TRACON PHARMACEUTICALS, INC.

FORM 10-K
(Annual Report)

Filed 03/01/17 for the Period Ending 12/31/16

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Telephone 858-550-0780
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SIC Code 2836 - Biological Products, (No Diagnostic Substances)
Industry Biotechnology & Medical Research
Sector Healthcare
Fiscal Year 12/31
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, 2016

☐ 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
(State or Other Jurisdiction of Incorporation or Organization)

8910 University Center Lane, Suite 700,
San Diego CA
(Address of Principal Executive Offices)

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

34-2037594
(IRS Employer Identification No.)

92122
(Zip Code)

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

Common Stock, par value $0.001 per share
The NASDAQ Stock Market LLC

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

Indicate by check mark whether 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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐
Accelerated filer ☐
Non-accelerated filer ☒ (Do not check if a smaller reporting company)
Smaller reporting company ☒

As of June 30, 2016, 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 $37.8 million, based on the closing price of the registrant’s common stock on the NASDAQ Global Market on June 30, 2016 of $4.38 per share.

The number of outstanding shares of the registrant’s common stock as of February 12, 2017 was 16,163,559.

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 2017 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, 2016.
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Forward-Looking Statements

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

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

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

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

Item 1. Business.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration, or wet AMD, and fibrotic diseases. 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 for wet AMD, and a key contributor to the development of fibrosis, or tissue scarring. We are developing our lead product candidate, TRC105 (INN 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. The VEGF pathway regulates vascular development in the embryo, or vasculogenesis, and angiogenesis. We believe treatment with TRC105 in combination with VEGF inhibitors may improve survival in cancer patients when compared to treatment with a VEGF inhibitor alone. TRC105 has been studied in eight completed Phase 2 clinical trials and three completed Phase 1 clinical trials, and is currently being dosed in one Phase 3 clinical trial, four Phase 2 clinical trials and three Phase 1 clinical trials. Our TRC105 oncology clinical development plan is broad and involves a tiered approach. We are initially focused on two indications, angiosarcoma and gestational trophoblastic neoplasia, or GTN, both of which are tumors that highly express endoglin, the target of TRC105, and therefore may be more responsive to treatment with TRC105. We have seen complete ongoing responses in these tumor types and have initiated dosing in an international multicenter Phase 3 trial in angiosarcoma and an international multicenter Phase 2 trial in GTN. 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 angio sarcoma 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 next tier of TRC105 development includes ongoing Phase 2 trials in renal cell carcinoma, which is a randomized trial expected to produce top-line data in the second half of 2017, and hepatocellular carcinoma, that is expected to produce top-line data in the first half of 2018. Positive data from either of these Phase 2 trials could enable Phase 3 development. We consider these indications attractive because the endpoints for regulatory approval may be attained more quickly than the endpoints for other indications. We also expect that these initial indications would be for the same lines of treatment for which the companion VEGF inhibitor is approved.

Finally, the third tier of TRC105 development includes large indications including an ongoing Phase 1 trial in lung cancer and a Phase 1/2 trial in breast cancer. Positive data in these larger indications would enable further development.

We have produced a formulation of TRC105 for development in ophthalmology, which is being developed 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, including TRC105, for ophthalmology indications. We retain global rights to develop our endoglin antibodies outside of the field of ophthalmology. In June 2015, Santen filed an Investigational New Drug, or IND, application with the FDA for the initiation of clinical studies for DE-122, the ophthalmic formulation of TRC105, in patients with wet AMD. The Phase 1/2 PAVE trial is recruiting patients with wet AMD, including patients receiving a VEGF inhibitor, and top-line data are expected in the second half of 2017. We also expect Santen to initiate the Phase 2 AVANTE trial in wet AMD in 2017.

TRC205, a humanized, deimmunized endoglin antibody, is being developed for the treatment of fibrotic diseases. Diseases characterized by fibrosis, the harmful buildup of excessive fibrous tissue from cells, including the fibroblast, that leads to scarring and ultimately organ failure, include nonalcoholic steatohepatitis, or NASH, idiopathic pulmonary fibrosis, or IPF, renal fibrosis, cardiac fibrosis and scleroderma. Clinical data have demonstrated increased endoglin expression on fibroblasts in patients with heart failure and inhibiting endogin reduced cardiac fibrosis, preserved heart function and improved survival in mouse models of heart failure. Subsequent preclinical research in mouse models indicated that antibodies to endoglin inhibit cardiac, liver, and pulmonary fibrosis. These findings indicate endoglin’s importance in cardiac, lung and liver fibrosis, and we believe these findings may be applicable to multiple fibrotic diseases, including NASH, IPF, myelofibrosis and other indications. In addition, a patient with cutaneous neurofibromatosis treated with TRC105 and a VEGF inhibitor in an oncology trial demonstrated reduction in the cutaneous lesions that characterize the disease. We may study TRC105 in additional patients with cutaneous neurofibromatosis.

