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, 2018

☐ **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	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	**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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 30, 2018, 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 $58.0 million, based on the closing price of the registrant's common stock on the NASDAQ Global Market on June 29, 2018 of $2.70 per share.

The number of outstanding shares of the registrant's common stock as of February 8, 2019 was 29,898,698.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the Registrant's 2019 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the Registrant's fiscal year ended December 31, 2018.

TRACON Pharmaceuticals, Inc.

FORM 10-K — ANNUAL REPORT
For the Fiscal Year Ended December 31, 2018

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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 and, through our license to Santen Pharmaceutical Co. Ltd. (Santen), wet age-related macular degeneration, or wet AMD. We are a leader in the field of endoglin biology and are using our expertise to develop antibodies that bind to the endoglin receptor. Endoglin is essential to angiogenesis, the process of new blood vessel formation required for solid cancer growth and wet AMD. We are developing our lead product candidate, TRC105 (carotuximab), an endoglin antibody, for the treatment of multiple solid tumor types in combination with inhibitors of the vascular endothelial growth factor, or VEGF, pathway, or in combination with inhibitors of the programmed cell death protein 1, or PD-1, pathway. The VEGF pathway regulates vascular development in the embryo, or vasculogenesis, and angiogenesis, while the PD-1 pathway represents an adaptive immune resistance mechanism that protects tumors from host immunity. We believe treatment with TRC105 in combination with VEGF inhibitors or PD-1 inhibitors may improve survival in cancer patients when compared to treatment with a VEGF inhibitor or PD-1 inhibitor alone. TRC105 has been studied in 13 completed Phase 2 clinical trials and four completed Phase 1 clinical trials, and is currently being dosed in one Phase 3 clinical trial, three Phase 2 clinical trials and one Phase 1 clinical trial.

Our TRC105 oncology clinical development plan is broad and involves a tiered approach. We are initially focused on angiosarcoma which is a tumor that highly expresses endoglin, the target of TRC105, and therefore may be more responsive to treatment with TRC105. We have seen complete durable responses in this tumor type and are currently enrolling the international multicenter Phase 3 TAPPAS trial in angiosarcoma. We obtained Special Protocol Assessment (SPA) agreement from the U.S. Food and Drug Administration (FDA) on our clinical trial design for the Phase 3 trial in angiosarcoma and also incorporated scientific advice from the European Medicines Agency (EMA) regarding the adequacy of the trial design. We also received orphan drug designation from the FDA and the EMA for TRC105 for the treatment of soft tissue sarcoma, including angiosarcoma, in 2016. The trial is an adaptive design and based on the planned interim analysis, the trial will accrue a variable number of patients into one of four zones: 190 patients if the interim results lie in the favorable or unfavorable zones, 340 patients if the interim results lie in the promising zone, or 220 patients with cutaneous disease if the interim results lie in the enrichment zone. In the case the interim results are in the unfavorable zone, the DMC could also terminate the trial for futility. The TAPPAS trial has enrolled more than 120 patients to date and based on current accrual rates and the occurrence of events that define the primary endpoint of Progression Free Survival (PFS), we expect to conduct the interim analysis to determine the final sample size and eligible population for the trial in April 2019 and expect final data in 2020, which could vary dependent upon the final sample size and the rate at which events occur.

The next tier of TRC105 development includes a Phase 2 trial in the mid-size indication of hepatocellular carcinoma (HCC). The trial is ongoing, with completion of enrollment of up to 33 patients and top-line data expected by the first quarter of 2020. Positive data from this Phase 2 trial could enable Phase 3 development and we consider this indication attractive because the endpoint for regulatory approval may be attained more quickly than the endpoint for other indications. We also expect this indication would be for the same line of treatment for which the companion VEGF inhibitor is approved.

Finally, the third tier of TRC105 development includes large indications including a Phase 1/2 trial in breast cancer, a Phase 2 trial in prostate cancer, and a Phase 1 trial in lung cancer. Positive data in these larger indications could enable further development. The lung cancer trial represents the initial study of TRC105 in combination with Opdivo® (nivolumab), an inhibitor of the PD-1 checkpoint pathway, and is based on preclinical data demonstrating that TRC105 potentiated PD-1 checkpoint inhibitor treatment in three separate tumor models that were presented at the International Cancer Microenvironment Society meeting in 2018.

We have produced a formulation of TRC105 called DE-122 for ophthalmology indications, which is being developed by Santen 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 DE-122 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 has expanded enrollment in the randomized Phase 2a AVANTE study and we expect top-line data in early 2020.

Our second clinical stage product oncology candidate is TRC102, a small molecule being developed for the treatment of lung cancer and mesothelioma. TRC102 reverses 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, including agents approved for the treatment of lung cancer and mesothelioma. TRC102 is being studied in a Phase 2 trial with Temodar in patients with ovarian, colorectal, and lung cancer and with Alimta (pemetrexed) in patients with mesothelioma, in addition to two Phase 1 trials.

We are also developing TRC253, a small molecule compound we licensed from Janssen Pharmaceutica N.V. (Janssen) in September 2016. 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. We initiated a Phase 1/2 clinical trial of TRC253 in March 2017, established the recommended Phase 2 dose in July 2018, and subsequently commenced the Phase 2 portion of the trial, which is currently enrolling. We expect to present top-line data from the Phase 1 portion of the study in 2019 and expect top-line data from the Phase 2 portion of the study by the end of 2020. Until 90 days after we complete the initial Phase 1/2 study, 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 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. We also licensed TRC694 (formerly JNJ-6420694), a novel, potent, orally bioavailable inhibitor of NF-kB inducing kinase (NIK), from Janssen in September 2016. Following completion of the pre-clinical development of TRC694, we determined the compound did not warrant further development and in February 2019, we issued written notice to terminate the agreement with respect to TRC694 and returned TRC694 and all rights thereto to Janssen.

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. 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 ongoing clinical trials including our international Phase 3 TAPPAS trial in angiosarcoma. We have also leveraged our product development platform to diversify our product pipeline without payment of upfront license fees. In 2016 we executed a license agreement with Janssen for TRC253 and TRC694 without an upfront payment. In November 2018 we entered into separate strategic collaboration and clinical trial agreements (the Collaboration Agreements) with I-Mab Biopharma (I-Mab) for TJ004309 (the TJ004309 Agreement), a novel, humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to adenosine, which is highly immunosuppressive, and for the development of up to 5 bi-specific antibodies (the Bispecific Agreement) that includes US commercialization rights, which were both executed without an upfront payment to I-Mab. We continue to evaluate ex-U.S. companies that are in need of 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. We believe we can become a preferred clinical developmental and U.S. commercialization partner through a cost- and risk-sharing partnership structure which may include U.S. commercialization.

Pursuant to the TJ004309 Agreement, we have begun development of I-Mab's proprietary CD73 antibody TJ004309, also known as TJD5. In December 2018, we submitted an IND application to the FDA, which was subsequently cleared in January 2019. We expect to initiate a Phase 1 clinical study and begin enrollment in the U.S. in the first half of 2019 to assess safety and preliminary efficacy of TJ004309 as a single agent and when combined with a PD-1/PD-L1 checkpoint inhibitor in patients with advanced solid tumors. The Bispecific Agreement 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.

We have also collaborated with the National Cancer Institute (NCI), which selected TRC105 and TRC102 for federal funding of clinical development, as well as Case Western Cancer Center (Case Western), the University of Alabama – Birmingham (UAB), and Cedars-Sinai Medical Center. Under these collaborations, NCI sponsored or is sponsoring ten completed or ongoing clinical trials of TRC105 and TRC102, Case Western sponsored two clinical trials of TRC102, UAB is sponsoring one clinical trial of TRC105, and Cedars-Sinai Medical Center is sponsoring one clinical trial of TRC105. All TRC105 NCI sponsored trials have been completed.

The following table summarizes key information regarding ongoing development of our product candidates:

	Phase	Data Expected
TRC105		
Angiosarcoma	Randomized Phase 3	Interim analysis April 2019
Hepatocellular Carcinoma	Phase 1/2	2020
Lung Cancer	Phase 1	2019
Breast Cancer	Phase 1/2	2019
Prostate Cancer	Phase 2	2019
DE-122 (ophthalmic formulation of TRC105)		
Wet AMD (Santen)	Randomized Phase 2	2020
TRC102		
Mesothelioma	Phase 2	2020
Solid Tumors	Phase 1	2020
Solid Tumors and Lymphomas	Phase 1/2	2019
Lung Cancer	Phase 1	2020
TRC253		
Prostate Cancer	Phase 1/2	2020
TJ004309 (I-Mab)		
Solid Tumors	Phase 1	2020

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. As key components of our strategy, we intend to:

- ***Focus the initial tier of clinical development of TRC105 on oncology indications that highly express endoglin and have demonstrated durable complete responses to treatment, and have potential reduced time to regulatory approval.*** We initiated dosing in 2017 and are currently enrolling our international multicenter randomized Phase 3 TAPPAS clinical trial of TRC105 in angiosarcoma, a type of soft tissue sarcoma that highly expresses endoglin, in combination with the approved VEGF inhibitor Votrient® (pazopanib) versus single agent Votrient. We expect an interim analysis in

April 2019 that will determine the final sample size and we expect top-line data in 2020, which could vary dependent upon the final sample size and the rate at which events occur. We obtained SPA agreement from the FDA on our clinical trial design for the Phase 3 TAPPAS trial in angiosarcoma and also incorporated scientific advice from the EMA regarding the adequacy of the trial design. The primary endpoint of the trial is progression-free survival, or the time a patient lives without the cancer progressing, rather than overall survival. A progression-free survival primary endpoint can be achieved sooner than an overall survival endpoint, thereby reducing the time to complete the clinical trial and submit applications for regulatory approval. We also received orphan drug designation from the FDA and the EMA for TRC105 for the treatment of soft tissue sarcoma, including angiosarcoma, in 2016.

- ***Focus the second tier of clinical development of TRC105 on oncology indications that have potential reduced time to regulatory approval.*** We plan to continue ongoing Phase 2 development of TRC105 in combination with an approved VEGF inhibitor in the oncology indication of hepatocellular carcinoma, which is associated with reduced time to achieve the endpoint necessary for regulatory approval, with the goal of enabling a Phase 3 clinical trial in this indication. Although the endpoint for approval for HCC is overall survival, this endpoint is typically reached sooner for HCC than for many other solid tumors. The trial is ongoing, with the completion of enrollment of up to 33 patients and a presentation of data expected in the first quarter of 2020. Positive data from this Phase 2 trial could enable Phase 3 development. Our Phase 2 randomized TRAXAR study in renal cell carcinoma did not meet the primary endpoint of improved PFS and we have discontinued TRC105 development in this indication. We expect to report final data from the TRAXAR study at a scientific conference later this year.

- ***Focus the third tier of clinical development of TRC105 on large market oncology indications.*** To maximize the commercial opportunity of TRC105, we intend to continue developing TRC105 in additional oncology indications with large patient populations. We initiated dosing in a Phase 2 trial of TRC105 in combination with either Zytiga (abiraterone) or Xtandi (enzalutamide) in prostate cancer in 2018, a Phase 1 trial of TRC105 in combination with Opdivo in lung cancer in 2017, and a Phase 1/2 trial of TRC105 with Afinitor® (everolimus) and Femara® (letrozole) in breast cancer in 2016. We expect top-line data in the prostate cancer, lung cancer, and breast cancer studies in 2019 that, if positive, could enable further development in these indications.

- ***Continue to leverage our collaborative relationship with NCI to accelerate and broaden development of TRC105 and TRC102.*** Our collaboration with NCI allows us to pursue more indications with our assets than we would otherwise be able to pursue on our own. If merited by Phase 2 data, we expect to fund additional Phase 3 clinical trials of TRC105 and TRC102 and, based on NCI's past course of conduct with similarly situated pharmaceutical companies in which it has sponsored pivotal clinical trials following receipt of positive Phase 2 data, we anticipate that NCI would sponsor Phase 3 clinical trials in additional indications.

- ***Support Santen during clinical development to advance DE-122 in wet AMD.*** We are using our expertise in the development of endoglin antibodies to assist Santen in the development of DE-122. Santen filed an IND in June 2015 for the development of DE-122, reported safety and bioactivity data from the Phase 1/2 PAVE trial of DE-122 in February 2018, and is currently enrolling wet AMD patients into the Phase 2a AVANTE trial of DE-122, with top-line data expected in 2020.

- ***Continue development of TRC253 in patients with prostate cancer.*** 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, which is currently enrolling. We expect to complete enrollment of the Phase 2 portion in 2020. Until 90 days after we complete the initial Phase 1/2 study, 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.

- ***Begin development of TJ004309 in patients with solid tumors.*** We filed an IND for TJ004309 in December 2018 and in January 2019 the FDA completed their safety review and concluded that we may proceed with our proposed clinical trial for solid tumor patients. We expect to begin dosing patients in a Phase 1/2 study in the first half of 2019 and expect to report Phase 1 data in 2020.

- ***Leverage internal capabilities to advance other programs efficiently and cost effectively through our product development platform.*** We have assembled a management team that has contributed to the approval of seven therapeutics, including VEGF inhibitors in cancer and in wet AMD, and that has core competencies relating to clinical operations, regulatory affairs, quality assurance and Chemistry, Manufacturing, and Controls (CMC). We expect to continue to benefit from these capabilities through the development of additional early and mid-stage product candidates, both from internal programs and potential in-licensed programs, and continue to evaluate ex-U.S. companies who are in

need of a rapid and capital-efficient U.S. drug development solution that includes U.S. and EU clinical development expertise and U.S. commercialization expertise. We believe we can become a preferred clinical developmental and U.S. commercialization partner through a cost- and risk-sharing partnership structure which may include U.S. commercialization.

Our Lead Product Candidate– TRC105

Rationale for Developing Endoglin Antibodies to Treat Cancer and Wet AMD

We focus on developing antibodies that target the endoglin receptor. Endoglin is a protein that is overexpressed on endothelial cells, the cells that line the interior surface of blood vessels, when they experience hypoxia, which is a condition characterized by inadequate oxygen supply. Endoglin allows endothelial cells to proliferate in a hypoxic environment and is required for angiogenesis. These properties render endoglin an attractive target for the treatment of diseases that require angiogenesis, including solid cancers and wet AMD, especially in combination with VEGF inhibitors.

We believe the endoglin pathway serves as the dominant escape pathway that allows continued angiogenesis despite inhibition of the VEGF pathway. We believe that a combination of VEGF and our endoglin antibodies may have application in wet AMD as well as a number of oncology indications where VEGF inhibitors are currently approved by regulatory authorities. Tumor types for which VEGF inhibitors have been approved include colorectal cancer, gastrointestinal stromal tumor, glioblastoma, hepatocellular carcinoma, lung cancer, neuroendocrine tumors, renal cell carcinoma, soft tissue sarcoma, ovarian cancer and thyroid cancer.

In addition, endoglin is expressed on activated macrophages and myeloid derived suppressor cells (MDSCs). MDSCs are implicated as a mechanism of tumor evasion from immune surveillance that operates independently of PD-1/PD-L1 checkpoint inhibition. Endoglin antibodies potentiated the activity of PD-1 checkpoint inhibitors in three preclinical models of tumor growth, one of early stage cancer and two of late stage cancer. In a model of late stage cancer, the combination of TRC105 and a PD-1 antibody caused complete regression of 30-60% of palpable tumors in mice.

We believe inhibition of the endoglin pathway may sensitize tumors that are insensitive to treatment with single agent PD-1/PD-L1 checkpoint inhibitors. We believe that a combination of PD-1/PD-L1 checkpoint inhibitors and our endoglin antibodies may have application in a number of oncology indications where PD-1/PD-L1 checkpoint inhibitors are currently approved by regulatory authorities, including colorectal cancer, hepatocellular carcinoma, lung cancer, renal cell carcinoma, melanoma, Hodgkin’s lymphoma, head and neck cancer, Merkel cell carcinoma and urothelial cancer.

Anti-Angiogenesis VEGF and PD-1/PD-L1 Checkpoint Inhibitors in Oncology Indications

Cancer is the second leading cause of death in the Western world and may affect any organ in the human body. Localized cancer is generally treated and cured with surgery. However, metastatic cancer that has spread beyond the location where it started is generally incurable. Metastatic cancer is treated with chemotherapeutics or targeted agents that specifically inhibit pathways implicated in tumor growth or angiogenesis.

There are several FDA-approved drugs that inhibit the VEGF pathway or the PD-1/PD-L1 checkpoint, with over $10.0 billion in reported aggregate worldwide sales in oncology in 2018. VEGF inhibitors or PD-1/PD-L1 checkpoint inhibitors are approved in the following oncology indications, among others:

- *Soft Tissue Sarcoma, Including Angiosarcoma.* The American Cancer Society, or the ACS, estimates there were approximately 13,000 new cases of soft tissue sarcoma in the United States in 2018 with more than 5,100 deaths. Localized tumors are curable, but patients with metastatic disease have a median survival of approximately 12 months following diagnosis. Standard systemic chemotherapy regimens are poorly tolerated and of limited usefulness with response rates of approximately 20% to 30%. Votrient, a small molecule VEGF inhibitor, was approved in the United States for the second line treatment of soft tissue sarcoma in 2013. Votrient is also approved for angiosarcoma where there are an estimated 600 cases annually in the United States and 1,200 cases annually in the European Union.

- *Hepatocellular Carcinoma.* The ACS estimates there were approximately 42,200 new cases of hepatocellular carcinoma in the United States in 2018 with more than 30,000 deaths. Nexavar, a VEGF inhibitor, is approved in the United States, European Union, Japan and China for the first line treatment of hepatocellular carcinoma. In 2017, reported global sales of Nexavar were over $900 million worldwide. Opdivo, a PD-1 checkpoint inhibitor, is approved in the United States for use following prior Nexavar treatment.

