive experience in finance, his experience as a public company director and his educational background provide him with the qualifications and skills to serve on our Board.

Paul Walker

Mr. Walker has served on our Board since September 2014. Mr. Walker has been a partner of New Enterprise Associates, an investment firm focused on venture capital and growth equity investments, since April 2008, where Mr. Walker focuses on later-stage biotechnology and life sciences investments. From January 2001 to March 2008, Mr. Walker worked at MPM Capital, a life sciences venture capital firm, where he specialized in public, PIPE and mezzanine-stage life sciences investing as a general partner with the MPM BioEquities Fund. From July 1996 to December 2000, Mr. Walker served as a portfolio manager at Franklin Resources, Inc., a global investment management organization known as Franklin Templeton Investments. Mr. Walker was a member of the board of directors of TESARO, Inc., an oncology-focused biopharmaceutical company, from May 2010 to May 2014, and is a board observer of Sunesis Pharmaceuticals, Inc., and manages a number of NEA's other late-stage and public investments. In addition, Mr. Walker is a member of the board of directors of Allakos, Inc., a privately held company focused on the development of drugs to treat eosinophil and mast-cell driven diseases. Mr. Walker received a B.S. in biochemistry and cell biology from the University of California at San Diego and holds the Chartered Financial Analyst designation.

Our Board believes that Mr. Walker's experience in the life sciences and venture capital industries, his educational background and his experience as a public company director provide him with the qualifications and skills to serve on our Board.

Stephen T. Worland, Ph.D.

Dr. Worland has served as a member of our Board since February 2015. Since May 2012, Dr. Worland has served as the President and Chief Executive Officer and a director of eFFECTOR Therapeutics, Inc., a company focused on new treatments for cancer. Dr. Worland was President and Chief Executive Officer and a director of Anadys Pharmaceuticals, Inc., a biopharmaceutical company which discovered and developed treatments for Hepatitis C and cancer, from August 2007 until the company's acquisition by Roche in November 2011. Dr. Worland joined Anadys in 2001 and served in a number of executive roles prior to being named Chief Executive Officer, including President, Pharmaceuticals, and Chief Scientific Officer. Dr. Worland began his healthcare industry career in 1988 at Agouron Pharmaceuticals, Inc. and remained with the company through its successful commercialization of an HIV protease inhibitor and successive acquisitions by Warner-Lambert and Pfizer. During this period, Dr. Worland held a number of positions, including Vice President, Antiviral Research and Director, Molecular Biology and Biochemistry. Dr. Worland was a National Institutes of Health Postdoctoral Fellow in Molecular Biology at Harvard University from 1985 to 1988. Dr. Worland currently serves on the board of directors of Forge Therapeutics, Inc., a biotechnology company discovering first-in-class antibiotics using a breakthrough drug discovery platform, a position he has held since April 2017. Dr. Worland received his B.S. with highest honors in Biological Chemistry from the University of Michigan and his Ph.D. in Chemistry from the University of California, Berkeley.

Our Board believes that Dr. Worland's experience as an executive officer of a public company in the biotechnology and pharmaceuticals industries, his educational background and his experience as a public company director provide him with the qualifications and skills to serve on our Board.

Board Composition

Our business and affairs are organized under the direction of our Board, which currently consists of six members. The primary responsibilities of our Board are to provide oversight, strategic guidance, counseling and direction to our management. Our Board meets on a regular basis and additionally as required.

Two of our six current directors were originally elected to serve on our Board pursuant to an amended and restated voting agreement, dated September 19, 2014, by and among us and certain of our stockholders. Pursuant to the voting agreement, Mr. LaRue and Mr. Walker were selected to serve on our Board as representatives of our preferred stockholders, as designated by the holders of a majority of our outstanding preferred stock with respect to Mr. LaRue, and by New Enterprise Associates 14, L.P. with respect to Mr. Walker. The amended and restated voting agreement terminated in connection with the closing of our initial public offering, and each director previously elected to our Board pursuant to the amended and restated voting agreement will continue to serve as a director until his successor is duly elected and qualified. Dr. Theuer was selected to serve on our Board as the director then serving as our Chief Executive Officer.

Our Board is divided into three classes, as follows:

- Class I, which consists of Dr. Worland, whose term will expire at our annual meeting of stockholders to be held in 2022;
- Class II, which consists of Dr. Mattingly and Dr. Twiford, whose terms will expire at our annual meeting of stockholders to be held in 2020; and
- Class III, which consists of Mr. LaRue, Dr. Theuer and Mr. Walker, whose terms will expire at our annual meeting of stockholders to be held in 2021.

At each annual meeting of stockholders, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our Board is currently seven members and currently consists of six members. The authorized number of directors may be changed only by resolution by a majority of the Board. This classification of the Board may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66$_{2/3}$% of our voting stock.

Role of the Board in Risk Oversight

One of the key functions of our Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Committees

Our Board has established three standing committees: an audit committee, a compensation committee and a nominating and corporate governance committee. Below is a description of each standing committee of the Board.

Audit Committee

Our audit committee consists of Mr. LaRue, Mr. Walker and Dr. Worland. Our Board has determined that each of the members of this committee satisfies the Nasdaq independence requirements. Each member of our audit committee can read and understand fundamental financial statements in accordance with Nasdaq audit committee requirements. In arriving at this determination, the board has examined each audit committee member's scope of experience and the nature of their prior and/or current employment.

Mr. LaRue serves as the chair of our audit committee. Our Board has determined that Mr. LaRue qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the pertinent listing standards of Nasdaq, as in effect from time to time. In making this determination, our board has considered Mr. LaRue's formal

education and previous and current experience in financial roles. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis the performance of the audit committee and the audit committee charter.

The audit committee has adopted a written charter that is available to stockholders on the Company's website at www.traconpharma.com. The information on our website is not incorporated by reference into this Annual Report.

Compensation Committee

Our compensation committee consists of Dr. Mattingly, Dr. Twiford, and Mr. LaRue. Dr. Mattingly serves as the chair of our compensation committee. Our Board has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, and satisfies the Nasdaq independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full Board regarding) our overall compensation strategy and policies;
- making recommendations to the full Board regarding the compensation and other terms of employment of our executive officers;

- reviewing and making recommendations to the full Board regarding performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;

- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;

- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;

- reviewing and making recommendations to the full Board regarding the type and amount of compensation to be paid or awarded to our non-employee board members;

- establishing policies with respect to votes by our stockholders to approve executive compensation to the extent required by Section 14A of the Exchange Act and, if applicable, determining our recommendations regarding the frequency of advisory votes on executive compensation;

- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;

- administering our equity incentive plans;

- establishing policies with respect to equity compensation arrangements;

- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;

- reviewing and making recommendations to the full Board regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

- reviewing with management and approving our disclosures under the caption “Compensation Discussion and Analysis” in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;

- preparing the report that the SEC requires in our annual proxy statement; and

- reviewing and evaluating on an annual basis the performance of the compensation committee and the compensation committee charter.

Compensation Committee Processes and Procedures

Typically, our compensation committee meets multiple times per year and with greater frequency if necessary. The agenda for each meeting is usually developed by the Chair of the compensation committee, in consultation with our Chief Executive Officer. Our compensation committee meets regularly in executive session. However, from time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the compensation committee to make presentations, to provide financial or other background information or advice or to otherwise participate in compensation committee meetings. Our Chief Executive Officer may not participate in, or be present during, any deliberations or determinations of the compensation committee regarding his compensation. The charter of our compensation committee grants the compensation committee full access to all of our books, records, facilities and personnel, as well as authority to obtain, at our expense, advice and assistance from internal and external legal, accounting or other advisors and consultants and other external resources that the compensation committee considers necessary or appropriate in the performance of its duties. In particular, the compensation committee has the sole authority to retain compensation consultants to assist in its evaluation of executive and director compensation, including the authority to approve the consultant’s reasonable fees and other retention terms.

Under its charter, our compensation committee may form, and delegate authority to, subcommittees as appropriate. In 2015, the compensation committee approved the formation of a CEO stock option sub-committee of the compensation committee, currently composed of Dr. Theuer, our Chief Executive Officer, to which authority has been delegated to grant, without any further action required by the compensation committee, stock options and restricted stock units, or RSUs, to employees who are not our officers. The

purpose of this delegation of authority is to enhance the flexibility of equity award administration and to facilitate the timely grant of equity awards to non-management employees, particularly new employees, within specified limits approved by our compensation committee. In particular, the subcommittee may grant options or RSUs only within pre-approved guidelines. Typically, as part of its oversight function, our compensation committee will review on a regular basis the list of grants made by the subcommittee. During the year ended December 31, 2019, the subcommittee did not exercise its authority to grant equity awards to purchase shares of our common stock to non-officer employees.

Historically, our compensation committee has made most of the significant adjustments to annual compensation, determined bonus and equity awards and established new performance objectives at one or more meetings held toward the end of the year or the beginning of the following year. However, the compensation committee also considers matters related to individual compensation, such as compensation for new executive hires, as well as high-level strategic issues, such as the efficacy of our compensation strategy, potential modifications to that strategy and new trends, plans or approaches to compensation, at various meetings throughout the year. Generally, our compensation committee's process comprises two related elements: the determination of compensation levels (including bonus amounts based upon performance objectives for the prior year) and the establishment of performance objectives for the current year. For executives other than the Chief Executive Officer, the compensation committee solicits and considers evaluations and recommendations submitted to it by the Chief Executive Officer. In the case of our Chief Executive Officer, the evaluation of his performance is conducted by the compensation committee, which determines any adjustments to his compensation as well as awards to be granted. For all executives and directors as part of its deliberations, the compensation committee may review and consider, as appropriate, materials such as financial reports and projections, operational data, tax and accounting information, tally sheets that set forth the total compensation that may become payable to executives in various hypothetical scenarios, executive and director stock ownership information, company stock performance data, analyses of historical executive compensation levels and current Company-wide compensation levels and analyses of executive and director compensation paid at other companies.

The compensation committee has adopted a written charter that is available to stockholders on the Company's website at www.traconpharma.com. The information on our website is not incorporated by reference into this Annual Report.

The specific determinations of the compensation committee with respect to executive compensation for fiscal 2019 are described in greater detail below under the heading "Executive Compensation."

Compensation Committee Interlocks and Insider Participation

None of the members of our Compensation Committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our Board or compensation committee.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Mr. Walker, Dr. Mattingly and Dr. Worland. Our Board has determined that each of the members of this committee satisfies the Nasdaq independence requirements. Mr. Walker serves as the chair of our nominating and corporate governance committee. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our Board;
- determining the minimum qualifications for service on our Board;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our Board;
- evaluating nominations by stockholders of candidates for election to our Board;
- considering and assessing the independence of members of our Board;
- developing a set of corporate governance policies and principles and recommending to our Board any changes to such policies and principles;

- considering questions of possible conflicts of interest of directors as such questions arise; and

- reviewing and evaluating on an annual basis the performance of the nominating and corporate governance committee and the nominating and corporate governance committee charter.

Our nominating and corporate governance committee believes that candidates for director, both individually and collectively, can and do provide the integrity, experience, judgment, commitment (including having sufficient time to devote to us and level of participation), skills, diversity and expertise appropriate for us. In assessing the directors, both individually and collectively, the nominating and corporate governance committee may consider the current needs of the Board and of us to maintain a balance of knowledge, experience and capability in various areas. However, the nominating and corporate governance committee retains the right to modify these qualifications from time to time. Candidates for director nominees are reviewed in the context of the current composition of the Board, our operating requirements and the long-term interests of stockholders. In conducting this assessment, the nominating and corporate governance committee typically considers diversity, age, skills and such other factors as it deems appropriate given the current needs of the Board and us, to maintain a balance of knowledge, experience and capability. In the case of incumbent directors whose terms of office are set to expire, the nominating and corporate governance committee reviews these directors' overall service to us during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence. In the case of new director candidates, the nominating and corporate governance committee also determines whether the nominee is independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The nominating and corporate governance committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm. The nominating and corporate governance committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board. The nominating and corporate governance committee meets to discuss and consider the candidates' qualifications and then selects a nominee for recommendation to the Board by majority vote.

The Board has adopted a written nominating and corporate governance committee charter that is available to stockholders on the Company's website at www.traconpharma.com. The information on our website is not incorporated by reference into this Annual Report.

Procedures for Stockholders to Recommend Director Nominees

The nominating and corporate governance committee will consider director candidates recommended by stockholders. The nominating and corporate governance committee does not intend to alter the manner in which it evaluates candidates based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the nominating and corporate governance committee to become nominees for election to the Board may do so by delivering a written recommendation to the nominating and corporate governance committee at the following address: 4350 La Jolla Village Drive, Suite 800, San Diego, CA, 92122, Attn: Secretary, no later than the close of business on the 90th day and no earlier than the close of business on the 120th day prior to the one year anniversary of the preceding year's annual meeting. Submissions must include (1) the name and address of the Company stockholder on whose behalf the submission is made; (2) number of Company shares that are owned beneficially by such stockholder as of the date of the submission; (3) the full name of the proposed candidate; (4) description of the proposed candidate's business experience for at least the previous five years; (5) complete biographical information for the proposed candidate; (6) a description of the proposed candidate's qualifications as a director and (7) any other information required by the Company's Bylaws. The Company may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as an independent director of the Company or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such proposed nominee.

Corporate Governance

During fiscal 2019, our Board met ten times, the audit committee met four times, the compensation committee met three times and the nominating and corporate governance committee met one time. Each member of our board attended 75% or more of the board meetings during the year ended December 31, 2019 that were held during the period for which he or she was a director (if any). Each member of the board who served on the audit, compensation or nominating and corporate committees attended at least 75% of the respective committee meetings during the year ended December 31, 2019 that were held during the period for which he or she was a committee member, with the exception of Dr. Twiford who attended 33% of the compensation committee meetings held during the year ended December 31, 2019.

We do not have a formal policy regarding director attendance at our annual meetings; however, we encourage directors to attend. All of our directors attended the Company's annual meeting of stockholders held in 2019.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any of the legal proceedings specified in Item 401(f) of Regulation S-K in the past 10 years.

Code of Business Conduct and Ethics

We maintain a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is available on the Corporate Governance section of our website, www.traconpharma.com. The information on our website is not incorporated by reference into this Annual Report. We intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to SEC rules.

Item 11. Executive Compensation.

Our named executive officers for the year ended December 31, 2019, which consist of our principal executive officer and two other executive officers as of December 31, 2019, were:

- Charles P. Theuer, M.D., Ph.D., our President and Chief Executive Officer,
- Mark C. Wiggins, M.B.A., our Chief Business Officer, and
- Scott B. Brown, CPA, M.S., our Chief Accounting Officer.

Summary Compensation Table

Name and principal position	Year	Salary ($)	Option awards ($)(1)	Non-equity incentive plan compensation ($)(2)	All other compensation ($)	Total ($)
Charles P. Theuer, M.D., Ph.D.	2019	552,921	258,566	262,637	11,200	1,085,324
President and Chief Executive Officer	2018	542,079	341,505	216,832	11,200	1,111,616
Mark C. Wiggins, M.B.A.	2019	354,164	101,178	136,474	11,200	603,016
Chief Business Officer	2018	208,205	545,580	71,556	8,328	833,669
Scott B. Brown, CPA, M.S. (3)	2019	240,000	56,210	193,843	11,200	401,253
Chief Accounting Officer	2018	191,982	30,356	36,710	9,308	268,356

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards computed in accordance with FASB ASC Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of these amounts are included in Note 6 to our consolidated financial statements and notes thereto included within Part IV of this Annual Report. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying the stock options.

(2) Amounts shown represent annual performance-based bonuses earned for the respective fiscal year, including a $100,000 retention bonus paid to Mr. Brown in 2019. For more information, see below under "—Annual Performance-Based Bonus Opportunity."

(3) Mr. Brown was appointed Chief Accounting Officer on September 18, 2019.

Annual Base Salary

The compensation of our named executive officers is generally determined and approved by our Board, based on the recommendation of the compensation committee of our Board. The table below shows the annual base salaries for our named executive officers in 2019:

Name	2019 Base Salary ($)
Charles P. Theuer, M.D., Ph.D.	$ 552,921
Mark C. Wiggins, M.B.A.	$ 354,164
Scott B. Brown, CPA, M.S.	$ 240,000

Annual Performance-Based Bonus Opportunity

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve defined annual corporate goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus each named executive officer is eligible to receive is generally based on the extent to which we achieve the corporate goals that our Board establishes each year. At the end of the year, our Board reviews our performance against each corporate goal and determines the extent to which we achieved each of our corporate goals.

For 2019, Dr. Theuer was eligible to receive a target bonus of up to 50% of his base salary, Mr. Wiggins was eligible to receive a target bonus of up to 40% of his base salary, and Mr. Brown was eligible to receive a target bonus of up to 40% of his base salary each pursuant to the terms of their employment agreement that was in effect during 2019, as described below under "—Agreements with our Named Executive Officers." Our Board will also consider each named executive officer's individual contributions towards reaching our annual corporate goals. There is no minimum bonus percentage or amount established for the named executive officers and, as a result, the bonus amounts vary from year to year based on corporate and individual performance. In June 2019, our Board approved our corporate goals for 2019, with finance goals assigned a 40% weight, project-based goals assigned a 30% weight and business development goals assigned a 30% weight.

On January 28, 2020, the compensation committee determined that we had achieved 95% of the 2019 corporate goals for purposes of 2019 annual performance-based bonuses. Based on the determination of 95% corporate goal achievement, Dr. Theuer was awarded a 2019 annual performance-based cash bonus in the amount of $262,637. Additionally, based on the committee's and Dr. Theuer's assessment, Mr. Wiggins and Mr. Brown were awarded a 2019 annual performance-based cash bonus in the amount of $136,474 and $93,843, respectively.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests with those of our employees and consultants, including our named executive officers. In the fiscal year ending December 31, 2019, stock option awards were the only form of equity awards we granted to our named executive officers. Vesting of the stock option awards is tied to continuous service with us and serves as an additional retention measure. Our executives generally are awarded an initial new hire grant of option awards upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

With the exception of stock option awards granted to Dr. Theuer, described below under "—Potential Payments Upon Termination or Change in Control," all of our outstanding stock option awards to executives as of December 31, 2019 contain a double trigger acceleration feature. Pursuant to such double trigger acceleration feature, in the event of the holder's cessation of continuous service without cause, and not due to a death or disability, in connection with or within either 12 or 18 months following consummation of a change in control, the vesting and exercisability of the option will be accelerated in full.

Agreements with Our Named Executive Officers

Below are descriptions of our employment agreements with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, please see "—Potential Payments upon Termination or Change in Control" below.

Agreement with Dr. Theuer. On February 5, 2019, we entered into an Amended and Restated Employment Agreement with Charles P. Theuer, our President and Chief Executive Officer, which amended, restated and superseded in its entirety Dr. Theuer's employment agreement entered into in February 2017. Pursuant to the amended employment agreement, Dr. Theuer is entitled to an initial annual base salary of $552,921 and is eligible to receive an annual performance bonus of up to 50% of his base salary, as determined by our Board. Dr. Theuer is additionally entitled to certain severance benefits pursuant to his agreement, the terms of which are described below under "—Potential Payments Upon Termination or Change of Control."

Agreement with Mr. Wiggins. On May 29, 2018, we entered into an Employment Agreement with Mark C. Wiggins, our Chief Business Officer, which governs the terms of his employment with us. Pursuant to the agreement, Mr. Wiggins is entitled to an initial base salary of $350,000, is eligible to receive an annual target performance bonus of up to 40% of his base salary, as determined by our Board, and was granted an option to purchase an aggregate of 280,000 shares of our common stock. Mr. Wiggins is additionally entitled to certain severance benefits pursuant to a severance agreement that we entered into with Mr. Wiggins on May 29, 2018, the terms of which are described below under "—Potential Payments Upon Termination or Change of Control."

Agreement with Mr. Brown. On January 28, 2020, we entered into an Employment Agreement with Scott B. Brown, our Chief Accounting Officer, which governs the terms of his employment with us. Pursuant to the agreement, Mr. Brown is entitled to an initial base salary of $254,400 and is eligible to receive an annual target performance bonus of up to 40% of his base salary, as determined by our Board. Mr. Brown is additionally entitled to certain severance benefits pursuant to a severance agreement that we entered into with Mr. Brown on December 4, 2019, the terms of which are described below under "—Potential Payments Upon Termination or Change of Control."

Potential Payments Upon Termination or Change of Control

Regardless of the manner in which a named executive officer's service terminates, the named executive officer is entitled to receive amounts earned during his or her term of service, including salary and unused vacation pay. In addition, each of our named executive officers is eligible to receive certain benefits pursuant to his agreement with us described above under "—Agreements with our Named Executive Officers."

Dr. Theuer. If Dr. Theuer's employment is terminated without cause or he resigns for good reason, in each case, other than in connection with a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for 12 months, employee benefit coverage for up to 12 months and 100% automatic vesting of any unvested time-based stock option awards. If Dr. Theuer's employment is terminated without cause or he resigns for good reason within 12 months following a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for 18 months, 150% of his annual performance bonus, employee benefit coverage for up to 18 months and 100% automatic vesting of any unvested time-based stock option awards. In addition, if Dr. Theuer's employment is terminated as a result of his death, his estate would be entitled to a one-time lump-sum payment equal to his base salary for 12 months and his stock option awards would vest on an accelerated basis as if his termination occurred six months later. If Dr. Theuer's employment is terminated as a result of disability, his stock option awards would vest on an accelerated basis as if his termination occurred six months later. If Dr. Theuer's employment is terminated for cause or if he resigns without good reason, he would be entitled to his base salary owed to him, any expense reimbursement owed to him, and any other benefits accrued, in each case, as of the date of his termination.

Mr. Wiggins. On May 29, 2018, we entered into a severance agreement with Mr. Wiggins. Pursuant to the severance agreement, Mr. Wiggins is entitled to certain severance benefits and other payments upon the occurrence of certain events. If Mr. Wiggins' employment is terminated without cause or he resigns for good reason, in each case, other than in connection with a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for nine months, employee benefit coverage for up to nine months and accelerated vesting on any unvested time-based stock option awards as if Mr. Wiggins had completed an additional nine months of employment following the termination date. If Mr. Wiggins' employment is terminated without cause or he resigns for good reason within 12 months following a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for 12 months, 100% of his annual performance bonus, employee benefit coverage for up to 12 months and 100% automatic vesting of any unvested time-based stock option awards.

Mr. Brown. On December 4, 2019, we entered into a severance agreement with Mr. Brown. Pursuant to the severance agreement, Mr. Brown is entitled to certain severance benefits and other payments upon the occurrence of certain events. If Mr. Browns' employment is terminated without cause or he resigns for good reason, in each case, other than in connection with a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for nine months, employee benefit coverage for up to nine months and accelerated vesting on any unvested time-based stock option awards as if Mr. Brown had completed an additional nine months of employment following the termination date. If Mr. Browns' employment is terminated without cause or he resigns for good reason within 12 months following a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for 12 months, 100% of his annual performance bonus, employee benefit coverage for up to 12 months and 100% automatic vesting of any unvested time-based stock option awards.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding equity awards held by our named executive officers that remain outstanding as of December 31, 2019.

			Option Awards(1)				Stock Awards	
	Grant date	Vesting commencement date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price per share ($)(2)	Option expiration date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Charles P. Theuer, M.D., Ph.D.	9/20/2011	3/31/2011	17,733	—	$ 7.01	9/19/2021		
	3/14/2013	7/13/2012	2,583	—	$ 13.35	3/13/2023		
	5/23/2013	5/15/2013	6,801	—	$ 13.35	5/22/2023		
	10/3/2014	10/3/2014	8,257	—	$ 70.43	10/2/2024		
	10/3/2014	10/3/2014	5,137 (3)	—	$ 70.43	10/2/2024		
	3/26/2015	3/26/2015	14,721	—	$ 143.40	3/25/2025		
	1/21/2016	1/21/2016					2,272	$ 5,316
	1/20/2017	1/20/2017	13,852	5,147	$ 51.50	1/19/2027		
	2/21/2018	2/21/2018	10,307	12,192	$ 21.50	2/20/2028		
	1/29/2019	1/29/2019	—	45,999	$ 7.90	1/28/2029		
Mark Wiggins, M.B.A.	5/29/2018	5/29/2018	11,083	16,917	$ 27.50	5/28/2028		
	1/29/2019	1/29/2019	—	18,000	$ 7.90	1/28/2029		
Scott B. Brown, CPA, M.S.	8/31/2015	8/31/2015	2,352	—	$ 104.90	8/20/2025		
	1/21/2016	1/21/2016					43	$ 101
	1/20/2017	1/20/2017	968	364	$ 51.50	1/19/2027		
	2/21/2018	2/21/2018	916	1,084	$ 21.50	2/20/2028		
	1/29/2019	1/29/2019	—	10,000	$ 7.90	1/28/2029		

(1) Except as specifically noted, all of the option awards have a four-year vesting schedule. Dr. Theuer's options granted prior to October 3, 2014 vest in equal monthly tranches over the four-year vesting period. The options are also eligible for accelerated vesting on a qualifying termination as described above under "—Potential Payments Upon Termination or Change of Control."

(2) All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our Board prior to our initial public offering in February 2015. Following our initial public offering in February 2015, we use the closing stock price on the date of grant for the fair value of our common stock.

(3) Option award includes an additional vesting condition that our initial public offering be completed prior to March 31, 2015, and such offering was completed in February 2015.

Option Exercises

None.

Option Repricings

We did not engage in any repricings or other modifications or cancellations to any of our named executive officers' outstanding equity awards during the year ended December 31, 2019.

Health, Welfare and Retirement Benefits

All of our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, and life and disability insurance plans, in each case on the same basis as all of our other employees. We provide a 401(k) plan to our employees, including our named executive officers, as discussed in the section below entitled "—401(k) Plan."

401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our named executive officers are also eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code, and is also intended to qualify as a safe harbor plan. During 2019, we made matching contributions of 100% of the amount of each participant's contributions, up to 4% of each participant's compensation. The 401(k) plan currently does not offer the ability to invest in our securities.