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

We are also developing TRC253 and TRC694, small molecule compounds we licensed from Janssen Pharmaceutica N.V. (Janssen) in September 2016. TRC253 is a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR) and multiple AR mutant receptors which display drug resistance to currently approved treatments, and is intended for the treatment of men with prostate cancer. We filed an IND in December 2016, which was cleared by the FDA in January 2017, and expect to initiate first in human testing for TRC253 in a Phase 1/2 clinical study in the first half of 2017. 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 to the program, 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.

TRC694 is a novel, potent, orally bioavailable inhibitor of NF-kB inducing kinase (NIK), which is intended for the treatment of patients with hematologic malignancies, including myeloma. We plan to conduct preclinical activities, including formulation development and companion diagnostic development, and expect to file an IND for TRC694 in 2018.

We operate a product development platform that emphasizes capital efficiency. Our experienced clinical operations, data management, quality assurance and regulatory affairs groups are responsible for significant aspects of our clinical trials, including site monitoring, regulatory compliance, database management and clinical study report preparation. We use this internal resource to
minimize the costs associated with hiring contract research organizations, or CROs, to manage clinical, regulatory and database aspects of the clinical trials that we sponsor. In our experience, this model has resulted in capital efficiencies and improved communication with clinical trial sites, which expedites patient enrollment and access to patient data as compared to a CRO-managed model, and we have begun to leverage this capital efficient model in our recently initiated international clinical trials. In addition, we have an experienced chemistry, manufacturing and controls (CMC) group that completes our product development platform.

We have collaborated with the National Cancer Institute (NCI), which has selected TRC105 and TRC102 for federal funding of clinical development, as well as Case Western Cancer Center (Case Western) and certain other academic institutions. Under these collaborations, NCI has sponsored or is sponsoring nine completed or ongoing clinical trials of TRC105 and TRC102, and Case Western has sponsored or is sponsoring three clinical trials of TRC102. We anticipate that NCI will complete ongoing Phase 1 and Phase 2 clinical trials of TRC105 and TRC102 and may initiate other clinical trials. If merited by Phase 2 data, we expect to fund additional Phase 3 clinical trials of TRC105 in certain indications beyond angiosarcoma and initial Phase 3 clinical trials of 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.

The following chart summarizes our pipeline of product candidates:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Pre-Clinical</th>
<th>Phase 1</th>
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<tr>
<td><strong>TRC105</strong></td>
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<tr>
<td>Angiosarcoma</td>
<td></td>
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<tr>
<td>RCC, HCC, GTN</td>
<td></td>
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<tr>
<td>Lung, Breast</td>
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<tr>
<td><strong>TRC102</strong></td>
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<tr>
<td>GBM, Mesothelioma</td>
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<tr>
<td>Lung, Solid Tumors</td>
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<td>DE-122</td>
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<td>Wet AMD</td>
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<td><strong>TRC253</strong></td>
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<tr>
<td>Prostate</td>
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<td><strong>TRC694</strong></td>
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<td>TRC205</td>
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<tr>
<td>Fibrosis</td>
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1 Partnered with Santen Pharmaceutical Co., Ltd. (Santen)
2 Janssen Pharmaceutica N.V. (Janssen) retains a buyback option
The following table summarizes key information regarding ongoing and planned development of our product candidates:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Data Expected</th>
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<td>Ongoing trials:</td>
<td></td>
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<tr>
<td>Angiosarcoma</td>
<td>Phase 3</td>
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<tr>
<td>Renal Cell Carcinoma</td>
<td>Randomized Phase 2</td>
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<td>Soft Tissue Sarcoma</td>
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<td>Hepatocellular Carcinoma</td>
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<tr>
<td>Hepatocellular Carcinoma (NCI Sponsored)</td>
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<tr>
<td>Lung Cancer</td>
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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 have initiated dosing in our international multicenter randomized Phase 3 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 the first half of 2018 that will determine the final sample size. We expect top line data in 2019. We obtained SPA agreement from the FDA on our clinical trial design for the Phase 3 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 described here 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. We have initiated an international multicenter Phase 2 clinical trial of TRC105 as a single agent and in combination with Avastin (bevacizumab) in GTN with overall response as the primary endpoint, and expect topline data in the second half of 2018. In the case of GTN, response can be reliably assessed by serum β-hCG, a known and reliable marker of disease burden, and we expect that regulatory approval would be based on overall response rate in a single arm trial.

- *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 approved VEGF inhibitors in the oncology indications of renal cell carcinoma and hepatocellular carcinoma, both of which are associated with reduced time to achieve the endpoints necessary for regulatory approval, with the goal of enabling one or more Phase 3 clinical trials in these indications. The FDA has granted approval for drugs in renal cell carcinoma based on a primary endpoint of progression-free survival, rather than overall survival. Although the endpoint for approval for hepatocellular carcinoma is overall survival, this endpoint is typically reached sooner for hepatocellular carcinoma than for many other solid tumors.

- *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 1 trial of TRC105 in combination with chemotherapy and Avastin in lung cancer, and in a Phase 1/2 trial of TRC105 with Afinitor (everolimus) and Femara (letrozole) in breast cancer in 2016. We expect to present data in lung cancer in 2017 that, if positive, could enable further development.