- *Colorectal Cancer.* The ACS estimates there were approximately 140,300 new cases of colon cancer or rectal cancer in the United States in 2018 with more than 50,600 deaths. Multiple VEGF inhibitors are approved in colorectal cancer: Avastin is approved with chemotherapy for first and second line treatment; Cyramza® (ramucirumab) is approved with chemotherapy for second line treatment; Zaltrap® (ziv-aflibercept) is approved with chemotherapy for second line treatment; Stivarga (regorafenib) is approved for use following prior treatment with chemotherapy and a VEGF inhibitor. The PD-1 checkpoint inhibitors Opdivo and Keytruda (pembrolizumab) are approved in microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer following prior treatment with chemotherapy.

- *Non-Small Cell Lung Cancer.* The ACS estimates there were approximately 234,000 new cases of lung cancer in the United States in 2018 with more than 154,000 deaths. Avastin is approved for the first line treatment of patients with locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer, in combination with chemotherapy and Cyramza is approved for the treatment of patients with metastatic non-small cell lung cancer. Opdivo is approved for second line treatment and Keytruda is approved for first line treatment (with chemotherapy) and second line treatment (as a single agent) of patients with metastatic non-small cell lung cancer.

TRC105 Development in Oncology

Clinical Development Overview

TRC105 is our investigational novel human chimeric IgG1 monoclonal antibody that is currently being dosed weekly or every two weeks by intravenous, or IV, infusion in clinical trials. Commercialized chimeric antibodies include Rituxan® (rituximab), Erbitux® (cetuximab) and Adcetris® (brentuximab vedotin), which collectively had reported global sales of over $7.0 billion in 2018.

Clinical trials of TRC105 as a single agent in patients whose cancer had progressed on multiple prior therapies indicated limited single agent activity in treatment-resistant patients with prostate cancer, metastatic bladder cancer, advanced or metastatic hepatocellular carcinoma, glioblastoma and ovarian cancer. However, single agent activity, as evidenced by progression-free survival greater than 18 months or partial response, was achieved in individual treatment-resistant patients with soft tissue sarcoma, hepatocellular carcinoma and prostate cancer. VEGF levels are elevated following TRC105 treatment and the collective clinical data support the development of TRC105 in combination with VEGF inhibitors rather than development as a single agent. Initially, TRC105 was studied in the last line treatment setting, where patients tend to be resistant to additional treatments, but ongoing development focuses on the treatment of cancer patients in the first and second line treatment settings, where we expect increased susceptibility to anti-angiogenic treatment. Additionally, TRC105 may be more effective as a single agent in tumor types, including angiosarcoma, known to densely express endoglin.

TRC105 is being studied in five ongoing clinical trials and has been studied in 17 completed clinical trials as a single agent or with VEGF inhibitors. The following table summarizes certain key information regarding clinical trials of TRC105 in cancer patients:

Ongoing Clinical Trials of TRC105

Phase	Indication	Sponsor	Companion Treatment	Design (Number of Patients)
3	Angiosarcoma	TRACON	Votrient	Randomized (Up to 340)
1/2	Hepatocellular carcinoma	TRACON	Nexavar	Dose escalation portion and single arm portion (up to 33)
1	Lung cancer	TRACON	Opdivo	Dose escalation portion and single arm portion (up to 30)
1/2	Breast cancer	UAB	Afinitor and Femara	Dose escalation portion and single arm portion (up to 35)
2	Prostate cancer	Cedars-Sinai	Zytiga or Xtandi	Parallel cohort single arm (up to 40)

Ongoing Clinical Trials of TRC105

Phase 3 TAPPAS Randomized Clinical Trial of TRC105 with Votrient in Patients with Angiosarcoma

We are currently enrolling the randomized multicenter international Phase 3 TAPPAS clinical trial of TRC105 following SPA from the FDA and scientific advice from the EMA regarding the adequacy of the trial design. The trial compares single agent Votrient, an approved VEGF inhibitor, to the combination of Votrient and TRC105, in patients with cutaneous and non-cutaneous angiosarcoma. The primary endpoint is PFS assessed by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 by central radiographic review with overall survival as a secondary endpoint. In August 2018, we submitted an amendment to the FDA to increase the sample size to account for the fewer than expected number of events that define the endpoint of progression free survival,

reflecting a higher than expected rate of withdrawal for disease progression unconfirmed by central review. The FDA accepted the amendment, with retention of the SPA, which increased the size of the trial to 190 patients if the interim results lie in the favorable or unfavorable zones, 340 patients if the interim results lie in the promising zone, or 220 patients with cutaneous disease if the interim results lie in the enrichment zone. In the case the interim results are in the unfavorable zone, the DMC could also terminate the trial for futility. The amendment increased the number of patients analyzed at the interim analysis from 70 to 120. At this time, over 120 patients have enrolled, the interim analysis is expected in April 2019, and top line data are expected in 2020, which could vary dependent upon the final sample size and the rate at which events occur.

Phase 1/2 Clinical Trial of TRC105 with Nexavar in Patients with Hepatocellular Carcinoma

We are currently enrolling patients with advanced or metastatic HCC in a Phase 1/2 clinical trial of TRC105 in combination with Nexavar, which is approved for the first line treatment of HCC. We reported updated positive data at the ASCO 2019 Gastrointestinal Cancers Symposium in January 2019. Key results included confirmed partial responses by RECIST 1.1 occurred in 3 of 15 (20%) evaluable patients and a reduction of 50% or greater in alpha fetoprotein (AFP) concentration occurred in 6 of 12 (50%) evaluable patients. Reduction in AFP, a tumor marker expressed in patients with HCC, in early treatment may help predict a favorable response to treatment. Since the presentation, one additional patient developed a partial response, such that four of seventeen evaluable patients (24%) have achieved partial responses by RECIST to date. TRC105 trough concentrations were lower in HCC patients compared with prior TRC105 studies in other tumor types, and weekly dosing at 10 mg/kg was required to exceed target concentrations consistently. This may reflect increased target mediated clearance in HCC patients, many of whom had fibrotic or cirrhotic liver disease. Anti-drug antibody (ADA) was observed more frequently in patients with HCC (76%) compared with prior studies of TRC105 in other tumor types (e.g., RCC, sarcoma, and lung where ADA has been approximately 5%) and may prevent prolonged dosing of TRC105 in some patients with HCC. Adverse events typical of each drug did not increase in frequency or severity when TRC105 and sorafenib were administered concurrently. The trial is ongoing, with the completion of enrollment of up to 33 patients and presentation of data expected in the first quarter of 2020.

Phase 1 Clinical Trial of TRC105 with Opdivo in Patients with Metastatic Non-Small Cell Lung Cancer

We initiated dosing in a Phase 1 clinical trial of TRC105 in combination with Opdivo for the treatment of non-small cell lung cancer in late 2017. Endoglin is expressed on activated myeloid derived suppressor cells, and we have observed encouraging activity of TRC105, or its preclinical surrogate antibody, in combination with PD-1 inhibitors in preclinical syngeneic mouse tumor models. Patients were treated with 8 mg/kg or 10 mg/kg of TRC105 weekly for four doses and then 15 mg/kg every two weeks, in combination with the approved dose of Opdivo of 240 mg every two weeks. Best response was assessed by immune RECIST 1.1. In February 2019, at the International Association for the Study of Lung Cancer Targeted Therapies for Lung Cancer conference, an update was presented on the positive top-line data from the dose escalation portion of the trial previously reported in December 2018. The combination of TRC105 and Opdivo was well-tolerated without the development of dose limiting toxicity in six patients who were treated as part of dose escalation. One of these six patients, whose archival tumor did not express PD-L1 and who had not received prior PD-1/PD-L1 checkpoint inhibition treatment, developed a partial response and remains on study for more than 12 months. Two of the other five patients, one of whom progressed following prior Opdivo treatment, remain on trial with stable disease. Patients are currently enrolling into two parallel 12 patient expansion cohorts, one that includes patients who have progressed following prior PD-1/PD-L1 checkpoint inhibition treatment and one that includes patients who have not received prior PD-1/PD-L1 checkpoint inhibition treatment. We expect to report top-line data in late 2019.

Phase 2 Clinical Trial of TRC105 with Afinitor and Femara in Postmenopausal Women with Newly Diagnosed Local or Locally Advanced Potentially Resectable Hormone-Receptor Positive and Her-2 Negative Breast Cancer

UAB is conducting a two-part Phase 2 clinical trial of TRC105 as a neoadjuvant in combination with Afinitor and Femara, each of which is approved for the treatment of breast cancer. The trial is enrolling patients with locally advanced breast cancer who will receive TRC105 in combination with Afinitor and Femara prior to surgical removal of the tumor. Part 1 of the trial is expected to enroll up to 18 patients to determine whether TRC105 can be administered safely concurrently with Afinitor and Femara and assess pharmacokinetic parameters. Part 2 of the trial is expected to enroll up to 20 patients with locally advanced potentially resectable hormone-receptor positive and Her-2 negative breast cancer to determine the pathologic complete response rate and downstaging rate, or rate of tumor size reduction, at the time of surgery. We expect to report data in 2019.

Phase 2 Clinical Trial of TRC105 with Zytiga and with Xtandi in Prostate Cancer Patients Progressing on Therapy

Cedars-Sinai Medical Center is conducting a Phase 2 clinical trial consisting of parallel single arm cohorts of TRC105 in combination with Zytiga (abiraterone) or TRC105 in combination with Xtandi (enzalutamide), in patients who have biochemical but not radiographic progression on prior Zytiga or Xtandi treatment, respectively. The trial is expected to enroll up to 20 patients with metastatic castrate resistant prostate cancer into each cohort. The primary outcome measure is the proportion of participants with stabilization of disease for at least 2 months or disease improvement at any time from start of combination therapy by radiographic

and/or biochemical criteria through treatment completion, up to an estimated period of 24 months. We expect Cedars-Sinai Medical Center to report data in 2019.

Recently Completed Clinical Trials of TRC105

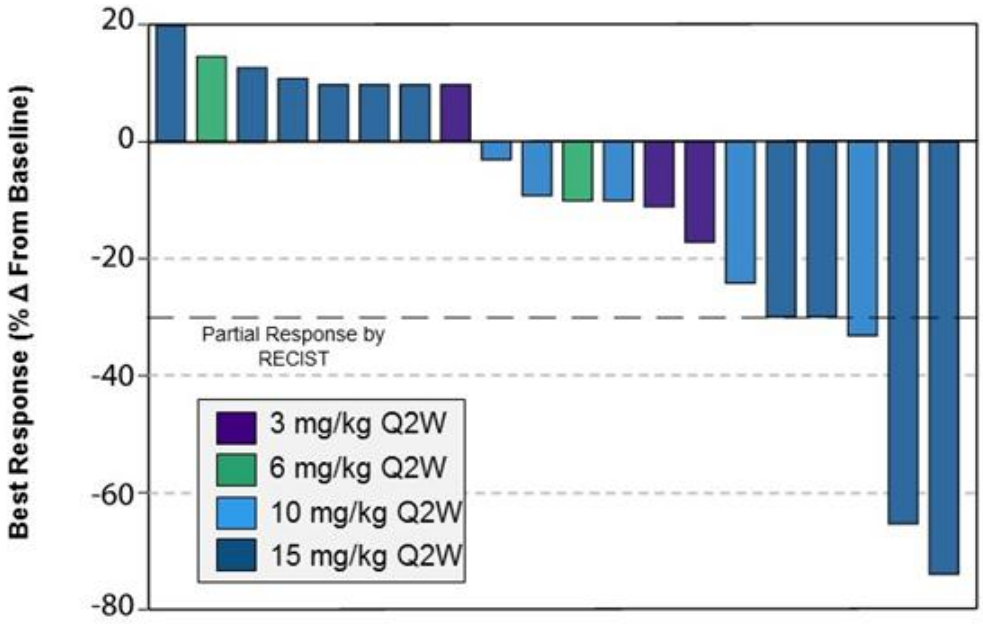
Phase 2 Randomized Clinical Trial of TRC105 with Inlyta in Patients with Clear Cell Renal Cell Carcinoma

In December 2018, we announced our Phase 2 TRAXAR study did not meet its primary endpoint of improvement in PFS from 4.8 to 7.7 months. Prespecified statistical analyses of PFS according to expression of two plasma biomarkers, TGFβ receptor III and osteopontin, also did not achieve statistical significance. The safety profile observed in TRAXAR was consistent with that observed in previously reported studies of TRC105 in combination with VEGF inhibitors. We are evaluating additional data from the study and plan to present data at a scientific conference in 2019.

Phase 2 Clinical Trial of TRC105 with Nexavar in Patients with Hepatocellular Carcinoma

NCI conducted a two-part Phase 2 clinical trial of TRC105 in combination with Nexavar, an approved VEGF inhibitor, in 27 patients with hepatocellular carcinoma. Part 1 of the trial was completed following the enrollment of 20 patients with hepatocellular carcinoma, 15 of whom were evaluable by RECIST 1.1, and Part 2 of the trial was initiated in the third quarter of 2014 and enrolled 22 patients. Part 1 of the trial was designed as an ascending dose trial with an expansion stage with the primary endpoint of evaluating the safety and tolerability of 3, 6, 10 and 15 mg/kg TRC105 every two weeks in combination with the approved dose of Nexavar to select a dose level of TRC105 (in combination with Nexavar) for further study if merited. The NCI published the results from the trial in 2017 in the journal *Clinical Cancer Research*. These data assessed the overall response rate by RECIST across four dose groups. All observed responses occurred in the two highest dose groups, in which 5 of 15 (33%) patients demonstrated a response. Four patients had confirmed stable disease, one of whom was treated for 22 months. Median PFS was 3.8 months (95% CI: 3.2-5.6 months) and median overall survival was 15.5 months (95% CI: 8.5-26.3 months). Nexavar was approved for the treatment of patients with advanced HCC based on median OS of 10.7 months (95% CI: 9.4-13.3 months) versus 7.9 months (95% CI: 6.8-9.1 months) with placebo in the multicenter SHARP trial. The overall response rate by RECIST for Nexavar treatment in the SHARP trial was 2%.

Maximum percentage change in target lesion size in hepatocellular carcinoma patients treated with TRC105 and Nexavar



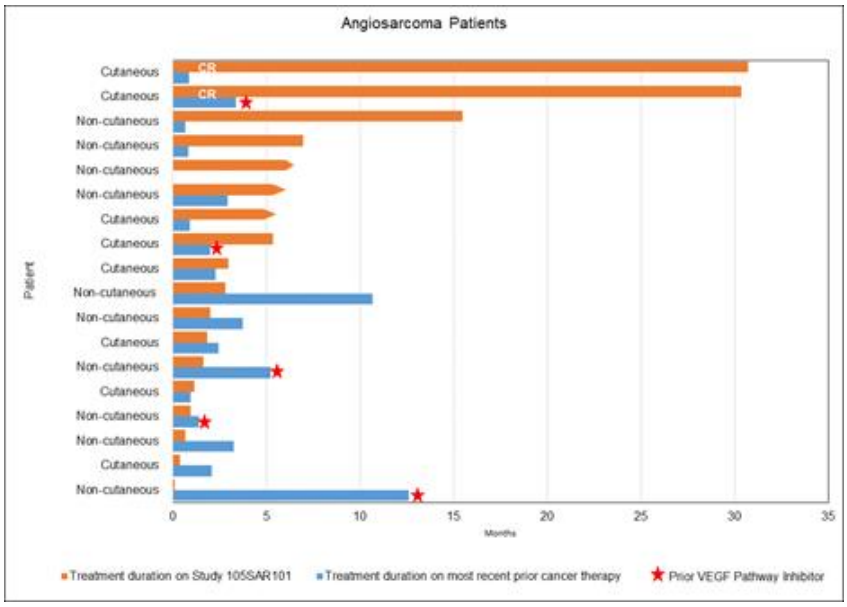
Based on these data, we initiated dosing in a multicenter Phase 1b/2 study of TRC105 in hepatocellular carcinoma and reported updated response rate data in January 2019.

Phase 2 Clinical Trial of TRC105 with Votrient in Patients with Soft Tissue Sarcoma

We conducted a two-part Phase 2 clinical trial of TRC105 in combination with Votrient, an approved VEGF inhibitor, in patients with advanced soft tissue sarcoma. Part 1 of the trial completed enrollment of 18 evaluable patients. TRC105 and Votrient demonstrated encouraging preliminary signs of activity in a highly pretreated population, including partial responses by Choi criteria in six of 18 (33%) patients, including a complete response by RECIST 1.1 that was sustained for over two years in a patient with cutaneous angiosarcoma.

Based on the tolerability and anti-tumor activity observed, Part 2 of the trial began enrollment in September 2014. Part 2 of the trial completed accrual of the planned 63 patients at eight sites in the United States in November 2015, and top-line data indicate that median PFS unstratified by histology or tumor endoglin expression (3.9 months) was similar to the PFS expected for Votrient alone, based on data from the Votrient Phase 3 PALETTE trial in soft tissue sarcoma. However, median PFS in patients with angiosarcoma was superior to that reported in five prior trials of single agent VEGF inhibitors. Therefore, additional angiosarcoma patients were enrolled, such that 18 in total were treated initially with the combination of TRC105 and Votrient and nine were treated with single agent TRC105 followed by the combination of TRC105 and Votrient at progression. PFS in patients treated with single agent TRC105 was similar to the PFS reported following treatment with single agent VEGF inhibitors in angiosarcoma. However, PFS and complete response rate with the combination of TRC105 and Votrient was superior to prior studies of single agent VEGF inhibitors in angiosarcoma.

Updated data were presented in November 2017 at the Connective Tissue Oncology Society (CTOS) annual meeting for the 18 angiosarcoma patients treated with the combination of TRC105 and Votrient, two of whom had complete responses to treatment. Median PFS was 7.8 months in 13 VEGF inhibitor naïve angiosarcoma patients treated with the combination of TRC105 and Votrient using either 10 mg/kg weekly dosing or the hybrid dosing schedule of TRC105. The median PFS compared favorably to the median PFS of 1.8 to 3.8 months reported in five studies of single agent VEGF inhibitors (including Votrient) in patients with angiosarcoma. In the 17 patients who received prior treatment for metastatic disease, treatment duration on TRC105 and Votrient exceeded treatment duration of the most recent prior therapy in seven of 12 VEGF naïve angiosarcoma patients and two of five patients who received a prior VEGF inhibitor as part of their most recent therapy. TRC105 administered at its recommended Phase 2 dose of 10 mg/kg weekly was well-tolerated in combination with Votrient at its approved dose, which allowed for prolonged dosing without an increase in the frequency or severity of adverse events typical of each individual drug.