Nonqualified Deferred Compensation

None of our named executive officers participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. Our Board may elect to provide our officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Bonus Plan

On January 28, 2020, the compensation committee of our Board adopted a revised written bonus plan, which sets forth the terms of the annual incentive bonus opportunity for eligible employees of our company. Under the bonus plan, our executive officers are eligible to receive bonus awards that are determined based on the achievement of our corporate goals for the applicable plan year. Bonuses, if any, under the bonus plan will be payable in cash or equity, or a combination of both, after the end of the applicable plan year and no later than December 31 of the following year.

Equity Benefit Plans

2015 Equity Incentive Plan

Our Board adopted the 2015 Equity Incentive Plan, or the 2015 Plan, in January 2015 and our stockholders approved the 2015 Plan in January 2015, which became effective on January 29, 2015, and since that date, no further grants have been made under the 2011 plan.

Stock Awards. The 2015 Plan provides for the grant of incentive stock options, or ISOs, nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation, or collectively, stock awards, all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Additionally, the 2015 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

Share Reserve. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2015 Plan was the sum of (1) 80,103 shares, plus (2) the number of shares (not to exceed 106,258 shares) (a) reserved for issuance under our 2011 plan at the time our 2015 Plan became effective, and (b) any shares subject to outstanding stock options or other stock awards that were granted under our 2011 plan that are forfeited, terminate, expire or are otherwise not issued. Additionally, the number of shares of our common stock reserved for issuance under our 2015 Plan will automatically increase on January 1st of each year, beginning on January 1, 2016 and continuing through and including January 1, 2025, by 4% of the total number of shares of our capital stock outstanding on December 31st of the preceding calendar year, or a lesser number of shares determined by our Board. The maximum number of shares of our common stock that may be issued upon the exercise of ISOs under our 2015 Plan is 361,757 shares.

No person may be granted stock awards covering more than 25,839 shares of our common stock under our 2015 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the stock award is granted. Additionally, no person may be granted in a calendar year a performance stock award covering more than 25,839 shares of our common stock or a performance cash award having a maximum value in excess of $1,000,000.

If a stock award granted under the 2015 Plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2015 Plan. In addition, the following types of shares of our common stock under the 2015 Plan may become available for the grant of new stock awards under the 2015 Plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2015 Plan may be previously unissued shares or reacquired shares bought by us on the open market.

In December 2015, the 2015 Plan was amended to allow an additional 50,000 shares of common stock to be used exclusively for the grant of awards as a material inducement for individuals to commence employment in compliance with Nasdaq Listing Rule 5635(c)(4). As of February 14, 2020, 548,182 shares of common stock were subject to outstanding awards under the 2015 Plan and 55,468 shares remained available for grant.

Administration. Our Board, or a duly authorized committee thereof, has the authority to administer the 2015 Plan. Our Board may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of

certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2015 Plan, our Board or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2015 Plan. Subject to the terms of our 2015 Plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2015 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2015 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2015 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

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

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

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

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

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2015 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2015 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provides otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2015 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation. Our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected include one or more of the following: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) earnings before interest, taxes, depreciation, amortization and legal settlements; (5) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (6) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (7) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (8) total stockholder return; (9) return on equity or average stockholder's equity; (10) return on assets, investment, or capital employed; (11) stock price; (12) margin (including gross margin); (13) income (before or after taxes); (14) operating income; (15) operating income after taxes; (16) pre-tax profit; (17) operating cash flow; (18) sales or revenue targets; (19) increases in revenue or product revenue; (20) expenses and cost reduction goals; (21) improvement in or attainment of working capital levels; (22) economic value added (or an equivalent metric); (23) market share; (24) cash flow; (25) cash flow per share; (26) share price performance; (27) debt reduction; (28) implementation or completion of projects or processes (including, without limitation, clinical trial initiation, clinical trial enrollment, clinical trial results, new and supplemental indications for existing products, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals, and product supply); (29) stockholders' equity; (30) capital expenditures; (31) debt levels; (32) operating profit or net operating profit; (33) workforce diversity; (34) growth of net income or operating income; (35) billings; (36) bookings; (37) employee retention; (38) initiation of phases of clinical trials and/or studies by specific dates; (39) patient enrollment rates; (40) budget management; (41) submission to, or approval by, a regulatory body (including, but not limited to the FDA) of an applicable filing or a product candidate; (42) regulatory milestones; (43) progress of internal research or clinical programs; (44) progress of partnered programs; (45) partner satisfaction; (46) timely completion of clinical trials; (47) submission of INDs and NDAs and other regulatory achievements; (48) research progress, including the development of programs; (49) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; and (50) other measures of performance selected by our Board.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (1) in the award agreement at the time the award is granted or (2) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (a) to exclude restructuring and/or other nonrecurring charges; (b) to exclude exchange rate effects; (c) to exclude the effects of changes to generally accepted accounting principles; (d) to exclude the effects of any statutory adjustments to corporate tax rates; (e) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles; (f) to exclude the dilutive effects of acquisitions or joint ventures; (g) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (h) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (i) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (j) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted

accounting principles; (k) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; (l) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; and (m) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the FDA or any other regulatory body. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the performance goals and to define the manner of calculating the performance criteria we select to use for such performance period. The performance goals may differ from participant to participant and from award to award.

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

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2015 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of ISOs, (4) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under the 2015 Plan) and (5) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

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

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our Board may deem appropriate; or
- make a payment equal to the excess of (1) the value of the property the participant would have received upon exercise of the stock award over (2) the exercise price otherwise payable in connection with the stock award.

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

Under the 2015 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our consolidated assets, (2) a sale or other disposition of at least 90% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change of Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. For example, certain of our employees may receive an award agreement that provides for vesting acceleration upon the individual's termination without cause or resignation for good reason (including a material reduction in the individual's base salary, duties, responsibilities or authority, or a material relocation of the individual's principal place of employment with us) in connection with a change of control. Under the 2015 Plan, a change of control is generally (1) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (2) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; or (3) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets.

Amendment and Termination. Our Board has the authority to amend, suspend, or terminate our 2015 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our Board adopted our 2015 Plan.

2011 Equity Incentive Plan

Our Board initially adopted, and our stockholders approved the 2011 Equity Incentive Plan, or the 2011 plan, in August 2011. The 2011 plan provides for the grant of stock options (ISOs and NSOs), stock appreciation rights, restricted stock awards and RSU awards to our employees, directors, and consultants. No additional awards will be granted under the 2011 plan, and all awards granted under the 2011 plan that are repurchased, forfeited, expired, cancelled or otherwise not issued will become available for grant under the 2015 Plan in accordance with its terms.

Administration. Our Board, or a duly authorized committee thereof, has the authority to administer the 2011 plan. Awards under the 2011 plan were granted pursuant to award agreements adopted by the plan administrator.

Share Reserve. The initial number of shares we reserved for issuance pursuant to the 2011 plan was 84,358 shares, which was increased in September 2014 to 107,097 shares in connection with our issuance of shares of our Series B redeemable convertible preferred stock. As of February 14, 2020, 27,621 shares of common stock were issued and outstanding pursuant to options under the plan that had been exercised and 55,299 shares of common stock were subject to outstanding awards. No additional awards will be granted under the 2011 plan, and all awards granted under the 2011 plan that are repurchased, forfeited, expired, are cancelled or otherwise not issued will become available for grant under the 2015 Plan in accordance with its terms.

Corporate Transactions. In the event of certain specified significant corporate transactions, each outstanding award will be subject to the terms of the applicable transaction agreement. Such transaction agreement may provide, without limitation, for the assumption or substitution of awards, for their continuation, for accelerated vesting or for cancellation with or without consideration, in all cases without the consent of the award holder.

Amendment and Termination. Our Board has the authority to amend, suspend or terminate our 2011 plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. As of January 29, 2015, no additional awards will be granted under the 2011 plan. However, any outstanding awards already granted under the 2011 plan will remain outstanding, subject to the terms of such plan and the applicable award agreements, until such outstanding awards are exercised or until they terminate or expire by their terms.

2015 Employee Stock Purchase Plan

Our Board adopted the 2015 Employee Stock Purchase Plan, or the ESPP, in January 2015 and our stockholders approved the ESPP in January 2015. The ESPP became effective on January 29, 2015. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates.

Share Reserve. The ESPP initially authorized the issuance of 18,346 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1st of each calendar year, from January 1, 2016 through January 1, 2025 by the least of (1) 1% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, (2) 36,692 shares, or (3) a number determined by our Board that is less than (1) and (2). The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. As of February 14, 2020, 20,715 shares of our common stock had been purchased under the ESPP and 110,164 shares remained available for issuance.

Administration. Our Board has delegated its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our Board, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (1) 85% of the fair market value of a share of our common stock on the first date of an offering or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our Board: (1) customarily employed for more than 20 hours per week, (2) customarily employed for more

than five months per calendar year or (3) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the Board will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year and (3) the number of shares and purchase price of all outstanding purchase rights.

Corporate Transactions. In the event of certain significant corporate transactions, including the consummation of: (1) a sale of all our assets, (2) the sale or disposition of 90% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction and (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then- outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days prior to such corporate transaction, and such purchase rights will terminate immediately.

Amendment and Termination. Our Board has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

DIRECTOR COMPENSATION

Our Board adopted a new compensation policy in January 2020, and is applicable to all of our non-employee directors. This compensation policy provides that each non-employee director will receive the following compensation for service on our Board:

- an annual cash retainer of $35,000;
- an annual cash retainer of $60,000 for service as chairman of our Board;
- an additional annual cash retainer of $7,500, $5,000 and $3,750 for service on our audit committee, compensation committee and the nominating and corporate governance committee, respectively;
- an additional annual cash retainer of $15,000, $10,000 and $7,500 for service as chairman of the audit committee, compensation committee and the nominating and corporate governance committee (in lieu of regular committee member fees), respectively;
- an automatic annual option grant to purchase 4,500 shares of our common stock or a restricted stock unit award of 2,250 shares of our common stock for each non-employee director serving on the Board on the date of our annual stockholder meeting (including by reason of his or her election at such meeting), in each case vesting 100% as of the earlier of the date of our next annual stockholder meeting and the one-year anniversary of the date of grant; and
- upon first joining our Board an automatic initial grant of an option to purchase 6,000 shares of our common stock that vests ratably in annual installments over a three-year period following the grant date.

Each of the option grants described above will vest and become exercisable subject to the director's continuous service with us, provided that each option will vest in full upon a change of control, as defined under our 2015 plan. The options will be granted under our 2015 plan, the terms of which are described in more detail above under "Equity Benefit Plans—2015 Equity Incentive Plan."

Director Summary Compensation Table

The following table summarizes director compensation for the year ended December 31, 2019:

Director	Fees Earned or Paid in Cash ($)	Stock awards ($)(2)(3)	Total ($)
William R. LaRue	55,000	6,753	61,753
Martin A. Mattingly, Pharm.D.	48,750	6,753	55,503
J. Rainer Twiford, J.D., Ph.D.	40,000	6,753	46,753
Paul Walker	50,000	6,753	56,753
Stephen T. Worland, Ph.D.	46,250	6,753	53,003
Theodore Wang, Ph.D.(1)	17,500	—	17,500

(1) On April 5, 2019, Dr. Wang informed us that he did not intend to stand for re-election at the June 13, 2019 annual meeting of stockholders.

(2) Other than Dr. Wang, each listed member of our Board received an option to purchase 1,500 shares of our common stock pursuant to the non-employee directors' policy in effect on June 13, 2019. Amounts shown in this column reflect the aggregate grant date fair value of the options computed in accordance with FASB ASC Topic 718. For more information on how this amount is calculated, see Note 6 in the Notes to Consolidated Financial Statements contained within Item 8 of this Annual Report for the year ended December 31, 2019.

(3) As of December 31, 2019, the aggregate number of stock options held by Mr. LaRue, Dr. Mattingly, Dr. Twiford, Mr. Walker, Dr. Worland, and Dr. Wang were 7,660, 8,499, 6,000, 6,000, 8,499 and 0, respectively.

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

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2019, with respect to shares of the Company's common stock that may be issued under its existing equity compensation plans:

	(a)	(b)	(c)
Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by stockholders(1):			
2011 Equity Incentive Plan(2)	55,299	$ 31.97	—
2015 Equity Incentive Plan(4)	279,068	$ 38.16	111,093
2015 Employee Stock Purchase Plan(5)	—	$ —	110,164
Equity compensation plans not approved by stockholders:			
Inducement awards(6)	32,504	$ 31.35	17,496

(1) The weighted average exercise price does not take into account the shares subject to outstanding RSUs which have no exercise price.

(2) For a description of our equity compensation plans, see above under "Equity Benefit Plans."

(3) Effective as of January 29, 2015, no additional awards will be granted under the 2011 plan, and all awards granted under the 2011 plan that are repurchased, forfeited, expire, are cancelled or otherwise not issued will become available for grant under the 2015 plan in accordance with its terms.

(4) The 2015 plan allows an additional 50,000 shares of common stock to be used exclusively for the grant of awards as a material inducement for individuals to commence employment with us in compliance with Nasdaq Listing Rule 5635(c)(4).

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding ownership of our common stock as of February 14, 2020 based on information available to us and filings with the SEC by (a) each person known to us to own more than 5% of the outstanding shares of our common stock, (b) each of our directors, (c) each of our named executive officers, and (d) all of our directors and named executive officers as a group. Each stockholder's percentage ownership is based on 5,397,938 shares of our common stock being outstanding as of February 14, 2020.

Name and address of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned
5% or greater stockholders:		
Puissance Capital Management(1)	536,224	9.15%
950 3rd Ave. 25th Floor		
New York, NY 10022		
New Enterprise Associates 14, L.P.(2)	417,514	7.63%
1954 Greenspring Drive, Suite 600		
Timonium, MD 21093		
Linden Capital L.P.(3)	567,748	9.99%
Victoria Place, 31 Victoria St		
Hamilton D0 HM10, Bermuda		
Directors and Named Executive Officers:		
Charles P. Theuer, M.D., Ph.D.(4)	112,176	2.04%
Mark C. Wiggins(5)	23,083	*
Scott B. Brown(6)	8,789	*
William R. LaRue(7)	7,499	*
Martin A. Mattingly, Pharm.D.(8)	7,749	*
J. Rainer Twiford, J.D., Ph.D.(9)	22,389	*
Paul Walker(10)	5,250	*
Stephen T. Worland, Ph.D.(11)	7,749	*
All executive officers and directors as a group (8 persons)(12)	194,684	3.51%

* Represents beneficial ownership of less than 1%.

(1) Represents 76,048 shares of common stock owned by Puissance Cross-Border IV, LLC and Puissance Cross-Border V LLC (in the aggregate) and 460,176 shares of common stock issuable upon exercise of warrants. The warrants are only exercisable to the extent that the holders thereof and their affiliates would beneficially own no more than 19.99% of the outstanding common stock after exercise. Puissance Cross-Border Opportunities V, Puissance Cross-Border Opportunities IV, Puissance GP, Puissance Capital Management GP, and Theodore Wang, share voting and dispositive power with respect to the shares held by Puissance Capital Management. Theodore Wang, the managing member of Puissance and a member of our Board through June 2019, disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

(2) Represents 346,718 outstanding shares of common stock beneficially owned by New Enterprise Associates 14, L.P., or NEA, and 70,796 shares of common stock issuable upon exercise of warrants. The warrants are only exercisable to the extent that the holders thereof and their affiliates would beneficially own no more than 19.99% of the outstanding common stock after exercise. The shares and warrants directly held by NEA are indirectly held by NEA Partners 14, L.P., the sole general partner of NEA; NEA 14 GP, LTD, the sole general partner of NEA Partners 14, L.P.; and each of the individual directors of NEA 14 GP, LTD. The directors of NEA 14 GP, LTD are M. James Barrett, Peter J. Barris, Forest Baskett, Ryan D. Drant, Anthony A. Florence, Jr., Patrick J. Kerins, Krishna "Kittu" Kolluri, David M. Mott, Scott D. Sandell, Peter Sonsini, Ravi Viswanathan and Harry R. Weller. NEA, NEA Partners 14, L.P., NEA 14 GP, LTD and the directors of NEA 14 GP, LTD share voting and dispositive power with respect to the shares held by NEA. Paul Walker, a partner at New Enterprise Associates, has no voting or dispositive power with regard to any of the above referenced shares and disclaims beneficial ownership of such shares except to

the extent of his pecuniary interest therein, if any. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their pecuniary interest therein.

(3) Represents 284,248 outstanding shares of common stock held by Linden Capital L.P. and 283,500 shares of common stock issuable upon exercise of warrants. The warrants are only exercisable to the extent that the holders thereof and their affiliates would beneficially own no more than 9.99% of the outstanding common stock after exercise. The shares and warrants directly held by Linden Capital L.P. are indirectly held by Linden Advisors LP, the investment manager of Linden Capital L.P., Linden GP LLC, the general partner of Linden Capital L.P., and Siu Min (Joe) Wong (Mr. Wong), the principle owner and controlling person of Linden Advisors and Linden GP LLC. Linden Capital L.P., Linden Advisors LP, Linden GP LLC and Mr. Wong share voting and dispositive power with respect to the shares held by Linden Capital L.P.

(4) Includes 95,399 shares of common stock subject to options exercisable as of April 7, 2020.

(5) Includes 18,083 shares of common stock subject to options exercisable as of April 7, 2020.

(6) Includes 7,361 shares of common stock subject to options exercisable as of April 7, 2020.

(7) Includes 6,160 shares of common stock subject to options exercisable as of April 7, 2020.

(8) Includes 6,999 shares of common stock subject to options exercisable as of April 7, 2020.

(9) Includes 1,057 shares of common stock beneficially owned by Brookline Investment Fund, LLC, 4,938 shares of common stock beneficially owned by CSA Biotechnology Fund I, LLC and 9,346 shares of common stock beneficially owned by CSA Biotechnology Fund II, LLC. J. Rainer Twiford, J.D., Ph.D., one of our directors, has voting and dispositive control over these shares. Dr. Twiford disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein. Also includes 1,796 shares of outstanding common stock held by MCT Investments, LLC. Dr. Twiford's spouse, Marsha C. Twiford, has voting and investment power with respect to the shares held by MCT Investments, LLC. Also includes 4,500 shares of common stock subject to options exercisable as of April 7, 2020.

(10) Includes 4,500 shares of common stock subject to options exercisable as of April 7, 2020. Paul Walker is a partner of New Enterprise Associates.

(11) Includes 6,999 shares of common stock subject to options exercisable as of April 7, 2020.

(12) Consists of the shares of outstanding common stock and shares of common stock subject to options exercisable as of April 7, 2020, if any, referred to in footnotes (4), (5), (6), (7), (8), (9), (10), and (11).

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

The following includes a summary of transactions since January 1, 2018 to which we have been a party, in which the amount involved in the transaction exceeded the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "*Executive Compensation*."

2018 PIPE Transaction

In March and April 2018, we entered into a private placement with certain purchasers to sell approximately 1.2 million shares of our common stock at a price of $27.00 per share, along with approximately 0.2 million pre-funded warrants to purchase common stock at a price of $26.90 per warrant with an exercise price of $0.10 per share, and approximately 1.4 million warrants to purchase common stock at a price of $1.25 per warrant with an exercise price of $27.00 per share. The transaction resulted in gross proceeds to us of $38.7 million and the final closing occurred on April 4, 2018. Each warrant provides that the holder may not exercise the warrant if the exercise would result in the holder beneficially owning more than either 9.99% or 19.99% of our outstanding common stock. The following table sets forth the number of shares of common stock purchased by holders of more than 5% of our common stock or entities affiliated with them (including those holders who became a greater than 5% holder as a result of the transaction):

Name(1)	Shares of Common Stock	Warrants	Aggregate Purchase Price ($)
Puissance Capital Management(2)	460,176	460,176	12,999,995
New Enterprise Associates 14, L.P.(3)	70,796	70,796	1,999,998
683 Capital Management	123,893	123,893	3,500,000
Linden Capital L.P.(4)	284,248	637,355	12,999,998
Aspire Capital Fund, LLC	106,194	106,194	2,999,997
Laurence W. Lytton	70,796	70,796	1,999,998

(1) Additional detail regarding these stockholders and their equity holdings is provided under *"Security Ownership of Certain Beneficial Owners and Management."*

(2) Theodore Wang, Ph.D., one of the members of our Board through June 13, 2019, is the Chief Investment Officer and Chief Executive Officer of Puissance Capital Management.
(3) Paul Walker, one of the members of our Board, is a partner of New Enterprise Associates 14, L.P.
(4) Warrants are comprised of 176,554 pre-funded warrants to purchase common stock and 460,801 warrants to purchase common stock.

In connection with the private placement, we engaged Angel Pond Capital LLC as a placement agent and paid Angel Pond a placement agent fee in the amount of $1.9 million. Angel Pond is affiliated through common control with Puissance which, as a result of the private placement, holds more than 5% of our common stock. Following the completion of the private placement, Theodore T. Wang, Ph.D., the sole member of Angel Pond, was appointed to our Board and served on our Board through June 13, 2019.

Policies and Procedures for Transactions with Related Persons

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years.

Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director or a holder of more than 5% of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our Board) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our Board takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

Indemnification of Officers and Directors

We have entered into, and intend to continue to enter into, separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our Bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Independence of Directors

As required under the pertinent listing standards of the Nasdaq Stock Market ("*Nasdaq*"), a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by its board of directors. Our Board consults with the Company's counsel to ensure that the board of directors' determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time. Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, our Board has determined that all of our directors, with the exception of Dr. Theuer, are independent directors within the meaning of the applicable listing standards of Nasdaq. In making this determination, the Board found that none of these directors had a material or other disqualifying relationship with the Company.

Item 14. Principal Accountant Fees and Services.

The following table presents fees for services rendered by Ernst & Young LLP, our independent registered public accounting firm, for 2019 and 2018 in the following categories:

	Years ended December 31,	
	2019	2018
Audit Fees (1)	$ 355,067	$ 343,053
Audit-Related Fees (2)	—	23,000
Tax Fees (3)	27,634	55,699
	$ 382,701	$ 421,752

(1) Audit fees consist of fees billed for professional services by Ernst & Young LLP for audit and quarterly review of our financial statements, review of our registration statements, and related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Audit-related fees consist of fees billed for professional services by Ernst & Young LLP for assurance and related services related to the audit of the financial statements.

(3) Tax fees consist of fees for professional services performed by Ernst & Young LLP with respect to tax compliance, tax advice and tax planning.

Policy on Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our audit committee has established a policy governing our use of the services of our independent registered public accounting firm. Under the policy, our audit committee is required to pre-approve all audit and permissible non-audit services performed by our independent registered public accounting firm in order to ensure that the provision of such services does not impair such accounting firm's independence. All fees paid to Ernst & Young LLP during the years ended December 31, 2019 and 2018 were pre-approved by our audit committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this report.

1. Financial Statements

The consolidated financial statements of TRACON Pharmaceuticals, Inc. listed below are set forth in Item 8 of this Annual Report for the year ended December 31, 2019:

2. Financial Statement Schedules

These schedules have been omitted because the required information is included in the financial statements or notes thereto or because they are not applicable or not required.

3. Exhibits

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(13)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.3(1)	Amended and Restated Bylaws.
4.1(2)	Form of Common Stock Certificate of the Registrant.
4.2(2)	Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated September 19, 2014.
4.3(7)	Investor Agreement by and between the Registrant and Johnson & Johnson Innovation-JJDC, Inc. dated September 27, 2016.
4.4(7)	Stock Purchase Agreement by and between the Registrant and Johnson & Johnson-JJDC, Inc. dated September 27, 2016.
4.5(12)	Registration Rights Agreement, dated October 18, 2019, by and between the Registrant and Aspire Capital Fund, LLC
4.6(15)	Securities Purchase Agreement, dated March 22, 2018, among TRACON Pharmaceuticals, Inc. and the purchasers listed on Exhibit A thereto.
4.7(15)	Form of Pre-Funded Warrant dated March 27, 2018.
4.8(15)	Form of Common Warrant dated March 27, 2018.
4.9	Description of Capital Stock.
10.1+(2)	Form of Indemnity Agreement by and between the Registrant and its directors and officers.
10.2+(2)	TRACON Pharmaceuticals, Inc. 2011 Equity Incentive Plan and Forms of Stock Option Agreement and Notice of Exercise thereunder.
10.3+(3)	TRACON Pharmaceuticals, Inc. 2015 Equity Incentive Plan and Forms of Stock Option Grant Notice, Stock Option Agreement, Notice of Exercise and Restricted Stock Unit Agreement thereunder, as amended December 14, 2015.
10.4+	TRACON Pharmaceuticals, Inc. Non-Employee Director Compensation Policy, as amended January 31, 2020.
10.5+(4)	TRACON Pharmaceuticals, Inc. 2015 Employee Stock Purchase Plan.