- **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. We anticipate that NCI will complete ongoing Phase 1 and Phase 2 clinical trials of TRC105 and TRC102 and may initiate other clinical trials. 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, is currently enrolling wet AMD patients into the Phase 1/2 PAVE trial of DE-122 and we expect them to initiate the Phase 2 AVANTE trial of DE-122 in 2017.

- **Continue preclinical studies of endoglin antibodies in fibrotic diseases.** TRC205, a humanized and deimmunized endoglin antibody, is our lead product candidate for the treatment of fibrotic diseases, including NASH and IPF, each of which presents a large commercial opportunity. We reported data for TRC205 in a preclinical model of NASH in 2016, and plan to report additional preclinical studies of our endoglin antibodies in 2017. We also may study TRC105 in patients with cutaneous neurofibromatosis.

- **Initiate first in human Phase 1/2 clinical trial of TRC253 in patients with prostate cancer.** We filed an IND in December 2016 for TRC253, that was cleared by the FDA in January 2017, and expect to initiate dosing in a Phase 1/2 clinical trial of TRC253 in the first half of 2017 in castrate resistant prostate cancer patients.

- **Continue preclinical development of TRC694.** We plan to conduct preclinical activities for TRC694 to enable filing of an IND in 2018.

- **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 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.

**Our Lead Product Candidate—TRC105**

**Rationale for Developing Endoglin Antibodies to Treat Cancer, Wet AMD and Fibrotic Diseases**

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. Endoglin is also expressed on fibroblasts, the cells that mediate fibrosis, and is a key contributor to the development of fibrosis. Finally, endoglin is also expressed on activated macrophages.

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 endoglin inhibitors 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.

**Anti-Angiogenesis VEGF 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 anti-angiogenesis drugs that inhibit the VEGF pathway, with over $10.0 billion in reported aggregate worldwide sales in oncology in 2016. VEGF 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 12,000 new cases of soft tissue sarcoma in the United States in 2016 with more than 4,900 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 500 cases annually in each of the United States and the European Union.

- **Renal Cell Carcinoma.** The ACS estimates there were 62,700 new cases of renal cell carcinoma in the United States in 2016 with 14,240 deaths. Sutent (sunitinib), Nexavar (sorafenib) and Votrient are small molecule VEGF inhibitors approved as single agents for the first line treatment of advanced or metastatic renal cell carcinoma, Inlyta (axitinib) and Cabometyx (cabozantinib) are small molecule VEGF inhibitors approved for second line treatment, Avastin is approved with interferon. Inlyta was approved in 2012 for the treatment of renal cell carcinoma, with reported global sales of $401 million in 2016, compared to $430 million in 2015.

- **Hepatocellular Carcinoma.** The ACS estimates there were 39,230 new cases of hepatocellular carcinoma in the United States in 2016 with 27,170 deaths. The only drug approved in the United States for the first line treatment of hepatocellular carcinoma is the VEGF inhibitor Nexavar. In 2016, reported global sales of Nexavar were $1.0 billion worldwide.

- **Colorectal Cancer.** The ACS estimates there were 134,490 new cases of colon cancer or rectal cancer in the United States in 2016 with 49,190 deaths. Avastin is approved with chemotherapy for the first and second line treatment of patients with metastatic colorectal cancer, Cyramza (ramucirumab) is approved with chemotherapy for second line treatment of patients with metastatic colorectal cancer, and Zaltrap (ziv-aflibercept) is approved with chemotherapy for the second line treatment of patients with metastatic colorectal cancer. Stivarga (regorafenib) is approved following prior treatment with chemotherapy and VEGF inhibitor.

- **Non-Small Cell Lung Cancer.** The ACS estimates there were 224,390 new cases of lung cancer in the United States in 2016 with 158,080 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.

VEGF inhibitors are also used off-label in other indications, including GTN. GTN is a form of gestational trophoblastic disease (GTD), a group of rare diseases that originate in the placenta and have the potential to locally invade the uterus and metastasize. The pathogenesis of GTD is unique because the maternal tumor arises from gestational rather than maternal tissue. The major histologic entities for this disease include complete molar pregnancy, partial molar pregnancy, invasive mole, and choriocarcinoma. The term GTN is used when molar and non-molar pregnancies become malignant, and comprise the morphologic entities of invasive mole and choriocarcinoma. Choriocarcinoma metastasizes hematogenously and can follow any type of pregnancy, but most commonly develops after complete hydatidiform mole. The reported incidence of GTD in the United States is about 110 to 120 per 100,000 pregnancies. The reported incidence of choriocarcinoma, the most aggressive form of GTD, in the United States is about 2 to 7 per 100,000 pregnancies.

**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 2016.

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 with TRC105 and VEGF inhibitors in the first and second line treatment settings, where increased susceptibility to anti-angiogenic treatment is expected. Additionally, TRC105 may be more effective as a single agent in tumor types, including angiosarcoma, known to overexpress endoglin.