Phase 1 Clinical Trial of TRC105 with Taxol, Carboplatin and Avastin in Patients with Lung Cancer

We initiated dosing in a Phase 1 clinical trial of TRC105 in combination with Taxol, carboplatin and Avastin for the initial treatment of advanced or metastatic non-squamous non-small cell lung cancer in 2016. The combination of Taxol, carboplatin and Avastin is approved for the initial treatment of advanced or metastatic non-squamous non-small cell lung cancer, and the combination of Taxol and Avastin is approved for the treatment of ovarian cancer. The primary endpoint of the trial was to determine whether TRC105 can be safely administered concurrently with Taxol, carboplatin and Avastin. Thirteen patients were treated with TRC105

concurrently with Taxol, carboplatin and Avastin. Secondary endpoints included pharmacokinetics, overall response rate by RECIST 1.1, progression-free survival and overall survival.

In September 2018, data were presented at the International Association for the Study of Lung Cancer (IASLC) in Toronto, Canada. Four of 13 (31%) evaluable patients had partial response by RECIST 1.1, including one patient who achieved an 81% reduction in tumor volume. The combination of TRC105 with Taxol, carboplatin and Avastin was determined to be able to be safely administered. However, current development of TRC105 in lung cancer is focused on combining TRC105 with Opdivo.

Safety of TRC105 as a Single Agent and in Combination with Approved VEGF Inhibitors and/or Chemotherapy

In clinical trials as of December 31, 2018, TRC105 has been administered to more than 600 patients and was generally well tolerated as a single agent and in combination with VEGF inhibitors and chemotherapy. The most commonly reported adverse events related to TRC105 therapy, either alone or in combination, have included anemia, dilated small vessels in the skin and mucosal membranes (which may result in nosebleeds and bleeding of the gums), headache, and gastrointestinal and other symptoms during the initial infusion of TRC105, or infusion reactions. Infusion reactions were reduced in frequency and severity through the use of premedication. The majority of treatment-related adverse events have been mild. Serious adverse events considered related to TRC105 have largely been isolated events.

TRC105 does not appear to be highly immunogenic and patients with anti-drug-antibodies have not demonstrated specific clinical effects, however we have observed a higher frequency of immunogenicity in patients with HCC.

TRC105 Investigational New Drug Applications

We are evaluating TRC105 in the United States in clinical trials under three INDs, the first of which we filed with the FDA in November 2007 for the treatment of patients with advanced solid tumors, the second of which we filed with the FDA in September 2014 for the treatment of patients with renal cell carcinoma, and subsequently gestational trophoblastic neoplasia, and the third of which we filed with the FDA in June 2016 for the treatment of patients with sarcoma. Subsequent amendments to the first IND have included clinical protocols to study TRC105 alone, or in combination with VEGF inhibitors, in patients with multiple tumor types. TRC105 has also been studied in the United States under three INDs sponsored by NCI to evaluate TRC105 in patients with prostate cancer, liver cancer and bladder cancer, which NCI filed in December 2009, December 2010 and August 2010, respectively, and one IND sponsored by NCI to evaluate TRC105 in patients with renal cell carcinoma and glioblastoma, which NCI filed in April 2012. The INDs filed by NCI cross reference our initial solid tumor IND. TRC105 is also being administered to oncology patients under investigator-sponsored and compassionate use protocols.

Translational Research

Soluble biomarker studies in patients with renal cell carcinoma in a Phase 1b trial indicated that baseline osteopontin and TGF-β receptor 3 concentrations were associated with response rate. These markers were assessed for correlation with efficacy in the randomized Phase 2 TRAXAR trial, and expression of these baseline biomarkers were not associated with efficacy. In the Phase 1b sarcoma trial, patients who had a greater than 10% reduction in tumor volume following treatment with TRC105 and Votrient were significantly more likely to have lower baseline levels of soluble intracellular adhesion molecule-1 and thrombospondin-2. These markers will be evaluated for correlation with efficacy in the randomized Phase 3 TAPPAS angiosarcoma trial to assess if expression of a baseline biomarker is associated with efficacy.

Endoglin expressing circulating tumor cells (CTCs) are being studied in the Phase 3 TAPPAS angiosarcoma trial. Updated data were presented in November 2018 at the Connective Tissue Oncology Society (CTOS) annual meeting. Paired patient plasma samples taken at baseline and six weeks following treatment with either TRC105 and Votrient or single agent Votrient were analyzed in a blinded manner, without knowledge of treatment assignment. Endoglin expressing CTCs decreased overall after 6 weeks of study treatment. Three key findings emerged in the blinded analysis:

- 18 of 51 patients (35%) had a greater than two-fold reduction in endoglin expressing CTCs, including 13/51 patients (25%) with a greater than 10-fold reduction.
- 19 of 51 patients (37%) had a greater than two-fold increase in endoglin expressing CTCs, including 13/51 patients (25%) with a greater than 10-fold increase.
- 14 of 51 patients (27%) had no significant change in endoglin expressing CTCs, all but one of whom had fewer than four endoglin expressing CTCs per mL detected at baseline.

Role of Endoglin Antibodies in AMD Treatment

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® 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 2017, annual worldwide sales of Lucentis and Eylea for all indications totaled more than $8.0 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 TRC105 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. Santen is currently enrolling the Phase 2a AVANTE clinical trial of DE-122 in wet AMD patients and top-line data are expected in early 2020. In addition, 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.

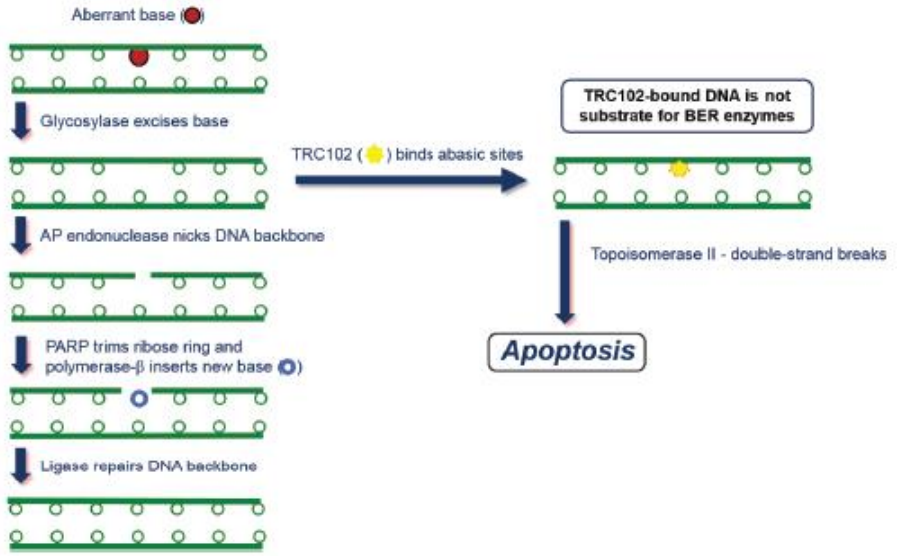
Our Second Product Candidate – TRC102

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 stable disease for three or more cycles 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.

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 can be used as a predictive biomarker of TRC102 activity are expected to continue in ongoing TRC102 trials in 2019.

Our Third 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).

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.

Initial clinical development of TRC253 is focusing on the safety and activity in patients with resistance to current AR inhibitors, by specifically enrolling patients with mutations in the AR ligand binding domain, including F877L. AR mutations were identified using circulating tumor DNA in the Phase 1 portion of the trial, that determined the recommended Phase 2 dose of TRC253. The Phase 2 portion of the trial began in August 2018, and will enroll two cohorts, one will consist of 15 patients with the F877L mutation and one cohort will consist of 30 patients with other mutations conferring resistance to Xtandi or other drugs. We completed the Phase 1 portion of the Phase 1/2 trial in July 2018 and expect to complete the Phase 2 portion of the trial in 2020, due to a slower than expected enrollment resulting from a lower than expected frequency of the F877L mutation targeted by TRC253 among metastatic prostate cancer patients. 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.

Other Product Candidates

TJ004309

TJ004309, is a novel, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular AMP to adenosine, which is highly immunosuppressive. In December 2018, we submitted an IND application with the U.S. 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. TJ004309 is expected to begin clinical testing in the United States in the first half of 2019 in a trial to assess safety and preliminary signs of efficacy as a single agent and when combined with a PD-1/PD-L1 checkpoint inhibitor. We expect to report Phase 1 data in 2020.

Collaboration and License Agreements

Strategic collaboration and clinical trial agreements with I-Mab Biopharma

In November 2018, we entered into the Collaboration Agreements with I-Mab for the development of programs for multiple immuno-oncology product candidates, including I-Mab's proprietary CD73 antibody TJ004309 as well as up to five proprietary bispecific antibodies currently under development by I-Mab.

In the TJ004309 Agreement, we will collaborate with I-Mab on developing TJ004309, 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 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 out-licenses the 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 certain territories outside of Greater China. In the event that I-Mab commercializes TJ004309, we 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 we would be entitled will 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 study, 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 study, in which case we 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.

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 for and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, while we will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical studies, and we will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical studies, 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 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 study costs for a product candidate or the JSC decides to cease development over our objections after initiating Phase 3 clinical studies, 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 the 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: (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 study 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 study but before completion of 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 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 Ambrx, Inc.

In December 2017, we entered into a license agreement with Ambrx, Inc., for the development and commercialization of TRC105 in Greater China.

In consideration of the rights granted to Ambrx under the agreement, we received a one-time upfront fee of $3.0 million. In February 2019, following discussions between us and Ambrx regarding Ambrx's progress towards initiating a Phase 1 clinical trial of

TRC105 in China, Ambrx notified us that it had elected to terminate the license agreement, resulting in all rights to TRC105 in Greater China reverting to us.

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, and TRC694 (formerly JNJ-6420694), a novel, potent, orally bioavailable inhibitor of NF-kB inducing kinase (the NIK Program and, together with the AR Mutant Program, the Programs), which is intended for the treatment of patients with hematologic malignancies, including myeloma. Following completion of the pre-clinical development of TRC694, in February 2019, we determined the compound did not warrant further development and issued written notice to terminate the agreement with respect to the TRC694 NIK Program, thereby returning 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 Programs), 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 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 TRC105, or the TRC105 Technology. Under the agreement, as amended, 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, 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 TRC105 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 TRC105 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 TRC105 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 TRC105 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 TRC105 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 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 our 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. As of December 31, 2018, $10.0 million of the development milestones have been achieved and received in accordance with the agreement.

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 TRC105, 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 TRC105, 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 two Cooperative Research and Development Agreements, or CRADAs, with the U.S. Department of Health and Human Services, as represented by NCI, for the development of TRC105 and TRC102 for the treatment of cancer. We entered into the CRADA governing the development of TRC105 in January 2011, or the 2011 CRADA, with NCI's Center for Cancer Research. We entered into the CRADA governing the development of TRC102 in August 2012.

Under the CRADAs, as amended, NCI conducts clinical trials and non-clinical studies of either TRC105 or TRC102. We are responsible for supplying TRC105 for NCI's activities under the TRC105 CRADAs. Pursuant to the terms of the 2011 CRADA, we are required to pay NCI $5,000 per year for support for its research activities, as well as up to $5,000 per year for personnel-related expenses. We may also provide funding for mutually agreed upon animal studies. Under 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 2011 CRADA or the TRC102 CRADA will be determined in an amendment to the applicable CRADA.

Under each 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 each 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.

Each CRADA had an original five-year term, with the 2011 CRADA, as amended, expiring on January 28, 2021, and the TRC102 CRADA expiring on August 7, 2020. Each CRADA may be terminated at any time by mutual written consent, and we or NCI may unilaterally terminate any of the CRADAs 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 for the production of our product candidates. TRC105 drug substance for our preclinical studies and clinical trials is manufactured by Lonza, a contract manufacturer that also manufactures approved biologic cancer treatments marketed by other companies and is compliant to U.S. and European regulatory standards.

TRC105 drug substance is produced by Chinese hamster ovary, or CHO, cells developed at Lonza and manufactured using Lonza's proprietary manufacturing and purification processes.

On February 22, 2017, we entered into a manufacturing agreement, or the Manufacturing Agreement, with Lonza Biologics Tuas Pte Ltd, or Lonza, for the long-term manufacture and supply of registration and commercial batches of TRC105.

Under the Manufacturing Agreement, Lonza has agreed to manufacture TRC105 pursuant to purchase orders and in accordance with the manufacturing specifications agreed upon between us and Lonza. Initially, we are required to purchase and Lonza is obligated to supply certain batches prior to approval of TRC105 by the FDA or EMA. Following regulatory approval, we will be required to purchase and Lonza will be required to supply a minimum number of batches annually. In the event we cancel any purchase orders, we may be obligated to pay certain cancellation fees. In addition, we are obligated to pay a milestone fee to Lonza upon the earlier of the first approval of TRC105 by the FDA or EMA or our receipt of a complete response letter or non-approvability letter (or equivalent communication) indicating that the rejection of the marketing application was not due to a deficiency in Lonza's facility, the manufacturing process or services performed by Lonza.

The Manufacturing Agreement has an initial term beginning on the effective date and ending on the seventh anniversary of the date of first regulatory approval of TRC105 by the FDA or EMA. The Manufacturing Agreement may be renewed for an additional three years upon the written agreement of both parties no later than the fifth anniversary of the date of first approval by the FDA or EMA.

Either party may terminate the Manufacturing Agreement due to a material breach of the Manufacturing Agreement by the other party, subject to prior written notice and a cure period, due to the insolvency or bankruptcy of the other party, or due to a force majeure event that prevents performance under the Manufacturing Agreement for at least six months. We may terminate the Manufacturing Agreement, subject to 60 days' written notice, if we discontinue the TRC105 program, whether due to a notice of non-approval or withdrawal of marketing approval by a regulatory agency or otherwise. In the event of a termination by us due to discontinuation of the TRC105 program or a termination by Lonza due to our material breach or insolvency or bankruptcy, we would be obligated to pay to Lonza certain batch cancellation and/or early termination fees.

TRC105 drug product is produced by an FDA-registered contract manufacturer. Drug product is filter-sterilized and aseptically filled into single-use pharmaceutical grade vials and stoppered using an automated filling machine. The final drug product is stored refrigerated until used.

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

We are developing TRC105 to be used in combination with VEGF or PD-1 inhibitors for the treatment of cancer. If TRC105 is approved, it could compete with other non-VEGF angiogenesis inhibitors in development, including some that also target the endoglin pathway and have the potential to be combined with VEGF inhibitors or used independently of VEGF inhibitors to inhibit angiogenesis. Amgen, Inc., Boehringer Ingelheim, Eli Lilly and Company, MedImmune LLC, OncoMed Pharmaceuticals Inc., and Roche AG are each developing non-VEGF angiogenesis inhibitors, which are in various phases of clinical development. In addition, drugs have recently been approved or are being developed that target other oncologic pathways, including immune surveillance targets, that may decrease the need for treatments like TRC105 that target angiogenesis.

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., 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, ODM-201 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 already in clinical development sponsored by Bristol Meyers Squibb, AstraZeneca, 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), 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, such as Allergan’s VEGF inhibitor, DARPin, and Novartis’ brolucizumab which are both in late stage clinical development in wet AMD.

Commercialization

We hold worldwide commercialization rights for our 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 North America to support their commercialization and seek a partner to support commercialization outside of North America. 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. 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, 2018, on a worldwide basis, includes 19 issued patents/allowed applications and 14 pending patent applications in the United States and 60 issued patents/allowed applications and 104 pending patent applications outside the United States with pending and issued claims relating to our product candidates. Forty-four (44) of our issued US and foreign patents and allowed applications cover antibodies to endoglin and uses thereof that we have selected as the core focus of our development approach. These figures include in-licensed patents and patent applications to which we hold exclusive commercial rights in non-ophthalmologic fields of use.

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 2019 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:

TRC105/TRC205 Patent Coverage

We hold issued patents covering methods for inhibiting breast cancer or colon cancer with a combination of TRC105 and cyclophosphamide (CPA) or doxorubicin in the United States. The expected expiration date for these method-of-use patents is 2023, exclusive of possible patent term extensions.

We are co-owners with Health Research, Inc., to issued patents covering the combination therapy of cancer with TRC105 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, New Zealand, Singapore, South Korea, Ukraine, and the United States, and patent applications are pending in Brazil, Canada, China, Europe, Hong Kong, India, Indonesia, Israel, Japan, South Korea, Malaysia, Mexico, Philippines, Singapore, Thailand, Ukraine, the United States, Uzbekistan, and Vietnam. The expected expiration date for any patent that may issue from this application is 2033, exclusive of possible patent term extensions.

We have filed an International Patent Cooperation Treaty (PCT) patent application directed to a combination therapy for treatment of renal cell carcinoma, brain cancer or breast cancer with an anti-endoglin antibody and a VEGF inhibitor. Also disclosed are methods of biomarker assessment prior to, during, and after treatment of an individual. The expected expiration date for any patent that may arise from these applications is 2037, 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, Brazil, and China. 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.

We have filed an International PCT application directed to the treatment of cancers with a combination of TRC105 and anti-programmed death receptor agents. The expected expiration date for any patent that may arise from these applications is 2038, exclusive of possible patent term extensions.

TRC102 Patent Coverage

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

We hold an issued patent covering the formulation of TRC102 and temozolomide and methods of using the formulation in the United States. The expected expiration date for this patent is 2019, exclusive of possible patent term extensions. We also hold three issued patents covering methods of using TRC102 and other agents in the United States. It is expected that these three patents will also expire in 2019, exclusive of any 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 Eurasia and Japan, and to patent applications in Armenia, Australia, 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, Ukraine, 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.

Trade Secrets

In addition to patents, we rely upon unpatented trade secrets 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.