Exhibit Number	Description of Document
10.6+	TRACON Pharmaceuticals, Inc. Bonus Plan, as amended January 28, 2020.
10.7+(17)	Amended and Restated Employment Agreement by and between the Registrant and Charles P. Theuer, M.D., Ph.D., dated February 5, 2019.
10.8+(17)	Employment Agreement by and between the Registrant and Mark Wiggins, dated May 29, 2018.
10.9+(17)	Severance Agreement by and between the Registrant and Mark Wiggins, dated May 29, 2018.
10.10+	Employment Agreement by and between the Registrant and Scott Brown, dated January 28, 2020.
10.11+	Severance Agreement by and between the Registrant and Scott Brown, dated December 4, 2019.
10.12+(2)	TRACON Pharmaceuticals, Inc. Severance Plan and Summary Plan Description.
10.13*(2)	License Agreement by and between the Registrant and Santen Pharmaceutical Co., Ltd., dated March 3, 2014, as amended.
10.14*(5)	Second Amendment to License Agreement by and between the Registrant and Santen Pharmaceutical Co., Ltd., dated January 31, 2016.
10.15*(2)	License Agreement by and between the Registrant and Roswell Park Cancer Institute and Health Research, Inc., dated November 1, 2005, as amended on November 12, 2009, February 11, 2010 and September 18, 2014.
10.16*(2)	License Agreement by and between the Registrant and Case Western Reserve University, dated August 2, 2006.
10.17*(4)	Amendment to License Agreement by and between the Registrant and Case Western Reserve University, dated April 3, 2015.
10.18*	Collaboration and Clinical Trial Agreement by and among the Registrant, 3D Medicines (Beijing) Co., LTD. and Jiangsu Alphamab Biopharmaceuticals Co., LTD. dated December 20, 2019.
10.19*(9)	License and Option Agreement by and between the Registrant and Janssen Pharmaceutica N.V. dated September 27, 2016.
10.20(2)	Warrant to Purchase Stock issued to Silicon Valley Bank on November 14, 2013.
10.21(2)	Warrant to Purchase Stock issued to Silicon Valley Bank on June 4, 2014.
10.22(4)	Warrant to Purchase Stock issued to Silicon Valley Bank on May 13, 2015.
10.23(8)	Warrant to Purchase Stock issued to Silicon Valley Bank on January 25, 2017.
10.24(15)	Warrant to Purchase Stock issued to Silicon Valley Bank on May 3, 2018.
10.25(16)	Capital on Demand™ Sales Agreement, dated as of September 6, 2018, by and between TRACON Pharmaceuticals, Inc. and JonesTrading Institutional Services LLC.
10.26*(17)	Amendment One to License and Option Agreement between the Registrant and Janssen Pharmaceutica N.V. dated January 15, 2019.
10.27(14)	Amendment No. 1 to Capital on Demand™ Sales Agreement, dated as of February 28, 2019, by and between the Registrant and JonesTrading Institutional Services LLC.
10.28(4)	Amended and Restated Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, dated May 13, 2015.
10.29(6)	First Amendment to Amended and Restated Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, dated August 9, 2016.
10.30(8)	Second Amendment to Amended and Restated Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, dated January 25, 2017.
10.31(15)	Third Amendment to Amended and Restated Loan and Security Agreement between the Registrant and Silicon Valley Bank dated May 3, 2018.

Exhibit Number	Description of Document
10.32*(2)	Cooperative Research and Development Agreement by and between the Registrant and the U.S. Department of Health and Human Services, as represented by National Cancer Institute, dated December 22, 2010.
10.33(5)	Amendment #2 to Cooperative Research and Development Agreement by and between the Registrant and the U.S. Department of Health and Human Services, as represented by National Cancer Institute, dated November 12, 2015.
10.34*(2)	Cooperative Research and Development Agreement by and between the Registrant and the U.S. Department of Health and Human Services, as represented by National Cancer Institute, dated January 28, 2011, as amended on March 12, 2013.
10.35(5)	Amendment #2 to Cooperative Research and Development Agreement by and between the Registrant and the U.S. Department of Health and Human Services, as represented by National Cancer Institute, dated January 27, 2016.
10.36*(2)	Cooperative Research and Development Agreement by and between the Registrant and the U.S. Department of Health and Human Services, as represented by National Cancer Institute, dated August 7, 2012.
10.37*(2)	Sponsored Research Agreement by and between the Registrant and Tufts Medical Center, Inc., dated December 16, 2014.
10.38(12)	Common Stock Purchase Agreement, dated October 18, 2019 between TRACON Pharmaceuticals, Inc. and Aspire Capital Fund, LLC.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of the Principal Executive and Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive and Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

* Confidential treatment has been granted or requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on February 4, 2015.

(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-201280), as amended.

(3) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on December 17, 2015.

(4) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 14, 2015.

(5) Incorporated by reference to the Registrant's Annual Report on Form 10-K, filed with the SEC on February 19, 2016.

(6) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 11, 2016.

(7) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 9, 2016.

(8) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on January 31, 2017.

(9) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q/A for the quarter ended September 30, 2016, filed with the SEC on February 16, 2017.

(10) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on December 13, 2016.

(11) Incorporated by reference to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 1, 2017.

(12) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on October 21, 2019.

(13) Incorporated by reference to TRACON Pharmaceuticals, Inc.'s Current Report on Form 8-K, filed with the SEC on November 6, 2019.
(14) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 5, 2019.
(15) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 9, 2018.
(16) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 7, 2018.
(17) Incorporated by reference to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 1, 2019.

Signatures

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

TRACON Pharmaceuticals, Inc.

Date: February 27, 2020

By: /s/ CHARLES P. THEUER, M.D., PH.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dr. Charles Theuer, M.D., Ph.D. and Scott B. Brown, CPA, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the 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 in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated

Signature	Title	Date
/s/ Charles P. Theuer, M.D., Ph.D. Charles P. Theuer, M.D., Ph.D.	President, Chief Executive Officer and Member of the Board of Directors *(Principal Executive Officer and Principal Financial Officer)*	February 27,2020
/s/ Scott B. Brown, CPA Scott B. Brown, CPA	Chief Accounting Officer (*Principal Accounting Officer*)	February 27, 2020
/s/ William R. LaRue William R. LaRue	Member of the Board of Directors	February 27, 2020
/s/ Martin A. Mattingly, Pharm. D. Martin A. Mattingly, Pharm.D.	Member of the Board of Directors	February 27, 2020
/s/ J. Rainer Twiford, J.D., Ph.D. J. Rainer Twiford, J.D., Ph.D.	Member of the Board of Directors	February 27, 2020
/s/ Paul Walker Paul Walker	Member of the Board of Directors	February 27, 2020
/s/ Stephen T. Worland, Ph.D. Stephen T. Worland, Ph.D.	Member of the Board of Directors	February 27, 2020

DESCRIPTION OF COMMON STOCK

The following summary description of the common stock of TRACON Pharmaceuticals, Inc., or we, our or us, is based on the provisions of our amended and restated certificate of incorporation, as amended ("Certificate of Incorporation"), as well as our amended and restated bylaws, and the applicable provisions of the Delaware General Corporation Law. This information is qualified entirely by reference to the applicable provisions of our Certificate of Incorporation, amended and restated bylaws, and the Delaware General Corporation Law. Our Certificate of Incorporation and amended and restated bylaws, have previously been filed as exhibits with the Securities and Exchange Commission.

Voting Rights

Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Our Certificate of Incorporation and amended and restated bylaws do not provide for cumulative voting rights. Accordingly, the holders of a majority of our outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any outstanding shares of preferred stock, the holders of our common stock are entitled to receive ratably such dividends as may be declared by our board of directors out of legally available funds.

Liquidation, Dissolution or Winding Up

Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Non-assessable

All of our outstanding shares of common stock are fully paid and non-assessable.

Anti-takeover Effects of Provisions of Delaware Law and Charter Documents

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock
  plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the consummation of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our Certificate of Incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our Certificate of Incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as it may designate (including the right to approve an acquisition or other change in our control);

- provide that the authorized number of directors may be changed only by resolution adopted by a majority of the board of directors;

- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock;

- provide that all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of preferred stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- divide our board of directors into three classes;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;

- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and

- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exist any vacancies).

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock.

Forum for Disputes

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our Certificate of Incorporation or amended and restated bylaws, or (4) any action asserting a claim against us governed by the internal affairs doctrine. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction. This choice of forum provision may limit a stockholder’s ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find this choice of forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar’s address is 6201 15th Avenue, Brooklyn, New York 11219.

Listing on The Nasdaq Capital Market

Our common stock is listed on The Nasdaq Capital Market under the symbol “TCON.”

TRACON PHARMACEUTICALS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of TRACON Pharmaceuticals, Inc. (the "***Company***") or any of its subsidiaries (each such member, a "***Non-Employee Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (the "***Director Compensation Policy***") for his or her Board service.

The Director Compensation Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

A Non-Employee Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

Annual Cash Compensation

Each Non-Employee Director will receive the cash compensation set forth below for service on the Board. The annual cash compensation amounts will be payable in equal quarterly installments, in arrears following the end of each quarter in which the service occurred, pro-rated for any partial months of service. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $35,000
   b. Chairman/Lead Independent Director (as applicable): $60,000 (in lieu of above)

2. Annual Committee Member Service Retainer:
   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $5,000
   c. Member of the Nominating and Corporate Governance Committee: $3,750

3. Annual Committee Chair Service Retainer (in lieu of Committee Member Service Retainer):
   a. Chairman of the Audit Committee: $15,000
   b. Chairman of the Compensation Committee: $10,000
   c. Chairman of the Nominating and Corporate Governance Committee: $7,500

Equity Compensation

Equity awards will be granted under the Company's 2015 Equity Incentive Plan or any successor equity incentive plan (the "***Plan***"). All stock options granted under this policy will be Nonqualified Stock Options (as defined in the Plan), with a term of ten years from the date of grant

1.

and an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of the Company on the date of grant.

(a) Automatic Equity Grants.

(i) Initial Grant for New Directors. Without any further action of the Board, on the date of the Non-Employee Director's initial election to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Non-Employee Director will automatically be granted a Nonstatutory Stock Option to purchase 6,000 shares of common stock (the "***Initial Grant***"). Each Initial Grant will vest in a series of 3 successive equal annual installments over the 3-year period measured from the date of grant.

(ii) Annual Grant. Without any further action of the Board, at the close of business on the date of each annual meeting of the Company's stockholders, each person who is then a Non-Employee Director will automatically be granted either (A) a Nonstatutory Stock Option to purchase 4,500 shares of common stock or (B) a restricted stock unit ("***RSU***") covering 2,250 shares of common stock ((A) or (B) as applicable, the "***Annual Grant***"). Whether the Annual Grant for any particular year takes the form of a Nonstatutory Stock Option or an RSU shall be determined prior to each annual meeting of the Company's stockholders by the Board or the Compensation Committee; provided that absent a determination for any given year, the Annual Grant shall take the form of a Nonstatutory Stock Option. Each Annual Grant will vest in full on the earlier of the one-year anniversary of date of grant, or the date of the next annual meeting of the Company's stockholders.

(b) Vesting; Change in Control. All vesting is subject to the Non-Employee Director's "***Continuous Service***" (as defined in the Plan) on each applicable vesting date. Notwithstanding the foregoing vesting schedules, for each Non-Employee Director who remains in Continuous Service with the Company until immediately prior to the closing of a "***Change in Control***" (as defined in the Plan), the shares subject to his or her then-outstanding equity awards that were granted pursuant to this policy will become fully vested immediately prior to the closing of such Change in Control.

(c) Remaining Terms. The remaining terms and conditions of each stock option, including transferability, will be as set forth in the Company's standard Option Agreement, in the form adopted from time to time by the Board. The remaining terms and conditions of each RSU, including transferability, will be as set forth in the Company's standard Restricted Stock Unit Award Agreement, in the form adopted from time to time by the Board.

Expenses

The Company will reimburse Non-Employee Director for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; *provided*, that the Non-Employee Director timely submit to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

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TRACON PHARMACEUTICALS, INC.
BONUS PLAN

The TRACON Pharmaceuticals, Inc. ("***TRACON***" or the "***Company***") Bonus Plan (the "***Plan***") is designed to reward eligible employees for the achievement of corporate objectives, as well as measured individual objectives that are consistent with and support the overall corporate objectives.

ELIGIBILITY

All regular employees are eligible to participate in the Plan. In order to be eligible, a participant must have been in an eligible position for at least three (3) full months prior to the end of the Plan year, and the participant must remain continuously employed through the end of the Plan year and until awards are paid. The Plan year is January 1 through December 31. If the participant is not continuously employed through the date awards are paid, the participant will not have earned any bonus. If the participant has been subject to any performance improvement plan or other disciplinary procedure during the Plan year, any award to such individual will be at the discretion of the President/CEO or the Compensation Committee of the Board of Directors (the "***Compensation Committee***"), and may be reduced or withheld regardless of corporate performance as outlined below.

Change in Status During the Plan Period:

a. *Participants hired during the Plan year:*

- Participants hired during the Plan year are eligible for a prorated award based on the number of calendar days employed in an eligible position.
- Participants hired during the months of October through December are not eligible to participate for the Plan year.
- If an employee has worked in a temporary or consulting capacity for TRACON, this time will NOT impact the eligibility start date which is the date of hire. Only as an exception and with approval by the Compensation Committee or the Board of Directors will time worked as a consultant be considered when determining the bonus award proration for an employee.

b. *Promotion/change in level:*

- Participants promoted during the Plan year with a change to bonus target and/or bonus corporate and individual performance factor percentages are eligible for an award that will be prorated based on the number of calendar days employed in each eligible position.

c. *Termination of employment:*

- If a participant's employment is terminated voluntarily prior to the date awards are paid, the participant will not be eligible to receive an award.
- If a participant's employment is terminated involuntarily prior to the date awards are paid, it will be at the absolute discretion of the Company whether or not an award payment is made to such terminated participant.

d. *Leave of absence:*

- Bonus award will be prorated to reflect the calendar days on a leave of absence that exceed 60 calendar days in the Plan year.

AWARD CALCULATION

Awards will be determined by applying a "bonus percentage" to the participant's base salary that is in effect at the end of the Plan year, regardless if the salary has changed at any point during the calendar year.

The President/CEO will present to the Compensation Committee/Board of Directors a list of the overall corporate objectives for the applicable Plan year, which are subject to approval by the Compensation Committee/Board of Directors. All participants in the Plan whose performance is measured in part based on individual performance

factors will then develop a list of key individual objectives, which must be approved by the responsible Vice President, Senior Vice President, Chief Officer, or President/CEO.

The relative weight between "corporate and individual performance factors" varies based on the individual's assigned level within the organization. The bonus percentage and/or the weighting may be reviewed periodically and may be adjusted for any Plan year by the Compensation Committee. The Compensation Committee will use the weighting between the corporate and individual performance factors in effect at the end of the Plan year in making its bonus determination. The bonus percentages and weighting for the performance factors will initially be as follows:

LEVEL/POSITION				
			Individual Factors	
	Bonus Percentage	**Corporate Factor**	**Core Competency**	**Individual Goal Achievement**
President and CEO	50%	100%		
Chief Officer	40%	100%		
Executive/Senior Vice President	35%	100%		
Vice President	30%	60%	16%	24%
Senior Director	20%	40%	24%	36%
Director	20%	40%	24%	36%
Associate Director	20%	40%	24%	36%
Senior Manager II, I	20%	25%	30%	45%
Manager II, I	20%	25%	30%	45%
Individual Contributor II, I	20%	25%	30%	45%
Support	20%	25%	30%	45%

Performance Award Multiplier

Separate award multipliers will be established for both the corporate and the individual components of each award. The award multiplier for the corporate component will be determined by the Compensation Committee/Board of Directors each Plan year, in its sole discretion, based on the achievement of the approved corporate objectives for the Plan year. The same award multiplier for the corporate component of the award shall be used for all such Plan participants.

The award multiplier for the individual component shall be approved by the responsible Chief Officer or President/CEO and consists of the Core Competency Assessment and the achievement of Individual goals, each weighted 40% and 60%, respectively.

The ratings used for the Annual Performance Core Competency Assessment is as follows:

5 = Exceptional; Far exceeds all goals and objectives on a consistent basis
4 = Exceeds; Consistently exceeds goals and objectives
3 = Meets; Consistently meets goals and objectives
2 = Marginal; Met some goals and objectives but requires improvement
1 = Unsatisfactory

Numerical Rating Scale	Multiplier for Core Competency Individual Performance
5	120.00%
4.9	118.37%
4.8	116.70%
4.7	115.03%
4.6	113.36%
4.5	111.69%
4.4	110.02%
4.3	108.35%
4.2	106.68%
4.1	105.01%
4	103.34%
3.9	101.67%
3.8	100.00%
3.7	97.50%
3.6	95.00%
3.5	92.50%
3.4	90.00%
3.3	87.50%
3.2	85.00%
3.1	82.50%
3	80.00%
2.9	72.00%
2.8	64.00%
2.7	56.00%
2.6	48.00%
2.5	40.00%
2.4	32.00%
2.3	24.00%
2.2	16.00%
2.1	8.00%
2	0.00%

For Executives (Vice President level and above): The actual performance bonus awarded in any year, if any, may be more or less than the applicable target, depending primarily on the Compensation Committee's determination of the award multiplier for the corporate component and the executive's individual performance with respect to the corporate objectives. Whether or not a performance bonus is paid for any year is within the discretion of the Compensation Committee/Board of Directors based on such achievement.

Example:

Step # 1: Potential bonus award calculation
Position: Manager
Base salary at end of calendar year: $100,000
Target bonus percentage: 20%
Potential base bonus: $ 20,000

Step # 2: Split award target amount based on weighting of performance factors
Potential corporate performance bonus (25%): $ 5,000
Target individual performance bonus (75%):
Core Competency (40% of 75%, or 30%) $6,000
Personal Goal Achievement (60% of 75%, or 45%) $9,000
$ 20,000

Step # 2: Actual bonus award calculation
Payment multipliers are determined and approved based on assessment of corporate and individual performance, for example:

Corporate multiplier	75.0%
Core Competency Assessment multiplier	116.7% - performance assessed at 4.8
Personal Goal Objective Performance	85.0%

Corporate component	$ 3,750	($5,000 x 75.0%)
Individual component:		
Core Competency Assessment	$ 7,002	($6,000 x 116.7%)
Individual Goals Achieved	$ 7,650	($9,000 x 85.0%)
Total Award	$ 18,402	

AWARD PAYMENTS

Bonus award payments may be made in cash, through the issuance of stock, stock options or another form of equity award, or by a combination of cash, stock, stock options and/or another form of equity award, at the discretion of the Compensation Committee. All bonus award payments are subject to applicable tax withholdings. In the event that the Compensation Committee and/or the Board of Directors elect to pay bonus awards in stock or stock options, the Compensation Committee, in its sole discretion, will make a determination as to the number of shares of stock or stock options to be issued to each Plan participant based, in part, upon the overall corporate performance and each participant's individual performance, as described. The issuance of stock and stock options may also be subject to the approval of the Company's stockholders, and any stock options issued will be subject to the terms and conditions of the Company's equity incentive award plan, as amended from time to time by the Company.

Payment of bonus awards will be made as soon as practicable after the Company's year-end, but not later than December 31 of the year following the Plan year. Payments will not be impacted by any benefits, with the exception of elected 401(k) contributions which will be applied.

PLAN PROVISIONS

Governance

The Plan will be governed by the Compensation Committee. The President and/or CEO of TRACON will be responsible for the administration of the Plan. The Compensation Committee will be responsible for recommending to the Board of Directors a bonus amount for the President and/or CEO. Additionally, the Compensation Committee will be responsible for approving any compensation or incentive awards to other executive officers of the Company and all other officers who are subject to the reporting requirements of Section 16(a) of the Securities Exchange Act of 1934, as amended. All determinations of the Compensation Committee, under the Plan, shall be final and binding on all Plan participants.

Compensation Committee's Absolute Right to Alter or Abolish the Plan

The Compensation Committee reserves the right in its absolute discretion to terminate the Plan, or any portion of the Plan, at any time or to alter the terms and conditions under which a bonus will be paid. In the event of the Plan's termination prior to the payment of a bonus, such bonus will not be payable under this Plan. Such discretion may be exercised any time before, during, and after the Plan year is completed. No participant shall have any vested right to receive any compensation hereunder until actual delivery of such compensation. Participation in the Plan at any given time does not guarantee ongoing participation.

Employment Duration/Employment Relationship

This Plan does not, and TRACON's policies and practices in administering this Plan do not, constitute an express or implied contract or other agreement concerning the duration of any participant's employment with the Company. The employment relationship of each participant is "at will" and may be terminated at any time by TRACON or by the participant, with or without cause.

TRACON PHARMACEUTICALS, INC.

EMPLOYMENT AGREEMENT

For

SCOTT BROWN

This **EMPLOYMENT AGREEMENT** (the ***"Agreement"***) is made and entered into effective as of January 28, 2020 (the ***"Effective Date"***), by and between TRACON Pharmaceuticals, Inc., a Delaware corporation (the ***"Company"***), and Scott Brown (the ***"Executive"***). The Company and Executive are hereinafter collectively referred to as the ***"Parties"***, and individually referred to as a ***"Party"***.

RECITALS

WHEREAS, the Company desires to employ Executive to provide personal services to the Company in that capacity, and wishes to provide Executive with certain compensation and benefits in return for such services, and Executive wishes to be so employed and to receive such benefits; and

WHEREAS, the Company and Executive wish to enter into this Agreement to define their mutual rights and duties with respect to Executive's compensation and benefits;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, the Parties, intending to be legally bound, agree as follows:

AGREEMENT

1. Employment by the Company.

1.1 Position. Executive shall serve as the Company's Chief Accounting Officer. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company, except as permitted in Section 10 below, and except for approved vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies.

1.2 Duties and Location. Executive shall report to the Company's Chief Executive Officer (the ***"CEO"***), and shall have such duties and responsibilities as are customary for the position of Chief Accounting Officer. Executive's primary office location shall be the Company's San Diego, California office. The Company reserves the right to reasonably require Executive to perform Executive's duties at places other than Executive's primary office location from time to time, and to require reasonable business travel.

1.3 Policies and Procedures. The employment relationship between the Parties shall be governed by the general employment policies and practices of the Company,

except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Salary. Executive shall receive a base salary at the rate of $254,400 per year, subject to standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule.

2.2 Bonus. Executive will be eligible for an annual discretionary bonus of up to forty-percent (40%) of Executive's base salary in effect during the bonus year (the ***"Annual Bonus"***). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Company's Board of Directors (the "***Board***") (or the Compensation Committee thereof) in its sole discretion, based upon the Company's and Executive's achievement of objectives and milestones to be determined on an annual basis by the Board (or the Compensation Committee thereof). No Annual Bonus amount is guaranteed and, in addition to the other conditions for earning such Annual Bonus, Executive must remain an employee in good standing of the Company on the scheduled Annual Bonus payment date in order to earn any Annual Bonus.

3. Standard Company Benefits. Executive shall be entitled to participate in all employee benefit programs for which Executive is eligible under the terms and conditions of the benefit plans that may be in effect from time to time and provided by the Company to its employees. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time. Executive will be included as an insured under the Company's D&O insurance policy to the same extent as other executive officers of the Company.

4. Vacation. Executive shall be entitled to accrue accordance with the terms of the Company's vacation policy and practices (including but not limited to maximum vacation accrual caps).

5. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in furtherance or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

6. Equity

6.1 Prior Awards. Any stock, stock options, or other equity awards that Executive has already been granted by the Company shall continue to be governed in all respects by the terms of the applicable grant agreements, grant notices, and plan documents, except as otherwise provided in this agreement.

6.2 Additional Awards. The Board (or the Compensation Committee thereof) may grant additional stock, stock options, or other equity awards to Executive in its sole discretion.

7. Termination of Employment.

7.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without cause or advance notice.

7.2 Termination Benefits. In the event that Executive's employment terminates for any reason, including due to Executive's death or disability, no further payments shall be due under this Agreement, except that Executive shall be entitled to any amounts earned, accrued or owing but not yet paid under Section 2 above, any benefits accrued or earned under the Company's benefit plans and programs or to which Executive is otherwise entitled under applicable law, and any outstanding equity awards vested as of the termination date, which awards must be exercised within 90 days of the termination date or the earlier expiration of such equity award, whichever occurs first. Executive may also be eligible for other post-employment payments and benefits pursuant to the terms and conditions of that certain June 2, 2014 TRACON Pharmaceuticals, Inc. Severance Plan (the "***Severance Plan***"), and the Severance Agreement entered into by and between Executive and the Company on December 4, 2019 (the "***Severance Agreement***").

8. Section 409A. It is intended that all of the benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A.

9. Proprietary Information Obligations.

9.1 Confidential Information Agreement. As a condition of employment, and in consideration for the benefits provided for in this Agreement and the Severance Agreement, Executive shall sign and comply with the Company's Employee Proprietary Information and Inventions Agreement (the "***Confidential Information Agreement***").

9.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's employment by the Company, except as expressly authorized by that third party. During Executive's employment by the Company, Executive will use in the performance of Executive's duties only information which is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company.

10. Outside Activities During Employment.

10.1 **Non-Company Business.** Except with the prior written consent of the Board, Executive will not during the term of Executive's employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder.

10.2 **No Adverse Interests.** Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

11. **Dispute Resolution.** To ensure the rapid and economical resolution of disputes that may arise in connection with Executive's employment and services for the Company, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive's employment with and services for the Company, or the termination of Executive's employment with and services for the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §§1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted in San Diego, California (or such other location as mutually agreed by the parties) by JAMS, Inc. (***"JAMS"***) or its successors by a single arbitrator. ***Both Executive and the Company acknowledge that by agreeing to this arbitration procedure, they each waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.*** Any such arbitration proceeding will be governed by JAMS' then applicable rules and procedures for employment disputes, which can be found at http://www.jamsadr.com/rules-clauses/ and which will be provided to Executive upon request. In any such proceeding, the arbitrator shall (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. Executive and the Company each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. Nothing in this Agreement is intended to prevent either the Company or Executive from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. The Company shall pay all filing fees in excess of those that would be required if the dispute were decided in a court of law, and shall pay the arbitrator's fees and any other fees or costs unique to arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

12. **General Provisions.**

12.1 **Notices.** Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

12.2 **Severability.** Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any

provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

12.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

12.4 Complete Agreement. This Agreement, together with the Severance Plan, the Severance Agreement, and the Confidential Information Agreement, constitutes the entire agreement between Executive and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the Parties' agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. It cannot be modified or amended except in a writing signed by a duly authorized officer of the Company and Executive.

12.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

12.6 Headings. The headings of the paragraphs hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

12.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

12.8 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to the Agreement.

12.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

In Witness Whereof, the Parties have executed this Agreement on the day and year first written above.

TRACON PHARMACEUTICALS, INC.

By: /s/ Charles P. Theuer
Charles P. Theuer, M.D., Ph.D.
Chief Executive Officer

EXECUTIVE

/s/ Scott Brown
Scott Brown

TRACON PHARMACEUTICALS, INC. SEVERANCE PLAN

SEVERANCE AGREEMENT

This Severance Agreement (the "***Agreement***") is entered into effective December 4, 2019 (the "***Effective Date***"), by and between Scott Brown ("***you***" or "***your***") and TRACON Pharmaceuticals, Inc. (the "***Company***") pursuant to the TRACON Pharmaceuticals, Inc. Severance Plan ("***Plan***"). Capitalized terms used herein but not otherwise defined have the meanings set forth in the Plan.