TRC105 is being studied in eight ongoing clinical trials in combination with VEGF inhibitors and has been studied in 11 completed clinical trials as a single agent or with VEGF inhibitors. The following table summarizes certain key information regarding our clinical trials of TRC105 in cancer patients:

### Ongoing Clinical Trials of TRC105

<table>
<thead>
<tr>
<th>Phase</th>
<th>Indication</th>
<th>Sponsor</th>
<th>Companion Treatment</th>
<th>Design (Number of Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Angiosarcoma</td>
<td>TRACON</td>
<td>Votrient</td>
<td>Randomized (Up to 200)</td>
</tr>
<tr>
<td>2*</td>
<td>Clear cell renal cell carcinoma</td>
<td>TRACON</td>
<td>Inlyta</td>
<td>Randomized (150)</td>
</tr>
<tr>
<td>1/2</td>
<td>Soft tissue sarcoma</td>
<td>TRACON</td>
<td>Votrient</td>
<td>Single arm (113)</td>
</tr>
<tr>
<td>2</td>
<td>GTN</td>
<td>TRACON</td>
<td>Avastin</td>
<td>Single Arm (30)</td>
</tr>
<tr>
<td>1/2</td>
<td>Hepatocellular carcinoma</td>
<td>NCI</td>
<td>Nexavar</td>
<td>Dose escalation portion and single arm portion (up to 44)</td>
</tr>
<tr>
<td>1/2</td>
<td>Hepatocellular carcinoma</td>
<td>TRACON</td>
<td>Nexavar</td>
<td>Dose escalation portion and single arm portion (up to 28)</td>
</tr>
<tr>
<td>1</td>
<td>Breast cancer</td>
<td>UAB</td>
<td>Afinitor and Femara</td>
<td>Dose escalation portion and single arm portion (up to 35)</td>
</tr>
<tr>
<td>1</td>
<td>Lung cancer</td>
<td>UAB</td>
<td>Taxol, Carboplatin and Avastin</td>
<td>Dose escalation (18)</td>
</tr>
</tbody>
</table>

### Completed Clinical Trials of TRC105

<table>
<thead>
<tr>
<th>Phase</th>
<th>Indication</th>
<th>Sponsor</th>
<th>Companion Treatment</th>
<th>Design (Number of Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Solid tumors</td>
<td>TRACON</td>
<td>None</td>
<td>Dose escalation (50)</td>
</tr>
<tr>
<td>1/2</td>
<td>Solid tumors</td>
<td>TRACON</td>
<td>Avastin</td>
<td>Dose escalation portion and single arm portion (38 total)</td>
</tr>
<tr>
<td>2</td>
<td>Glioblastoma</td>
<td>TRACON</td>
<td>Avastin</td>
<td>Single arm (22)</td>
</tr>
<tr>
<td>1</td>
<td>Breast cancer</td>
<td>TRACON</td>
<td>Xeloda</td>
<td>Dose escalation (19)</td>
</tr>
<tr>
<td>1</td>
<td>Prostate cancer</td>
<td>NCI</td>
<td>None</td>
<td>Dose escalation (21)</td>
</tr>
<tr>
<td>2</td>
<td>Bladder cancer</td>
<td>NCI</td>
<td>None</td>
<td>Single arm (13)</td>
</tr>
<tr>
<td>2</td>
<td>Hepatocellular carcinoma</td>
<td>NCI</td>
<td>None</td>
<td>Single arm (11)</td>
</tr>
<tr>
<td>2</td>
<td>Ovarian cancer</td>
<td>TRACON</td>
<td>None</td>
<td>Single arm (23)</td>
</tr>
<tr>
<td>2*</td>
<td>Renal cell carcinoma (all histologies)</td>
<td>NCI</td>
<td>Avastin</td>
<td>Randomized (62)</td>
</tr>
<tr>
<td>2</td>
<td>Choriocarcinoma</td>
<td>TRACON</td>
<td>Avastin</td>
<td>Single patient (2)</td>
</tr>
<tr>
<td>2*</td>
<td>Glioblastoma</td>
<td>NCI</td>
<td>Avastin</td>
<td>Randomized (101)</td>
</tr>
</tbody>
</table>

* Each of these trials was designed with a Phase 1 open-label portion, which demonstrated that the recommended single agent dose of TRC105 could be administered in combination with the approved dose of the companion VEGF inhibitor.

### Ongoing Clinical Trials of TRC105

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

We have initiated dosing in a randomized multicenter international Phase 3 clinical trial of TRC105 following SPA agreement 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 progression-free survival (PFS) as assessed by RECIST 1.1 with overall survival as a secondary endpoint. The trial is designed to enroll 124 patients to provide greater than 80% power to determine an improvement in median PFS from 4.0 to 7.3 months using a two-tailed alpha of 0.05, and includes an adaptive design, whereby the conditional power
determined at the time of interim analysis may dictate an increase in the sample size to a total of 200 patients or the enrollment of 100 additional patients with cutaneous disease only. We expect the interim analysis to be completed in the first half of 2018.