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, or FFDCA, and other laws, including, in the case of biologics, the Public Health Service Act, or PHSA, in addition to the FDA's implementing regulations. We expect TRC105 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 BLA;
- 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 BLA 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 FDA and an IND sponsor may agree in writing on the design and size of clinical studies intended to form the primary basis of a claim of effectiveness in a BLA or NDA. This process is known as a Special Protocol Assessment, or SPA. A SPA agreement may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA, or if the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began. For certain types of protocols, including carcinogenicity protocols, stability protocols, and Phase 3 protocols for clinical trials that will form the primary basis of an efficacy claim, the FDA has agreed under its performance goals associated with the Prescription Drug User Fee Act, or PDUFA, to provide a written response on most protocols within 45 days of receipt. However, the FDA does not always meet its PDUFA goals, and additional FDA questions and resolution of issues leading up to a SPA agreement may result in the overall SPA process being much longer, if an agreement is reached at all.

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 BLA requesting approval to market the drug candidate for a proposed indication. Under the PDUFA, the fees payable to the FDA for reviewing a BLA, as well as annual program fees for approved products, can be substantial. The fees typically increase each year. Each BLA 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 BLA is found complete, the FDA will file the BLA, triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goal is to review 90% of priority BLA applications within six months after the application is accepted for filing and 90% of standard BLA 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 BLA, 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 BLA 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 BLA supplement or a new BLA 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 BLA 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.

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 anti-kickback, fraud and abuse, 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. 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, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and 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

TRC105 has received orphan drug designation for the treatment of soft tissue sarcoma, which includes angiosarcoma in the US and EU. 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

TRC105 and TRC205, as 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.

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, 2018, we had 26 full-time employees and one part-time employee, 20 of whom are involved in research, development or manufacturing, and four 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 our product candidates, including our most advanced product candidate, TRC105, will require substantial additional development time and resources before we 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 $35.0 million and $19.1 million for the years ended December 31, 2018 and 2017, respectively. At December 31, 2018, we had an accumulated deficit of $139.7 million.

We expect to continue to incur substantial and increased expenses as we expand our development activities and advance our clinical programs, particularly with respect to our additional clinical development and manufacturing activities for TRC105.

To become and remain profitable, we or our partners must succeed in developing our 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 of our 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 development expenses to remain relatively constant in connection with our ongoing activities as we advance our clinical programs, including our planned and future clinical trials of TRC105 and TRC253, and conduct manufacturing activities for TRC105.

At December 31, 2018, we had cash, cash equivalents and short-term investments totaling $39.1 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital requirements into the first quarter of 2020. We will need additional funding to complete the development and commercialization of our product candidates, specifically our lead product candidate, TRC105, including for the completion of our Phase 3 TAPPAS trial in angiosarcoma. In addition, in 2016 we licensed two early-stage oncology programs from Janssen Pharmaceutica N.V., or Janssen, and are subject to obligations to develop the programs through clinical proof of concept for TRC253. We will need additional funds to complete clinical proof of concept for the TRC253 program and, to the extent we retain the program afterwards, 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 Phase 3 development of, filing for regulatory approval for, or commercializing, TRC105 or any of our other product candidates.

In September 2018, we entered into a Capital on Demand™ Sales Agreement, or the JonesTrading Agreement, 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. In March 2017, we entered into a Common Stock Purchase Agreement, or the Aspire Agreement, with Aspire Capital Fund, LLC, or Aspire, pursuant to which, upon the terms and subject to the conditions and limitations set forth in the Aspire Agreement, Aspire committed to purchase up to an aggregate of $21.0 million of shares of our common stock at our request from time to time. As of the date of this report, we have not sold any shares of our common stock under the JonesTrading Agreement and have sold $1.0 million of shares of our common stock under the Aspire Agreement. While the JonesTrading Agreement and Aspire 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 is obligated to purchase shares of our common stock under the Aspire 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 Aspire 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 our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to 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 our 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 our 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 our 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 Our Product Candidates

We are heavily dependent on the success of our lead product candidate TRC105, which is in a later stage of development than our other product candidates. We cannot give any assurance that TRC105 will successfully complete clinical development or receive regulatory approval, which is necessary before it can be commercialized.

Our business and future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize our lead product candidate, TRC105, which is currently in Phase 3 and Phase 2 development for the treatment of multiple solid tumor types. Any delay or setback in the development of any of our product candidates, particularly TRC105, could adversely affect our business and cause our stock price to decline. We cannot assure you that our planned clinical development for TRC105 will be completed in a timely manner, or at all, or that we or our partner, Santen, or any additional future partners, will be able to obtain approval for TRC105 from the FDA or any foreign regulatory authority. We obtained Special Protocol Assessment, or SPA, agreement from the FDA on our clinical trial design for the Phase 3 TAPPAS trial of TRC105 in angiosarcoma, but that agreement does not ensure that the FDA will approve TRC105 for angiosarcoma, even if the trial is successful. If the DMC determines that the TAPPAS trial is futile, our prospects for TRC105 will be significantly limited. In addition, while we have the right to terminate our long-term manufacturing agreement with Lonza Sales AG, or Lonza, if we were to cease the TRC105 program, we may still be required to pay batch cancellation fees that could harm our financial position and ability to continue development of our other drug candidates. Even if TRC105 is approved, if it is not approved in indications that justify the minimum number of batches we are required to purchase from Lonza following regulatory approval, our ability to commercialize TRC105 profitably would be harmed.

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 December 2018 that the combination of TRC105 with Inlyta (axitinib) did not meet the primary endpoint in a randomized Phase 2 clinical trial in renal cell carcinoma and we have therefore discontinued the development of TRC105 in this indication and are no longer pursuing it as a fast track indication. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials. In particular, the positive results observed in certain Phase 1 and 2 clinical trials of TRC105 do not ensure that the ongoing or planned clinical trials of TRC105 will demonstrate similar results. In addition, further interim results or the final results from these trials could be negative.

Even if our 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 our 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. 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 TRC105 or any other product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be materially harmed. For example, if the results of ongoing or planned clinical trials of TRC105 demonstrate unexpected safety issues, do not achieve the primary efficacy endpoints or are terminated prior to completion due to analysis of interim results, as applicable, the prospects for approval of TRC105 as well as 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 our 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 our product candidates could be materially harmed, which could have a material adverse effect on our business. For example, we recently determined that we will

need to increase the sample size for our Phase 3 TAPPAS trial of TRC105 for the treatment of angiosarcoma due to a fewer than expected number of events that define the endpoint of progression-free survival, which reflects a higher rate of withdrawal for disease progression unconfirmed by central review. We submitted an amendment to the FDA, which was agreed to by the FDA with retention of the SPA agreement, proposing the sample size of the trial will be 190 patients if the interim results lie in the favorable or unfavorable zones, 340 patients if the interim results lie in the promising zone, or 220 patients with cutaneous disease if the interim results lie in the enrichment zone, however if the interim results are in the unfavorable zone, the data monitoring committee could terminate the trial for futility. We expect that this will delay the planned interim analysis in the trial until April 2019, delay the availability of top-line data until 2020, which could vary dependent upon the final sample size and the rate at which events occur, and increase the cost of completing the trial. We have also experienced slower than anticipated enrollment in our on-going 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 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 our product candidates or other potentially harmful characteristics of our 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 TRC105 and TRC102 conducted to date have generated AEs related to the study drug, some of which have been serious. The most common AEs identified to date and related to TRC105 have been anemia, dilated small vessels in the skin and mucosal membranes (which may result in nosebleeds and bleeding of the gums), headache, fatigue and gastrointestinal and other symptoms during the initial infusion of TRC105. While we have not observed an exacerbation of side effects commonly associated with VEGF inhibitors in clinical trials of TRC105 in combination with a VEGF inhibitor, it is possible that future trials, including larger and lengthier Phase 3 clinical trials, may show this effect due to both drugs acting to inhibit angiogenesis simultaneously. Because our development and regulatory approval strategy for TRC105 is focused on combining TRC105 with VEGF inhibitors, if we encountered safety issues associated with combining TRC105 with VEGF inhibitors, it would be a significant setback for our development program and our ability to obtain regulatory approval for TRC105 may be adversely impacted. 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 it is possible that we could observe AEs in our Phase 2 study of TRC253 that would 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 our product candidates will not be observed. As is typical in drug development, we have a program of ongoing toxicology studies in animals for our 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 of our 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 our 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 our 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.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design, 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 our 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;
- the FDA or comparable foreign regulatory authorities may fail to approve our validation methods for detecting TRC105 serum levels and antibodies to TRC105 and assessing TRC105 activity in a biologic release assay; 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 TRC105 or our other 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 of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates. For example, we anticipate that if we were to obtain regulatory approval for TRC105 in some or all of the initial oncology indications we are pursuing, we or our partners such as NCI would still need to conduct additional Phase 3 clinical trials in order to obtain approval for additional indications and expand TRC105's market potential. In addition, we believe that TRC105 may be most effective as a treatment of solid tumors which express high levels of endoglin, such as angiosarcoma. We previously analyzed endoglin expression on archival tumor tissue across various sarcoma subtypes and did not find a correlation between endoglin expression and response to TRC105 treatment in sarcoma subtypes other than angiosarcoma. We believe that this analysis may have limited utility due to tumor heterogeneity, the long period of time between sampling and treatment, and the effects of tumor evolution resulting from prior treatment. If we are unable to establish a correlation between endoglin expression and response to TRC105 treatment in subsequent analyses or to identify additional tumor types that express endoglin, our ability to successfully identify target patient populations for future clinical development or to expand TRC105's market potential may be limited.

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

We have not previously submitted a BLA or NDA, 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 of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our 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.

We received Fast Track designation for TRC105 in renal cell carcinoma in May 2015, and we intend to seek Fast Track designation or other appropriate expedited development options for our eligible product candidates in other indications. 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. Despite our receipt of Fast Track designation for TRC105 in renal cell carcinoma, and even if additional product candidates receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. 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. The combination of TRC105 with Inlyta (axitinib) did not meet the primary endpoint in a randomized Phase 2 clinical trial in renal cell carcinoma and we have therefore discontinued the development of TRC105 in this indication and have communicated to FDA that we are no longer pursuing it as a fast track indication.

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

We received orphan drug designation for TRC105 in soft tissue sarcoma in 2016 in the United States and European Union and we intend to seek orphan drug designation for our eligible product candidates in other 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. Despite our receipt of orphan drug designation for TRC105 in soft tissue sarcoma, we cannot guarantee that we will be able to receive orphan drug status from the FDA for any other product candidates or indications. For example, we previously withdrew an application for orphan drug designation in gestational trophoblastic neoplasia. If we are unable to secure orphan drug designation for additional 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 of our 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 our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our 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 will be harmed.

Even if we receive regulatory approval of our 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 our product candidates.

Any of our 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 our 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 our product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for our 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. Moreover, a product may not be promoted for 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. Later discovery of previously unknown problems with our 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 our 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 our 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 our 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 rely on third party manufacturers to make our 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 biologics such as TRC105 and 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.

For TRC105, we have relied on Lonza for drug substance clinical supply manufacture. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including filling into vials, shipping and storage. For our clinical stage pipeline programs, while we believe that our existing supplies of drug product and our contract manufacturing relationships will be sufficient to accommodate clinical trials through Phase 3 for TRC105, Phase 2 for TRC102, and proof of concept for TRC253, there can be no guarantee that lack of clinical supplies will not force us to delay or terminate any of our ongoing or planned clinical trials.

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. For example, we rely on Lonza to manufacture TRC105 drug substance and separately license from Lonza its proprietary cell line and other methods of producing TRC105 drug substance. While we have the right to transfer the manufacture of TRC105 drug substance to additional or alternate suppliers and to sublicense Lonza's TRC105 manufacturing technology to such other suppliers under specified conditions, we may encounter delays in any such transfer due to the time and effort required for another party to understand and successfully implement Lonza's proprietary process. In February 2017, we entered into a long-term manufacturing agreement with an affiliate of Lonza for the manufacture of TRC105 drug substance intended for registration batches and future commercial supply if TRC105 receives regulatory approval. As part of the manufacturing agreement, we and Lonza have transferred the TRC105 manufacturing process to a separate Lonza facility. This transfer may result in setbacks in replicating the current manufacturing process at a new facility that has not previously manufactured TRC105. In particular, for biologics, it is not uncommon to experience setbacks and delays in process transfer, which may delay our ability to obtain regulatory approval or may result in higher costs to manufacture commercial drug product than we currently expect.

Other than our TRC105 manufacturing agreement with Lonza, we do not have any long-term supply agreements for the manufacture of our product candidates and cannot guarantee that Lonza or any other 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, our manufacturing agreement with Lonza may be terminated early by Lonza if we are in material breach of the agreement, subject to prior written notice and a cure period, due to our insolvency or bankruptcy, or due to a force majeure event that prevents performance under the agreement for at least six months.

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 our 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 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 our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates.

We depend in part on NCI and other third party sponsors to advance clinical development of TRC105 and TRC102.

NCI is currently sponsoring and funding multiple clinical trials involving TRC102. The University of Alabama, Birmingham Cancer Center is also funding trials with TRC105 in breast cancer and lung cancer. In addition, Case Western has sponsored and funded two separate clinical trials involving TRC102. The advancement of our product candidates 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 our 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 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 TRC105, 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 previously entered into a license agreement with Ambrx pursuant to which Ambrx was granted an exclusive license to TRC105 in Greater China for all indications other than ophthalmology. In February 2019, Ambrx notified us that it had elected to terminate the license agreement and return the rights to TRC105 in Greater China to us, following which we will again be solely responsible for development activities of TRC105 in these territories. 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 and otherwise plan our own development of TRC105, including TRC105, in non-ophthalmology indications;
- 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, bi-specific 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.

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional out-licensing and collaboration agreements, including potentially with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate partners for our product candidates, 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. 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.

We rely on third parties to conduct preclinical studies and clinical trials of our 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 our product candidates.

We do not have our own capabilities to perform preclinical testing of our 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 our 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 our product candidates. As a result, our financial results and the commercial prospects for our product candidates 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.

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, 2018, we are the exclusive licensee of six issued U.S. patents, two pending U.S. patent applications, sixteen issued non-U.S patents and two 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,” “Methoxyamine Potentiation of Temozolomide Anti-Cancer Activity,” “Methoxyamine Combinations in the Treatment of Cancer,” “Alkylating Agent Combinations in the Treatment of Cancer” and “Combination Therapy of Cancer with Anti-Endoglin Antibodies and Anti-VEGF Agents.” We are also the exclusive licensee of 2 issued U.S. patents, 2 issued non-U.S. patents, 1 pending U.S. patent application, and 41 pending non-U.S. applications related to TRC253.

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. TRC105 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. TRC253 and associated intellectual property have been licensed from Janssen.

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 Our Product Candidates

Even if we obtain regulatory approval of our 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.

The use of endoglin antibodies as a means of inhibiting angiogenesis, including in combination with VEGF inhibitors for the treatment of cancer, is a recent clinical development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, third party payors and others in the medical community. Factors that will influence whether our product candidates are accepted in the market include:

- the clinical indications for which our product candidates are approved, if any;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our 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 our 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.

In addition, we expect that in oncology indications, TRC105 will be most effective as a combination treatment with VEGF inhibitors. If VEGF inhibitors become associated with presently unknown safety concerns, are withdrawn from the market or otherwise fall out of favor as cancer treatments among physicians, patients, hospitals, cancer treatment centers or others in the medical community, the market potential for TRC105 would likely be significantly harmed.

If, for any of these or other reasons, our 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.

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 our 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. For example, other pharmaceutical and biotechnology companies, including Pfizer, Inc., have active programs to develop therapies targeting proteins in the endoglin pathway that would compete directly with certain of our product candidates, including TRC105. Many other companies are developing other cancer therapies that, if successful, could change the standard of care for cancer patients and relegate anti-angiogenesis therapy to a last-line or niche role or make it obsolete.

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 our 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. 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 our product candidates, which could make it difficult for us to sell our product candidates profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third party payors. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our 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 our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our 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 our product candidates will depend significantly on the availability of coverage and adequate reimbursement from third party payors for our 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 Affordable Care Act, or ACA, was enacted in the United States. Some of the provisions of the ACA have yet to be implemented, and there have been 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". On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the District Court Judge, as well as the current U.S presidential administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA. 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 2027 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 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the 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) has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, HHS through CMS proposed a rule that would require drug manufacturers to disclose drug prices in television advertisements. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although a number of these and other potential proposals may require authorization through additional legislation 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 our 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.

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

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 are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although we intend to establish a specialty sales and marketing organization to promote or co-promote our product candidates in North America, if approved in oncology indications, we currently have no such organization or capabilities, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must build sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services.

In addition, we do not intend to establish our own sales and marketing organizations outside the United States and will therefore depend on third parties to commercialize our product candidates outside of the United States. Any third parties upon which we rely for commercializing our product candidates may not dedicate sufficient resources to the commercialization effort or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective third party arrangements to enable the sale of our product candidates in territories outside of the United States, or if our potential future partners do not successfully commercialize our product candidates in these territories, our ability to generate revenue from product sales will be adversely affected.

If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all, when we are otherwise ready and able to commercially launch a product candidate. If we do not have sufficient funds, we will not be able to bring any product candidates to market or generate product revenue, including in the United States.

We and any partners that we may engage will be competing with many companies that currently have extensive and well-funded marketing and sales operations to commercialize alternative therapies. If we, alone or with commercialization partners, are unable to compete successfully against these established companies, the commercial success of any approved products will be limited.