You are a Covered Employee (as defined in the Plan) and participant in the Plan as provided by the Plan. This Agreement is the Severance Agreement described in the Plan and this Agreement enumerates the Plan benefits that may be provided to you as a Covered Employee as referenced in Section II of the Plan. All provisions of this Agreement are subject to and governed by the terms of the Plan. In the event of any conflict in terms between the Plan and this Agreement, the terms of the Plan shall prevail and govern.

In consideration of the mutual covenants and promises made in this Agreement, you and the Company agree as follows:

1. ***Certain Definitions.*** In addition to terms defined elsewhere herein or in the Plan, the following terms have the following terms have the following meanings when used in this Agreement:

(a) **"Base Salary"** means your then current base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation), at the rate in effect during the last regularly scheduled payroll period immediately preceding the date of your Qualifying Termination, and determined prior to any reduction in base pay that would permit you to voluntarily resign employment for Good Reason or any reduction in your base pay which occurs following a Change in Control.

(b) "**Board**" means the Company's Board of Directors.

(c) "**Cause**" means the occurrence of one or more of the following:

(i) Your commission of fraud or other unlawful conduct in your performance of duties for the Company;

(ii) your conviction of, or a plea of guilty or nolo contendere to, a felony or other crime (except for misdemeanors which are not materially injurious to the business or reputation of the Company or a Company affiliate); or

(iii) your willful refusal to perform in any material respect your duties and responsibilities for the Company or a Company affiliate or your failure to comply in any material respect with the terms of any agreement between you and the Company, including any proprietary information and assignment of inventions agreement or and the policies and procedures of the Company or a Company affiliate at which you are employed or serve as an officer and/or director if such refusal or failure causes or reasonably expects to cause injury to the Company or a Company affiliate;

(iv) fraud or other illegal conduct in your performance of duties for the Company or a Company affiliate;

(v) any conduct by you which is materially injurious to the Company or a Company affiliate or materially injurious to the business reputation of the Company or a Company affiliate.

The foregoing events are an exhaustive list for which your employment can be terminated by the Company for Cause for purposes of this Agreement. Prior to your termination for Cause at any time within 12 months following a Change in Control, you will be provided with written notice from the Company describing the conduct forming the basis for the alleged Cause and to the extent curable as determined by the Board in its good faith discretion, an opportunity of 15 days to cure such conduct before the Company may terminate you for Cause. If the Board determines that the Cause event is curable, you may during this 15 day period present your case to the full Board before any termination for Cause is finalized by the Company. Any termination for "Cause" will not limit any other right or remedy the Company may have under this Agreement or otherwise.

(a) "**Change in Control Related Termination**" means that a Qualifying Termination where your Termination Date occurs on or within 12 months after a Change in Control.

(b) "**Change in Control**" has the meaning as defined in the Company's 2015 Equity Incentive Plan. For purposes of this Agreement, only the first Change in Control occurring after the Effective Date will be a "Change in Control."

(c) "**Company**" shall mean TRACON Pharmaceuticals, Inc., a Delaware corporation, and shall include any successor company following a Change in Control.

(d) "**Good Reason**" means a resignation of your employment after the first occurrence of any one or more of the following events without your written consent.

(i) a material diminution in your responsibilities, duties or authority;

(ii) a material diminution in your Base Salary; or

(iii) a relocation of the Company's principal place of business where you are assigned to work outside of the San Diego metropolitan area;

provided, however that your resignation will only be for Good Reason if each of the following additional conditions is met: (i) you provide the Company with written notice describing in detail the basis and underlying facts supporting your belief that a Good Reason event has occurred within 45 days of the initial existence of such Good Reason event, (ii) the Company has not cured or remedied the Good Reason event within 30 days after its receipt of your written notice, and (iii) your resignation occurs within ninety (90) days of the initial existence of the Good Reason event. This "Good Reason" definition and process is intended to comply with the safe harbor provided under Treasury Regulation Section 1.409A-1(n)(2)(ii) and shall be interpreted accordingly.

(e) "**Non-Change in Control Related Termination**" means a Qualifying Termination that is not a Change in Control Related Termination.

(f) "**Qualifying Termination**" means a termination of your employment by the Company without Cause or your resignation of employment for Good Reason. A Qualifying Termination does not include any termination of your employment due to death or disability.

(g) "**Separation Agreement**" means the separation agreement and general release of all claims in substantially the form attached as **Exhibit A** hereto, with such other changes as the Company may reasonably require in order to provide for an effective release of claims, and delivered to you no later than five days following your Termination Date.

(h) **"Target Bonus"** means the applicable percentage of your annual Base Salary that you were eligible to earn as an annual bonus for the year including your Termination Date, and calculated without giving effect to any reduction in your Base Salary that would give rise to your right to resign for Good Reason or any reduction in Base Salary implemented following a Change in Control.

(i) "**Termination Date**" means your last day of employment with the Company.

2. ***Non-Change in Control Related Termination of Employment.*** If your employment is terminated due to a Non-Change in Control Related Termination, you will be eligible to receive the severance benefits provided in this Section 2, provided that you must: (i) within not later than forty-five (45) days after your Termination Date, execute and deliver to the Company the Separation Agreement and permit it to become effective in accordance with its terms, and (ii) remain in full compliance with the terms of such Separation Agreement. Upon any breach of the terms of your Separation Agreement, severance benefits provided under this Section 2 will immediately cease.

(a) You will receive a severance payment equal to nine months of your Base Salary ("**Cash Severance**"). The Cash Severance shall be paid to you in substantially equal installments in accordance with the Company's regular payroll practices over the nine month period following your Termination Date; provided, however, the first payment shall be made on the 60th day following your Termination Date and such first installment shall be in an amount to cover the first two months of Cash Severance payments otherwise scheduled to occur following your Termination Date.

(b) Provided that you timely elect COBRA coverage and you continue to timely pay the same portion (if any) of the necessary group health insurance premium that you were responsible to pay as of immediately before your Termination Date, the Company shall continue to pay the Company portion of the premiums for your Company group health insurance coverage for you and your dependents (the "***COBRA Premiums***") until the earlier of: (i) nine months following the Termination Date, (ii) the date you are provided with other group health insurance coverage, or (iii) the date you cease to be eligible for COBRA coverage (the "***COBRA Payment Period***"). For purposes of this Agreement, COBRA Premiums do not include amounts paid by you for coverage under a Section 125 health care reimbursement account plan. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay you on the first day of each calendar month following the Termination Date, a fully taxable cash payment equal to the applicable COBRA Premiums for that month, subject to applicable tax withholdings for the remainder of the COBRA Payment Period.

(c) In addition to the Cash Severance and COBRA Premiums, all of your outstanding equity awards that are subject to vesting solely upon the passage of time and your continued employment with the Company shall be accelerated in accordance with their applicable vesting schedules as if you had completed an additional nine months of employment as of your Termination Date.

3. ***Change in Control Related Termination of Employment.*** If your employment is terminated due to a Change in Control Related Termination, you will be eligible to receive severance benefits provided in this Section 3, provided that you must: (i) within not later than forty-five (45) days after your Termination Date, execute and deliver to the Company the Separation Agreement and permit it

to become effective in accordance with its terms, and (ii) remain in full compliance with the terms of such Separation Agreement. Upon any breach of the terms of your Separation Agreement, severance benefits provided under this Section 3 will immediately cease.

(a) You will receive a severance payment equal to your annual Base Salary and Target Bonus ("**CIC Cash Severance**"). The CIC Cash Severance shall be paid to you in substantially equal installments in accordance with the Company's regular payroll practices over the twelve month period following your Termination Date; provided, however, the first payment shall be made on the 60th day following your Termination Date and such first installment shall be in an amount to cover the first two months of CIC Cash Severance payments otherwise scheduled to occur following your Termination Date.

(b) Provided that you timely elect COBRA coverage and you continue to timely pay the same portion (if any) of the necessary group health insurance premium that you were responsible to pay as of immediately before your Termination Date, the Company shall continue to pay the Company portion of the premiums for your Company group health insurance coverage for you and your dependents (the "***COBRA Premiums***") until the earlier of: (i) twelve months following the Termination Date, or (ii) the date you are provided with other group health insurance coverage (the "***CIC COBRA Payment Period***"). For purposes of this Agreement, COBRA Premiums do not include amounts paid by you for coverage under a Section 125 health care reimbursement account plan. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay you on the first day of each calendar month following the Termination Date, a fully taxable cash payment equal to the applicable COBRA Premiums for that month, subject to applicable tax withholdings for the remainder of the CIC COBRA Payment Period.

(c) In addition to the Cash Severance and COBRA Premiums, all of your outstanding equity awards that are subject to vesting solely upon the passage of time and your continued employment with the Company shall be accelerated such that 100% of such outstanding equity awards shall be deemed immediately vested and exercisable as of your Termination Date.

4. ***Assignability; Binding Nature.*** Commencing on the Effective Date, this Agreement will be binding upon you and the Company. This Agreement may not be assigned by you except that your rights to compensation and benefits hereunder, subject to the limitations of this Agreement, may be transferred by will or operation of law. No rights or obligations of the Company under this Agreement may be assigned or transferred except in the event of a merger or consolidation in which the Company is not the continuing entity, or the sale or liquidation of all or substantially all of the assets of the Company provided that the assignee or transferee is the successor to all or substantially all of the assets of the Company and assumes the Company's obligations under this Agreement contractually or as a matter of law. The Company will require any such purchaser, successor or assignee to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such purchase, succession or assignment had taken place. Your rights and obligations under this Agreement shall not be transferable by you by assignment or otherwise provided, however, that if you die, all amounts then payable to you hereunder shall be paid in accordance with the terms of this Agreement to your devisee, legatee or other designee or, if there be no such designee, to your estate.

5. ***Governing Law.*** This Agreement is governed by the Employee Retirement Income Security Act of 1974, as amended, and, to the extent applicable, the laws of the State of Delaware, without reference to the conflict of law provisions thereof.

6. **Taxes.** The Company shall have the right to withhold and deduct from any payment hereunder any federal, state or local taxes of any kind required by law to be withheld with respect to any such payment. The Company (including without limitation members of its Board) shall not be liable to you or other persons as to any unexpected or adverse tax consequence realized by you and you shall be solely responsible for the timely payment of all taxes arising from this Agreement that are imposed on you. This Agreement is intended to comply with the applicable requirements of Internal Revenue Code (the "**Code**") Section 409A and shall be limited, construed and interpreted in a manner so as to comply therewith. Each payment made pursuant to any provision of this Agreement shall be considered a separate payment and not one of a series of payments for purposes of Code Section 409A. While it is intended that all payments and benefits provided under this Agreement to you will be exempt from or comply with Code Section 409A, the Company makes no representation or covenant to ensure that the payments under this Agreement are exempt from or compliant with Code Section 409A. The Company will have no liability to you or any other party if a payment or benefit under this Agreement is challenged by any taxing authority or is ultimately determined not to be exempt or compliant. In addition, if upon your Termination Date, you are then a "specified employee" (as defined in Code Section 409A), then solely to the extent necessary to comply with Code Section 409A and avoid the imposition of taxes under Code Section 409A, the Company shall defer payment of "nonqualified deferred compensation" subject to Code Section 409A payable as a result of and within six (6) months following your Termination Date until the earlier of (i) the first business day of the seventh month following your Termination Date or (ii) ten (10) days after the Company receives written confirmation of your death. Any such delayed payments shall be made without interest.

7. ***Section 280G. Limitation on Payments.*** If any payment or benefit you will or may receive from the Company or otherwise (a "***280G Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then any such 280G Payment pursuant to this Agreement (a "***Payment***") shall be equal to the Reduced Amount. The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "***Reduction Method***") that results in the greatest economic benefit for you. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "***Pro Rata Reduction Method***").

Notwithstanding any provision of the preceding paragraph to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A of the Code that would not otherwise be subject to taxes pursuant to Section 409A of the Code, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A of the Code as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for you as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A of the Code shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A of the Code.

Unless you and the Company agree on an alternative accounting firm or law firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting or law firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting or law firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to you and the Company within fifteen (15) calendar days after the date on which your right to a 280G Payment becomes reasonably likely to occur (if requested at that time by you or the Company) or such other time as requested by you or the Company.

If you receive a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section 7 and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, you shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section 7 so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of the first paragraph of this Section 7, you shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

8. ***No Change in At-Will Status.*** Your employment with the Company is and shall continue to be at-will, as defined under applicable law. If your employment terminates for any reason, you shall not be entitled to any payments, benefits, damages, awards or compensation other than as provided by this Agreement or required by applicable law, or as may otherwise be established under the Company's then existing employee benefit plans or policies at the time of termination. Nothing in this Agreement modifies your at-will employment status and either you or the Company can terminate the employment relationship at any time, with or without Cause.

9. ***Entire Agreement.*** Except as otherwise specifically provided in this Agreement, the Plan and this Agreement (and the agreements referenced herein) contain all the legally binding understandings and agreements between you and the Company pertaining to the subject matter of this Agreement and supersedes all such agreements, whether oral or in writing, previously discussed or entered into between the parties.

10. ***Covenants***

(a) (a) As a condition of this Agreement and to your receipt of any post-employment benefits, you agree that you will fully and timely comply with all of the covenants set forth in this Section 10(a) (which shall survive your termination of employment and termination or expiration of this Agreement):

(i) You will fully comply with all obligations under the proprietary information and inventions agreement between you and the Company (as amended from time to time, the "**Confidentiality Agreement**") and further agree that the provisions of the Confidentiality Agreement shall survive any termination or expiration of this Agreement or termination of your employment or any subsequent service relationship with the Company;

(ii) Within five (5) days of the Termination Date, you shall return to the Company all Company confidential information including, but not limited to, intellectual property, etc. and you shall not retain any copies, facsimiles or summaries of any Company proprietary information;

(iii) You will not at any time during or following your employment with the Company, make (or direct anyone to make) any disparaging statements (oral or written) about the Company, or any of its affiliated entities, officers, directors, employees, stockholders, representatives or agents, or any of the Company's products or services or work-in-progress, that are harmful to their businesses, business reputations or personal reputations; provided that nothing in this Section 10(a)(iii) will be interpreted or construed to prevent you from giving truthful testimony to any law enforcement officer, court, administrative proceeding or as part of an investigation by any governmental agency;

(iv) You agree that, upon the Company's request and without any payment therefore, you shall reasonably cooperate with the Company (and be available as necessary) after the Termination Date in connection with any matters involving events that occurred during your period of employment with the Company.

(b) You also agree that you will fully and timely comply with all of the covenants set forth in this Section 10(b) (which shall survive your termination of employment and termination or expiration of this Agreement):

(i) You will fully pay off any outstanding amounts owed to the Company no later than their applicable due date or within thirty days of your Termination Date (if no other due date has been previously established);

(ii) Within five (5) days of the Termination Date, you shall return to the Company all Company property including, but not limited to, computers, cell phones, pagers, keys, business cards, etc.;

(iii) Within fifteen (15) days of the Termination Date, you will submit any outstanding expense reports to the Company on or prior to the Termination Date; and

(iv) As of the Termination Date, you will no longer represent that you are an officer, director or employee of the Company and you will immediately discontinue using your Company mailing address, telephone, facsimile machines, voice mail and e-mail.

(c) You acknowledge that (i) upon a violation of any of the covenants contained in Section 10 of this Agreement or (ii) if the Company is terminating your employment for Cause, the Company would as a result sustain irreparable harm, and, therefore, you agree that in addition to any other remedies which the Company may have, the Company shall be entitled to seek equitable relief including specific performance and injunctions restraining you from committing or continuing any such violation; and

11. ***Offset***. Any Severance or other payments or benefits made to you under this Agreement may be reduced, in the Company's discretion, by any amounts you owe to the Company provided that any such offsets do not violate Code Section 409A. To the extent you receive severance or similar payments and/or benefits under any other Company plan, program, agreement, policy, practice, or the like, or under the WARN Act or similar state law, the payments and benefits due to you under this Agreement will be correspondingly reduced on a dollar-for-dollar basis (or vice-versa) in a manner that complies with Code Section 409A.

12. ***Notice.*** Any notice that the Company is required to or may desire to give you shall be given by personal delivery, recognized overnight courier service, email, telecopy or registered or certified mail, return receipt requested, addressed to you at your address of record with the Company, or at such other place as you may from time to time designate in writing. Any notice that you are required or may

desire to give to the Company hereunder shall be given by personal delivery, recognized overnight courier service, email, telecopy or by registered or certified mail, return receipt requested, addressed to the Company's Chief Executive Officer at its principal office, or at such other office as the Company may from time to time designate in writing. The date of actual delivery of any notice under this Section 10 shall be deemed to be the date of delivery thereof.

13. ***Waiver; Severability.*** No provision of this Agreement may be amended or waived unless such amendment or waiver is agreed to by you and the Company in writing. No waiver by you or the Company of the breach of any condition or provision of this Agreement will be deemed a waiver of a similar or dissimilar provision or condition at the same or any prior or subsequent time. Except as expressly provided herein to the contrary, failure or delay on the part of either party hereto to enforce any right, power, or privilege hereunder will not be deemed to constitute a waiver thereof. In the event any portion of this Agreement is determined to be invalid or unenforceable for any reason, the remaining portions shall be unaffected thereby and will remain in full force and effect to the fullest extent permitted by law.

14. ***Voluntary Agreement.*** You acknowledge that you have been advised to review this Agreement with your own legal counsel and other advisors of your choosing and that prior to entering into this Agreement, you have had the opportunity to review this Agreement with your attorney and other advisors and have not asked (or relied upon) the Company or its counsel to represent you or your counsel in this matter. You further represent that you have carefully read and understand the scope and effect of the provisions of this Agreement and that you are fully aware of the legal and binding effect of this Agreement. This Agreement is executed voluntarily by you and without any duress or undue influence on the part or behalf of the Company.

By signing below, you expressly acknowledge that you (i) have received a copy of the Plan and its Summary Plan Description, (ii) understand the terms of the Plan and this Agreement, (iii) are voluntarily entering into this Agreement and (iv) are agreeing to be bound by the terms of the Plan and this Agreement.

Please acknowledge your acceptance and understanding of this Agreement by signing and returning it to the undersigned. A copy of this signed Agreement will be sent to you for your records.

ACKNOWLEDGED AND AGREED:

TRACON PHARMACEUTICALS, INC.	**SCOTT BROWN**
/s/ Charles P. Theuer	/s/ Scott Brown
BY: Charles P. Theuer, President and CEO	

[Signature Page to Severance Agreement]

EXHIBIT A

SEPARATION AGREEMENT AND GENERAL RELEASE OF ALL CLAIMS

This Separation Agreement and General Release, dated [DATE] (the "**Agreement**"), is made pursuant to that certain Severance Agreement dated [DATE], 2019 (the "**Severance Agreement**") entered into by and between Scott Brown ("**Employee**") on the one hand, and TRACON Pharmaceuticals, Inc. (the "**Company**"), on the other. This Agreement is entered into in consideration for and as condition precedent to the Company providing separation benefits to Employee pursuant to the Severance Agreement. It is understood and agreed that the Company is not otherwise obligated to provide such benefits under the terms of the Severance Agreement and that the Company is doing so as a direct result of Employee's willingness to agree to the terms hereof. Collectively, Employee and the Company shall be referred to as the "**Parties**."

1. Employee was formerly employed by the Company. Employee's employment with the Company ended effective [DATE] (the "**Termination Date**").

2. The purpose of this Agreement is to resolve any and all disputes relating to Employee's employment with the Company, and the termination thereof (the "**Disputes**"). The Parties desire to resolve the above-referenced Disputes, and all issues raised by the Disputes, without the further expenditure of time or the expense of contested litigation. Additionally, the Parties desire to resolve any known or unknown claims as more fully set forth below. For these reasons, they have entered into this Agreement.

3. Employee acknowledges and agrees that Employee has received all wages due to Employee through the Termination Date, including but not limited to all accrued but unused vacation, bonuses, commissions, options, benefits, and monies owed by the Company to Employee. Employee further agrees and acknowledges that Employee has been fully paid and reimbursed for any and all business expenses which Employee incurred during his/her employment with the Company.

4. The Company expressly denies any violation of any federal, state or local statute, ordinance, rule, regulation, policy, order or other law. The Company also expressly denies any liability to Employee. This Agreement is the compromise of disputed claims and nothing contained herein is to be construed as an admission of liability on the part of the Company hereby released, by whom liability is expressly denied. Accordingly, while this Agreement resolves all issues referenced herein, it does not constitute an adjudication or finding on the merits of the allegations in the Disputes and it is not, and shall not be construed as, an admission by the Company of any violation of federal, state or local statute, ordinance, rule, regulation, policy, order or other law, or of any liability alleged in the Disputes.

5. In consideration of and in return for the promises and covenants undertaken by the Company and Employee herein and the releases given by Employee herein:

a. [The Company has previously granted to Employee the following options (collectively, the "**Options**") to purchase shares of the Company's common stock (the "**Shares**") under the Company's 2015 Equity Incentive Plan (the "**Plan**"): [List all Option Grants]. As of the Termination Date of [DATE], a total of [_____] shares underlying Employee's stock options are vested (collectively, the "**Vested Stock Options**"). The remaining shares underlying Employee's stock options are unvested and have been forfeited and canceled as of the Termination Date. Employee has until the date that is ninety (90) days after the Termination Date to exercise any or all of the Vested Options (the "**Option Termination Date**"). Any portion of Employee's Vested Stock Options that remain unexercised as of the Option Termination Date shall be forfeited and canceled as of such date.]

b. In addition to any compensation otherwise due Employee for actual work performed up to and including the Termination Date, Employee shall receive severance compensation as outlined in Section ____ of the Severance Agreement. Pursuant to Section ____ of the Severance Agreement, Employee will receive a total sum of $_____, less standard withholdings, representing [_____] month[s] of Employee's base salary [and Employee's Target Bonus] (the "**Severance Pay**"). The Severance Pay shall be paid to Employee in cash, in substantially equal monthly installments, payable over the [_____] month period following the Termination Date; provided, however, the first payment shall be made on the 60th day following the Termination Date and such first installment shall be in an amount to cover the first two months following the Termination Date. As a condition to receiving and continuing to receive the Severance Pay, Employee must (i) within but not later than forty-five (45) days after the Termination Date, execute and deliver to the Company this Agreement, (ii) permit this Agreement to become effective, and (iii) remain in full compliance with this Agreement and the Severance Agreement. Employee shall not be entitled to accrue any additional leave or other benefits subsequent to the Termination Date.

c. Provided Employee timely elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**"), and Employee continues to timely pay the same portion (if any) of the necessary group health insurance premium that Employee was responsible to pay as of immediately before the Termination Date, the Company shall continue to pay the Company portion of the premiums for Employee's Company group health insurance coverage for Employee and Employee's dependents through [DATE], which represents [_____] month[s] following the Termination Date. Thereafter, Employee shall be eligible to continue his or her group health insurance coverage at his or her own cost in accordance with COBRA. If at any time subsequent to the Termination Date, Employee obtains group health insurance coverage through another employer, Employee shall immediately notify the Company that he or she has obtained such coverage and the Company shall no longer be required to pay any premiums for Employee's group health insurance coverage as of the date that Employee's new group health insurance coverage begins.

d. Any tax liabilities resulting from or arising out of the benefits to Employee referred to in paragraphs 5a, 5b and 5c, above, shall be the sole and exclusive responsibility of Employee. Employee agrees to indemnify and hold the Company and the others released herein harmless from and for any tax liability (including, but not limited to, assessments, interest, and penalties) imposed on the Company by any taxing authority on account of the Company failing to withhold for tax purposes any amount from the benefits made as consideration of this Agreement.

6. Except for any rights created by this Agreement, in consideration of and in return for the promises and covenants undertaken herein by the Company, and for other good and valuable consideration, receipt of which is hereby acknowledged:

a. Employee does hereby acknowledge full and complete satisfaction of and does hereby release, absolve and discharge the Company, and each of its parents, subsidiaries, divisions, related companies and business concerns, past and present, as well as each of its partners, trustees, directors, officers, agents, attorneys, servants and employees, past and present, and each of them (hereinafter collectively referred to as "**Releasees**") from any and all claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, grievances, wages, vacation payments, severance payments, obligations, commissions, overtime payments, debts, profit sharing claims, expenses, damages, judgments, orders and liabilities of whatever kind or nature in law, equity or otherwise, whether known or unknown to Employee which Employee now owns or holds or has at any time owned or held as against Releasees, or any of them, including specifically but not exclusively and without limiting the generality of the foregoing, any and all claims, demands, grievances, agreements, obligations and causes of action, known or unknown, suspected or unsuspected by Employee: (1) arising out of or in any way connected

with the Disputes; or (2) arising out of Employee's employment with the Company; or (3) arising out of or in any way connected with any claim, loss, damage or injury whatever, known or unknown, suspected or unsuspected, resulting from any act or omission by or on the part of the Releasees, or any of them, committed or omitted on or before the Effective Date hereof. Additionally, Employee in any future claims may not use against Releasees as evidence any acts or omissions by or on the part of the Releasees, or any of them, committed or omitted on or before the Effective Date hereof, and no such future claims may be based on any such acts or omissions. Also without limiting the generality of the foregoing, Employee specifically releases the Releasees from any claim for attorneys' fees. EMPLOYEE ALSO SPECIFICALLY AGREES AND ACKNOWLEDGES EMPLOYEE IS WAIVING ANY RIGHT TO RECOVERY BASED ON STATE OR FEDERAL AGE, SEX, PREGNANCY, RACE, COLOR, NATIONAL ORIGIN, MARITAL STATUS, RELIGION, VETERAN STATUS, DISABILITY, SEXUAL ORIENTATION, MEDICAL CONDITION OR OTHER ANTI-DISCRIMINATION LAWS, INCLUDING, WITHOUT LIMITATION, TITLE VII OF THE CIVIL RIGHTS ACT OF 1964, THE AGE DISCRIMINATION IN EMPLOYMENT ACT, THE EQUAL PAY ACT, THE AMERICANS WITH DISABILITIES ACT, THE CALIFORNIA FAIR EMPLOYMENT AND HOUSING ACT, THE CALIFORNIA FAMILY RIGHTS ACT, CALIFORNIA LABOR CODE SECTION 970, THE FAMILY AND MEDICAL LEAVE ACT, THE EMPLOYEE RETIREMENT INCOME SECURITY ACT, THE WORKER ADJUSTMENT AND RETRAINING ACT, THE FAIR LABOR STANDARDS ACT, AND ANY OTHER SECTION OF THE CALIFORNIA LABOR OR GOVERNMENT CODE, ALL AS AMENDED, WHETHER SUCH CLAIM BE BASED UPON AN ACTION FILED BY EMPLOYEE OR BY A GOVERNMENTAL AGENCY. This release does not release claims that cannot be released as a matter of law.