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

We are conducting a two-part multicenter international Phase 2 clinical trial of TRC105 in combination with Inlyta, an approved VEGF inhibitor, in patients with advanced or metastatic renal cell carcinoma (RCC). We have completed enrollment of Part 1 of the trial, which was conducted at five sites in the United States and enrolled 18 patients, and are currently enrolling patients in Part 2 of the trial.

Data were presented at the European Society for Medical Oncology (ESMO) 2016 Congress for the updated results from the Phase 1b clinical trial combining TRC105 with Inlyta in patients with advanced or metastatic RCC. Median progression free survival (PFS) of 11.3 months was observed in all RCC patients in the study, including those patients with clear cell RCC, the most prevalent form of RCC. An objective response rate (ORR) of 29% was also seen in the trial. For comparative purposes, median PFS observed in the large subgroup of VEGFR TKI-refractory patients treated with Inlyta (n=194) in the Inlyta AXIS Phase 3 study in second line clear cell RCC patients (a separate trial) was 4.8 months and ORR was 11.3%.

**Maximum percentage change in target lesion size in renal cell carcinoma patients treated with TRC105 and Inlyta**

![Graph showing percentage change in target lesion size](image)

Based on the tolerability and anti-tumor activity observed in Part 1 of the trial, Part 2 of the trial began enrollment in November 2014 and is expected to enroll 150 advanced clear cell renal cell carcinoma patients at approximately 50 sites in the United States and Europe to compare TRC105 in combination with Inlyta to single agent Inlyta. The patients are randomly allocated in equal numbers to the two treatment arms, and the primary endpoint of Part 2 of the trial is progression-free survival as assessed by RECIST 1.1. We expect to complete enrollment and we expect to announce top line data in the second half of 2017.

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

We are conducting 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 ongoing at 129 weeks of treatment 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) is similar to the PFS expected for Votrient alone, based on data from the Votrient PALETTE Phase 3 trial in soft tissue sarcoma. Of the 81 patients enrolled in Parts 1 and 2 of the trial, five of the patients had angiosarcoma. An additional group of 13 angiosarcoma patients were then enrolled, nine patients which were
treated initially with single agent TRC105 followed by the combination of TRC105 and Votrient at progression. We are currently enrolling an additional cohort of up to 13 angiosarcoma patients while our Phase 3 study is undergoing the approval process at the participating sites.

In November 2016, data were presented at the Connective Tissue Oncology Society (CTOS) annual meeting for the 18 angiosarcoma patients treated with either the combination of TRC105 and Votrient, or with single agent TRC105 followed by combination of TRC105 and Votrient. For the initial five angiosarcoma patients enrolled in the original Phase 1b/2 clinical trial, the median progression-free survival (mPFS) is greater than 16.6 months. For the nine chemotherapy-refractory angiosarcoma patients treated with the combination of TRC105 and Votrient, three of whom had also previously progressed on Votrient treatment (and includes the initial five patients), mPFS is 5.6 months. Three of the nine patients remain on treatment, including two patients with durable complete responses (CRs), on treatment for 23 and 30 months, respectively, as of February 28, 2017. For comparison, mPFS with single agent Votrient was 3.0 months with no CRs in a previously completed retrospective analysis of 40 chemotherapy-refractory and Votrient-naive angiosarcoma patients. An additional group of nine angiosarcoma patients was enrolled and treated initially with single agent TRC105 followed by the combination of TRC105 and Votrient at progression. The mPFS in these nine patients treated initially with single agent TRC105 was similar to the mPFS reported in late-stage trials of single agent VEGF inhibitors, including Votrient and Nexavar. Four of the nine patients remain on study with either single agent TRC105 or the combination of TRC105 and Votrient, including one patient with a partial response. 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 2 Clinical Trial of TRC105 with or without Avastin in Patients with GTN, including Choriocarcinoma

We initiated a Phase 2 multicenter international clinical trial that employs a sequential treatment design in 2016, whereby patients will receive initially TRC105 as a single agent, and will also have the opportunity to receive TRC105 in combination with Avastin if they do not respond to single agent TRC105. The trial is designed to enroll 30 patients with GTN, including choriocarcinoma, placental site trophoblastic tumor (PSTT) and epithelioid trophoblastic tumor (ETT). Patients will be enrolled who are refractory to at least one prior multiagent chemotherapeutic regimen and the primary endpoint will be overall response rate as assessed by β-hCG for choriocarcinoma and by a combination of β-hCG and RECIST 1.1 for PSTT and ETT. We expect that positive data from this trial could be registration enabling. We expect top line data in the second half of 2018.