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 TRC105 or other 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 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 and our collaboration with I-Mab with respect to I-Mab's proprietary CD73 antibody, TJ004309, and potential bi-specific 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. 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 our 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 our 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 our 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 our 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 and state 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 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 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 and civil monetary penalty laws, including the federal False Claims Act, 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 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 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 Affordable Care Act, 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 Affordable Care Act 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, 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 our 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. 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 our product candidates; and
- decreased demand for our 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 our 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, 2018 we had federal and California net operating loss carryforwards, or NOLs, of approximately $114.6 million and $117.8 million, respectively, which expire in various years beginning in 2030, if not utilized. Under the Tax Act, federal NOLs generated in 2018 and in future years may be carried forward indefinitely, but the deductibility of such NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act. As of December 31, 2018, we had federal and California research and development and Orphan Drug tax credit carryforwards of approximately $9.2 million and $2.0 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the current U.S. President signed into law the Tax Act which significantly revises the Code. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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, 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 and consultants, 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. In addition, NCI may be affected by government shutdowns 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 to obtain clinical supplies of our product candidates could be disrupted if the operations of our third party manufacturers, including Lonza, 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 Global 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 filing a BLA or an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that BLA or NDA;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our product candidates;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for our 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 Global 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 Global 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 Global 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, Nasdaq could determine to delist our common stock. As of February 8, 2019, the closing price of our common stock on the Nasdaq Global Market was $1.03 per share. 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. Although Nasdaq may provide us with a compliance period in which to regain compliance with the listing requirements, we cannot assure you that we would be able to regain compliance within the period provided by Nasdaq.

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.

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

As of December 31, 2018, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned over 45% of our voting stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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 Global Market under the ticker symbol "TCON".

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,		
	2018	2017	2016
	(in thousands, except share and per share data)		
Statement of Operations Data:			
Collaboration revenue	$ 3,000	$ 8,755	$ 3,449
Operating expenses:			
Research and development	30,460	19,355	21,566
General and administrative	7,280	7,610	7,859
Total operating expenses	37,740	26,965	29,425
Loss from operations	(34,740)	(18,210)	(25,976)
Other expense	(219)	(893)	(1,032)
Net loss	$ (34,959)	$ (19,103)	$ (27,008)
Net loss per share, basic and diluted	$ (1.30)	$ (1.14)	$ (2.13)
Weighted-average shares outstanding, basic and diluted	26,945,705	16,806,094	12,677,910

	As of December 31,	
	2018	2017
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 25,136	$ 29,467
Short-term investments	13,968	4,999
Working capital	27,108	24,259
Total assets	40,648	36,130
Long-term debt, less current portion	5,343	4,603
Accumulated deficit	(139,660)	(104,701)
Total stockholders' equity	21,442	16,987

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 and, through our license to Santen Pharmaceutical Co. Ltd. (Santen), wet age-related macular degeneration, or wet AMD. We are a leader in the field of endoglin biology and are using our expertise to develop antibodies that bind to the endoglin receptor. Endoglin is essential to angiogenesis, the process of new blood vessel formation required for solid cancer growth and wet AMD. We are developing our lead product candidate, TRC105 (carotuximab), an endoglin antibody, for the treatment of multiple solid tumor types in combination with inhibitors of the vascular endothelial growth factor, or VEGF, pathway, or in combination with inhibitors of the programmed cell death protein 1, or PD-1, pathway. The VEGF pathway regulates vascular development in the embryo, or vasculogenesis, and angiogenesis, while the PD-1 pathway represents an adaptive immune resistance mechanism that protects tumors from host immunity. We believe treatment with TRC105 in combination with VEGF inhibitors or PD-1 inhibitors may improve survival in cancer patients when compared to treatment with a VEGF inhibitor or PD-1 inhibitor alone. TRC105 has been studied in 13 completed Phase 2 clinical trials and four completed Phase 1 clinical trials, and is currently being dosed in one Phase 3 clinical trial, three Phase 2 clinical trials and one Phase 1 clinical trial.

Our TRC105 oncology clinical development plan is broad and involves a tiered approach. We are initially focused on angiosarcoma which is a tumor that highly expresses endoglin, the target of TRC105, and therefore may be more responsive to treatment with TRC105. We have seen complete durable responses in this tumor type and are currently enrolling the international multicenter Phase 3 TAPPAS trial in angiosarcoma. We obtained Special Protocol Assessment (SPA) agreement from the U.S. Food and Drug Administration (FDA) on our clinical trial design for the Phase 3 trial in angiosarcoma and also incorporated scientific advice from the European Medicines Agency (EMA) regarding the adequacy of the trial design. We also received orphan drug designation from the FDA and the EMA for TRC105 for the treatment of soft tissue sarcoma, including angiosarcoma, in 2016. The trial is an adaptive design and based on the planned interim analysis, the trial will accrue a variable number of patients into one of four zones: 190 patients if the interim results lie in the favorable or unfavorable zones, 340 patients if the interim results lie in the promising zone, or 220 patients with cutaneous disease if the interim results lie in the enrichment zone. In the case the interim results are in the unfavorable zone, the DMC could also terminate the trial for futility. The TAPPAS trial has enrolled more than 120 patients to date and based on current accrual rates and the occurrence of events that define the primary endpoint of Progression Free Survival (PFS), we expect to conduct the interim analysis to determine the final sample size and eligible population for the trial in April 2019 and expect final data in 2020, which could vary dependent upon the final sample size and the rate at which events occur.

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. 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 ongoing clinical trials including our international Phase 3 TAPPAS trial in angiosarcoma. We have also leveraged our product development platform to diversify our product pipeline without payment of upfront license fees. In 2016 we executed a license agreement with Janssen Pharmaceutica N.V. (Janssen) for TRC253 and TRC694 without an upfront payment and in November 2018, we entered into separate strategic collaboration and clinical trial agreements (the Collaboration Agreements) with I-Mab Biopharma (I-Mab) for TJ004309 (the TJ004309 Agreement), a novel, humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to adenosine, which is highly immunosuppressive, and for the development of up to 5 bi-specific antibodies (the Bispecific Agreement) that includes US commercialization rights, which were both executed without an upfront payment to I-Mab. We continue to evaluate ex-U.S. companies who are in need of 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. We believe we can become a preferred clinical developmental and U.S. commercialization partner through a cost- and risk-sharing partnership structure which may include U.S. commercialization.

We have produced a formulation of TRC105 called DE-122 for ophthalmology indications, which is being developed by Santen 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 has expanded enrollment in the randomized Phase 2a AVANTE study and we expect top-line data in early 2020.

Our other product candidates are TRC102, which is a small molecule that is in Phase 2 clinical development for the treatment of mesothelioma, lung cancer and glioblastoma, and 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 in September 2016.

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 lung cancer and glioblastoma. 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 mesothelioma 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.

We have also collaborated with the NCI, which selected TRC105 and TRC102 for federal funding of clinical development, as well as Case Western Cancer Center (Case Western), the University of Alabama – Birmingham (UAB), and Cedars-Sinai Medical Center. Under these collaborations, NCI sponsored or is sponsoring ten completed or ongoing clinical trials of TRC105 and TRC102, Case Western sponsored two clinical trials of TRC102, UAB is sponsoring one clinical trial of TRC105, and Cedars-Sinai Medical Center is sponsoring one clinical trial of TRC105. All TRC105 NCI sponsored trials have been completed. If merited by Phase 2 data, we expect to fund additional Phase 3 clinical trials of TRC105 and TRC102 and, based on NCI's past course of conduct with similarly situated pharmaceutical companies in which it has sponsored pivotal clinical trials following receipt of positive Phase 2 data, we anticipate that NCI will sponsor Phase 3 clinical trials in additional indications.

The following table summarizes key information regarding ongoing development of our product candidates:

	Phase	Data Expected
TRC105		
Angiosarcoma	Randomized Phase 3	Interim analysis April 2019
Hepatocellular Carcinoma	Phase 1/2	2020
Lung Cancer	Phase 1	2019
Breast Cancer	Phase 1/2	2019
Prostate Cancer	Phase 2	2019
DE-122 (ophthalmic formulation of TRC105)		
Wet AMD (Santen)	Randomized Phase 2	2020
TRC102		
Mesothelioma	Phase 2	2020
Solid Tumors	Phase 1	2020
Solid Tumors and Lymphomas	Phase 1/2	2019
Lung Cancer	Phase 1	2020
TRC253		
Prostate Cancer	Phase 1/2	2020
TJ004309 (I-Mab)		
Solid Tumors	Phase 1	2020

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, 2018, we had cash, cash equivalents and short-term investments totaling $39.1 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 for the manufacture of our product candidates, including with Lonza for the manufacture of TRC105 drug substance, 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 $35.0 million and $19.1 million for the years ended December 31, 2018 and 2017, respectively. At December 31, 2018, we had an accumulated deficit of $139.7 million.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses to remain relatively constant in connection with our ongoing activities as we:

- manufacture preclinical study and clinical trial materials and prepare for potential commercial manufacture of TRC105;
- continue to conduct clinical trials of our product candidates;
- continue our research and development efforts;
- maintain, expand and protect our intellectual property portfolio; and
- seek regulatory approvals for our 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 of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. 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 our product candidates. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources. However, 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 our product candidates.

Collaboration and License Agreements

Collaboration Agreements with I-Mab Biopharma

In November 2018, we entered into the Collaboration Agreements with I-Mab for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 as well as up to five proprietary bispecific antibodies currently under development by I-Mab.

In the TJ004309 Agreement, we will collaborate 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 study, 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 study, 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 studies, and we will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical studies, 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 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 study costs for a product candidate or the JSC decides to cease development over our objections after initiating Phase 3 clinical studies, 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 the 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: (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 P1a study 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 P1a study but before completion of 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 Phase 2 proof of concept study and before completion of 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 Ambrx, Inc.

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

In consideration of the rights granted to Ambrx under the agreement, we received a one-time upfront fee of $3.0 million. In February 2019, following discussions between us and Ambrx regarding Ambrx's progress towards initiating a Phase 1 clinical trial of TRC105 in China, Ambrx notified us that it had elected to terminate the license agreement, resulting in all rights to TRC105 in Greater China reverting to us.

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, and TRC694 (formerly JNJ-6420694), a novel, potent, orally bioavailable inhibitor of NF-kB inducing kinase (the NIK Program and, together with the AR Mutant Program, the Programs), which is intended for the treatment of patients with hematologic malignancies, including myeloma. Following completion of the pre-clinical development of TRC694, we determined the compound did not warrant further development and in February 2019 we issued written notice to terminate the agreement with respect to the NIK 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.

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 TRC105, or the TRC105 Technology. Under the agreement, as amended, 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, 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 TRC105 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 TRC105 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 TRC105 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 TRC105 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 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 our 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. As of December 31, 2018, $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 will become 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, as more fully described below, 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 our 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 as part of our collaboration, 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,		
	2018	2017	2016
	(in thousands)		
Third-party research and development expenses:			
TRC105	$ 18,732	$ 10,684	$ 14,240
TRC253	3,573	1,494	266
TRC102	164	87	523
TRC694	1,401	355	144
TRC205	—	16	71
TJ004309	21	—	—
Total third-party research and development expenses	23,891	12,636	15,244
Unallocated expenses	6,569	6,719	6,322
Total research and development expenses	$ 30,460	$ 19,355	$ 21,566

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

We expect our current level of research and development expenses to remain relatively constant for the foreseeable future as we continue development of TRC105, including our Phase 3 clinical trial in angiosarcoma, continue development activities for our licensed compound TRC253, including our Phase 1/2 clinical trial of TRC253 in castration-resistant prostate cancer, begin clinical development of TJ004309, and expand our manufacturing activities required for regulatory approval for TRC105.

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 our 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 are borne by third parties such as NCI;
- 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; and
- the efficacy and safety profile of the product candidate.

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 expense primarily consists of interest related to our loan agreements 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, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported 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, 2018, 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,		
	2018	2017	2016
	(in thousands)		
Research and development	$ 1,462	$ 1,482	$ 1,090
General and administrative	1,205	1,712	1,993
Total stock-based compensation expense	$ 2,667	$ 3,194	$ 3,083

As of December 31, 2018, the unrecognized stock-based compensation expense related to outstanding stock options and awards was $3.0 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, 2018, we had federal and California net operating loss, or NOL, carryforwards, of approximately $114.6 million and $117.8 million, respectively. The federal and California NOL carryforwards will begin expiring in 2030, unless previously utilized. The federal NOL generated in 2018 of $31.3 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year. At December 31, 2018, we had federal and California research and development and Orphan Drug

credit carryforwards of approximately $9.2 million and $2.0 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 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 may limit our ability to utilize our remaining NOL and research and development tax credit carryforwards. As of December 31, 2018, we had a full valuation allowance against our deferred tax assets.

JOBS Act

On April 5, 2012, the 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.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases*, which outlines a comprehensive lease accounting model and supersedes the current lease guidance. The new accounting standard requires lessees to recognize lease liabilities and corresponding right-of-use 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 new accounting standard must be adopted using the modified retrospective approach and is effective for public entities for annual reporting periods beginning after December 15, 2018 with early adoption permitted. We do not expect the adoption of ASU 2016-02 to have a material impact on our consolidated financial statements and related disclosures.

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 new accounting standard is effective for public entities for annual reporting periods beginning after December 15, 2018 with early adoption permitted. We do not expect the adoption of ASU 2018-07 to have a material impact on our consolidated financial statements and related disclosures.

Results of Operations

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, net	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 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 balance.

Comparison of the Years Ended December 31, 2017 and 2016

The following table summarizes our results of operations for the years ended December 31, 2017 and 2016:

	Years Ended December 31,		
	2017	2016	Change
	(in thousands)		
Collaboration revenue	$ 8,755	$ 3,449	$ 5,306
Research and development expenses	19,355	21,566	(2,211)
General and administrative expenses	7,610	7,859	(249)
Other expense, net	893	1,032	(139)

Collaboration revenue. Collaboration revenue was $8.8 million and $3.4 million for the years ended December 31, 2017 and 2016, respectively. The increase in revenue was due to the achievement of a $7.0 million development milestone by Santen in the third quarter of 2017 for which there was no comparable milestone in 2016, partially offset by fewer months of recognition of the license in 2017 due to the end of the term over which we provided regulatory and technical support to Santen.

Research and development expenses. Research and development expenses were $19.4 million and $21.6 million for the years ended December 31, 2017 and 2016, respectively. The decrease of $2.2 million was due to a decrease in manufacturing activities and nonclinical activities, partially offset by increased clinical study expenses related to the continued development of TRC105, as well as increased compensation related expenses.

General and administrative expenses. General and administrative expenses were $7.6 million and $7.9 million for the years ended December 31, 2017 and 2016, respectively.

Other expense, net. Other expense was $0.9 million and $1.0 million for the years ended December 31, 2017 and 2016, respectively.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception. As of December 31, 2018, we had an accumulated deficit of $139.7 million, and we expect to continue to incur net losses for the foreseeable future. We expect that our research and development expenses will remain relatively constant and because 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 Fund, LLC (Aspire) 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. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements into early 2020. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation.

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 53,639 shares of common stock at an exercise price of $2.61 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, which date may be extended through November 30, 2019 in the event certain funding and regulatory conditions are met. 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, or November 30, 2019, as applicable, 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 of the amounts borrowed. The 2018 Amended SVB Loan provides for prepayment fees of 3.0% of the amount prepaid if the prepayment occurs prior to May 3, 2019, 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.

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 11.9 million shares of common stock at a purchase price of $2.70 per share, pre-funded warrants to purchase approximately 1.8 million shares of common stock at a purchase price of $2.69 per share and an exercise price of $0.01 per share, and warrants to purchase approximately 13.7 million shares of common stock at a purchase price of $0.125 per share and an exercise price of $2.70 per share. We received total gross proceeds of $38.7 million.

Common Stock Purchase Agreement with Aspire Capital Fund, LLC

In March 2017, we entered into a common stock purchase agreement (the Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations of the Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of $21.0 million of shares of our common stock. Upon execution of the Purchase Agreement, we sold to Aspire Capital 222,222 shares of common stock at $4.50 per share for proceeds of $1.0 million and Aspire Capital is 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 Purchase Agreement and concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 195,726 shares of our common stock. As of December 31, 2018, we had issued 417,948 shares of common stock to Aspire Capital under the Purchase Agreement for net proceeds of approximately $0.9 million after offering expenses.

ATM Facility

In September 2018, we entered into a Sales Agreement with 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. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made on the Nasdaq Global 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 Global 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, 2018, we had not sold any shares of common stock through the Sales Agreement with JonesTrading and $11.6 million of common stock remained available for sale under the Sales Agreement.

In September 2018, we terminated a similar at-the-market sales agreement we had entered into with Stifel, Nicolaus & Company, Incorporated in February 2016. We had sold approximately 1,037,000 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,		
	2018	2017	2016
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ (30,783)	$ (13,243)	$ (27,150)
Investing activities	(8,869)	3,674	2,073
Financing activities	35,321	3,326	19,414
Decrease in cash and cash equivalents	$ (4,331)	$ (6,243)	$ (5,663)

Operating activities. Net cash used in operating activities was $30.8 million, $13.2 million, and $27.2 million for the years ended December 31, 2018, 2017 and 2016, 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 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 and $2.1 million for the years ended December 31, 2017 and 2016, respectively, 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 $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. Net cash provided by financing activities was $19.4 million for the year ended December 31, 2016 and resulted from net proceeds received totaling $16.1 million from our follow-on public offering, net proceeds of $5.0 million received from a private placement of our common stock in connection with our license agreements with Janssen, partially offset by repayments of our loan under our credit facility with SVB.

Funding Requirements

At December 31, 2018, we had cash, cash equivalents and short-term investments totaling $39.1 million. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements into early 2020, 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, specifically our lead product candidate, TRC105, including to complete our ongoing Phase 3 trial in angiosarcoma. 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 our product candidates;
- our ability to enter into and maintain our collaborations, including our collaborations with Santen and Janssen;
- 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 our product candidates for clinical trials and regulatory submissions;
- the scope, progress, results and costs of preclinical development, and clinical trials of our other product candidates;
- whether and when Janssen reacquires the rights to the AR Mutant Program;
- the costs, timing and outcome of regulatory review of our product candidates;
- the revenue, if any, received from commercial sales of our 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 of our 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 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, 2018:

		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)	$ 8,425	$ 2,012	$ 6,413	$ —	$ —
Operating lease obligations (2)	1,482	423	903	156	—
Purchase obligations (3)	1,424	1,424	—	—	—
Total	$ 11,331	$ 3,859	$ 7,316	$ 156	$ -

(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.