7. Employee agrees and understands as follows: It is the intention of Employee in executing this instrument that it shall be effective as a bar to each and every claim, demand, grievance and cause of action hereinabove specified. In furtherance of this intention, Employee hereby expressly waives any and all rights and benefits conferred upon Employee by the provisions of Section 1542 of the California Civil Code and expressly consents that this Agreement shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected claims, demands and causes of action, if any, as well as those relating to any other claims, demands and causes of action hereinabove specified. Section 1542 provides:

> "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."

Having been so apprised, Employee nevertheless hereby voluntarily elects to and does waive the rights described in Civil Code section 1542 and elects to assume all risks for claims that now exist in Employee's favor, known or unknown, that are released under this Agreement.

8. Employee agrees: (l) the fact of and the terms and conditions of this Agreement; and (2) any and all actions by Releasees taken in accordance herewith, are confidential, and shall not be disclosed, discussed, publicized or revealed by the parties or their attorneys to any other person or entity, including but not limited to radio, television, press media, newspapers, magazines, professional journals and professional reports, excepting only the Parties' accountants, lawyers, immediate family members (mother, father, brother, sister, child, spouse), the persons necessary to carry out the terms of this Agreement or as required by law. Should Employee be asked about the Disputes or this Agreement, Employee shall limit Employee's response, if any, by stating that the matters have been amicably resolved.

9. Nothing in this Agreement prevents Employee from filing a charge or complaint with the Equal Employment Opportunity Commission, the California Department of Fair Employment and Housing, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission (collectively, the "**Government Agencies**"). This Agreement does not limit Employee's ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agencies. While this Agreement does not limit Employee's right to receive an award for information provided to the Securities and Exchange Commission, Employee understands and agrees that, to maximum extent permitted by law, Employee is otherwise waiving any and all rights Employee may have to individual relief based on any claims that Employee has released and any rights Employee has waived by signing this Agreement.

10. Employee agrees not to make any derogatory, disparaging or negative comments about the Company, its products, officers, directors, or employees; provided that nothing in this Section 10 will be interpreted or construed to prevent Employee from giving truthful testimony to any law enforcement officer, court, administrative proceeding or as part of a government investigation.

11. If any provision of this Agreement or application thereof is held invalid, the invalidity shall not affect other provisions or applications of the Agreement which can be given effect without the invalid provision or application. To this end, the provisions of this Agreement are severable.

12. Employee agrees and understands that this Agreement may be treated as a complete defense to any legal, equitable, or administrative action that may be brought, instituted, or taken by Employee, or on Employee's behalf, against the Company or the Releasees, and shall forever be a complete bar to the commencement or prosecution of any claim, demand, lawsuit, charge, or other legal proceeding of any kind against the Company and the Releasees.

13. This Agreement and all covenants and releases set forth herein shall be binding upon and shall inure to the benefit of the respective Parties hereto, their legal successors, heirs, assigns, partners, representatives, parent companies, subsidiary companies, agents, attorneys, officers, employees, directors and shareholders.

14. The Parties hereto acknowledge each has read this Agreement, that each fully understands its rights, privileges and duties under the Agreement, that each has had an opportunity to consult with an attorney of its choice and that each enters this Agreement freely and voluntarily.

15. This Agreement may not be released, discharged, abandoned, changed or modified in any manner, except by an instrument in writing signed by Employee and an officer of the Company. The failure of any Party to enforce at any time any of the provisions of this Agreement shall in no way be construed as a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part thereof or the right of any Party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach.

16. This Agreement and the provisions contained herein shall not be construed or interpreted for or against any party hereto because that party drafted or caused that party's legal representative to draft any of its provisions.

17. In the event of litigation arising out of or relating to this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

18. Employee acknowledges Employee may hereafter discover facts different from, or in addition to, those Employee now knows or believes to be true with respect to the claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, wages, obligations, debts, expenses, damages, judgments, orders and liabilities herein released, and agrees the release herein shall be and remain in effect in all respects as a complete and general release as to all matters released herein, notwithstanding any such different or additional facts.

19. The undersigned each acknowledge and represent that no promise or representation not contained in this Agreement has been made to them and acknowledge and represent that this Agreement and the Severance Agreement contains the entire understanding between the Parties and contains all terms and conditions pertaining to the compromise and settlement of the subjects referenced herein. The undersigned further acknowledge that the terms of this Agreement are contractual and not a mere recital.

20. Employee expressly acknowledges, understands and agrees that this Agreement includes a waiver and release of all claims which Employee has or may have under the Age Discrimination in Employment Act of 1967, as amended, 29 U.S.C. §621, et seq. ("**ADEA**"). The terms and conditions of Paragraphs 20 through 22 apply to and are part of the waiver and release of ADEA claims under this Agreement. Company hereby advises Employee in writing to discuss this Agreement with an attorney before signing it. Employee acknowledges the Company has provided Employee at least forty-five days within which to review and consider this Agreement before signing it. If Employee elects not to use all forty-five days, then Employee knowingly and voluntarily waives any claim that Employee was not in fact given that period of time or did not use the entire forty-five days to consult an attorney and/or consider this Agreement.

21. Within three calendar days of signing and dating this Agreement, Employee shall deliver the signed original of this Agreement to [_____] of the Company. However, the Parties acknowledge and agree that Employee may revoke this Agreement for up to seven calendar days following Employee's execution of this Agreement and that it shall not become effective or enforceable until the revocation period has expired. The Parties further acknowledge and agree that such revocation must be in writing addressed to and received by [_____]of the Company not later than midnight on the seventh day following execution of this Agreement by Employee. If Employee revokes this Agreement under this Paragraph, this Agreement shall not be effective or enforceable and Employee will not receive the benefits described above, including those described in Paragraph 5.

22. If Employee does not revoke this Agreement in the timeframe specified in Paragraph 21 above, the Agreement shall be effective at 12:00:01 a.m. on the eighth day after it is signed by Employee (the "**Effective Date**").

23. This Agreement is intended to be exempt from the requirements of section 409A of the Internal Revenue Code of 1986 as amended ("**Section 409A**") and will be interpreted accordingly. While it is intended that all payments and benefits provided under this Agreement to Employee or on behalf of Employee will be exempt from Section 409A, the Company makes no representation or covenant to ensure that such payments and benefits are exempt from or compliant with Section 409A. The Company will have no liability to Employee or any other party if a payment or benefit under this Agreement is challenged by any taxing authority or is ultimately determined not to be exempt from or compliant with Section 409A.

24. This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original and such counterparts shall together constitute one and the same Agreement.

25. This Agreement shall be construed in accordance with, and be deemed governed by, the Employee Retirement Income Security Act of 1974, as amended, and, to the extent applicable, the laws of the State of Delaware, without reference to the conflict of law provisions thereof.

26. The Company executes this Agreement for itself and on behalf of all other respective Releasees.

I have read the foregoing Separation Agreement and General Release of All Claims, consisting of [____] pages, and I accept and agree to the provisions contained therein and hereby execute it voluntarily and with full understanding of its consequences.

PLEASE READ CAREFULLY. THIS AGREEMENT CONTAINS A GENERAL RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

Dated: _____

Scott Brown

TRACON Pharmaceuticals, Inc.

Dated:_____

Name:
Title:

[Signature Page to Separation Agreement and General Release of All Claims]

Exhibit 10.18

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE TRACON PHARMACEUTICALS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO TRACON PHARMACEUTICALS, INC. IF PUBLICLY DISCLOSED.

December 20, 2019
Confidential

COLLABORATION AND CLINICAL TRIAL AGREEMENT

This **Collaboration and Clinical Trial Agreement** (the "**Agreement**") is entered into on December 20, 2019 (the "**Effective Date**") between **3D Medicines (Beijing) Co., Ltd.**, a company organized and existing under the laws of P.R.China and having its registered address at Suite 1201,Block B, Yicheng Fortune Center ,22 Ronghua Middle Road, BDA, Beijing, P.R. China ("**3DMed**") **Jiangsu Alphamab Biopharmaceuticals Co., Ltd.**, a company organized and existing under the laws of P.R. China and having its registered address at Building C23, 218 Xinghu Street, Suzhou, Jiangsu, P.R. China 215125 ("**Jiangsu Alphamab**") (Jiangsu Alphamab and 3DMed collectively, "**3DAlpha**"), and **Tracon Pharmaceuticals, Inc.**, a Delaware corporation, with its principal place of business at 4350 La Jolla Village Drive, Suite 800, San Diego, CA, USA ("**Tracon**"). Tracon, 3D, and Alphamab are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

Whereas, 3DMed is a biopharmaceutical company engaged in the research, development and commercialization of antibody products, currently being developed for oncology applications;

Whereas, 3DMed has acquired from Suzhou Alphamab Co. Ltd. ("**Suzhou Alphamab**") the rights to a single domain Fc-fusion antibody specific to PD-L1 pursuant to that certain Joint Development Agreement by and between 3DMed and Suzhou Alphamab dated February 29, 2016, and

Whereas, 3DMed, Suzhou Alphamab and Jiangsu Alphamab entered into a Supplementary Agreement on March 27, 2018, Suzhou Alphamab transferred all its rights and obligations under the Joint Development Agreement to Jiangsu Alphamab (the Joint Development Agreement and the Supplementary Agreement are collectively referred to as "**3D-Alphamab Agreement**") .3DAlpha collectively wish to collaborate with Tracon with respect to the clinical development and commercialization of such PD-L1 antibody known as KN035;

Whereas, Tracon is a biopharmaceutical company engaged in the research, development and future commercialization of pharmaceutical products, including novel targeted therapeutics for oncology applications; and

Whereas, the Parties wish to conduct the development and clinical trials for this PD-L1 antibody, and the Parties agree to share the economic interest in resulting product, all on the terms and conditions set forth herein.

Now Therefore, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, and for other good and valuable

1.

consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1.

1.1 "**3DAlpha**" has the meaning set forth in the preamble.

1.2 "**3DAlpha Exit**" means 3DAlpha's material, uncured breach of the Agreement.

1.3 "**3DAlpha Indemnitees**" has the meaning set forth in Section 7.1.

1.4 "**3DAlpha Territory**" means all territories of the world other than the Collaborative Territory.

1.5 "**Affiliate**" means, with respect to a Party, any corporation, firm, partnership or other entity, which directly or indirectly controls or is controlled by or is under common control with such Party. For the purpose of this definition, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, by contract or otherwise.

1.6 "**Agreement**" has the meaning set forth in the preamble.

1.7 "**Applicable Laws**" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including Regulatory Approvals) of or from any court, arbitration panel, Regulatory Authority, governmental agency, or any authority having jurisdiction over or related to subject item or subject person, including laws regulating pharmaceutical products, GCP, GMP, the FCPA, Export Control Laws and other applicable laws.

1.8 "**Antibody**" means 3DAlpha's proprietary single domain Fc-fusion antibody specific to PD-L1 known as KN035 or envafolimab, the rights to which 3DMed acquired under the 3D-Alphamab Agreement, as further described in the Patents listed in Exhibit A.

1.9 "**BLA**" means a biologics license application for Regulatory Approval of a biologic product.

1.10 "**Business Day**" means any day that is not a Saturday, a Sunday or other day on which banks are required or authorized by Applicable Laws to be closed in San Diego, California.

1.11 "**Change of Control**" means, with respect to a Party: (a) the sale of all or substantially all of such Party's (or any of its controlling Affiliates') assets or business relating to the subject matter of this Agreement; (b) a merger, reorganization or consolidation involving such Party (or a controlling Affiliate thereof) in which the voting securities of such Party (or such controlling Affiliate, as applicable) outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) the acquisition by a person or entity of more than fifty percent (50%) of the voting equity securities or management control of such Party (or a controlling Affiliate thereof) as a result of a single transaction or a series of related transactions.

1.12 "**CMO**" has the meaning set forth in Section 3.2(c).

1.13 "**Collaborative Product**" means any pharmaceutical composition or preparation comprising Antibody as a monospecific.

1.14 "**Collaborative Product IP**" means any and all intellectual property rights, including Patents, copyrights, trademarks and Know-How that are Controlled by 3DMed and/or Jiangsu Alphamab or any of their Affiliates as of the Effective Date or at any time during the Term (expressly including all rights and licenses acquired by 3DMed from Jiangsu Alphamab pursuant to the 3D-Alphamab Agreement) and (x) claim or cover a Collaborative Product, or (y) are necessary or useful for the Development, manufacture, marketing, promotion, distribution, use, sale, import or other exploitation of a Collaborative Product.

1.15 "**Collaborative Products License**" has the meaning set forth in Section 9.2.

1.16 "**Collaborative Territory**" means the U.S., Canada, Mexico and each of their dependent territories.

1.17 "**Commercialize**" or "Commercialization" means any and all activities effective to market, promote, advertise, sell, offer for sale, have sold or otherwise dispose of, transport, distribute, import or export, branding, preparation for the launch and medical education regarding a Collaborative Product, and interacting with Regulatory Authorities in connection with any of the foregoing after all Regulatory Approvals have been obtained in the applicable country or region. The term "**Commercialized**" has a correlative meaning.

1.18 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party pertaining to a particular objective, the objective, reasonable, diligent, good faith efforts to accomplish such objective in an active and ongoing program as a similarly situated (with respect to size, stage of development, and assets) biotechnology or pharmaceutical company, as the case may be. Such efforts shall be substantially equivalent to the efforts and resources commonly used by a similarly situated biotechnology or pharmaceutical company for pharmaceutical or biological products, as applicable, to accomplish a similar objective under similar circumstances exercising reasonable business judgment, taking into account the following factors to the extent applicable: stage of development, mechanism of action, efficacy and safety

issues, characteristics of competitive products in or anticipated to be in the marketplace, process development, scale-up or manufacturing, Third Party intellectual property rights, actual or anticipated Regulatory Authority approved labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), cost and likelihood of obtaining Regulatory Approval, and projected or actual economic return. Commercially Reasonable Efforts shall be determined on a market-by-market and indication-by-indication basis for a particular Collaborative Product, and it is anticipated that the level of effort may be different for different markets, and may change over time, reflecting changes in the status of each such Collaborative Product and the market(s) involved.

1.19 "**Confidential Information**" means, with respect to a Party, all know-how, data and other information of a financial, commercial, business, operational or technical nature of such Party that is: (a) disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, whether made available orally, in writing or in electronic form; or (b) learned by the other Party pursuant to this Agreement.

1.20 "**Control**" means, with respect to an item of Know-How, Patent or other intellectual property rights, the ability and authority of a Party or its Affiliates, whether arising by ownership, possession, or pursuant to a license or sublicense (other than by operation of the license and other rights granted in this Agreement) or a right to acquire (by option or otherwise), to grant licenses, sublicenses, or other rights to the other Party under or to such item of Know-How, Patent or other intellectual property rights as provided for in this Agreement, without breaching the terms of any agreement between such Party and any Third Party. The term "**Controlled**" shall be construed accordingly.

1.21 **"Cost of Goods** or **'COGS"** means the per unit cost for clinical or commercial supply of Collaborative Product as set forth in Schedule 1.21.

1.22 "**Development**" (with a correlative meaning for "**Develop**" and "**Developed**") means all activities that relate to the development of a Collaborative Product for use in the Field or that are necessary or useful to obtain or maintain Regulatory Approval for such Collaborative Product, including all non-clinical studies and clinical trials of such Collaborative Product, technology transfer, manufacture process development, manufacture and distribution of such Collaborative Product for use in clinical trials (including placebos and comparators), statistical analyses, and the preparation and submission of regulatory materials and other regulatory activities related to such Collaborative Product.

1.23 "**Development Activities**" means all Development activities performed by or on behalf of either or both Parties pursuant to this Agreement.

1.24 "**Development Costs**" means all costs incurred by or on behalf of either Party or its Affiliates that are reasonably allocable in accordance with GAAP to the Development of a Collaborative Product in the Field in the Collaborative Territory as delineated herein, which for clarity may include costs for conducting clinical trials in the European Union as determined by the

JSC. For avoidance of doubt, Jiangsu Alphamab shall bear all costs associated with the conduct of the IND-enabling studies and the preparation of the chemistry-manufacturing-controls ("**CMC**") activities sections of the IND for such Collaborative Products.

1.25 "**Development Data**" means all data generated by or on behalf of Tracon or its Affiliates in the course of, and as a result of, the performance of the Development Activities and directly relating to the Development of a Collaborative Product in the Field in the Collaborative Territory, including data related to all non-clinical studies and clinical trials of such Collaborative Product, which for clarity may include data from clinical trials in the European Union as determined by the JSC, technology transfer, manufacture process development, manufacture and distribution of such Collaborative Product for use in clinical trials (including placebos and comparators), statistical analyses, and the preparation and submission of regulatory materials and other regulatory activities related to such Collaborative Product.

1.26 "**Development IP**" means any and all inventions, other than Development Data, that are related to the use of Collaborative Product in the Field and generated in connection with the Development of the Collaborative Product in the Field in the Collaborative Territory by or on behalf of a Party during the Term and any and all intellectual property rights therein (including Patents, copyrights, trademarks and Know-How) that are filed in the Collaborative Territory and Controlled by such Party or any of its Affiliates at any time during the Term. All Development IP will be shared amongst the Parties. To clarify, the Development IP does not include any intellectual property rights (including Patents, copyrights, trademarks and Know-How) that are filed outside the Collaborative Territory.

1.27 "**Development Plan**" has the meaning set forth in Section 3.2.

1.28 "**Disclosing Party**" has the meaning set forth in Section 8.1.

1.29 "**Effective Date**" has the meaning set forth in the preamble.

1.30 "**European Union**" means the economic, scientific and political organization of European Union member states as it may be constituted from time to time, specifically including any territory that was a European Union member state as of the Effective Date, whether or not such territory is a participating member as of the applicable time.

1.31 "**Export Control Laws**" means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

1.32 "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1,

et. seq.), as amended.

1.33 "**FDA**" means the U.S. Food and Drug Administration, or any successor Regulatory Authority thereto in the U.S. having substantially the same function.

1.34 "**Field**" means human therapeutic applications of the Collaborative Product for any sarcoma. "**3DAlpha Field**" means all applications of the Collaborative Product outside of the Field.

1.35 "**First Commercial Sale**" means the first sale by a Party, its Affiliate or its Licensee for value for end use or consumption of such Collaborative Product in a country in the Collaborative Territory after the governing Regulatory Authority of such country has granted Regulatory Approval of such Collaborative Product. For clarity, any sale of a Collaborative Product prior to receipt of Regulatory Approval, such as compassionate use, named patient use, clinical trial purposes or other similar uses will not constitute a First Commercial Sale.

1.36 "**First Indication**" shall mean the indication of one or more subtypes of refractory soft tissue sarcoma. "**Second Indication**" shall mean first line treatment of one or more subtypes of soft tissue sarcoma.

1.37 "**GAAP**" means generally accepted accounting principles in the U.S., or internationally, as appropriate, consistently applied and shall mean the international financial reporting standards ("**IFRS**") if a Party uses IFRS.

1.38 "**GCP**" means the Good Clinical Practices officially published by the European Medicines Agency and any successor agency, the FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the Development of Collaborative Product.

1.39 "**GMP**" means those laws and regulations applicable in the U.S. and European Union, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients", US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC that may be in effect from time to time and are applicable to the Development or manufacture of Collaborative Product.

1.40 "**ICC**" has the meaning set forth in Section 11.3(a).

1.41 **"IND**" means an investigational new drug application, clinical trial application, clinical trial exemption, or similar application or submission filed with or submitted to a Regulatory Authority in a jurisdiction that is necessary to commence human clinical trials in such jurisdiction, including any such application filed with the FDA pursuant to 21 C.F.R. Part 312.

1.42 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 2.1.

1.43 "**Know-How**" means tangible and intangible information, techniques, technology, practices, trade secrets, inventions (whether patentable or not), processes, formulations, compounds, products, biological materials, cell lines (it being understood that any rights to use "Know-How" include the rights to use such cell lines), samples of assay components, media, designs, formulas, ideas, programs, software models, algorithms, developments, experimental works, protocols, methods, knowledge, know-how, skill, experience, test data and results (including pharmacological, toxicological and non-clinical and clinical data and results), compilations of data, other works of analytical and quality control data, results, descriptions, compositions of matter, regulatory submissions, minutes, correspondence and strategy.

1.44 "**Leading Company**" means Tracon, 3DAlpha or any Third Party that, by subsequent mutual written agreement of the Parties, will act as the major stakeholder for the Collaborative Product in the Collaborative Territory.

1.45 "**License**" means any (i) license, sublicense or option to license or sublicense a Collaborative Product or any Collaborative Product IP for the Development, manufacture, marketing, promotion, distribution, use, sale, import or other exploitation of a Collaborative Product, (ii) other agreement not to assert or seek a legal remedy for the practice of the Collaborative Product IP for the Development, manufacture, marketing, promotion, distribution, use, sale, import or other exploitation of a Collaborative Product, or (iii) any agreement that creates an obligation to grant any of the foregoing.

1.46 "**Licensee**" means any Third Party granted a License by a Party or any of its Affiliates.

1.47 "**Losses**" has the meaning set forth in Section 7.1.

1.48 "**Net Sales**" shall mean the gross amounts received for sales or other dispositions of a Collaborative Product by a Party or any of its Affiliates or Licensees (each, a "**Selling Party**") to Third Parties, less deductions actually incurred, allowed, paid, accrued or otherwise reasonably allocated to such Collaborative Product by the Selling Party in accordance with GAAP, for:

(a) trade, cash and quantity discounts or rebates actually allowed or taken;

(b) credits or allowances given or made for rejection of or return of previously sold Collaborative Products or for retroactive price reductions and billing errors or for stocking allowances;

(c) governmental and other rebates (or credits or other equivalents thereof) granted to managed health care organizations, commercial insurance companies, pharmacy benefit managers (or equivalents thereof), distributors, national, state/provincial, local, and other governments, their agencies and purchasers, and reimbursors, or to trade customers;

(d) costs of freight, insurance, and other transportation charges directly related to the distribution of Collaborative Products, to the extent included in gross invoiced sales prices; and

(e) taxes, duties or other governmental charges (including any tax such as a value added or similar tax or government charge other than an income tax) levied on or measured by the billing amount for Collaborative Products, as adjusted for rebates and refunds.

In no event shall any particular amount, identified above, be deducted more than once in calculating Net Sales (*i.e.*, no "double counting" of reductions). Sales of a Collaborative Product between a Party and its Affiliates or Licensees for resale shall be excluded from the computation of Net Sales, provided that the subsequent resale of such Collaborative Product to a Third Party are included in the computation of Net Sales. Sale, disposal or use of such Collaborative Product for Development or charitable purposes, such as clinical trials, compassionate use, named patient use, or indigent patient programs, without consideration, shall not be deemed a sale hereunder.

1.49 "**Party**" or "**Parties**" has the meaning set forth in the preamble.

1.50 "**Patents**" means (a) patents, re-examinations, reissues, renewals, extensions and term restorations, and foreign counterparts of any of the foregoing, and (b) pending applications for patents, including provisional applications, continuations, continuations-in-part, requests for continued examination, divisional and substitute applications, including inventors' certificates, and foreign counterparts of any of the foregoing.

1.51 "**Phase 1 Study**" means a human clinical trial in the U.S. that would satisfy the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) (or any amended or successor regulations), or its substantial equivalence if such clinical trial is conducted outside the U.S.

1.52 "**Phase 2 Study**" means a human clinical trial in the U.S. that would satisfy the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations), or its substantial equivalence if such clinical trial is conducted outside the U.S.

1.53 "**Phase 3 Study**" means a human clinical trial in the U.S. that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations), or its substantial equivalence if such clinical trial is conducted outside the U.S.

1.54 "**Pivotal Trial**" means: (a) a Phase 3 Study; or (b) any other human clinical trial that the applicable Regulatory Authority has agreed, whether before first dosing of the first patient in such trial (*e.g.*, pursuant to a special protocol assessment agreement with the FDA) or after first dosing of the first patient in such trial (*e.g.*, based on an interim data analysis), is sufficient to form the primary basis of an efficacy claim in an application for Regulatory Approval, regardless of whether the sponsor of such trial characterizes or refers to such trial as a "Phase 3," "Phase 2b" or "Phase 2b/3" trial (or otherwise) in the applicable protocol, on clinicaltrials.gov, or in any other context. If a human clinical trial does not constitute a Pivotal Trial at the time of first dosing of the first patient in such trial, but is later determined by the applicable Regulatory Authority to be

sufficient to form the primary basis of an efficacy claim in an application for Regulatory Approval, then, for purposes of this Agreement, "Initiation" of such Pivotal Trial shall be deemed to have occurred on the date of such determination by the applicable Regulatory Authority.

1.55 "**Receiving Party**" has the meaning set forth in Section 8.1.

1.56 "**Regulatory Approval**" means all approvals, including pricing approvals, that are necessary for the commercial sale of a Collaborative Product in a given country or regulatory jurisdiction.

1.57 "**Regulatory Authority**" means any country, federal, supranational, state or local regulatory agency, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country or other jurisdiction, including the FDA.

1.58 "**SEC**" has the meaning set forth in Section 8.3(b).

1.59 "**Supply Agreement**" has the meaning set forth in Section 3.2(c).