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

NCI is conducting a two-part Phase 2 clinical trial of TRC105 in combination with Nexavar, an approved VEGF inhibitor, in up to 42 patients with hepatocellular carcinoma. Part 1 of the trial was completed following the enrollment of 20 patients with hepatocellular carcinoma, 15 of which were evaluable by RECIST 1.1, and Part 2 of the trial was initiated in the third quarter of 2014 and is expected to enroll up to 23 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. Data reported at the American Society of Clinical Oncology (ASCO) annual meeting in June 2015 indicated that TRC105 was well tolerated at all doses tested (3, 6, 10 and 15 mg/kg) in combination with approved doses of Nexavar. As shown in the figure below, anti-tumor activity was noted, including reductions in tumor burden in the majority of treated patients, and partial response by RECIST 1.1 in four of the ten patients (40%) with measurable disease treated at the highest two dose levels of TRC105 (10 mg/kg or 15 mg/kg dosed)
once every two weeks). This response rate exceeded the response rate reported for Nexavar in its pivotal Phase 3 trial of 2%, as assessed by RECIST 1.1. The primary endpoint of Part 2 of the trial is overall response rate as assessed by RECIST 1.1. We expect the NCI to publish trial results in a peer reviewed journal in 2017.

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 2 study of TRC105 in hepatocellular carcinoma in 2016, as described below.

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

We initiated dosing in a Phase 1/2 clinical trial of TRC105 in combination with Nexavar, which is approved for the treatment of hepatocellular carcinoma, in patients with advanced or metastatic hepatocellular carcinoma in 2016. Prior completed clinical trials indicate that 10 mg/kg of TRC105 given weekly for four doses and then given every other week at 15 mg/kg is well tolerated with Votrient or with Inlyta, and Part 1 of the trial will determine whether this dose and schedule of TRC105 can be administered safely concurrently with Nexavar. Part 2 of the trial is expected to enroll up to 21 patients with advanced or metastatic hepatocellular carcinoma to determine the overall response rate, progression-free survival and overall survival following treatment with the recommended Phase 2 dose of TRC105 determined from Part 1 of the trial given concurrently with Nexavar. We expect to have top line data in the first half of 2018.

**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**

The University of Alabama, Birmingham Cancer Center, or 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 have top line data in the first half of 2018.
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 is to determine whether TRC105 can be safely administered concurrently with Taxol, carboplatin and Avastin. Up to 18 patients are expected to be treated with TRC105 concurrently with Taxol, carboplatin and Avastin. Secondary endpoints include pharmacokinetics, overall response rate by RECIST 1.1, progression-free survival and overall survival. We expect to have top line data in the second half of 2017.

**Completed Clinical Trials of TRC105**

**Phase 2 Randomized Clinical Trial of TRC105 with Avastin in Patients with Glioblastoma**

NCI sponsored a two-part Phase 2 clinical trial in patients with glioblastoma that included more than 50 sites in the United States. Part 1 of the trial was a dose escalation study of TRC105 in combination with Avastin in 12 patients and completed enrollment in January 2014. In Part 2 of the trial, 101 glioblastoma patients who received chemotherapy or radiation therapy and had not been treated previously with Avastin or another VEGF inhibitor were randomized in equal proportions to receive TRC105 and Avastin or Avastin alone. The primary endpoint was a three month improvement in PFS from the expected value of 3.45 for single agent Avastin. Top-line data indicate that the combination of TRC105 and Avastin did not improve median PFS versus single agent Avastin. However the combination was associated with a non-significant increase in overall survival. Detailed data and correlative analyses are expected to be presented at an oncology conference in 2017.

**Phase 1 First-in-Human Clinical Trial of TRC105 in Patients with Advanced and Treatment-Resistant Cancer**

We conducted a Phase 1, single agent, first-in-human ascending dose clinical trial evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and anti-tumor activity of TRC105 in patients with advanced solid tumors. The primary endpoint of the trial was to determine the recommended dose of TRC105 for Phase 2 clinical trials and assess overall safety and tolerability. Secondary endpoints included analysis of TRC105 distribution in the blood, assessment of whether antibodies were made in response to treatment with TRC105 and assessment of preliminary signs of antitumor activity. Given the limited number of patients in this clinical trial, no statistical analyses were performed. Fifty patients were treated with escalating doses of TRC105 until cancer progression or unacceptable toxicity was reached using a standard dose escalation design at dose levels of 0.01, 0.03, 0.1, 0.3, 1, 3, 10 and 15 mg/kg given weekly or every two weeks. The maximum tolerated dose was exceeded at 15 mg/kg given weekly due to anemia, an expected adverse event of TRC105 treatment. TRC105 exposure increased with increasing dose, and continuous serum concentrations that saturate endoglin receptors were maintained at 10 mg/kg given weekly and 15 mg/kg every two weeks. The safety profile was distinct from that of VEGF inhibitors, and the adverse effects of hypertension and proteinuria seen commonly with VEGF inhibitors were rarely observed with TRC105. Pulmonary edema and low platelet counts, which are side effects of other inhibitors of the endoglin pathway, were not observed. Lastly, patients at the 10 mg/kg and 15 mg/kg dose levels were observed to have dilated blood vessels in the skin or mucosal membranes, similar to those in patients with Osler-Weber-Rendu syndrome, indicating inhibition of the endoglin pathway. Results of this clinical trial were published in Clinical Cancer Research in 2012.