(3) The purchase obligations are primarily comprised of our non-cancellable purchase commitments under our 2008 master services agreement with Lonza Sales AG (Lonza) and our manufacturing agreement with Lonza Biologics Tuas Pte Ltd (Lonza Biologics), and amounts include estimates based on forecasts which may differ from actual amounts we pay.

Under our long-term manufacturing agreement with Lonza Biologics executed in February 2017, we are required to purchase certain batches of TRC105 prior to regulatory approval with a total estimated cost of approximately $16.6 million at December 31, 2018. Following regulatory approval, we will be required to purchase a specified minimum number of batches annually

with a total annual estimated cost of approximately $26.1 million. If we cancel any purchase orders, we may be obligated to pay certain cancellation fees. In addition, we may be obligated to pay a milestone fee to Lonza Biologics related to the approval or qualifying response upon the earlier of the first approval of TRC105 by the U.S Food and Drug Administration (FDA) or European Medicines Agency (EMA) or the Company's receipt of a complete response letter or non-approvability letter (or equivalent communication) indicating that the rejection of the marketing application was not due to a deficiency in Lonza's facility, the manufacturing process or services performed by Lonza. At December 31, 2018, the Company had non-cancelable purchase obligations totaling $1.4 million under this agreement.

The manufacturing agreement has an initial term beginning on the effective date and ending on the seventh anniversary of the date of first regulatory approval of TRC105 by the FDA or EMA. The Manufacturing Agreement may be renewed for an additional three years upon the written agreement of both parties no later than the fifth anniversary of the date of first approval of TRC105 by the FDA or EMA.

We or Lonza Biologics may terminate the manufacturing agreement due to a material breach of the agreement by the other party, subject to prior written notice and a cure period, due to the insolvency or bankruptcy of the other party, or due to a force majeure event that prevents performance under the agreement for at least six months. We also have the right to terminate the manufacturing agreement, subject to sixty days' written notice, if we discontinue the TRC105 program, whether due to a notice of non-approval or withdrawal of marketing approval by a regulatory agency or otherwise. In the event we terminate the manufacturing agreement due to discontinuation of the TRC105 program or a termination by Lonza Biologics due to our material breach or insolvency or bankruptcy, we would be obligated to pay to Lonza Biologics certain batch cancellation and/or early termination fees.

In addition, 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, 2018, 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 ($1.4 million of which has been paid) upon the achievement of certain milestones for products utilizing certain intellectual property licensed from RPCI, or the RPCI Technology, including TRC105, 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. 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, 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 Lonza, 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.

- 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, 2018, our cash, cash equivalents and short-term investments consist of cash, money market funds and U.S. Treasury securities. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes and we believe that our exposure to interest rate risk is not significant as the majority of our investments are short-term in duration and due to the low risk profile of our investments, a 1% change in interest rates would not have a material impact on the total market value of our portfolio. 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. 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 2018 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, 2018 and 2017, the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

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 28, 2019

TRACON Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31,	
	2018	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 25,136	$ 29,467
Short-term investments	13,968	4,999
Prepaid and other assets	1,499	1,591
Total current assets	40,603	36,057
Property and equipment, net	45	73
Total assets	$ 40,648	$ 36,130
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,947	$ 6,800
Accrued compensation and related expenses	1,464	1,494
Current portion of deferred revenue	—	667
Long-term debt, current portion	1,084	2,837
Total current liabilities	13,495	11,798
Deferred revenue	—	2,333
Other long-term liabilities	368	409
Long-term debt, less current portion	5,343	4,603
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value, authorized shares — 10,000,000 at December 31, 2018 and December 31, 2017; issued and outstanding shares — none	—	—
Common stock, $0.001 par value; authorized shares — 200,000,000 at December 31, 2018 and December 31, 2017; issued and outstanding shares — 29,871,327 and 17,711,928 at December 31, 2018 and December 31, 2017, respectively	30	18
Additional paid-in capital	161,072	121,670
Accumulated deficit	(139,660)	(104,701)
Total stockholders' equity	21,442	16,987
Total liabilities and stockholders' equity	$ 40,648	$ 36,130

See accompanying notes.

TRACON Pharmaceuticals, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Years Ended December 31,		
	2018	2017	2016
Collaboration revenue	$ 3,000	$ 8,755	$ 3,449
Operating expenses:			
Research and development	30,460	19,355	21,566
General and administrative	7,280	7,610	7,859
Total operating expenses	37,740	26,965	29,425
Loss from operations	(34,740)	(18,210)	(25,976)
Other income (expense):			
Interest expense, net	(231)	(886)	(1,119)
Other income (expense), net	12	(7)	87
Total other expense	(219)	(893)	(1,032)
Net loss	(34,959)	(19,103)	(27,008)
Net loss per share, basic and diluted	$ (1.30)	$ (1.14)	$ (2.13)
Weighted-average shares outstanding, basic and diluted	26,945,705	16,806,094	12,677,910

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, 2015	12,175,942	12	89,556	(58,590)	30,978
Issuance of common stock under equity plans	37,672	—	178	—	178
Stock-based compensation expense	—	—	3,083	—	3,083
Vested shares related to repurchase liability	—	—	13	—	13
Issuance of common stock in a public offering, net of offering costs	3,018,750	3	16,110	—	16,113
Other issuances of common stock, net	840,022	1	4,955	—	4,956
Issuance of common stock in exchange for services	12,335	—	23	—	23
Net loss	—	—	—	(27,008)	(27,008)
Balance at December 31, 2016	16,084,721	16	113,918	(85,598)	28,336
Issuance of common stock under equity plans	172,120	—	35	—	35
Stock-based compensation expense	—	—	3,194	—	3,194
Vested shares related to repurchase liability	—	—	14	—	14
Other issuances of common stock, net of offering costs	1,455,087	2	4,306	—	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	17,711,928	18	121,670	(104,701)	16,987
Issuance of common stock under equity plans	228,874	—	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	11,930,525	12	36,444	—	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	29,871,327	$ 30	$ 161,072	$ (139,660)	$ 21,442

See accompanying notes.

TRACON Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities			
Net loss	$ (34,959)	$ (19,103)	$ (27,008)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	2,667	3,194	3,083
Common stock issued for services	—	29	23
Depreciation and amortization	28	48	94
Amortization of debt discount	94	117	100
Amortization of premium/discount on short-term investments	(100)	(9)	3
Noncash interest	272	354	522
Deferred rent	11	60	(53)
Deferred revenue	(3,000)	1,741	(2,094)
Changes in assets and liabilities:			
Prepaid expenses and other assets	92	(356)	(42)
Accounts payable and accrued expenses	4,142	776	(2,203)
Accrued compensation and related expenses	(30)	(94)	425
Net cash used in operating activities	(30,783)	(13,243)	(27,150)
Cash flows from investing activities			
Purchase of property and equipment	—	(39)	(3)
Purchases of available-for-sale short-term investments	(32,869)	(13,992)	(17,506)
Proceeds from the maturity of available-for-sale short-term investments	24,000	17,705	19,582
Net cash (used in) provided by investing activities	(8,869)	3,674	2,073
Cash flows from financing activities			
Proceeds from long-term debt	7,000	8,000	—
Repayment of long-term debt	(8,320)	(8,850)	(2,000)
Proceeds from sale of common stock and warrants, net of offering costs	36,456	4,141	21,236
Proceeds from issuance of common stock under equity plans	263	172	178
Payment of tax withholdings related to net share settlements of vested restricted stock awards	(78)	(137)	—
Net cash provided by financing activities	35,321	3,326	19,414
Decrease in cash and cash equivalents	(4,331)	(6,243)	(5,663)
Cash and cash equivalents at beginning of period	29,467	35,710	41,373
Cash and cash equivalents at end of period	$ 25,136	$ 29,467	$ 35,710
Supplemental disclosure of cash flow information			
Interest paid	$ 642	$ 664	$ 622
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	$ —	$ 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 lead product candidate is an antibody that binds to the endoglin receptor, which is essential to angiogenesis (the process of new blood vessel formation). 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 subsidiary, TRACON Pharma Limited, which was formed in September 2015 and is currently inactive. All significant intercompany accounts and transactions have been eliminated.

Basis of Presentation

As of December 31, 2018, 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, 2018, the Company had an accumulated deficit of $139.7 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, 2018, the Company had cash, cash equivalents, and short-term investments of $39.1 million. Based on the Company's current business plan, management believes that there is substantial doubt as to whether existing cash, cash equivalents, and short-term investments 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 through 2020 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 Company entered into with Aspire Capital Fund, LLC in March 2017 for the purchase of up to $21.0 million of the Company's common stock over a 30 month period and/or the Capital on Demand™ Sales Agreement (the Sales Agreement) the Company entered into with JonesTrading Institutional Services LLC (JonesTrading) in September 2018, pursuant to which the Company could sell, at its option, up to an aggregate of $11.6 million of the Company's common stock, all of which remains available for sale. 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.

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, expenses incurred for clinical trials, and the valuation of equity awards. 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, cash equivalents, and investments. 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.

Deferred Rent

Rent expense is recorded on a straight-line basis over the term of the lease. The difference between rent expense and amounts paid under the lease agreements is recorded as deferred rent in the accompanying consolidated balance sheets. Tenant improvement allowances and other lease incentives are recorded as liabilities and are amortized on a straight-line basis over the term of the lease as reductions to rent expense.

Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (ASU 2014-09)*, which supersedes all existing revenue recognition requirements, 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. ASU 2014-09 was applied to all contracts on January 1, 2018, the date of adoption. The Company did not identify any accounting changes that impacted the amount of historically reported retained earnings and therefore no adjustment to retained earnings was required upon adoption. The following is the total revenue that would have been recorded in the year ended December 31, 2018 under the superseded revenue recognition guidance, Accounting Standards Codification 605, *Revenue Recognition (ASC 605)*, had ASU 2014-09 not been adopted (in thousands):

	For the Year Ended December 31, 2018		
	As Reported	Amount under ASC 605	Effect of Change
Statement of Operations			
Revenue	$ 3,000	$ 667	$ 2,333

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 the three years ended December 31, 2018, 2017 and 2016, 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 stock price on the date of grant. Equity award forfeitures are recorded as they occur.

The Company accounts for stock options granted to non-employees using the fair value approach. These option grants, if any, are subject to periodic revaluation over their vesting terms.

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,		
	2018	2017	2016
Warrants to purchase common stock	15,619,113	103,865	57,173
Common stock options and restricted stock units	3,007,804	2,516,246	2,023,478
ESPP shares	12,753	3,653	2,857
	18,639,670	2,623,764	2,083,508

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 May 2014, the Financial Accounting Standard Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which supersedes all existing revenue recognition requirements, 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. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2017. The Company adopted ASU 2014-09 on January 1, 2018 using the modified retrospective approach and did not identify any accounting changes that impacted the amount of historically reported retained earnings, and therefore no adjustment to retained earnings was required upon adoption.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases*, which outlines a comprehensive lease accounting model and supersedes the current lease guidance. The new accounting standard requires lessees to recognize lease liabilities and corresponding right-of-use 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 new accounting standard must be adopted using the modified retrospective approach and is effective for public entities for annual reporting periods beginning after December 15, 2018 with early adoption permitted. The Company does not expect the adoption of ASU 2016-02 to have a material impact on its consolidated financial statements and related disclosures.

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 new accounting standard is effective for public entities for annual reporting periods beginning after December 15, 2018 with early adoption permitted. The Company does not expect the adoption of ASU 2018-07 to have a material impact on its consolidated financial statements and related disclosures.

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

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. At December 31, 2018, the remaining contractual maturities of all available-for-sale investments were less than one year.

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

	December 31, 2017			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	$ 5,488	$ —	$ —	$ 5,488
U.S. treasury securities	4,999	—	—	4,999
	$ 10,487	$ —	$ —	$ 10,487
Classified as:				
Cash equivalents				$ 5,488
Short-term investments				4,999
Total cash equivalents and short-term investments				$ 10,487

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):

	Total	Fair Value Measurements at Reporting Date Using: 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	$ —
At December 31, 2017				
Money market funds and U.S. treasury securities, included in cash equivalents and short-term investments	$ 10,487	$ —	$ 10,487	$ —

3. Property and Equipment

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

	December 31, 2018	December 31, 2017
Computer and office equipment	$ 133	$ 133
Furniture and fixtures	19	19
Leasehold improvements	21	21
	173	173
Less accumulated depreciation and amortization	(128)	(100)
	$ 45	$ 73

Depreciation expense related to property and equipment totaled approximately $28,000, $48,000 and $94,000 for the years ended December 31, 2018, 2017 and 2016, respectively.

4. Long-Term Debt

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

	December 31, 2018	December 31, 2017
Long-term debt	$ 7,000	$ 8,000
Less debt discount, net of current portion	(257)	(197)
Long-term debt, net of debt discount	6,743	7,803
Less current portion of long-term debt	(1,400)	(3,200)
Long-term debt, net of current portion	$ 5,343	$ 4,603
Current portion of long-term debt	$ 1,400	$ 3,200
Current portion of debt discount	(316)	(363)
Current portion of long-term debt, net	$ 1,084	$ 2,837

In May 2018, the Company entered into a third amendment to its Amended and Restated Loan and Security Agreement with Silicon Valley Bank (the 2018 Amended SVB Loan) 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 are due monthly through June 30, 2019, which may be extended through November 30, 2019 in the event certain conditions are met. 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, or November 30, 2019, as applicable, 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 3.0% of the amount prepaid if the prepayment occurs on or prior to May 3, 2019, 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, 2018, the Company is 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 53,639 shares of its common stock at an exercise price of $2.61 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, 2018, 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	18,415	$ 10.86
November 14, 2023 through June 4, 2024	38,758	$ 7.74
January 25, 2024	46,692	$ 5.14
May 25, 2025	53,639	$ 2.61
	157,504	

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

2019	$ 2,012
2020	3,195
2021	3,218
	8,425
Less interest and final payment	(1,425)
Long-term debt	$ 7,000

5. Commitments and Contingencies

Lonza Biologics Tuas Pte Ltd (Lonza)

On February 22, 2017, the Company entered into a long-term manufacturing agreement, or the Manufacturing Agreement, with Lonza for the long term manufacture and supply of registration and commercial batches of TRC105, the Company's lead drug product candidate. Under the Manufacturing Agreement, Lonza has agreed to manufacture TRC105 pursuant to purchase orders and in accordance with the manufacturing specifications agreed upon between the Company and Lonza. The Company is required to purchase certain batches of TRC105 prior to regulatory approval with a total estimated cost of approximately $16.6 million at December 31, 2018. Following regulatory approval, the Company will be required to purchase a specified minimum number of batches annually with a total annual estimated cost of approximately $26.1 million at December 31, 2018. If the Company cancels any purchase orders, the Company may be obligated to pay certain cancellation fees. In addition, the Company will be obligated to pay a milestone fee to Lonza upon the earlier of the first approval of TRC105 by the U.S Food and Drug Administration (FDA) or European Medicines Agency (EMA) or the Company's receipt of a complete response letter or non-approvability letter (or equivalent communication) indicating that the rejection of the marketing application was not due to a deficiency in Lonza's facility, the manufacturing process or services performed by Lonza. At December 31, 2018, the Company had non-cancelable purchase obligations totaling $1.4 million under this agreement.

The Manufacturing Agreement has an initial term beginning on the effective date and ending on the seventh anniversary of the date of first regulatory approval of TRC105 by the FDA or EMA. The Manufacturing Agreement may be renewed for an additional three years upon the written agreement of both parties no later than the fifth anniversary of the date of first approval of TRC105 by the FDA or EMA.

Either party may terminate the Manufacturing Agreement due to a material breach of the Manufacturing Agreement by the other party, subject to prior written notice and a cure period, due to the insolvency or bankruptcy of the other party, or due to a force majeure event that prevents performance under the Manufacturing Agreement for at least six months. The Company may terminate the Manufacturing Agreement, subject to 60 days' written notice, if the Company discontinues the TRC105 program, whether due to a notice of non-approval or withdrawal of marketing approval by a regulatory agency or otherwise. In the event of a termination by the Company due to discontinuation of the TRC105 program or a termination by Lonza due to the Company's material breach or insolvency or bankruptcy, the Company would be obligated to pay to Lonza certain batch cancellation and/or early termination fees.

Facility Lease

The Company leases its office space under a non-cancelable operating lease that expires in April 2022 that may be extended for an additional term of 60 months. 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. Rent expense for each of the years ended December 31, 2018, 2017 and 2016 was $0.4 million, $0.4 million and $0.4 million, respectively.

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.

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

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, 2018, 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 (Deficit)

Sales of Common Stock

In March and April 2018, the Company sold 11,930,525 shares of its common stock at a purchase price of $2.70 per share, warrants to purchase 1,765,542 shares of its common stock at a purchase price of $2.69 per share and an exercise price of $0.01 per share (the Pre-Funded Warrants) and warrants to purchase 13,696,067 shares of its common stock at a purchase price of $0.125 per share and an exercise price of $2.70 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, a fee totaling approximately $1.9 million as consideration for acting as a nonexclusive placement agent for this financing.

In March 2017, the Company entered into a Common Stock Purchase Agreement (the Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations, Aspire Capital is

committed to purchase up to an aggregate of $21.0 million of shares of the Company's common stock. Under the terms of the Purchase Agreement, the Company sold 222,222 shares of the Company's common stock to Aspire Capital at $4.50 per share for net proceeds of approximately $0.9 million upon execution of the Purchase Agreement and Aspire Capital is committed to purchase up to $20.0 million of additional shares of its common stock solely at the Company's request from time to time during a 30 month period that began on May 1, 2017 and at prices based on the market price at the time of each sale, subject to certain conditions. In consideration for entering into the Purchase Agreement and concurrently with the execution of the Purchase Agreement, the Company issued 195,726 shares of its common stock to Aspire Capital, the fair value of which was recorded as offering costs in connection with the transaction.

At-The-Market Issuance Sales Agreement

In September 2018, 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. 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, 2018, the Company sold no shares of common stock through the Sales Agreement with JonesTrading and $11.6 million of common stock remains available for sale under the Sales Agreement.