1.60 "**Term**" has the meaning set forth in Section 10.1.

1.61 "**Third Party**" means any person or entity other than Tracon or 3DMed or Jiangsu Alphamab or an Affiliate of a Party.

1.62 "**Third Party Claim**" has the meaning set forth in Section 7.1.

1.63 "**Tracon**" has the meaning set forth in the preamble.

1.64 "**Tracon Exit**" means (i) notice to 3DAlpha by Tracon of Tracon's election not to continue the Development or Commercialization of Collaborative Product, or (ii) Development Abandonment, or (iii) Tracon's material breach of the Agreement, including without limitation Tracon's breach of its obligation under Section 5.3.

1.65 "**Tracon Indemnitees**" has the meaning set forth in Section 7.2.

1.66 "**Tracon IP**" means any and all intellectual property rights, including Patents, copyrights, trademarks and Know-How that are (a) Controlled by Tracon or any of its Affiliates before the Effective Date, (b) developed or acquired by Tracon or any of its Affiliates independent of its performance of the Development Activities, and are not related to Collaborative Product.

1.67 "**U.S.**" shall mean the United States of America and its territories and possessions.

ARTICLE 2
GOVERNANCE

2.1 Joint Steering Committee. The Parties hereby establish a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**") to oversee and coordinate the Development Activities and Commercialization of the Collaborative Products in the Collaborative Territory, and to encourage and facilitate the ongoing cooperation and communication between the Parties regarding matters related to such activities. The JSC, in its discretion, may establish a Joint Development Committee ("**JDC**") and/or a Joint Commercialization Committee ("**JCC**") and delegate certain activities of the JSC to the JDC or JCC, as applicable.

2.2 The JSC shall in particular:

(a) Approve the Development Plan for Development of Collaborative Product in the Field in the Collaborative Territory and periodic modifications to such Development Plan;

(b) Monitor progress of the Development Plan for the Development of Collaborative Product in the Field in the Collaborative Territory, review relevant Development Data and timely share information on progress of such Development with the Parties;

(c) Approve the selection of the CMO for Collaborative Product, if applicable, and monitor the establishment, qualification, and maintenance of the manufacturing facilities and processes for purposes of pre-clinical (if applicable), clinical, and commercial supply of Collaborative Product;

(d) Decide to advance, suspend, or terminate Development of Collaborative Product in the Field in the Collaborative Territory at key decision points, including the initiation of any clinical trials and filing of applications for Regulatory Approval;

(e) Review and evaluate proposals by Tracon for the conduct of clinical trials, at Tracon's sole expense, of a Collaborative Product in the Field at clinical sites in the Collaborative Territory;

(f) Coordinate the Parties' activities with respect to the Commercialization of Collaborative Products in the Field in the Collaborative Territory;

(g) Determine whether any clinical study of a Collaborative Product should be terminated early for futility or safety reasons;

(h) Serve as a forum for the discussion of any safety, scientific or technical concerns regarding the Development, manufacture or Commercialization of Collaborative Products, provided that the JSC shall not have decision-making authority with respect to the Commercialization of Collaborative Products; and

(i) Perform such other appropriate activities and functions and making such other appropriate decisions as agreed by the Parties in writing.

2.3 Limitations of JSC Authority. The JSC shall only have the powers expressly assigned to it in this Article 2 and elsewhere in this Agreement and shall not have the authority to: (a) modify or amend the terms and conditions of this Agreement; or (b) decide any such issue in a manner that would conflict with the express terms and conditions of this Agreement.

2.4 JSC Membership and Meetings.

(a) JSC Members. The JSC shall consist of four (4) members, with two (2) appointed by 3DAlpha and two (2) appointed by Tracon, each of whom shall have appropriate technical credentials, experience, knowledge, and authority within such Party's organization. Within thirty (30) days following the Effective Date, each Party shall designate its initial members to serve on the JSC. Each Party may replace its representatives on the JSC by written notice to the other Party. In the event that the Leading Company is a Third Party, such Leading Company shall appoint two members to the JSC and have the rights of a Party with respect to the JSC under this Section 2.4. The Parties shall alternate, on a meeting by meeting basis, in appointing one (1) of their representatives on the JSC to act as the chairperson of the JSC for the meeting. The chairperson shall prepare and circulate agendas prior to each JSC meeting and subsequently, promptly provide to the Parties reasonably detailed drafts of the minutes of each such meeting. The Parties shall promptly discuss any comments on such minutes and finalize the minutes no later than seven (7) days prior to the date of the next JSC meeting.

(b) Meetings. The JSC (and, if applicable, the JDC) shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every quarter. Meetings of the JSC may be held in person, by audio or video teleconference; *provided* that at least one (1) meeting per year of the JSC shall be held in person. In-person JSC meetings shall be chaired by a JSC representative of the Parties on an alternating basis and held at locations selected on an alternating basis by the Parties, with the first in-person JSC meeting to be chaired by a 3DAlpha representative and held at a location to be selected by 3DAlpha. Each Party shall be responsible for all of its own expenses in connection with participating in the JSC meetings.

(c) Non-Member Attendance. Each Party may from time to time invite a reasonable number of its representatives, who are not members of the JSC, to attend the JSC meetings in a non-voting capacity; *provided* that such participants are bound by confidentiality and non-use obligations consistent with the terms of this Agreement; and *provided further* that each Party shall provide reasonable prior written notice to the other Party if it has invited any Third Party (including any consultant) to attend such a meeting and the attendance of such Third Party shall be subject to the consent of the other Party.

2.5 Decision-Making.

(a) All decisions of the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. No vote of the JSC may be taken unless at least one of each Party's representatives is present for the vote. Each Party shall be responsible for ensuring that, at all times, its representatives on the JSC act reasonably and in good faith in carrying out their respective responsibilities hereunder.

(b) If the JSC cannot reach consensus with regard to any matter within its authority within ten (10) Business Days after such matter has been brought to the JSC's attention, such matter shall be referred to the Chief Executive Officer of each Party, who shall promptly meet and attempt in good faith to resolve such issue within ten (10) Business Days from the date upon which such matter is referred to them. In the event that such Chief Executive Officers are unable to resolve such issue within ten (10) Business Days of the issue being referred to them, then (i) with respect to all matters solely concerning [***] in the Field in the Collaborative Territory, Tracon shall have the deciding vote; (ii) with respect to all matters solely concerning [***], 3DAlpha shall have the deciding vote; (iii) with respect to all matters solely relating to [***] in the Collaborative Territory other than [***] for the Collaborative Product, the Leading Company shall have the deciding vote; (iv) with respect to all matters concerning [***] in the Collaborative Territory, such matters shall only be determined by consensus consistent with Section 4.5; and (v) with respect to all other matters properly before the JSC and not reserved for consensus of the Parties, [***] shall have the deciding vote; *provided, however*, that [***] may not use such deciding vote to [***] in the Field in the Collaborative Territory in comparison with [***]. In all cases where a Party exercises its right to cast a deciding vote to resolve an impasse before the JSC, such Party shall give good faith consideration to the other Party's position, and make reasonable efforts to take such Party's position into account, in making such decision.

ARTICLE 3
DEVELOPMENT

3.1 Technology Transfer for Collaborative Products. 3DAlpha shall promptly present to the JSC and Tracon [***] the information in its possession concerning Collaborative Product including information regarding its characterization, summaries of the status of its Development, all INDs filed anywhere in the world with respect to Collaborative Product in the field of tumor, all human clinical trial results related to Collaborative Product's safety or effectiveness, and all existing IND-enabling data.

3.2 Development. The Parties shall apply their Commercially Reasonable Efforts to fulfill their obligations related to the Development of the Collaborative Products as set forth in this Section 3.2.

(a) Subject to the terms and conditions of this Agreement, the Parties through the JSC shall agree on and implement plans for the Development of Collaborative Product aimed at achieving Regulatory Approval of Collaborative Product in the Field in the United States and such other jurisdictions in the Collaborative Territory as selected by Tracon.

(b) 3DAlpha shall provide Tracon with assistance for the conduct, driven by Tracon [***], of all IND-enabling and BLA-enabling Development activities specific to the Field (excluding clinical trials) for Collaborative Product. 3DAlpha shall provide Tracon with Collaborative Product IP related materials necessary for the preparation of an IND for the Collaborative Product in the Field. 3DAlpha shall be responsible for transferring to Tracon the pharmacodynamic, pharmacokinetic, immunogenicity, and other bioanalytical assays and methods for human plasma sample analysis through all phases of Development, including the continued maintenance of such assays and methods used in current clinical trials (including without limitation, stability testing, non-clinical bridging studies, reagents etc.)

(c) Unless the JSC approves a Supply Agreement with a CMO for supply of the Collaborative Product according to this Section 3.2(c), Jiangsu Alphamab shall be solely responsible for manufacturing and supplying Tracon with the Collaborative Product for all clinical and commercial uses in the Collaborative Territory at [***]. Jiangsu Alphamab shall be responsible for the packaging, labelling, export, and shipment of Collaborative Product to a depot in the U.S. designated by Tracon, provided [***]. In the event that Jiangsu Alphamab elects not to use manufacturing facilities owned or operated by Jiangsu Alphamab or its Affiliate for supply of a Collaborative Product, Jiangsu Alphamab shall, with the JSC's approval, take the lead in selecting and, along with Tracon, entering into a contract manufacturing and services agreement (a "**Supply Agreement**") with a Third Party contract manufacturing organization (a "**CMO**") for Collaborative Product consistent with the terms of this Agreement. Approval of all CMOs and Supply Agreements shall [***]. Jiangsu Alphamab or the CMO, as applicable, shall have adequate capabilities for the production of cGMP quality Collaborative Products necessary for all Development Activities and experience in supporting the submission of IND and BLA applications to the FDA with respect to the chemistry-manufacturing-controls activities sections of such IND and BLA applications. Jiangsu Alphamab shall [***] associated with manufacturing at facilities owned or operated by Jiangsu Alphamab or its Affiliate in lieu of a CMO, subject only to [***] for supply of Collaborative Product. For clarity, upon Jiangsu Alphamab's entry into a Supply Agreement with a CMO for Collaborative Product, the supply price in such agreement shall be [***] for Collaborative Product supplied and charged from such CMO. Jiangsu Alphamab shall supply and cause the CMO to supply to Tracon the necessary documentation and information for the chemistry-manufacturing-controls activities section of the IND and BLA and all correspondence with the FDA and other Regulatory Authorities relevant to the supply of Collaborative Products. Tracon shall have conventional inspection and audit rights with respect to the manufacture and supply of Collaborative Products conducted by Jiangsu Alphamab or CMO including the right to participate in all FDA inspections concerning Collaborative Products, as a partner or consultant of Jiangsu Alphamab to the extent legally able to do so. The Supply Agreements shall provide for the supply of the Parties' requirements for Collaborative Product through the completion of all clinical trials and upon Commercialization of Collaborative Product in the Collaborative Territory. Jiangsu Alphamab and Tracon shall enter into a quality agreement themselves or with each CMO, as applicable, concerning the manufacture and supply of Collaborative Product (such agreement a "**Quality Agreement**"). Tracon shall have the right to review the Quality Agreement and provide input to Jiangsu Alphamab on its terms. Jiangsu

Alphamab and Tracon shall use best efforts to negotiate the terms and any necessary amendment to the Quality Agreement to [***]. Tracon shall have the right to review all source documents that are relevant to Collaborative Product (including batch records in English) and to request and participate as a partner or consultant of Jiangsu Alphamab in quality audits of the CMO no more than [***] per year, and in inspections by all Regulatory Authorities, with respect to records, processes and facilities relevant to Collaborative Product. In the event that Tracon requests more than [***] in a given year, Jiangsu Alphamab shall use best efforts to implement such audit, where applicable in coordination with the CMO, and [***] such additional audit.

(d) Subject to 3DAlpha's fulfillment of its obligations under Section 3.2(a)-(c), Tracon shall prepare and file, at its expense, an IND (or supplemental IND) for Collaborative Product for its First Indication in the U.S. The clinical trials of such Collaborative Product, seeking Regulatory Approval and all other Development of such Collaborative Product in the Field in the Collaborative Territory, which for clarity may include the conduct of clinical trials in the European Union as determined by the JSC, to be conducted under this Agreement by or on behalf of the Parties or their Affiliates shall be set forth in a series of written development plans, and any amendments thereto, approved by the JSC and/or the Parties, as applicable (each such plan, a "**Development Plan**"). The Development Plan, and any subsequent changes to such Development Plan or to the then-current Development Plan shall, at a minimum and where appropriate, include the following information:

(i) tumor type and stage of therapy;

(ii) single agent and combinations dosed, control arms, and randomization;

(iii) proposed dose and dosing intervals, including dose modifications and therapy for adverse events (including immune related adverse events);

(iv) estimated number of patients (in each arm);

(v) inclusion and exclusion criteria, such as age, labs, co-morbidities, or previous therapies;

(vi) primary and secondary endpoints, including a brief description of how such endpoints will be measured and evaluated; and

(vii) the clinical trials to be conducted during the time period covered by such plan, and a budget and a timeline for such clinical trials.

Each Development Plan shall be subject to amendment from time to time with approval by the JSC in accordance with Section 2 as applicable. The Development Plan with respect to plans for Development of the Collaborative Product in the First Indication as of the Effective Date is attached to this Agreement as Schedule 3.2(d).

(e) With respect to the First Indication, Tracon shall be responsible, at its own expense, for the conduct of the Phase 1 Studies and Phase 2 Studies and Phase 3 Studies for Collaborative Product (including PK and immunogenicity sample testing, and PD sample testing in support of the clinical trials); provided that Tracon shall have the right to terminate Development activities with respect to Collaborative Product (x) immediately if reasonably required in view of patient safety, study futility, or other ethical concerns, or (y) as directed by the JSC. Tracon shall dose the first patient in a clinical trial for Collaborative Product consistent with the Development Plan no later than [***] following [***]; provided, further that if 3DAlpha gives notice to Tracon of its failure to timely dose such first patient and Tracon fails to cure such breach within [***] of such notice, 3DAlpha will have the right to terminate the Agreement for material breach of Tracon.

(f) Following successful completion of the Phase 3 Studies and/or Pivotal Trials for a Collaborative Product sufficient for the submission of an application for Regulatory Approval for First Indication, (i) Tracon shall, with the approval of the JSC, prepare and submit such an application for Regulatory Approval in the United States and such other jurisdictions in the Collaborative Territory as the Parties may agree; and (ii) Tracon shall, with the approval of the JSC, undertake the Development of the Collaborative Product for the Second Indication.

(g) Development in the Collaborative Territory of Collaborative Product for indications other than the First Indication and Second Indication shall be subject to the review and approval of the JSC.

(h) In the event that prior to the submission of an application for Regulatory Approval for the First Indication for Collaborative Product in the U.S., Tracon does not make any advancement of, or ceases all, Development of Collaborative Product for greater than [***] (including (x) [***], or (y) [***] except where such cessation or failure to advance the Development of Collaborative Product is a consequence of [***], or such other circumstance not under the reasonable control of Tracon ("**Development Abandonment**"), then 3DAlpha shall have the right to give notice to Tracon that it believes that Development Abandonment has occurred and [***] unless within [***] days of such notice Tracon contests such notice and states its detailed basis for contending that Development Abandonment has not occurred [***]. If Tracon so disputes the occurrence of Development Abandonment, the Parties shall discuss the matter in good faith and, absent mutual agreement, determination of the occurrence of Development Abandonment shall be made by dispute resolution pursuant to Article 11. Upon confirmation of Development Abandonment, 3DAlpha shall have the right to terminate the Agreement upon notice to Tracon as set forth in Section 3.4(a).

3.3 Development by 3DAlpha. 3DAlpha shall have the right but not the obligation to engage in Development Activities at its sole expense for Collaborative Product in the 3DAlpha Territory or in the 3DAlpha Field in the Collaborative Territory and 3DAlpha shall have the right to reference all existing Development Data for such Collaborative Product in support of such Development Activities. 3DAlpha shall keep Tracon and the JSC reasonably informed regarding the status of all Development Activities for Collaborative Products in the 3DAlpha Territory or in the 3DAlphaField in the Collaborative Territory.

3.4 Ending Development; Exits. The JSC shall have the authority to elect to end Development of a Collaborative Product in the Field in the Collaborative Territory either (i) by consensus of the representatives of the Parties or (ii) by a Party exercising its tie-breaking authority at the JSC, but only if done so as a consequence of (x) subject or patient injury or Collaborative Product toxicity, (y) trial futility or other failure to establish sufficient efficacy of the Collaborative Product, or (z) material change in the marketplace impairing the economic viability or competitiveness of the Collaborative Product for the First Indication and/or Second Indication under investigation. Development may be suspended or terminated as follows.

(a) If the JSC decides to stop Development of a Collaborative Product or if a Tracon Exit occurs for a Collaborative Product, (i) all rights and responsibilities of Tracon with respect to its Development shall revert to 3DAlpha, (ii) Tracon shall within ninety (90) calendar days after such termination transfer sponsorship of the IND and, to the extent applicable, ownership of any Regulatory Approvals for such Collaborative Product and management of clinical trials to 3DAlpha, (iii) the Collaborative Products License granted to Tracon in Section 9.2 shall terminate, and (iv) 3DAlpha shall thereafter be free to Develop and Commercialize such Collaborative Product anywhere in the Collaborative Territory in its sole discretion and at its sole expense.

(b) If a 3DAlpha Exit occurs, (i) apart from the orderly wrapping up of any ongoing clinical trials under Section 3.4(c), Tracon shall have no further obligation under this Agreement to perform any Development activities for or pursue Commercialization of such Collaborative Product; (ii) upon Tracon's request following a 3DAlpha Exit, 3DAlpha shall [***] and Tracon shall have the right to [***] under the terms of this Agreement, provided that (x) 3DAlpha shall compensate Tracon for [***], provided that [***] the costs for the establishment of an alternative source of supply of Collaborative Product, and (y) 3DAlpha shall not supply Collaborative Product for use in the 3DAlpha Field in the Collaborative Territory if 3DAlpha is not supplying Tracon's requirements for Collaborative Product in the Collaborative Territory and Tracon has not yet established and qualified an alternative source of supply for its requirements of Collaborative Product in the Field in the Collaborative Territory. Certain details of the foregoing supply arrangements shall be set forth in the applicable Supply Agreement.

(c) If a human clinical trial for a Collaborative Product in the Field is terminated by a Party or the JSC under this Agreement or the Development of a Collaborative Product is ended while a clinical trial is ongoing, then [***] consistent with good clinical practices.

3.5 Manufacture and Supply. Jiangsu Alphamab shall supply, or cause to be supplied, to Tracon, consistent with the requirements of Section 3.2(c), all amounts of Collaborative Product necessary or useful to perform all pre-clinical and clinical studies for its Development, pursuant to a written clinical supply and quality agreement, which shall be separately discussed and agreed to in good faith by the Parties [***] and, if applicable, Jiangsu Alphamab and Tracon's entry into a Supply Agreement with the CMO, as may be extended by the written agreement of the Parties (the "**Clinical Supply and Quality Agreement**"). The Clinical Supply and Quality Agreement will include the terms set forth on **Exhibit B**. 3DAlpha acknowledges and agrees that Tracon's

performance of the Development Activities is conditioned upon and subject to Jiangsu Alphamab's supply of Collaborative Product in compliance with the terms and conditions of this Agreement and the Clinical Supply and Quality Agreement. While Jiangsu Alphamab supplies Collaborative Product for purposes of Commercialization of Collaborative Product both in the Field and in the Collaborative Territory as well as outside the Field and/or Collaborative Territory, the requirements for Commercialization in the Field in the Collaborative Territory shall be [***] in the event of a shortage or interruption of supply. In all events, Jiangsu Alphamab shall not discontinue supplying Collaborative Product to Tracon under the terms of this Agreement so long as Jiangsu Alphamab supplies Collaborative Product for any use or to any party in the Collaborative Territory.

3.6 Performance by the Parties. Each party shall perform its activities under the Development Plan in accordance with the terms and conditions of this Agreement and Applicable Laws, including GCP and GMP to the extent applicable. If there is any conflict between performance in accordance with Applicable Laws and this Agreement, performance in accordance with Applicable Laws shall prevail.

3.7 Safety Data Exchange. Prior to the initiation of the first clinical trial of Collaborative Product by Tracon, the Parties shall negotiate in good faith and enter into a safety data exchange agreement amongst 3DAlpha and Tracon regarding Collaborative Product, which shall be consistent with the provisions of Section 4.7 and set forth standard operating procedures governing the collection, investigation, reporting, and exchange of information concerning adverse drug reactions/experiences sufficient to permit each party to comply with its regulatory and other legal obligations within the applicable timeframes. Such safety data exchange agreement shall identify which party shall be responsible for the timely reporting of all relevant adverse drug reactions/experiences, Collaborative Product quality, Collaborative Product complaints and safety data relating to Collaborative Product to the appropriate Regulatory Authorities in the Collaborative Territory or outside the Collaborative Territory, as applicable, in accordance with all Applicable Laws. Such agreement shall allow each party to comply with all regulatory and legal requirements regarding the management of safety data by providing for the exchange of relevant information in the appropriate format within applicable timeframes. The safety data exchange agreement shall identify the party responsible for maintaining the global safety database for Collaborative Product.

ARTICLE 4
COMMERCIALIZATION

4.1 Leading Company. Tracon shall be the Leading Company within the Collaborative Territory unless (x) the first Regulatory Approval of Collaborative Product in the Collaborative Territory is outside of the Field and sale of Collaborative Product pursuant to such Regulatory Approval is launched in the Collaborative Territory, or (y) Regulatory Approval of Collaborative Product in the Collaborative Territory is achieved for a non-orphan indication and sale of Collaborative Product pursuant to such Regulatory Approval is launched by 3DAlpha in the Collaborative Territory, whereupon, in each case, 3DAlpha shall thereafter be the Leading

Company within the Collaborative Territory; *provided*, *however*, if Tracon and 3DAlpha mutually agree to grant a License to a Third Party for Commercialization of Collaborative Product in the Collaborative Territory, such Third Party shall be the Leading Company for the Collaborative Territory. The Leading Company shall be responsible for the Commercialization and booking of sales of Collaborative Product in the Collaborative Territory subject to the provisions regarding pricing below in Section 4.5. In the event that 3DAlpha replaces Tracon as Leading Company after Regulatory Approval of Collaborative Product in the Tracon Field and Tracon does not co-market Collaborative Product in the Field, 3DAlpha shall compensate Tracon for its costs in preparing for and conduct of Commercialization as set forth in Section 5.3(c).

4.2 Commercialization of Collaborative Products in the Collaborative Territory. So long as Tracon is the Leading Company, Tracon shall be responsible for the Commercialization of Collaborative Products in the Field in the Collaborative Territory and shall apply Commercially Reasonable Efforts to Commercialize in the United States in the Field Collaborative Product for which Regulatory Approval is granted and in such other jurisdictions of the Collaborative Territory where it is commercially viable to do so. Tracon shall own the Regulatory Approvals in the Field for Collaborative Product in the Collaborative Territory and, so long as Tracon is Leading Company, shall book all sales of Collaborative Products in the Field in the Collaborative Territory during the Term. In the event that Tracon does not achieve at least [***], 3DAlpha shall have the right to give notice to Tracon of a failure of diligence which Tracon may cure either by (x) achieving [***], or (y) demonstrating [***] in the Field in the Collaborative Territory. If such alleged failure of diligence remains uncured, 3DAlpha shall have the right to terminate the Agreement for breach pursuant to Section 10.2.

4.3 Co-marketing of Collaborative Products. In the event that 3DAlpha (or a Third Party) is Leading Company and no Tracon Exit has occurred, Tracon shall have the right to co-market Collaborative Product in the Field in the Collaborative Territory, provided that Tracon shall have the right at any time upon notice to 3DAlpha to decline or cease to co-market Collaborative Product. In connection with the Commercialization of Collaborative Products in the Field where Tracon has exercised its co-marketing rights, the Leading Company shall provide Tracon with quarterly sales and marketing reports and its annual marketing plan for the applicable Collaborative Product. Notwithstanding Tracon's role in co-marketing of Collaborative Product in the Field, the Leading Company shall nonetheless book all sales of Collaborative Product in the Field in the Collaborative Territory.

4.4 Commercial Supply. Jiangsu Alphamab shall be responsible for the commercial supply of Collaborative Products through the establishment and maintenance of Supply Agreements with one or more CMOs and/or by use of manufacturing facilities owned or operated by Jiangsu Alphamab or its Affiliate (in which case Jiangsu Alphamab shall be the CMO for purposes of this Agreement for the applicable Collaborative Product), which arrangements shall be on terms reasonably acceptable to Tracon. Within [***] of commercial launch of Collaborative Product, Jiangsu Alphamab shall use commercially reasonable efforts to establish [***] on terms that are reasonably acceptable to Tracon. In the event that the CMO supplies Collaborative Product for purposes of Commercialization of Collaborative Product in both the

Collaborative Territory and outside the Collaborative Territory, the requirements for Commercialization in the Collaborative Territory shall be [***] with respect to requirements for use outside of the Field and/or Collaborative Territory in the event of a shortage or interruption of supply.

4.5 Pricing. In all cases with respect to Commercialization of Collaborative Product in the Collaborative Territory, pricing of the Collaborative Product, whether sold as a monotherapy or along with other drug(s) for combinational therapy, shall be proposed by the Leading Company and subject to the consensus of Tracon and 3DAlpha; provided, that neither party may withhold consent unreasonably or for the purpose of disadvantaging the commercial prospects of the Collaborative Product in the Field in the Collaborative Territory. The parties agree not to [***], at a level less than [***] in the corresponding country of the Collaborative Territory.