**Phase 2 Compassionate Use Clinical Trials of TRC105 with Avastin in Patients with GTN**

We completed three single patient Phase 2 clinical trials of TRC105 in combination with Avastin, in two women with choriocarcinoma and one man with Epithelioid Trophoblastic Tumor (ETT), which are forms of GTN. Choriocarcinoma is a rare tumor of reproductive tissue that is typically vascular and may highly express endoglin on the tumor tissue. Data were reported at the Annual Meeting of the Society of Gynecologic Oncology in 2016 in one patient who had persistent and unresectable metastatic choriocarcinoma that had recurred despite multiple treatments, including laparoscopic hysterectomy, five prior chemotherapy regimens and autologous stem cell transplant. The patient was treated with TRC105 dosed 10 mg/kg weekly in combination with Avastin dosed 10 mg/kg every other week. The patient completed 9 cycles (36 weeks) of treatment and has now been off study for over 24 months with an ongoing durable complete response. Beta human chorionic gonadotropin (β-hCG), a known and reliable marker of disease burden in choriocarcinoma, normalized during the fourth cycle of treatment. A second patient also with refractory and unresectable metastatic choriocarcinoma was treated with TRC105 and Avastin and did not respond to treatment. A male patient with refractory ETT did not respond to treatment with single agent TRC105 or the combination of TRC105 and Avastin.

**Phase 1/2 Clinical Trial of TRC105 with Avastin in Patients with Advanced and Treatment-Resistant Cancer**

We completed a Phase 1/2 ascending dose trial evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and anti-tumor activity of TRC105 in combination with an approved dose of Avastin in patients with advanced and treatment-resistant
solid tumors. The primary endpoint of the trial was to determine the recommended dose of TRC105 to be used in combination with Avastin for Phase 2 clinical trials and assess overall safety and tolerability of the combination. Secondary endpoints included analysis of TRC105 distribution in the blood, assessment of whether antibodies were made in response to treatment with TRC105 and assessment of preliminary evidence of improved anti-tumor activity when TRC105 was combined with Avastin. Given the limited number of patients in this clinical trial, no statistical analyses were performed. Thirty-eight patients primarily with colorectal and ovarian cancer were treated with escalating doses of TRC105 until cancer progression or unacceptable toxicity was reached using a standard dose escalation design at dose levels of 3, 6, 8 and 10 mg/kg given weekly, in combination with an approved dose of Avastin. TRC105 and Avastin were generally well tolerated when dosed together at their recommended single agent doses (10 mg/kg each) when the initial dose of TRC105 was delayed by one week and divided over two days to reduce the frequency and severity of headache. The concurrent administration of Avastin and TRC105 did not otherwise appear to increase the frequency or severity of known toxicities of TRC105 or Avastin. Pharmacokinetic studies indicated that treatment with Avastin increased endoglin expression on endothelium, a finding that was consistent with preclinical studies indicating endoglin may allow continued angiogenesis despite inhibition of the VEGF pathway. This finding provides support for targeting angiogenesis with endoglin antibodies in combination with VEGF inhibitors. Pharmacokinetic studies also indicated that serum levels of TRC105 were continuously present at concentrations above levels needed to inhibit endoglin function. Antibodies to TRC105 were detected in two patients and were not associated with clinical effects. Biomarker studies indicated increased blood levels of platelet-derived growth factor, or PDGF, a soluble protein that plays a significant role in angiogenesis, in patients treated with TRC105 in combination with Avastin. Several patients, including patients with colorectal cancer and ovarian cancer whose cancer had previously progressed on Avastin or small molecule VEGF inhibitors, experienced responses, including ten partial responses as assessed by Choi criteria, two of which were also partial responses as assessed by RECIST 1.1.

The best response by maximum percent change decrease in target lesion size of each of 30 patients enrolled in the trial with measurable disease who underwent efficacy assessment is noted in the figure below, and patients who received prior treatment with at least one VEGF inhibitor are indicated by a star. Of 25 evaluable patients treated previously with VEGF inhibitors, 16 patients (64%) had stable disease, of whom two patients (8%) had partial responses as assessed by RECIST 1.1. Ten patients who received prior VEGF treatment (40%) had a partial response by Choi criteria and are denoted with a solid triangle and a star in the figure below. Six patients (24%) with responses by Choi criteria or RECIST 1.1 remained without cancer progression for longer than during their prior VEGF inhibitor therapy, and are therefore considered to have durable responses.