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, 2018, the Company had the following outstanding warrants for the purchase of common stock:

Expiration	Number of shares	Exercise price
May 13, 2022	18,415	$ 10.86
November 14, 2023 through June 4, 2024	38,758	7.74
January 25, 2024	46,692	5.14
March 27, 2024	13,696,067	2.70
March 27, 2025	1,765,542	0.01
May 3, 2025	53,639	2.61
	15,619,113	

During the year ended December 31, 2018, no warrants were exercised.

Stock Compensation Plans

2011 Equity Incentive Plan

The Company granted awards under the TRACON Pharmaceuticals, Inc. 2011 Equity Incentive 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 granted under the 2011 Plan.

2015 Equity Incentive Plan

Effective January 1, 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan (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 801,033 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 500,000 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 Board of Directors under the 2015 Equity Incentive Plan. The total grant-date fair value of RSUs that vested during the years ended December 31, 2018 and 2017 was $0.5 million and $0.8 million, respectively. The aggregate intrinsic value of outstanding RSUs at December 31, 2018 was $0.1 million and is based on the Company's closing market price per share on December 31, 2018 of $0.63. As of December 31, 2018, there was approximately $0.4 million of unrecognized compensation costs related to outstanding RSUs, which is expected to be recognized over a weighted average remaining period of 1.1 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, 2017	192,964	$ 7.92
Granted	-	-
Vested	(64,323)	7.92
Forfeited	(36,025)	7.92
Outstanding at December 31, 2018	92,616	$ 7.92

Stock Options

Stock option activity under all Plans is summarized as follows:

	Number of Options	Weighted-Average Exercise Price
Balance at December 31, 2017	2,323,282	$ 6.88
Granted	1,174,327	2.36
Exercised	(136,720)	1.23
Forfeited	(445,701)	7.19
Balance at December 31, 2018	2,915,188	$ 5.28

Information about the Company's outstanding stock options as of December 31, 2018 is as follows (in thousands, except share and per share data and contractual term):

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding	2,915,188	$ 5.28	7.34	$ -
Options vested and expected to vest	2,915,188	$ 5.28	7.34	$ -
Options exercisable	1,562,538	$ 7.07	5.94	$ -

The weighted-average grant date fair value per share of employee option grants during the years ended December 31, 2018, 2017 and 2016 was $1.67, $3.45 and $6.68, respectively. The aggregate intrinsic value used in the above table of options at December 31, 2018 is based on the Company's closing market price per common share on December 31, 2018 of $0.63. The Company received approximately $0.2 million, $44,900 and $6,500 in proceeds from the exercise of stock options during the years ended December 31, 2018, 2017 and 2016, respectively. The total intrinsic value of options exercised was approximately $0.2 million, $0.2 million and $78,000 during the years ended December 31, 2018, 2017 and 2016, respectively. The total grant-date fair value of options that vested during the years ended December 31, 2018, 2017 and 2016 was $2.6 million, $1.9 million and $3.4 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 183,462 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) 366,925 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, 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,		
	2018	2017	2016
Risk-free interest rate	2.8 %	2.1 %	1.6 %
Expected volatility	79.6 %	83.0 %	80.0 %
Expected term (in years)	6.2	6.2	6.3
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,		
	2018	2017	2016
Research and development	$ 1,462	$ 1,482	$ 1,090
General and administrative	1,205	1,712	1,993
	$ 2,667	$ 3,194	$ 3,083

As of December 31, 2018 and 2017, the unrecognized compensation cost related to outstanding time-based options was $2.6 million and $3.7 million, respectively, and is expected to be recognized as expense over approximately 2.6 years and 2.1 years, respectively.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance was as follows:

	December 31,	
	2018	2017
Common stock warrants	15,619,113	103,865
Common stock options and restricted stock units granted and outstanding	3,007,804	2,516,246
Awards available under the 2015 Plan	814,753	772,573
Shares available under the Employee Stock Purchase Plan	501,351	378,367
	19,943,021	3,771,051

7. Collaborations

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 will collaborate 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 study, 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 study, 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 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 studies, and the Company will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical studies, 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 study costs for a product candidate or the JSC decides to cease development over the Company's objections after initiating Phase 3 clinical studies, 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 study 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 study but before completion of Phase 2 proof of concept study 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 study 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 studies or after initiating Phase 3 clinical studies 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, 2018 and December 31, 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 chemistry, manufacturing and controls (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, 2018, 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 at December 31, 2017. The remaining $62.5 million of potential development and regulatory milestone payments are not considered probable at December 31, 2018, 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.

As of December 31, 2018, the Company had satisfied all of its performance obligations and recognized the full transaction price, 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, $8.8 million, and $3.4 million for the years ended December 31, 2018, 2017, and 2016, 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. For each program that the Company retains, the Company is further obligated 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. In addition, the Company was eligible to receive up to a total of $140.5 million in milestone payments upon the achievement of certain milestones, of which $10.5 million related to the submission of certain regulatory filings and receipt of certain regulatory approvals and $130.0 million related to the achievement of specified levels of product sales. Ambrx was 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 had TRC105 products been successfully commercialized in the territory.

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 and (2) a collaboration, including technical and regulatory support provided by the Company. In addition, customer options were identified that include manufacturing and supply obligations.

Upon the adoption of ASU 2014-09 and as of December 31, 2018, the transaction price consisted solely of the $3.0 million upfront payment. The remaining $10.5 million of potential regulatory milestone payments are fully constrained as the achievement of the milestones is not considered probable, due to the termination of the agreement by Ambrx in February 2019. In addition, in accordance with ASU 2014-09, any consideration related to the sales-based milestones (including royalties) would have been recognized when the related sales occur and therefore, have also been excluded from the transaction price. The Company re-evaluated the transaction price in each reporting period during 2018 and no changes in transaction price were identified.

At December 31, 2017, the $3.0 million upfront payment had been received and was recorded as deferred revenue in the accompanying condensed consolidated balance sheet. The license and know-how related to TRC105 was delivered to Ambrx in the first quarter of 2018, and accordingly, the $3.0 million was recognized as revenue. The Company recognized $3.0 million and $0 for the years ended December 31, 2018 and 2017, respectively.

8. 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,		
	2018	2017	2016
Federal income taxes	$ (7,341)	$ (6,686)	$ (9,453)
State income taxes, net of federal benefit	(2,340)	(1,404)	—
Permanent items	439	1,170	717
Uncertain tax positions	672	(1,158)	1,644
Research and development credits	(2,545)	(2,719)	(2,078)
California Net Operating Loss carryforwards	—	(2,208)	(1,054)
Rate change	629	—	(489)
Tax Cuts and Jobs Act	—	11,478	—
Other, net	—	(126)	5
Stock compensation	66	123	—
Change in valuation allowance	10,420	1,530	10,708
Provision for income taxes	$ —	$ —	$ —

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

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 32,182	$ 23,198
Research and development credits and Orphan Drug Credit	8,280	6,518
Depreciation and amortization	281	414
Other, net	1,609	1,802
Total deferred tax assets	42,352	31,932
Valuation allowance	(42,352)	(31,932)
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, 2018, 2017 and 2016 was $10.4 million, $1.5 million and $10.7 million, respectively.

At December 31, 2018, the Company had federal and California NOL carryforwards of approximately $114.6 million and $117.8 million, respectively. The federal and California NOL carryforwards will begin to expire in 2030, unless previously utilized. The federal NOL generated in 2018 of $31.3 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year. At December 31, 2018, the Company also had federal and California research and development and Orphan Drug credit carryforwards of approximately $9.2 million and $2.0 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 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 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. Future ownership changes may further limit the Company's ability to utilize the remaining NOL and research and development credit carryforwards.

On December 22, 2017, the Tax Cuts and Jobs Act 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, the Company has reduced the deferred tax asset balance as of December 31, 2017 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.

In December 2017, the SEC issued Staff Accounting Bulletin No. 118 (“SAB 118”), which provides guidance on accounting for the income tax effects of the TCJA. SAB 118 provides a measurement period that should not extend beyond one year from the TCJA enactment date for companies to complete the accounting relating to the TCJA under Accounting Standards Codification Topic 740, “Income Taxes” (“ASC 740”). In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the TCJA for which the accounting under ASC 740 is complete. To the extent that a company’s accounting for TCJA-related income tax effects is incomplete, but the company is able to determine a reasonable estimate, it must record a provisional estimate in its financial statements. If a company cannot determine a provisional estimate to be included in its financial statements, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the TCJA. The Company has completed its evaluation of the impacts of the TCJA, including IRC Section 162(m) as amended by the Act of 2017, which indicated there is no impact on its December 31, 2018 financial statements.

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

Balance at December 31, 2015		1,822
Increase related to prior year positions		1,902
Increase related to current year positions		453
Balance at December 31, 2016		4,177
Decrease 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

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, 2018 and 2017 and has not recognized interest or penalties in the accompanying consolidated statements of operations for the three years in the period ended December 31, 2018.

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.

9. 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, 2018, 2017 and 2016 totaled approximately $187,000, $181,000 and $172,000, respectively.

10. 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, 2018 and 2017 are as follows (in thousands, except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2018				
Revenue	$ 3,000	$ -	$ -	$ -
Total operating expenses	$ 11,189	$ 9,737	$ 9,083	$ 7,731
Consolidated net income (loss)	$ (8,364)	$ (9,754)	$ (9,085)	$ (7,756)
Basic and diluted net income (loss) attributable to common stockholders	$ (0.46)	$ (0.33)	$ (0.30)	$ (0.26)
2017				
Revenue	$ 626	$ 631	$ 7,498	$ -
Total operating expenses	$ 7,546	$ 6,961	$ 6,104	$ 6,354
Consolidated net income (loss)	$ (7,147)	$ (6,566)	$ 1,170	$ (6,560)
Basic and diluted net income (loss) attributable to common stockholders	$ (0.44)	$ (0.40)	$ 0.07	$ (0.37)

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, as appropriate, 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, 2018, 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, 2018.

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, 2018. 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, 2018, 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, 2018, 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.

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2019 Annual Meeting of Stockholders or the Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2018, under the headings “Executive Officers,” “Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance,” and “ Section 16(a) Beneficial Ownership Reporting Compliance,” and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled “Executive Compensation” in our Proxy Statement.

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

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement.

The information required by Item 201(d) of Regulation S-K is incorporated by reference to the information set forth in the section titled “Executive Compensation” in our Proxy Statement.

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

The information required by this item regarding certain relationships and related transactions and director independence is incorporated by reference to the information set forth in the sections titled “Transactions with Related Parties” and “Election of Directors – Independence of the Board of Directors,” respectively, in our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section titled “Principal Accountant Fees and Services” in our Proxy Statement.

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, 2018:

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, as currently in effect.
3.2(1)	Amended and Restated Bylaws, as currently in effect.
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(12)	Registration Rights Agreement, by and between the Registrant and Aspire Capital Fund, LLC, dated March 14, 2017.
4.5(12)	Common Stock Purchase Agreement, by and between the Registrant and Aspire Capital Fund, LLC, dated March 14, 2017.
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.
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+(6)	TRACON Pharmaceuticals, Inc. Non-Employee Director Compensation Policy, as amended June 1, 2016.
10.5+(4)	TRACON Pharmaceuticals, Inc. 2015 Employee Stock Purchase Plan.
10.6+(11)	TRACON Pharmaceuticals, Inc. Bonus Plan, as amended January 20, 2017.
10.7+	Amended and Restated Employment Agreement by and between the Registrant and Charles P. Theuer, M.D., Ph.D., dated February 5, 2019.

Exhibit Number	Description of Document
10.8+	Employment Agreement by and between the Registrant and Mark Wiggins, dated May 29, 2018.
10.9+(2)	TRACON Pharmaceuticals, Inc. Severance Plan and Summary Plan Description.
10.10+	Severance Agreement by and between the Registrant and Mark Wiggins, dated May 29, 2018.
10.11*(2)	License Agreement by and between the Registrant and Santen Pharmaceutical Co., Ltd., dated March 3, 2014, as amended.
10.12*(5)	Second Amendment to License Agreement by and between the Registrant and Santen Pharmaceutical Co., Ltd., dated January 31, 2016.
10.13*(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.
10.14*(2)	License Agreement by and between the Registrant and Case Western Reserve University, dated August 2, 2006.
10.15*(4)	Amendment to License Agreement by and between the Registrant and Case Western Reserve University, dated April 3, 2015.
10.16*(2)	License Agreement by and between the Registrant and Lonza Sales AG, dated June 29, 2009.
10.17*(9)	License and Option Agreement by and between the Registrant and Janssen Pharmaceutica N.V. dated September 27, 2016.
10.18(2)	Warrant to Purchase Stock issued to Silicon Valley Bank on November 14, 2013.
10.19(2)	Warrant to Purchase Stock issued to Silicon Valley Bank on June 4, 2014.
10.20(4)	Warrant to Purchase Stock issued to Silicon Valley Bank on May 13, 2015.
10.21(8)	Warrant to Purchase Stock issued to Silicon Valley Bank on January 25, 2017.
10.22(15)	Warrant to Purchase Stock issued to Silicon Valley Bank on May 3, 2018.
10.23*(7)	Stock Purchase Agreement by and between the Registrant and Johnson & Johnson-JJDC, Inc. dated September 27, 2016.
10.24*	Amendment One to License and Option Agreement between the Registrant and Janssen Pharmaceutica N.V. dated January 15, 2019.
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(4)	Amended and Restated Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, dated May 13, 2015.
10.27(6)	First Amendment to Amended and Restated Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, dated August 9, 2016.
10.28(8)	Second Amendment to Amended and Restated Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, dated January 25, 2017.
10.29(15)	Third Amendment to Amended and Restated Loan and Security Agreement between the Registrant and Silicon Valley Bank dated May 3, 2018.
10.30*(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.
10.31(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.
10.32*(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 January 28, 2011, as amended on March 12, 2013.
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 January 27, 2016.

Exhibit Number	Description of Document
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 August 7, 2012.
10.35*(2)	Sponsored Research Agreement by and between the Registrant and Tufts Medical Center, Inc., dated December 16, 2014.
10.36(10)	Lease by and between the Registrant and 4350 La Jolla Village LLC, dated December 12, 2016.
10.37*(13)	Manufacturing Agreement by and between the Registrant and Lonza Biologics Tuas Pte Ltd, dated March 27, 2017.
10.38*(14)	Amendment No. 1 to the Manufacturing Agreement by and between the Registrant and Lonza Biologics Tuas Pte Ltd dated May 24, 2017.
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 March 14, 2017.
(13) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-216962), filed with the SEC on March 27, 2017.
(14) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on May 26, 2017.
(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.

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 28, 2019

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, 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, Principal Financial Officer and Principal Accounting Officer)*	February 28, 2019
/s/ William R. LaRue William R. LaRue	Member of the Board of Directors	February 28, 2019
/s/ Martin A. Mattingly, Pharm. D. Martin A. Mattingly, Pharm.D.	Member of the Board of Directors	February 28, 2019
/s/ J. Rainer Twiford, J.D., PH.D J. Rainer Twiford, J.D., Ph.D.	Member of the Board of Directors	February 28, 2019
/s/ Paul Walker Paul Walker	Member of the Board of Directors	February 28, 2019
/s/ Stephen T. Worland Stephen T. Worland., Ph.D.	Member of the Board of Directors	February 28, 2019
/s/ Ted Wang Ted Wang, PhD	Member of the Board of Directors	February 28, 2019

TRACON PHARMACEUTICALS, INC.

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

For

CHARLES P. THEUER

This **Amended and Restated Employment Agreement** (the ***"Agreement"***) is made and entered into effective as of February 5, 2019 (the ***"Effective Date"***), by and between TRACON Pharmaceuticals, Inc., a Delaware corporation (the ***"Company"***), and Charles P. Theuer (the ***"Executive"***). The Company and Executive are hereinafter collectively referred to as the ***"Parties"***, and individually referred to as a ***"Party"***. From and following the Effective Date, this Agreement shall replace and supersede that certain Amended and Restated Employment Agreement between Executive and Company entered into as of February 27, 2017 (the ***"Prior Agreement"***). Certain capitalized terms used in this Agreement are defined in Section 11.

Recitals

Whereas, Executive and the Company are currently parties to the Prior Agreement that is superseded and replaced in its entirety by this Agreement; and

Whereas, the Company desires to continue 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 his 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 continue to serve as the Company's President and Chief Executive 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 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 continue to report to the Company's Board of Directors (the ***"Board"***), and shall have such duties and responsibilities as

are customary for the positions of President and Chief Executive Officer. Executive's primary office location shall continue to 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.

1.4 Board Seat. The Company shall use its best efforts to cause Executive to be elected as a member of its Board throughout his employment as Chief Executive Officer of the Company ("**CEO Term**"), and shall include him in the management slate for election as a director at every stockholders' meeting during the CEO Term at which his term as a director would otherwise expire. Executive agrees to accept election, and to serve during the CEO Term, as a director of the Company, without any compensation therefore other than as specified in this Agreement.

2. Compensation.

2.1 Salary. Executive shall receive a base salary at the rate of $552,921 per year (the ***"Base Salary"***), 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 fifty-percent (50%) of Executive's Base Salary (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 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). Executive must remain an active employee through the end of any given calendar year in order to earn an Annual Bonus for that year and any such bonus will be paid prior to March 15 of the year following the year in which Executive's right to such amount became vested. Executive will not be eligible for, and will not earn, any Annual Bonus (including a prorated bonus) if Executive's employment terminates for any reason before the end of the calendar year.

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.

4. Vacation. Executive shall be entitled to accrue vacation in 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; Severance.

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 Without Cause or Resignation for Good Reason Outside of Change in Control Period. If at any time other than during the Change in Control Period Executive's employment with the Company is terminated by the Company without Cause (other than due to Executive's death or Disability) or Executive resigns for Good Reason and provided that Executive satisfies the Release Requirement in Section 8 below and remains in compliance with Executive's continuing obligations to the Company, the Company shall provide Executive the following ***"Termination Benefits"***:

(i) The Company shall pay Executive the equivalent of twelve (12) months of Base Salary, subject to standard payroll deductions and withholdings (the ***"Termination Severance"***). Subject to Section 9 below, the Termination Severance will be paid to Executive in substantially equal installments on the Company's normal payroll periods during the twelve (12) month period following Executive's termination date, *provided, that*, any payments scheduled to be paid before the Effective Date of the Release and Waiver (as defined in Section 8 below), will be delayed and paid without interest no sooner than the first payroll period following the Effective Date, and all other payments of the Termination Severance shall be made on the scheduled payment dates.