4.6 Product Recalls. In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with a Collaborative Product, or in the event a Party reasonably believes that an event, incident or circumstance has occurred that may result in the need for a voluntary or mandatory recall, market withdrawal or other corrective action regarding a Collaborative Product, such Party shall promptly so advise the other Party (in the case of Tracon, the Chief Executive Officer or another senior executive designated in advance by the Chief Executive Officer of 3DMed and Jiangsu Alphamab; and in the case of 3DAlpha, the Chief Executive Officer or another senior executive designated in advance by the Chief Executive Officer of 3DMed and Jiangsu Alphamab) and the Leading Company by telephone or facsimile. The Leading Company shall decide and have control of whether to conduct a recall or market withdrawal (except in the event of a recall or market withdrawal mandated by a Regulatory Authority, in which case it shall be required) or to take other corrective action in any country of the Collaborative Territory and the manner in which any such recall, market withdrawal or corrective action shall be conducted; provided that the Leading Company shall notify the Parties prior to making any public disclosure of the recall, market withdrawal or corrective action and shall keep the Parties regularly informed regarding any such recall, market withdrawal or corrective action. Recall costs shall be borne by the Leading Company, provided that where the recall is a result of an actual or suspected [***], the costs of the recall shall be borne [***]. 3DAlpha shall decide and have control of whether to conduct a recall or market withdrawal (except in the event of a recall or market withdrawal mandated by a Regulatory Authority, in which case it shall be required) or to take other corrective action in any country outside of the Collaborative Territory and the manner in which any such recall, market withdrawal or corrective action shall be conducted; provided that 3DAlpha shall notify Tracon prior to making any public disclosure of the recall, market withdrawal or corrective action and shall keep Tracon regularly informed regarding any such recall, market withdrawal or corrective action. Recall costs outside the Collaborative Territory shall be borne by solely by 3DAlpha.

4.7 Pharmacovigilance. The Parties' safety data exchange agreement regarding Collaborative Product required under Section 3.9 shall include, without limitation, the following provisions except where the Parties agree to more stringent provisions in the safety data exchange agreement:

(a) With respect to clinical trials being carried out by or on behalf of Tracon and with respect to clinical trials being carried out by or on behalf of 3DAlpha in the 3DAlpha Territory, each Party agrees pursuant to this Agreement, during the Term hereof, to notify the other Party within three (3) calendar days, in English, of any information of which the first Party becomes aware concerning any serious side effect, injury, toxicity or sensitivity reaction, or any unexpected incident, whether or not determined to be attributable to the Collaborative Product (hereinafter "**Serious Adverse Experience**"), where such Adverse Experience is life threatening and associated with the clinical uses, studies, investigations and tests of Collaborative Product. With respect to all other Adverse Experiences (non-life threatening), the Party first learning of such experience shall furnish the other Party with copies of such Adverse Experiences reported to it, in English, within seven (7)calendar days after receipt. "**Life threatening**" as used in this Section refers to an experience which results in death, is immediately life-threatening, results in persistent and significant disability/incapacity or requires in-patient hospitalization or prolongation of existing hospitalization, or is an overdose. Other important medical events that may jeopardize the patient or may require intervention to prevent one of the outcomes previously listed should also be considered serious. "**Unexpected**" as used in this Section refers to a condition or development not listed in the current labeling or investigator's brochure for Collaborative Product, and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of increased frequency or greater severity or specificity.

(b) 3DAlpha shall provide Tracon with all legacy Adverse Experience (serious and non-serious events) data from all previously conducted trials of Collaborative Products (if any) prior to execution of the safety data exchange agreement.

4.8 Restrictions.

(a) During the Term, 3DAlpha, Tracon and their respective Affiliates shall not Develop, manufacture or Commercialize, or authorize (by License or otherwise) any third party to Develop, manufacture or Commercialize, any Competing Product in the Field in the Collaborative Territory. For purposes of this Agreement, a "**Competing Product**" shall mean any [***], whether sold alone or in combination with other products. For clarity, Competing Product shall not include [***]. In the event of a bona fide Change of Control with respect to a Party, the foregoing restrictions of this Section 4.8(a) shall not apply to any pre-existing programs of a Third Party acquirer of such Party, as long as the acquiring party can only keep either the existing Competing Product or the Collaborative Product.

(b) Tracon shall not, and shall ensure that its Affiliates and sub-licensees do not, either directly or indirectly, promote, market, distribute for sale, import for sale, sell or have sold the Collaborative Product, including via internet or mail order, into countries outside the Collaborative Territory. As to such countries outside the Collaborative Territory (which are exclusively reserved for 3DAlpha), Tracon shall not, and shall ensure that its Affiliates and sub-licensees do not: (a) establish or maintain any branch, warehouse or distribution facility for sale of the Collaborative Product in such countries, (b) engage in any advertising or promotional activities relating to the Collaborative Product that are directed primarily to customers or other purchasers

of the Collaborative Product located in such countries, (c) solicit orders for the Collaborative Product from any prospective purchaser located in such countries, or (d) sell or distribute for sale the Collaborative Product to any person in the Collaborative Territory who intends to sell or has in the past sold the Collaborative Product in such countries. If Tracon receives any order for the Collaborative Product from a prospective purchaser located in a country outside the Collaborative Territory, Tracon shall immediately refer that order to 3DAlpha and Tracon will not accept any such orders. Tracon shall not deliver or tender for sale (or cause to be so delivered or tendered) the Collaborative Product into a country outside of the Collaborative Territory. Tracon shall not, and shall ensure that its Affiliates and sub-licensees do not, restrict or impede in any manner 3DAlpha's exercise of its retained exclusive rights in the Collaborative Product outside the Collaborative Territory.

(c) Except as expressly permitted herein where 3DAlpha is Leading Company, 3DAlpha shall not, and shall ensure that its Affiliates and sub-licensees do not, either directly or indirectly, promote, market, distribute for sale, import for sale, sell or have sold the Collaborative Product in the Field, including via internet or mail order, into countries within the Collaborative Territory. As to such countries within the Collaborative Territory, 3DAlpha shall not, and shall ensure that its Affiliates and sub-licensees do not: (a) establish or maintain any branch, warehouse or distribution facility for sale of the Collaborative Product in such countries, (b) engage in any advertising or promotional activities relating to the Collaborative Product that are directed primarily to customers or other purchasers of the Collaborative Product located in such countries, (c) solicit orders for the Collaborative Product from any prospective purchaser located in such countries, or (d) sell or distribute for sale the Collaborative Product to any person outside the Collaborative Territory who intends to sell or has in the past sold the Collaborative Product in such countries within the Collaborative Territory. If 3DAlpha receives any order for the Collaborative Product from a prospective purchaser located in a country within the Collaborative Territory, 3DAlpha shall immediately refer that order to Tracon or the Leading Company and 3DAlpha shall not accept any such orders. Except as Leading Company, 3DAlpha shall not deliver or tender for sale (or cause to be so delivered or tendered) the Collaborative Product into a country within the Collaborative Territory. 3DAlpha shall not, and shall ensure that its Affiliates and sub-licensees do not, restrict or impede in any manner Tracon's exercise of its exclusive rights in the Collaborative Product in the Field within the Collaborative Territory.

ARTICLE 5
FINANCIAL PROVISIONS

5.1 Prior to Regulatory Approval. The Parties shall be responsible for the costs related to the Development of Collaborative Product for the First Indication in support of an application for grant of Regulatory Approval for the Collaborative Product in the United States as follows:

(a) 3DAlpha shall be solely responsible for one-hundred percent (100%) of the cost associated with the conduct of the IND-enabling studies and the preparation of the chemistry-manufacturing-controls activities sections of the IND for such Collaborative Product.

(b) Tracon shall be solely responsible for one-hundred percent (100%) of the cost associated with filing any new IND for the Collaborative Product in the U.S. and the costs of sponsoring such IND in the U.S., excluding any costs specifically allocated to 3DAlpha under subsections (a) and (d) of this Section.

(c) Tracon shall be solely responsible for one-hundred percent (100%) of its Development Costs related to any Phase 1 Study or Phase 2 Study or Phase 3 Study of the Collaborative Product in the Collaborative Territory conducted under this Agreement and agreed to by the JSC in any Development Plan, including [***] for such studies but excluding any [***].

5.2 Following the receipt of [***] for the First Indication in the United States and [***] for First Indication, Tracon shall be responsible for the Development Costs related to [***] and any post-approval clinical trials in connection with [***] for the Collaborative Product, provided that the costs constituting [***] for the Collaborative Territory shall be borne by Tracon as set forth in Section 3.2(c).

5.3 **Royalties**. If Tracon is the Leading Company, Tracon shall pay a royalty to 3DAlpha on Net Sales in the Field of Collaborative Product in the Collaborative Territory, and if 3DAlpha or a Third party is the Leading Company, 3DAlpha shall pay a royalty to Tracon on Net Sales of in the Field of Collaborative Product in the Collaborative Territory as follows: (i) if Tracon is the Leading Company, it shall pay 3DAlpha a royalty in the amount of the 3DAlpha Royalty on such Net Sales of Collaborative Product in the Field as set forth in the table below, which amounts shall be split between 3DMed and Jiangsu Alphamab according to a ratio to be provided by 3DAlpha; and (ii) if 3DAlpha (itself or through its sublicensee) or a Third Party is the Leading Company, 3DAlpha shall pay Tracon a royalty in the amount of the Tracon Royalty on such Net Sales in the Field of Collaborative Product as set forth in the table below according to whether Tracon exercises its rights to co-market the Collaborative Product in the Field in the Collaborative Territory.

Calendar year Net Sales threshold	3DAlpha Royalty (where Tracon is the Leading Company for Field)	Tracon Royalty (where 3DAlpha is the Leading Company, but Tracon continues to co-market in Field	Tracon Royalty (where 3DAlpha is the Leading Company for the Field and Tracon does not co-market in the Field)
Up to $[***]million	[***]%	[***]%	[***]%
Above $[***] million and up to $[***]million	[***]%	[***]%	[***]%

Above $[***]million and up to $[***]million	[***]%	[***]%	[***]%
Above $[***]million	[***]%	[***]%	[***]%

(a) The royalty set forth in this Section 5.3 shall be payable quarterly and due [***] days following the end of the applicable quarter. The royalty-paying Party shall provide to the other Party no later than the date when the applicable royalty is due a report summarizing the amount of Net Sales of Collaborative Product sold in the Field on a country-by-country basis in the Collaborative Territory and the amount of royalty owed with respect to such Net Sales. Royalties under this Section 5.3 shall be payable for the duration of the Term. Royalties under this Section 5.3 shall be payable on a country-by country basis until the expiration of the last to expire of the Patents within the Collaborative Product IP or Development IP covering the Collaborative Product or the use of Collaborative Product in the Field in such country.

(b) If Tracon is the Leading Company, all Net Sales of Collaborative Product in the Collaborative Territory shall be deemed to be within the Field. If Tracon is not the Leading Company, the Parties shall confer in good faith and agree upon a mechanism for determining the amount of Net Sales of Collaborative Product in the Field through the regular (quarterly or such other frequency as agreed by the Parties) quantitative surveys of prescribing physicians in the Field in the applicable countries of the Collaborative Territory where such surveys have sufficient statistical power and effect size to accurately estimate the quantity of Net Sales in the Field. The cost of such surveys shall be [***]. The results and supporting documentation for such survey-based analysis shall be shared with the Parties and the results shall be deemed to be the total Net Sales in the Field and all additional Net Sales in excess of such amount shall be deemed to be outside the Field. Any disputes between the Parties concerning the conduct or results of such surveys shall be resolved pursuant to the dispute resolution provisions of Article 11.

(c) In the event that (x) 3DAlpha replaces Tracon as Leading Company after Regulatory Approval of Collaborative Product in the Tracon Field, (y) such replacement occurs prior to the three year anniversary of the First Commercial Sale of Collaborative Product in the Field in the Collaborative Territory, and (z) Tracon elects, and 3DAlpha agrees (with such agreement not unreasonably conditioned, delayed or withheld), within six months of such replacement that Tracon will not co-market Collaborative Product, then 3DAlpha shall reimburse Tracon for its costs incurred in preparing for and conduct of Commercialization of Collaborative Product. Tracon shall provide notice to 3DAlpha within [***] days of 3DAlpha becoming Leading Company whether Tracon will elect to co-market the Collaborative Product in the Field. Within [***] days of 3DAlpha becoming Leading Company and where Tracon has given notice to 3DAlpha that it declines to co-market the Collaborative Product, Tracon shall provide to 3DAlpha written documentation of its costs incurred in preparing for and conduct of Commercialization of Collaborative Product (*e.g.*, headcount, marketing costs, honorarium, medical education, publications, advertising, travel) and 3DAlpha shall reimburse Tracon for such amount within [***] days of receipt of such documentation.

(d) No payment obligations between 3DMed and Jiangsu Alphamab pursuant to the 3D-Alphamab Agreement shall alter the royalties payable to Tracon hereunder. 3DAlpha shall disclose to Tracon all provisions of the agreements between 3DMed and Jiangsu Alphamab related to Collaborative Product to the extent that they relate to the supply, development or commercialization of Collaborative Product in the Collaborative Territory.

5.4 Currency; Exchange Rate. All payments to be made under this Agreement shall be made in US Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from the receiving Party. When conversion of payments from any foreign currency is required, such conversion shall be at an exchange rate equal to the weighted average of the rates of exchange for the currency of the country from which such payments are payable as published by *The Wall Street Journal*, Western U.S. Edition during the quarter for which a payment is due. The payment of such interest shall not limit the Party entitled to payment from exercising any other rights it may have as a consequence of the lateness of any payment.

5.5 Late Payments. If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a per-annum rate of prime reported in *The Wall Street Journal*, Western U.S. Edition on the due date of the payment plus [***] per annum, or the maximum rate allowable by Applicable Laws, whichever is less.

5.6 Financial Records; Audit.

(a) Each Party shall keep, and require its Affiliates and Licensees, to keep, reasonably detailed, fair and true books of accounts and records for the purpose of determining the amounts payable to the other Party pursuant to this Agreement. Such books and records shall be kept for at least five (5) full years following the end of the year to which they pertain.

(b) Each Party shall allow an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party to audit its records for such year to verify the accuracy of any financial report furnished by such Party and any amounts to be paid under this Agreement for the preceding three (3) full years. Such audits may be exercised during normal business hours and no more frequently than once per calendar year upon reasonable prior written notice by a Party to the other Party. The cost of such any audit shall be borne by the Party requesting such audit, unless the audit discloses an underpayment or an overpayment by the audited Party of more than [***] of the amount of payments due under this Agreement for any applicable quarter, in which case, the audited Party shall bear the cost of such audit.

(c) Any amounts shown to be owed but unpaid, or overpaid and in need of refund, shall be paid or refunded (as the case may be) within [***] days after the accountant's report, plus interest (as set forth in Section 5.5) from the original due date on any amounts underpaid (but interest shall not apply to overpayments).

5.7 Tax.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income, including any payments received, as contemplated in this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of any payments made by a Party to the other Party under this Agreement. The Parties acknowledge that 3DAlpha does not intend to engage in any reorganization or transfer any payment obligations that it has to Tracon in a transaction that would, solely due to any such action by 3DAlpha after the Effective Date, result in additional withholding taxes on any payments that may become due to Tracon under this Agreement. However, in the event of any such transaction that does result in any additional withholding taxes, the liability for such withholding taxes shall be the sole responsibility of 3DAlpha and such payment obligations shall be increased so that Tracon receives the full amount it would have received had no such additional withholding taxes been withheld.

(c) Payment of Tax. To the extent a Party is required by Applicable Laws to deduct and withhold taxes on any payment to the other Party, the paying Party shall pay the amounts of such taxes to the proper tax authority in a timely manner and promptly transmit to the other Party an official tax certificate or other evidence of such withholding sufficient to enable such other Party to claim such payment of taxes.

ARTICLE 6
REPRESENTATIONS, WARRANTIES AND COVENANTS

6.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows:

(a) Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder.

(b) Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) **No Conflict; Covenant.** It is not a party to any agreement that would materially prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement.

(d) **Compliance with Law.** It shall comply in all material aspects with all Applicable Laws in the course of performing its obligations and exercising its rights under this Agreement.

6.2 **Additional Representations and Warranties of 3DAlpha.** 3DAlpha represents, warrants, and covenants (as applicable) to Tracon that:

(a) 3DAlpha (i) has the right to grant the Collaborative Products License that it purports to grant in Section 9.2 and all other rights granted to Tracon herein; (ii) has not granted and will not grant any right to any Third Party that would conflict with or adversely affect such Collaborative Products License or rights; and (iii) possesses all necessary rights in intellectual property for the Development and Commercialization of Collaborative Product in the Collaborative Territory;

(b) as of the Effective Date, neither 3DAlpha nor any of its Affiliates has granted any license or right to obtain any license to any Third Party to the Collaborative Product IP in the Field in the Collaborative Territory;

(c) as of the Effective Date, there are no actual, pending, or to 3DAlpha's knowledge, alleged or threatened, adverse actions, suits, proceedings, or claims against 3DAlpha (or facts providing the basis for such an action, suit, proceeding or claim) involving the Collaborative Product or the Collaborative Product IP nor has 3DAlpha received any written communication from any Third Party, including, without limitation, any Regulatory Authority or other government agency, threatening such action, suit or proceeding;

(d) as of the Effective Date, neither 3DAlpha nor any of its Affiliates has filed any regulatory filing for the Collaborative Product in the Field in the Collaborative Territory;

(e) all tangible or recorded information and data provided by or on behalf of 3DAlpha to Tracon related to the Collaborative Product was and is true, accurate and complete in all material respects, and 3DAlpha has not failed to disclose, or failed to cause to be disclosed, any such information or data related to the Collaborative Product in its Control that would cause the information and data that has been disclosed to be misleading in any material respect;

(f) 3DAlpha is not debarred or disqualified under the United States Federal Food, Drug and Cosmetic Act or comparable Applicable Laws in the Territory, and it has not employed or used the services of any person who is debarred or disqualified in connection with activities relating to any pharmaceutical products; and

(g) As of the Effective Date, there are no legal claims, judgments or settlements against or owed by 3DAlpha or any of its Affiliates, or pending or, to 3DAlpha's knowledge,

threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations.

6.3 Additional Representations and Warranties of Tracon. Tracon represents, warrants, and covenants (as applicable) to 3DAlpha that:

(a) Tracon shall conduct the Development Activities performed by it pursuant to the Development Plan in a competent and professional manner and the personnel assigned to perform Development Activities rendered by Tracon under this Agreement shall be qualified and professionally capable of performing the such Development Activities;

(b) Tracon is not debarred or disqualified under the United States Federal Food, Drug and Cosmetic Act or comparable Applicable Laws in the Territory, and it has not employed or used the services of any person who is debarred or disqualified in connection with activities relating to any pharmaceutical products; and

(c) As of the Effective Date, there are no legal claims, judgments or settlements against or owed by Tracon or any of its Affiliates, or pending or, to Tracon's knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations.

6.4 3DAlpha Covenants. In addition to any covenants made by 3DAlpha elsewhere in this Agreement, 3DAlpha hereby covenants to Tracon as follows:

(a) 3DAlpha will not knowingly, during the Development Term or during any period in which it conducts Development of the Collaborative Product, employ or use the services of any person who is debarred or disqualified in connection with activities relating to such Collaborative Product; and, in the event that 3DAlpha becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to 3DAlpha with respect to any activities relating to the Collaborative Product, 3DAlpha will immediately notify Tracon in writing and 3DAlpha will cease employing, contracting with, or retaining any such person to perform any services relating to such Collaborative Product;

(b) 3DAlpha will not, in connection with the performance of its obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a public official or entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including 3DAlpha, nor will 3DAlpha directly or indirectly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a public official or entity or any other person in connection with the performance of 3DAlpha's obligations under this Agreement;

(c) 3DAlpha and its employees and contractors, in connection with the performance of 3DAlpha's obligations under this Agreement, shall not knowingly cause Tracon

to be in violation of the FCPA, Export Control Laws, or any other Applicable Laws;

(d) 3DAlpha has a policy or practice in place against corruption and bribery and in connection with the performance of its obligations under this Agreement, 3DAlpha shall comply and shall cause its and its Affiliates' employees to comply with 3DAlpha's such policy or practice; and

(e) 3DAlpha shall immediately notify Tracon if it has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws in connection with the performance of its obligations under this Agreement.

6.5 Tracon Covenants. In addition to any covenants made by Tracon elsewhere in this Agreement, Tracon hereby covenants to 3DAlpha as follows:

(a) Tracon will not knowingly, during the Development Term, employ or use the services of any person who is debarred or disqualified in connection with activities relating to the Collaborative Product; and in the event that Tracon becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to Tracon with respect to any activities relating to the Collaborative Product;, Tracon will immediately notify 3DAlpha in writing and Tracon will cease employing, contracting with, or retaining any such person to perform any services relating to such Collaborative Product;

(b) Tracon will not, in connection with the performance of its obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a public official or entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including Tracon, nor will Tracon directly or indirectly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a public official or entity or any other person in connection with the performance of Tracon's obligations under this Agreement;

(c) Tracon and its employees and contractors, in connection with the performance of Tracon's obligations under this Agreement, shall not knowingly cause 3DAlpha to be in violation of the FCPA, Export Control Laws, or any other Applicable Laws;

(d) Tracon has a policy or practice in place against corruption and bribery and in connection with the performance of its obligations under this Agreement, Tracon shall comply and shall cause its and its Affiliates' employees to comply with Tracon's such policy or practice; and

(e) Tracon shall immediately notify 3DAlpha if it has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws in connection with the performance of its obligations under this Agreement.

6.6 Performance by Affiliates and Subcontractors. The Parties recognize that each Party may perform some or all of its obligations or exercise some or all of its rights under this Agreement through one or more Affiliates or subcontractors; *provided*, in each case, that (a) none of the other Party's rights hereunder are diminished or otherwise adversely affected as a result of such delegation or subcontracting, and (b) each such Affiliate, subcontractor, licensee or sublicensee undertakes in writing obligations of confidentiality and non-use regarding Confidential Information and ownership of intellectual property rights which are substantially the same as those undertaken by the parties pursuant to Article 8; and *provided, further,* that such Party shall at all times be fully responsible for the performance and payment of such Affiliate, subcontractor, licensee or sublicensee.

6.7 Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 6, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL SUCH REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. Each Party understands that Collaborative Product is the subject of ongoing research and development and that neither Party can assure that the Collaborative Product can successfully complete clinical trials, nor that the Collaborative Product can be successfully developed and commercialized in the Field in the Territory.

ARTICLE 7
INDEMNIFICATION; LIMITATION OF LIABILITY

7.1 Indemnification by Tracon. Tracon hereby agrees to defend, hold harmless and indemnify each of 3DAlpha, its Affiliates and their agents, shareholders, directors, officers, employees and consultants and successors and assigns of any of the foregoing (the "**3DAlpha Indemnitees**") from and against any and all liabilities, expenses and losses, including reasonable legal expenses and attorneys' fees (collectively "**Losses**"), incurred by any 3DAlpha Indemnitee as a result of any suits, claims, actions and demands brought by a Third Party (each, a "**Third Party Claim**") arising directly or indirectly out of (a) any breach of any representations, warranties, covenants or agreements by Tracon under this Agreement, or (b) the negligence or willful misconduct of any Tracon Indemnitee, or (c) the research, development, manufacture, use, handling, storage, sale or other disposition of the Collaborative Product by Tracon or its Affiliates, licensees or sublicensees. Tracon's obligation to indemnify the 3DAlpha Indemnitees pursuant to the foregoing sentence shall not apply to the extent that any such Losses arise from any activities set forth in Section 7.2 for which 3DAlpha is obligated to indemnify Tracon Indemnitees under Section 7.2.

7.2 Indemnification by 3DAlpha. 3DAlpha hereby agrees to defend, hold harmless and indemnify Tracon, its Affiliates and their agents, directors, officers, employees and consultants and successors and assigns of any of the foregoing (the "**Tracon Indemnitees**") from and against any and all Losses incurred by any Tracon Indemnitee as a result of any Third Party Claims arising directly or indirectly out of (a) any breach of any representations, warranties, covenants or agreements by 3DAlpha under this Agreement, (b) the negligence or willful misconduct of 3DAlpha Indemnitees, or (c) the research, development, manufacture, use, handling, storage, sale or other disposition of the Collaborative Product by 3DAlpha or its Affiliates, licensees or sublicensees. 3DAlpha's obligation to indemnify the Tracon Indemnitees pursuant to the foregoing sentence shall not apply to the extent that any such Losses arise from any activities set forth in Section 7.1, for which Tracon is obligated to indemnify 3DAlpha Indemnitees under Section 7.1.

7.3 Procedure. The indemnified Party shall provide the indemnifying Party with prompt notice of the claim giving rise to the indemnification obligation pursuant to this Article 7 and the exclusive ability to defend (with the reasonable cooperation of the indemnified Party) or settle any such claim; *provided*, *however*, that the indemnifying Party shall not enter into any settlement for damages other than monetary damages without the indemnified Party's written consent, such consent not to be unreasonably withheld. The indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the indemnifying Party. If the Parties cannot agree as to the application of Sections 7.1 and 7.2 to any particular Third Party Claim, the Parties may conduct separate defenses of such Third Party Claim. Each Party reserves the right to claim indemnity from the other in accordance with Sections 7.1 and 7.2 above upon resolution of the underlying claim, notwithstanding the provisions of this Section 7.3 requiring the indemnified Party to tender to the indemnifying Party the exclusive ability to defend such claim or suit. The failure to deliver written notice to the indemnifying Party within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the indemnifying Party of its indemnification obligations under this Article 7 if and to the extent the indemnifying Party is actually prejudiced thereby.

7.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 7 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 7.1 OR 7.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 8.

7.5 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice in the region(s) where the Party operates and reasonable in light of its obligations under this Agreement.

Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

ARTICLE 8
CONFIDENTIALITY

8.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party (in such capacity, the "**Receiving Party**") agrees that, for the Term and for a period of ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information of the other Party (in such capacity, the "**Disclosing Party**"). Pursuant to Section 9.1, Development Data should be deemed as Confidential Information of 3DAlpha. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its, and its Affiliates', employees, directors, officers, agents, consultants, advisors (including legal, accounting, or other professional advisors) and other representatives (collectively the "**Representatives**") do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party may disclose Confidential Information only to the Representatives on a need-to-know basis. The Receiving Party will have executed or shall execute appropriate written agreements with its Representatives sufficient to enable it to comply with all the provisions of this Agreement, or the Representatives shall be bound by written confidentiality obligations no less stringent as those obligations imposed on the Receiving Party under this Agreement, and Receiving Party shall be responsible for the acts and or omissions of such Representative with regards to or any breach of the confidentiality obligations herein by such Representatives. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information and will cooperate with Disclosing Party in every reasonable way to help Disclosing Party regain possession of the Confidential Information and prevent its further unauthorized use or disclosure. The foregoing confidentiality and non-use obligations shall not apply to any portion of the Confidential Information that the Receiving Party can demonstrate by competent written proof:

(a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the Receiving Party by a Third Party who has a legal right to make such disclosure; or

(e) is subsequently independently discovered or developed by the Receiving Party without the aid, application, or use of the Disclosing Party's Confidential Information, as evidenced by a contemporaneous writing.

8.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 8.1, the Receiving Party may disclose the Disclosing Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary for (i) the Development, manufacture or Commercialization of the Collaborative Product, including obtaining and maintaining Regulatory Approval or patent protection, pursuant to the terms of this Agreement; or (ii) the prosecuting or defending litigation as contemplated by this Agreement; or

(b) such disclosure is reasonably necessary: (i) to the Receiving Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial advisors to provide advice to the Receiving Party, provided that in each such case on the condition that such directors, attorneys, independent accountants and financial advisors are bound in writing by confidentiality and non-use obligations consistent with those contained in this Agreement; or (ii) to actual or potential investors, acquirers, licensors, licensees, collaborators or other business partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, license or collaboration; *provided* that in each such case on the condition that such disclosures are bound in writing by confidentiality and non-use obligations consistent with those contained in the Agreement;

(c) such disclosure is required by Applicable Laws, including judicial or administrative process. Confidential Information that is disclosed under this Section 8.2(c) shall remain otherwise subject to the confidentiality and non-use provisions of this Article 8, and the Party disclosing Confidential Information pursuant to Applicable Laws may disclose, but only to the extent so required, and shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order to ensure the continued confidential treatment of such Confidential Information.

(d) Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 8(a)(ii) or Section 8(c), it will, except where impracticable, give reasonable advance written notice to the other Party of such disclosure to allow the other Party a reasonable opportunity to seek a protective order or equivalent and use efforts to secure confidential treatment of such information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Any such disclosure, however, shall not relieve the such Party of its obligations as the Receiving Party contained herein.

8.3 Public Announcements.

(a) Publicity. Subject to the rest of this Section 8, no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Laws.

(b) Press Releases. As soon as practicable following the Effective Date, the Parties shall issue a joint press release announcing the execution of this Agreement in substantially the form attached hereto as **Exhibit C**. Except as required by applicable securities laws (including disclosure requirements of the U.S. Securities and Exchange Commission ("**SEC**") or any stock exchange on which securities issued by a Party or its Affiliates are traded), neither Party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed*; provided* that each Party may make any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other Party pursuant to this Section 8 and which do not reveal non-public information about the other Party. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

(c) Filing of this Agreement. The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; *provided* that each Party will ultimately retain control over what information to disclose to the SEC or any stock exchange or other governmental agency, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC or any stock exchange or other governmental agency.

8.4 Publication. At least seven (7) days prior to a Party or of any of its Affiliates, or Licensees in the case of 3DAlpha, publishing, publicly presenting, and/or submitting for written or oral publication a manuscript, abstract or the like that includes Know-How relating to the Collaborative Product that has not been previously published, such Party shall provide to the other Party a draft copy thereof for its review (unless such Party is required by law to publish such Know-How sooner, in which case such Party shall provide such draft copy to the other Party as much in advance of such publication as possible). The publishing Party shall consider in good faith any comments provided by the other Party during such seven (7) day period. The review

period may be extended for an additional seven (7) days if a representative of the non-publishing Party can demonstrate a reasonable need for such extension including, but not limited to, the preparation and filing of patent applications. By mutual agreement of the Parties, this period may be further extended. In addition, the publishing Party shall, and shall cause its Affiliates and Licensees, as applicable, at the other Party's reasonable request, remove therefrom any Confidential Information of such other Party. The contribution of each Party shall be noted in all publications or presentations by acknowledgment or co-authorship, whichever is appropriate.

8.5 Prior Non-Disclosure Agreement. As of the Effective Date, the terms of this Section 8 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

8.6 Equitable Relief. Each Party acknowledges that a breach of this Section 8 cannot be reasonably or adequately compensated in damages in an action at law and that such a breach shall cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of the obligations relating to Confidential Information set forth herein.

ARTICLE 9
INTELLECTUAL PROPERTY

9.1 Ownership. As between the Parties and subject to the licenses granted under this Agreement, (i) 3DAlpha is the sole owner of all rights, title and interest in and to the Collaborative Product IP, (ii) Tracon is the sole owner of all rights, title and interest in and to the Tracon IP and the Development Data, (iii) 3DAlpha and Tracon shall jointly own all rights, title and interest in and to the Development IP. Each of Tracon and 3DAlpha agree and hereby irrevocably transfer and assign to the other sufficient rights to vest joint ownership in the Development IP. Each party shall perform and, if necessary, obligate its personnel to perform any and all other reasonable acts necessary to assist the other Party in obtaining, maintaining, implementing, securing and perfecting such any and all rights hereof, including but not limited to executing the necessary documents by such Party and/or its personnel.

9.2 Collaborative Product License. Subject to the terms and conditions of this Agreement, 3DAlpha hereby grants an exclusive (even with respect to 3DAlpha and its Affiliates), nontransferable, license to Tracon under the Collaborative Product IP and the Development IP for the (i) Development of the Collaborative Products in the Field in the Collaborative Territory (which for clarity may include the conduct of clinical trials in the European Union as determined by the JSC), and (ii) for Commercialization of the Collaborative Products in the Field in the Collaborative Territory (the "**Collaborative Products License**").

(a) As part of the Collaborative Products License, 3DAlpha hereby grants a non-exclusive, nontransferable license to Tracon under the Collaborative Product IP and Development IP for the conduct of clinical trials in the European Union in support of the Development of Collaborative Products in the Field in the Collaborative Territory. For clarity, the Collaborative Products License shall not include the right to Commercialize or seek Regulatory Approval of Collaborative Products outside of the Collaborative Territory and the Field.

(b) The Collaborative Products License shall not be sublicensable by Tracon except with the written consent of 3DAlpha.

(c) Notwithstanding the foregoing grant of the Collaborative Products License and subject to the other terms of this Agreement, 3DAlpha expressly reserves the right to grant Licenses to Third Parties in the Collaborative Product IP and Development IP outside the Collaborative Territory.

(d) If the Parties mutually agree in writing to stop Development of Collaborative Product, or after a Tracon Exit, all license rights granted to Tracon under the Collaborative Products License shall be terminated and 3DAlpha shall have the right to grant to a third party a License to Develop and Commercialize Collaborative Product under the Collaborative Product IP in the Field in the Collaborative Territory. 3DAlpha shall have the right to conduct, at 3DAlpha's sole expense, clinical trials for a Collaborative Product at clinical sites in the Collaborative Territory in connection with a clinical trial primarily being conducted by 3DAlpha in the 3DAlpha Territory for the purpose of seeking Regulatory Approval of a Collaborative Product in the 3DAlpha Territory or for a Collaborative Product outside the Field in the Collaborative Territory.

9.3 License to 3DAlpha. Tracon grants 3DAlpha an irrevocable, perpetual, royalty-free, exclusive license with the right to grant sublicenses to use Development Data and Development IP to develop, register, sell, offer to sell, have sold, market and distribute the Collaborative Product (x) in territories outside of the Collaborative Territory, and/or (y) in all territories in the 3DAlpha Field. Upon termination of the Agreement (other than by Tracon for bankruptcy or material breach of 3DAlpha), Tracon shall grant 3DAlpha an irrevocable, perpetual, royalty-free, non-exclusive license with the right to grant sublicenses to use Development Data and Development IP to develop, register, sell, offer to sell, have sold, market and distribute the Collaborative Product in the Collaborative Territory.

9.4 Prosecution and Maintenance of Collaborative Product IP and Development IP. 3DAlpha shall be responsible for, and shall have the sole rights in relation to, the preparation, filing, prosecution and maintenance of any Patents and other intellectual property rights within the Collaborative Product IP at its own expense. The Parties shall collaborate with respect to the prosecution and maintenance of any patents within the jointly owned Development IP.

9.5 Third Party Intellectual Rights. In the event that any Third Party asserts that the Commercialization of Collaborative Product in the Collaborative Territory infringes any Third Party intellectual property rights, [***] shall have the right to defend against such claim and/or, subject to [***]'s written consent, enter into a license agreement for the purpose of resolving such

claim and the costs of such defense and licensing arrangement shall be creditable against royalties otherwise payable by Tracon to 3DAlpha under Article 5.

9.6 Infringement by Third Parties. In the event either Party becomes aware of any Third Party infringement of the Collaborative Product IP in the Collaborative Territory (an "**Infringement**"), such Party shall promptly notify the other Party and the Parties shall confer in good faith regarding strategy for abating such infringement in view of its potential effect upon the Commercialization of Collaborative Products in the Collaborative Territory. [***], its Affiliates or their Licensees shall have the first right to bring an action for infringement of the Collaborative Product IP in the Collaborative Territory at its expense. Any recovery realized as a result of any such action or proceeding, whether by way of settlement or otherwise, shall first be used to reimburse the Parties for their costs in connection with such enforcement action and the balance shall be treated as Net Sales where [***] is the Leading Company. If [***] does not elect to bring an enforcement action against such Infringement, [***] shall have the right but not the responsibility to bring an enforcement action against such Infringement at its own expense and any recovery shall first be used to reimburse the Parties for their costs in connection with such enforcement action and the balance shall be treated as Net Sales where [***] is Leading Company. Each Party shall cooperate at the enforcing Party's expense with any enforcement action brought against an Infringement and, additionally, shall have the right to participate in such action with its own counsel at its own expense subject to the foregoing right of reimbursement from any recoveries from such action.

9.7 No Implied Licenses. No right or license is granted under this Agreement by either Party to the other Party, either expressly or by implication, except those specifically set forth herein.

ARTICLE 10
TERM AND TERMINATION

10.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 10, shall remain in effect until the later of (a) the date that the Parties cease Development and Commercialization of all Collaborative Products in the Field in the Collaborative Territory pursuant to this Agreement; or (b) the expiration of all payment obligations of the Parties under Section 5 (the "**Term**"). In the event the Agreement expires pursuant to the end of the Term as specified in this Section 10.1(b), the licenses granted herein shall become perpetual and paid-up.

10.2 Termination for Breach. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party, if the other Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail, such breaching party fails to cure such material breach within sixty (60) days (or twenty-five (25) days with respect to any payment breach) from the date of such notice. Any right to terminate under this Section 10.2, other than with respect to any payment breach, shall be stayed and the cure period tolled in the event that,

during any cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Article 11 with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Article 11.

10.3 Termination for Good Reason. Either Party shall have the right to terminate this Agreement upon written notice to the other Party if the terminating Party reasonably determines, based upon additional information that becomes available or an analysis of the existing information at any time, that the medical risk/benefit of Collaborative Product is so unfavorable that it would be incompatible with the welfare of patients to Develop or Commercialize or to continue to Develop or Commercialize Collaborative Product. Prior to any such termination, the terminating Party shall comply with such internal review and management approval processes as it would normally follow in connection with the termination of the development and commercialization of its own products for safety reasons and shall present and discuss the findings of such internal review for approval by the JSC.

10.4 Termination for Bankruptcy. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party, if the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of substantially all of its assets, or if such other Party proposes a written agreement of composition or extension of substantially all of its debts, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within ninety (90) days after the filing thereof, or if such other Party shall propose or be a party to any dissolution or liquidation, or if such other Party shall make an assignment of substantially all of its assets for the benefit of creditors.

10.5 Buyback. 3DAlpha shall have the option to reacquire the full rights to the Collaborative Product in the Field in the Collaborative Territory in connection with an arm's length sale to a Third Party of all rights to the Collaborative Product for all uses in the Collaborative Territory, which option shall be exercisable upon the negotiation of such an arm's length sale for the rights to the Collaborative Product as follows: (i) upon 3DAlpha's notice to Tracon of its exercise of the option, the Parties shall negotiate in good faith an amount of fair compensation to Tracon for the value of the rights and opportunity being reacquired by 3DAlpha from Tracon; (ii) such arm's length sale to a Third Party will not occur prior to completion of the Pivotal Trial in the First Indication without the written consent of Tracon; and (iii) 3DAlpha shall reacquire such rights in the Collaborative Product following mutual written agreement between the Parties on such terms and payment of the agreed consideration thereunder. In the event of a termination of the Agreement by 3DAlpha pursuant to Section 10.2 following a Tracon Exit, 3DAlpha shall have the right to reacquire the full rights to the Collaborative Product in the Collaborative Territory free of charge.

10.6 Effect of Termination.

(a) In the event of a termination of the Agreement by Tracon pursuant to Section 10.2 or 10.4 following a 3DAlpha Exit, the Collaborative Products License shall be perpetual and irrevocable in the Field and all royalties due 3DAlpha under Section 5.3 shall be paid by Tracon.

(b) In the event of a termination of the Agreement by 3DAlpha pursuant to Section 10.2 following a Tracon Exit, the Collaborative Products License shall be terminated, and 3DAlpha shall have the right to reacquire the full rights to the Collaborative Product in the Collaborative Territory free of charge.

(c) In the event of termination pursuant to Section 10.3 or by mutual agreement of the parties or by 3DAlpha pursuant to Section 10.2 or 10.4, the following terms shall apply:

(i) Development Data**.** Tracon shall, for a period of [***] following the effective date of such termination, provide 3DAlpha access to and transfer all Development Data for Collaborative Product in its possession to 3DAlpha as of the effective date of such termination.

(ii) Development Activities**.** 3DAlpha shall have the sole right to continue the Development and Commercialization of Collaborative Product in the Field in the Territory; and Tracon, in consultation with 3DAlpha, will promptly wind-down any of its ongoing Development and Commercialization activities (including any clinical studies) for Collaborative Product in an orderly fashion with the Parties sharing the costs for such wind-down consistent with Article 5, except as otherwise agreed to in any agreement entered into between the Parties.

10.7 Survival. Expiration or termination of this Agreement shall not relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. Without limiting the foregoing, the following provisions, including the Parties' rights and obligations thereunder, shall survive any expiration or termination of this Agreement: Articles 1, 7, 8, 11, 12 and Sections 9.1, 10.5 and 10.6 and those which, by their nature, are intended to survive.

ARTICLE 11
DISPUTE RESOLUTION

11.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 11 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

11.2 Internal Resolution. With respect to all disputes arising between the Parties under this Agreement, including, without limitation, any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement or any failure of the parties to reach consensus where consensus is required under the Agreement, if the Parties are unable to resolve such dispute within thirty (30) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Chief Executive Officers of the Parties for attempted resolution by good faith negotiations within ten (10) Business Days after such notice is received.

11.3 Binding Arbitration.

(a) Claims. If the Chief Executive Officers of the Parties are not able to resolve any disputed matter within thirty (30) days and either Party wishes to pursue the matter, each such dispute, controversy or claim shall be finally resolved by binding arbitration before a panel of three neutral experts with relevant industry experience, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The arbitration proceeding shall be administered by the International Court of Arbitration of the International Chamber of Commerce (the "**ICC**") in accordance with its then existing arbitration rules or procedures regarding commercial or business disputes, and the panel of arbitrators shall be selected in accordance with such rules. The arbitration and all associated discovery proceedings and communications shall be conducted in English, and the arbitration shall be held in New York, NY. Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of arbitration without the prior written consent of both Parties.

(b) Arbitrators' Award. The arbitrators shall, within fifteen (15) days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrators shall not be authorized to award any damages expressly excluded pursuant to Section 7.4. The decision or award rendered by the arbitrators shall be final and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction. Either Party may apply for interim injunctive relief with the arbitrators until the arbitration award is rendered or the controversy is otherwise resolved.

(c) Costs. Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided, however,* that the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), or the fees and costs of the tribunal and the arbitrators.

(d) Court Actions. Nothing contained in this Agreement shall deny either Party the right to seek, upon good cause, injunctive or other equitable relief from a court of competent jurisdiction in the context of an emergency or prospective irreparable harm, and such

an action may be filed and maintained notwithstanding any ongoing dispute resolution discussions or arbitration proceedings. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to this Section 11.

ARTICLE 12
MISCELLANEOUS

12.1 Entire Agreement; Amendment. This Agreement, including the Exhibits attached hereto, and the Clinical Supply and Quality Agreement(s) and Commercialization License(s), sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

12.2 Force Majeure. Each Party shall be excused from the performance of its obligations under this Agreement, other than obligations to make payments when due, to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues, the nonperforming Party takes reasonable efforts to remove the condition and provided that the nonperforming Party has not caused such condition to occur. For purposes of this Agreement, force majeure shall include conditions beyond the reasonable control of the nonperforming Party, including without limitation, an act of God or terrorism, involuntary compliance with any regulation, law or order of any government, war, civil commotion, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

12.3 Bankruptcy Code. All licenses and rights granted under this Agreement will be deemed licenses of rights to intellectual property for purposes of Section 365(n) of the United States Bankruptcy Code or any analogous provisions in any other country or jurisdiction and a licensee or sublicensee under this Agreement will retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

12.4 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and delivered either in person, by any

method of mail (postage prepaid) requiring return receipt, or by reputable overnight courier or facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 12. Notice shall be deemed to have been sufficiently given for all purposes upon the earliest of (a) the date of actual receipt, if hand-delivered, or sent by facsimile with electronic confirmation of receipt, or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Tracon: TRACON Pharmaceuticals, Inc.
4350 La Jolla Village Dr., Suite 800
San Diego, CA 92121 USA
Attention: Chief Business Officer
Fax: +1 858-550-078

If to 3DAlpha:

Attention:
Fax:

12.5 No Strict Construction; Headings. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

12.6 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party's consent to an Affiliate or to a successor to substantially all of the business of such Party to which this Agreement relates (whether by merger, sale of stock, sale of assets or other transaction) or as expressly permitted herein. Any permitted successor or assignee of rights or obligations hereunder shall, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the foregoing shall be null, void and of no legal effect.

12.7 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

12.8 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it, except as expressly provided with respect to the 3DAlpha Indemnitees and the Tracon Indemnitees.

12.9 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

12.10 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

12.11 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

12.12 Interpretations. In this Agreement, unless otherwise specified:

(a) "includes" and "including" shall mean respectively includes and including without limitation;

(b) the word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction is mutually exclusive;

(c) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(d) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear;

(e) all references to days, quarters and years in this Agreement shall mean calendar days, quarters and years, respectively, unless otherwise specified; and

(f) the Exhibits attached hereto form part of the operative provision of this Agreement and references to this Agreement shall include references to such Exhibits.

12.13 English Language. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. To the extent this Agreement requires a Party to provide to the other Party information, correspondence, notice or other documentation, such Party shall provide such information, correspondence, notice or other documentation in the English language and also a copy of the original of such information, correspondence, notice or other documentation if such original is not in the English language.

12.14 Governing Law. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of State of New York, U.S., without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction.

12.15 Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

In Witness Whereof, the Parties have executed this Collaboration and Clinical Trial Agreement in triplicate originals by their duly authorized officers as of the Effective Date.

Tracon Pharmaceuticals, Inc.

By: /s/ Charles P. Theuer

Name: CHARLES THEUER, M.D. Ph.D.

Title: President and CEO

3D Medicines (Beijing) Co., Ltd.

By: /s/ John Gong

Name: John Gong

Title: CEO

Jiangsu Alphamab Biopharmaceuticals Co., Ltd.

By: /s/ Ting Xu

Name: Ting Xu

Title: Chairman and CEO of Alphamab Oncology

Exhibit A

Patents describing Antibody

[***]

Exhibit B

Clinical Supply and Quality Agreement Terms

Scope. Jiangsu Alphamab agrees to manufacture/have manufactured and supply/have supplied to Tracon, Tracon's requirements for Collaborative Product (as agreed by the parties).

Subcontracting. Jiangsu Alphamab is entitled to select, qualify and contract CMO for any activities relevant to the manufacture or supply of Collaborative Product. Jiangsu Alphamab shall provide Tracon with a copy of any agreements between CMO and Jiangsu Alphamab to the extent that they relate to the manufacture or supply of Collaborative Product and Jiangsu Alphamab's consent (not to be unreasonably withheld) shall be required for all agreements with CMO entered into after the Effective Date and all amendments to agreements with a CMO in existence as of the Effective Date , in each case to the extent they relate to the manufacture or supply of Collaborative Product. Upon such entry by Jiangsu Alphamab into a supply agreement for Collaborative Product with CMO, the supply price in such agreement shall be [***] for Collaborative Product supplied and charged from such CMO.

Joint Steering Committee. Conduct under the CSQA shall be monitored and coordinated by the JSC or a subcommittee appointed by the JSC.

Forecast. The CSQA to provide for forecasting of requirements of Collaborative Product by Tracon and minimum periods for placement and fulfillment of orders for same.

Tracon shall submit a rolling forecast quarterly showing its monthly requirements covering the period of [***] months. The first [***] months are firm and can't be changed.

Delivery. Unless otherwise agreed by the parties, upon delivery, the Product will have the greater of (i) [***] remaining shelf life based on reasonably expected shelf-life, or (ii) [***] shelf life. Jiangsu Alphamab shall have ongoing stability studies for the purpose of establishing the Collaborative Product's shelf-life at a commercially reasonable length.

Change Management. Both parties will agree on a cGMP compliance change management process. Jiangsu Alphamab shall inform Tracon of any changes potentially impacting the quality dossier for Collaborative Product prior to their implementation and provide Tracon in good faith with an opportunity to comment upon and suggest alternatives to such proposed changes.

Compliance. All Product manufactured and supplied by Jiangsu Alphamab and/or on Jiangsu Alphamab's behalf to Tracon under the CSQA shall (i) comply with the specifications, (ii) comply with the relevant regulatory approvals, (iii) be manufactured, tested and released in a manner compliant with cGMP, all applicable laws and the applicable quality agreement(s), and (iv) not be adulterated or misbranded.

GMP Audits. Jiangsu Alphamab shall ensure that the CMOs are audited regularly (at least annually) according to cGMP and applicable law. Jiangsu Alphamab shall share with Tracon the

results of each audit after completion of the audit. In the case of any critical observations that affects the product distributed to Tracon, Jiangsu Alphamab shall notify Tracon immediately in writing. Jiangsu Alphamab will use Commercially Reasonable Efforts to negotiate the terms of Supply Agreements to allow Tracon to [***] concerning Collaborative Products and to [***] related documentation maintained at Jiangsu Alphamab, the CMO and its other suppliers or subcontractors (no more frequently than [***] per year). Both parties will agree on how to address findings with 3DAlpha leading the response.

Supply price. Cost of supply of Collaborative Product shall be consistent with the terms of the Agreement, and the [***] for clinical supply of Collaborative Product for the Collaborative Territory shall be charged to Tracon.

Jiangsu Alphamab shall be responsible for all of the costs associated with the retention, qualification and maintenance of the CMO as a supplier of Collaborative Product and Jiangsu Alphamab [***] shall not be included in Collaborative Product supply price. Jiangsu Alphamab will use Commercially Reasonable Efforts to include in its Supply Agreement with the CMO reasonable [***].

Process Improvements. Jiangsu Alphamab will use Commercially Reasonable Efforts to include in its Supply Agreement with the CMO reasonable provisions for [***], such that Tracon will receive a corresponding benefit through [***].

Term. Through Regulatory Approval and until up to [***] after first launch in Collaborative Territory. The Supply Agreement with CMO will include reasonable provisions for establishment of second source of supply and, at Tracon's reasonable request following actual or projected failure of supply of Collaborative Product, manufacturing technology transfer to Tracon or its designees and/or for Tracon to establish direct manufacturing and supply relationship with the CMO after the agreement by 3DAlpha or as provided in the Agreement.

The Parties will within 30 days of entry into the CSQA adopt a quality agreement for the allocation of quality management and assurance tasks.

Exhibit C

[Press Release]

Schedule 1.21

Jiangsu Alphamab shall supply Collaborative Product in filled and finished form DAP (Incoterms 2010) to Tracon's designated site in the US during the Term at the following prices:

For clinic supply:	$[***] per 200 mg
For commercial supply:	$[***] per 200 mg

Parties shall negotiate the supply price (Cost of Goods) for commercial supply in good faith amongst themselves and/or with a CMO, if, following First Commercial Sale, there is a significant increase/decrease in supply cost of raw materials or significant increase/decrease in inflation, or significant change in currency exchange rate.

Schedule 3.2(d)

[Development Plan]

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1)Registration Statement (Form S-8 No. 333-201808) pertaining to the 2011 Equity Incentive Plan, 2015 Equity Incentive Plan, and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(2)Registration Statement (Form S-8 No. 333-209592) pertaining to the 2015 Equity Incentive Plan, and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(3)Registration Statement (Form S-8 No. 333-216347) pertaining to the 2015 Equity Incentive Plan, and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(4)Registration Statement (Form S-8 No. 333-223333) pertaining to the 2015 Equity Incentive Plan, and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(5)Registration Statement (Form S-8 No. 333- 229988) pertaining to the 2015 Equity Incentive Plan, and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(6)Registration Statement (Form S-1 No. 333-216962) of TRACON Pharmaceuticals, Inc.,
(7)Registration Statement (Form S-1 No. 333- 234651) of TRACON Pharmaceuticals, Inc.,
(8)Registration Statement (Form S-3 No. 333-224809) of TRACON Pharmaceuticals, Inc.; and
(9)Registration Statement (Form S-3 No. 333- 229990) of TRACON Pharmaceuticals, Inc.

of our report dated February 27, 2020, with respect to the consolidated financial statements of TRACON Pharmaceuticals, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

San Diego, California
February 27, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles P. Theuer, M.D., Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of TRACON Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

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

I, Charles P. Theuer, M.D., PhD., President and Chief Executive Officer of TRACON Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) this Annual Report on Form 10-K of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

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

Date: February 27, 2020

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.