(ii) Provided that Executive timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable) (***"COBRA Premiums"***) through the period (the ***"COBRA Premium Period"***) starting on the Executive's termination date and ending on the earliest to occur of: (a) twelve (12) months following Executive's employment termination date; (b) the date Executive becomes eligible for group health insurance coverage through a new employer; or (c) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered

under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event. For purposes of this Agreement, COBRA Premiums do not include amounts paid by Executive 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 Executive, 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 (including premiums for Executive and Executive's eligible dependents who have elected and remain enrolled in such COBRA coverage), subject to applicable tax withholdings (such amount, the ***"Special Cash Payment"***), for the remainder of the COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of COBRA premiums.

(iii) In addition to the Termination Severance and COBRA Premiums, Executive's outstanding equity awards that are subject to vesting solely upon the passage of time and Executive's 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 Executive's employment termination date.

7.3 Termination Without Cause; Resignation for Good Reason in Connection with a Change in Control. If at any time during the Change in Control Period: (i) Executive's employment with the Company is terminated by the Company without Cause (other than due to Executive's death or Disability) or (ii) Executive resigns for Good Reason, and provided that Executive satisfies the Release Requirement in Section 8 below and remains in compliance with Executive's continuing obligations to the Company, the Company shall provide Executive the following ***"Change in Control Termination Benefits"***:

(i) The Company shall pay Executive the equivalent of (A) eighteen (18) months of Base Salary and (B) 150% of Executive's Target Bonus, subject to standard payroll deductions and withholdings (the ***"CIC Termination Severance"***). Subject to Section 9 below, the CIC Termination Severance will be paid to Executive in substantially equal installments on the Company's normal payroll periods during the eighteen (18) month period following Executive's termination date, *provided, that*, any payments scheduled to be paid before the Effective Date of the Release and Waiver (as defined in Section 8 below), will be delayed and paid without interest no sooner than the first payroll period following the Effective Date, and all other payments of the CIC Termination Severance shall be made on the scheduled payment dates.

(ii) Provided that Executive timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable) (***"CIC COBRA Premiums"***) through the period (the ***"CIC COBRA Premium Period"***) starting on the Executive's termination date and ending on the earliest to occur of: (a) eighteen (18) months following Executive's employment termination date; (b) the date Executive becomes eligible for group health insurance coverage through a new employer; or (c) the date Executive ceases to be eligible for COBRA

continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the CIC COBRA Premium Period, Executive must immediately notify the Company of such event. For purposes of this Agreement, CIC COBRA Premiums do not include amounts paid by Executive 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 CIC 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 Executive, on the first day of each calendar month following the termination date, a fully taxable cash payment equal to the applicable CIC COBRA premiums for that month (including premiums for Executive and Executive's eligible dependents who have elected and remain enrolled in such COBRA coverage), subject to applicable tax withholdings (such amount, the ***"Special Cash Payment"***), for the remainder of the CIC COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of CIC COBRA premiums.

(iii) In addition to the CIC Termination Severance and CIC COBRA Premiums, Executive's outstanding equity awards that are subject to vesting solely upon the passage of time and Executive's 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 Executive's employment termination date.

If Executive becomes eligible for Change In Control Termination Benefits under this Section 7.3 Executive is not eligible for any Termination Benefits under Section 7.2 above and any such Termination Benefits already provided to Executive under Section 7.2 above (in the event such termination occurs prior to a Change in Control) shall be used to offset the Change in Control Termination Benefits due to Executive under this Section 7.3)

7.4 **Termination Upon Death.** In the event Executive's employment with the Company is terminated due to Executive's death, and provided that Executive's estate satisfies the Release Requirement in Section 8 below, the Company shall provide Executive's estate with the following ***"Death Benefits"***:

(i) The Company shall pay Executive's estate the equivalent of twelve (12) months of Executive's Base Salary, subject to standard payroll deductions and withholdings (the ***"Death Severance"***). The Death Severance will be paid to Executive's estate in a single lump sum payment the first payroll period following Effective Date of the Release and Waiver (as defined in Section 8 below), and in all cases no later than March 15th of the calendar year following Executive's death.

(ii) In addition to the Death Severance, Executive's outstanding equity awards that are subject to vesting solely upon the passage of time and Executive's continued employment with the Company shall accelerate vesting in accordance with their applicable schedules as if Executive had remained in employment for an additional six (6) months as of his employment termination date.

7.5 Termination Upon Disability. In the event Executive's employment with the Company is terminated due to Executive's Disability, and provided that Executive satisfies the Release Requirement in Section 8 below and remains in compliance with Executive's continuing obligations to the Company, Executive's outstanding equity awards that are subject to vesting solely upon the passage of time and Executive's continued employment with the Company shall accelerate vesting in accordance with their applicable schedules as if Executive had remained in employment for an additional six (6) months as of his employment termination date (the ***"Disability Benefits"***).

7.6 Termination for Cause; Resignation Without Good Reason. In the event that the Executive terminates his employment for any reason other than Good Reason or in the event that Company terminates Executive for Cause no further payments shall be due under this Agreement, except that the 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 expiration of such equity award, whichever occurs first.

8. Release Requirement. To be eligible for the Termination Benefits, Change in Control Termination Benefits, Death Benefits or Disability Benefits pursuant to Section 7 above, Executive (or his estate, if applicable) must satisfy the following release requirement (the ***"Release Requirement"***): return to the Company a signed and dated general release of all known and unknown claims in a form acceptable to the Company (the ***"Release and Waiver"***) within the applicable deadline set forth therein, but in no event later than fifty-five (55) days following Executive's employment termination date, and permit the Release and Waiver to become effective and irrevocable in accordance with its terms (such latest permitted effective date of the Release and Waiver is the ***"Effective Date"*** of the Release and Waiver). No Termination Benefits, Death Benefits or Disability Benefits will be provided prior to the Effective Date of the Release and Waiver. The form of required Release and Waiver will be provided to Executive (or his estate, if applicable) by the Company no later than five (5) days following Executive's employment termination date.

9. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4) and 1.409A-1(b)(5), 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. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's Separation from Service (as defined under Treasury Regulation Section 1.409A-1(h)) to be a "specified employee" for purposes of Code Section

409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then, solely to the extent necessary to avoid adverse personal tax consequences under Section 409A such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable delay period, all payments deferred pursuant to this Section 9 shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred.

10. Limitation on Payments. If any payment or benefit Executive 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 Executive's 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 Executive. 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 Executive 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 the Executive 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 Executive and the Company within fifteen (15) calendar days after the date on which Executive's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section 10 and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive 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 10 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 10, Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

11. Definitions.

11.1 Base Salary. For purposes of Sections 7 and 11 of this Agreement, ***"Base Salary***" means Executive's base salary in effect as of the date of Executive's employment termination or death, as applicable, and calculated without giving effect to any reduction that would give rise to Executive's right to resign for Good Reason or any reduction implemented during the Change in Control Period.

11.2 Cause. For purposes of this Agreement, ***"Cause"*** for termination will mean: (i) conviction of the Executive of any felony or any crime involving moral turpitude; (ii) Executive's failure or refusal to follow reasonable and lawful instructions of the Board or reasonable and lawful policies, standards and regulations of the Company; (iii) Executive's failure or refusal to faithfully and diligently perform the usual, customary duties of his employment with the Company; (iv) unprofessional, unethical, immoral or fraudulent conduct by Executive; (v) conduct by Executive that materially discredits the Company or is materially detrimental to the reputation, character and standing of the Company or (vi) Executive's material breach of any written agreement with the Company (including but not limited to this Agreement or his Confidentiality Agreement (as defined in Section 12.1 below)). An event described in (ii) - (vi) above shall not be treated as "Cause" until after Executive has been given written notice of such event, failure or conduct and Executive fails to cure such event, failure, conduct or breach, if curable, within fifteen (15) days from such written notice.

11.3 Change in Control. For purposes of this Agreement, ***"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."

11.4 Change in Control Period. For purposes of this Agreement ***"Change in Control Period"*** means the 12 month period commencing on the date of a Change in Control.

11.5 Disability. For purposes of this Agreement, ***"Disability"*** shall mean Executive's inability for medical reasons to perform the essential duties of Executive's position for either ninety (90) consecutive calendar days or one hundred twenty (120) business days in a twelve month period by reason of any medically determined physical or mental impairment as determined by a medical doctor selected by written agreement of the Company and Executive upon the request of either party by notice to the other.

11.6 Good Reason. For purposes of this Agreement, Executive shall have ***"Good Reason"*** for resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent:

(i) any material breach of this Agreement by the Company;

(ii) a material reduction in Executive's base salary, which the parties agree is a reduction of at least 10% of Executive's base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees);

(iii) a material reduction in Executive's duties (including responsibilities and/or authorities), *provided, however,* that a change in job position (including a change in title) shall not be deemed a "material reduction" in and of itself unless Executive's new duties are materially reduced from the prior duties; or

(iv) relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than thirty-five (35) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation;

provided, however that, such termination by the Executive shall only be deemed for Good Reason pursuant to the foregoing definition if (i) the Company is given written notice from the Executive within thirty (60) days following the first occurrence of the condition that he considers to constitute Good Reason describing the condition and the Company fails to satisfactorily remedy such condition within thirty (30) days following such written notice, and (ii) the Executive terminates employment within thirty (60) days following the end of the period within which the Company was entitled to remedy the condition constituting Good Reason but failed to do.

11.7 Target Bonus. For purposes of this Agreement, ***"Target Bonus"*** means the applicable percentage of Base Salary that Executive was eligible to earn as an Annual Bonus for the year of Executive's termination, and calculated without giving effect to any reduction in Base Salary that would give rise to Executive's right to resign for Good Reason or any reduction in Base Salary implemented during the Change in Control Period.

12. Proprietary Information Obligations.

12.1 Confidential Information Agreement. As a condition of continued employment, Executive acknowledges and reaffirms his obligations to the Company under the

Employee Proprietary Information and Inventions Agreement he executed on or about September 17, 2014 (the ***"Confidentiality Agreement"***).

12.2 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.

13. Outside Activities During Employment.

13.1 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.

13.2 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.

14. Legal Fees. Not Used.

15. 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.

16. General Provisions.

16.1 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.

16.2 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.

16.3 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.

16.4 Complete Agreement. This Agreement, together with the Confidentiality 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 (including the Prior Agreement). It cannot be modified or amended except in a writing signed by a duly authorized officer of the Company.

16.5 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.

16.6 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.

16.7 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 his duties hereunder and he may not assign any of his rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

16.8 Tax Withholding and Indemnification. 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.

16.9 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/ Mark Wiggins
Mark Wiggins
Chief Business Officer

EXECUTIVE

/s/ Charles P. Theuer
Charles P. Theuer

TRACON PHARMACEUTICALS, INC.

EMPLOYMENT AGREEMENT

For

MARK WIGGINS

This **EMPLOYMENT AGREEMENT** (the ***"Agreement"***) is made and entered into effective as of May 29, 2018 (the ***"Effective Date"***), by and between TRACON Pharmaceuticals, Inc., a Delaware corporation (the ***"Company"***), and Mark Wiggins (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 Business 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 Business 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 $350,000 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 vacation at the rate of four (4) weeks per year (maximum vacation accrual caps will be in accordance with the Company's vacation policy).

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. As an inducement to Executive's commencement of employment with the Company, and subject to approval by the Company's Compensation Committee, Executive will be granted a non-statutory stock option to purchase up to 280,000 shares of common stock of the Company (the ***"Option"***). The Option will be an "Inducement Award" pursuant to and subject to the terms of the Company's 2015 Equity Incentive Plan (the ***"Plan"***) and its form of stock option agreement, in the forms to be provided to Executive, as well as compliance with applicable securities laws. The Option will have an exercise price equal to the closing price of the Company's common stock on the applicable date of grant and will vest beginning on Executive's employment start date (the ***"Vesting Commencement Date"***). Subject to Executive's continued provision of services to the Company through the applicable vesting dates, the Option

will vest as follows: 25% of the total number of shares subject to the Option will vest on the first anniversary of the Vesting Commencement Date and 1/36th of the remaining number of shares subject to the Option will vest on each monthly anniversary thereafter so that the Option would fully vest on the four (4) year anniversary of the Vesting Commencement Date.

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 concurrently with this Agreement (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; Non-Competition.

10.1 Outside Activities. During Executive's employment with the Company, Executive may engage in civic and not-for-profit activities so long as such activities do not interfere with the performance of Executive's duties hereunder or present a conflict of interest with the Company. Subject to the restrictions set forth herein and in the Confidential Information Agreement, **and only with prior written disclosure to and consent of the Board, Executive may engage in other types of business or public activities**. The Board may rescind such consent if the Board determines, in its reasonable discretion, that such activities compromise or threaten to compromise the Company's business interests or conflict with Executive's duties to the Company. Notwithstanding the foregoing, and so long as such activities (individually or in the aggregate) do not present a time commitment which conflicts with Executive's duties to the Company, (i) Executive shall be permitted to continue his current Board of Director roles with Zogenix, Inc. and SelectION, Inc.; (ii) Executive may continue activities with a maximum of two clients at any one time through his pre-existing consulting business (BioPharma Business Development, LLC) at times other than usual business hours for a period of time of two years from execution of this agreement, and (iii) Executive may manage his personal investments.

10.2 Non-Competition During Employment. During Executive's employment with the Company, Executive will not, without the prior written consent of the Board, directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venturer, associate, representative or consultant of any person or entity engaged in, or planning or preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company; provided, however, that Executive may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange

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/ Mark Wiggins
Mark Wiggins

TRACON PHARMACEUTICALS, INC. SEVERANCE PLAN

SEVERANCE AGREEMENT

This Severance Agreement (the "***Agreement***") is entered into effective May 29, 2018 (the "***Effective Date***"), by and between Mark Wiggins ("***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.	**MARK WIGGINS**
/s/ Charles P. Theuer	/s/ Mark Wiggins
BY: Charles P. Theuer, President and CEO	

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], 2018 (the "**Severance Agreement**") entered into by and between Mark Wiggins ("**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: _____

Mark Wiggins

TRACON Pharmaceuticals, Inc.

Dated:_____

Name:
Title:

[Signature Page to Separation Agreement and General Release of All Claims]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

AMENDMENT ONE TO LICENSE AND OPTION AGREEMENT

This **AMENDMENT ONE TO LICENSE AND OPTION AGREEMENT** (the "**Amendment**") is effective as of January 15, 2019 (the "**Amendment Effective Date**"), by and between Janssen Pharmaceutica N.V. ("**Janssen**") and TRACON Pharmaceuticals, Inc., a Delaware corporation ("**Licensee**"). Each of Janssen and Licensee is sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Janssen and Licensee are parties to that certain License and Option Agreement, effective as of September 27, 2016 (the "**Agreement**"), pursuant to which Janssen granted to Licensee an exclusive, worldwide license under certain Janssen technology and intellectual property rights to develop, manufacture and commercialize any AR Mutant Compound or NIK Compound (each as defined in the Agreement), and any product containing an AR Mutant Compound or NIK Compound, on the terms and conditions set forth in the Agreement; and

WHEREAS, the Parties now desire to amend the Agreement, in accordance with Section 13.8 thereof, to decrease the number of patients necessary to satisfy the conditions set forth in the definition of "AR Mutant POC Trial."

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. AMENDMENT OF THE AGREEMENT

The Parties hereby agree to amend the terms of the Agreement as provided below, effective as of the Amendment Effective Date. Except to the extent the Agreement is explicitly amended by this Amendment, the Agreement will remain in full force and effect in accordance with its terms. Capitalized terms used in this Amendment that are not otherwise defined herein shall have the meanings such terms are given in the Agreement.

Section 1.10 of the Agreement is hereby deleted and replaced in its entirety with the following:

"1.10. **AR Mutant POC Trial**" means the first Clinical Trial of the AR Mutant Product containing the AR Mutant Compound set forth on Schedule AR Mutant Compound of the Schedule Letter as the only active ingredient that satisfies the following criteria: (a) such Clinical Trial has [***]; and (b) such Clinical Trial has [***]

[***]. For purposes of this definition, [***] means that [***].”

2. MISCELLANEOUS

2.1 Full Force and Effect. This Amendment amends the terms of the Agreement and is deemed incorporated into the Agreement. The provisions of the Agreement, as amended by this Amendment, remain in full force and effect.

2.2 Entire Agreement. The Agreement, as amended by this Amendment, constitutes the entire agreement, both written and oral, between the Parties with respect to the subject matter hereof, and any and all prior agreements with respect to the subject matter hereof, either written or oral, expressed or implied, are superseded hereby, merged and canceled, and are null and void and of no effect.

2.3 Counterparts. This Amendment may be executed in one or more counterparts, each of which will be an original and all of which together will constitute one instrument.

[Signature Page Follows]

In Witness Whereof, the Parties have executed this Amendment as of the Amendment Effective Date.

JANSSEN PHARMACEUTICA N.V.

By: /s/ L. Verbeeck

Name: L. Verbeeck

Title: Member of Management Board Janssen Pharmaceutica N.V.

JANSSEN PHARMACEUTICA N.V.

By: /s/ Bart Van WaeyenBerge

Name: Bart Van WaeyenBerge

Title: General Manager

TRACON PHARMACEUTICALS, INC.

By: /s/ Charles Theuer, M.D., Ph.D.

Name: Charles Theuer, M.D., Ph.D.

Title: CEO

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-1 No. 333-216962) of TRACON Pharmaceuticals, Inc.,
(6)Registration Statement (Form S-3 No. 333-209313) of TRACON Pharmaceuticals, Inc.; and
(7)Registration Statement (Form S-3 No. 333-224809) of TRACON Pharmaceuticals, Inc.

of our report dated February 28, 2019, 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, 2018.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2019

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)) for the registrant and have:

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2019

/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 28, 2019

/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.