Maximum percentage change in target lesion size in cancer patients treated with TRC105 and Avastin

The six patients with reductions in tumor burden, who were partial responders as assessed by RECIST 1.1 or Choi criteria, and remained without cancer progression for longer than during their prior VEGF inhibitor therapy, are profiled further in the table below.
### Phase 1 Clinical Trial of TRC105 with Xeloda in Patients with Metastatic Breast Cancer

We completed a Phase 1 ascending dose clinical trial evaluating the safety, tolerability, pharmocokinetics and anti-tumor activity of TRC105 in combination with Xeloda. The primary endpoint of the trial was to determine the recommended dose of TRC105 to be used in combination with Xeloda for Phase 2 clinical trials and to assess overall safety and tolerability of the combination. Secondary endpoints included analysis of TRC105 distribution in the blood, assessment of whether antibodies were made in response to treatment with TRC105 and assessment of preliminary evidence of improved anti-tumor activity when TRC105 was combined with Xeloda. Given the limited number of patients in this clinical trial, no statistical analyses were performed. Nineteen patients, primarily with metastatic breast cancer, were treated with escalating doses of TRC105 until cancer progression or unacceptable toxicity was reached using a standard dose escalation design at dose levels of 7.5 and 10 mg/kg given weekly, in combination with the recommended single agent dose of Xeloda of 1,000 mg/m² given twice daily for two weeks followed by a one week rest period. TRC105 and Xeloda were generally well tolerated when dosed together at their recommended single agent doses. The concurrent administration of TRC105 with Xeloda did not otherwise appear to increase the frequency or severity of expected toxicities of TRC105 or Xeloda. Pharmacokinetic studies indicated continuous serum levels of TRC105 at doses above target concentrations at both TRC105 dose level. Antibodies to TRC105 were detected in one patient. Several patients demonstrated evidence of clinical benefit, including one patient with metastatic breast cancer who achieved a partial response as assessed by RECIST 1.1.

### Phase 2 Randomized Clinical Trial of TRC105 with Avastin in Patients with Renal Cell Carcinoma

NCI completed enrollment of a Phase 2 clinical trial to study the activity of TRC105 in combination with Avastin, compared to treatment with Avastin alone, in patients with renal cell carcinoma that included non-clear histology. The NCI-sponsored trial in renal cell carcinoma included approximately 20 centers in the United States and enrolled patients with all histologic types of renal cell carcinoma who had received as many as four prior systemic therapies, including as many as four prior VEGF inhibitors, and had not been treated with Avastin previously. The trial was designed to randomize 88 total patients in equal proportions to receive TRC105.

### Summary of patients with durable responses

<table>
<thead>
<tr>
<th>Patient Demographic</th>
<th>Primary Site of Cancer</th>
<th>Number of Prior Cancer Regimens</th>
<th>Last Prior VEGF InhibitorContaining Treatment</th>
<th>Duration of Last Prior VEGF InhibitorContaining Treatment (days)</th>
<th>Duration of TRC105 + Avastin Treatment (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-year-old woman</td>
<td>Ovarian</td>
<td>8</td>
<td>pegylated liposomal doxorubicin + Avastin</td>
<td>126</td>
<td>162</td>
</tr>
<tr>
<td>71-year-old woman</td>
<td>Ovarian</td>
<td>5</td>
<td>investigational treatment with small molecule VEGF inhibitor</td>
<td>141</td>
<td>218</td>
</tr>
<tr>
<td>66-year-old woman</td>
<td>Colorectal</td>
<td>7</td>
<td>Erbitux - cetuximab + Avastin</td>
<td>31</td>
<td>162</td>
</tr>
<tr>
<td>81-year-old woman</td>
<td>Ovarian</td>
<td>6</td>
<td>Topotecan + Avastin</td>
<td>71</td>
<td>224</td>
</tr>
<tr>
<td>53-year-old man</td>
<td>Colorectal</td>
<td>2</td>
<td>5-fluorouracil + irinotecan + leucovorin + Avastin</td>
<td>33</td>
<td>861</td>
</tr>
<tr>
<td>55-year-old man</td>
<td>Colorectal</td>
<td>3</td>
<td>5-fluorouracil + irinotecan + leucovorin + Avastin</td>
<td>146</td>
<td>164</td>
</tr>
</tbody>
</table>

These collective data demonstrate that TRC105 is active with Avastin based on decreases of tumor size and durability of treatment in patients whose cancer progressed on prior treatment with Avastin or other VEGF inhibitors.

### Phase 2 Clinical Trial of TRC105 as a Single Agent or Combined with Avastin in Patients with Glioblastoma that Progressed on Prior Avastin Treatment

We completed a Phase 2 clinical trial evaluating the safety, tolerability, and anti-tumor activity of TRC105 in combination with Avastin in patients with glioblastoma that progressed on prior initial treatment with combined chemotherapy and radiation therapy and subsequent treatment with Avastin. The primary endpoint of the trial was to determine median overall survival, and secondary endpoints included assessment of tolerability and determination of response rate and time to tumor progression. After an initial portion of the trial assessing the safety of TRC105 as a single agent, 16 patients were treated with TRC105 at 10 mg/kg given weekly with Avastin at 10 mg/kg given every two weeks until cancer progression or unacceptable toxicity was reached. The concurrent administration of TRC105 and Avastin did not appear to increase the frequency or severity of known toxicities of TRC105 or Avastin. Overall survival in the 16 patients treated with TRC105 and Avastin was 5.7 months, which was statistically longer than the overall survival of 4 month expected in this population specified in the protocol based on historical data. The majority of patients with Avastin-resistant glioblastoma who enrolled in the trial had cancer progression in fewer than four months on prior Avastin treatment, and median progression-free survival was two months following treatment with TRC105 and Avastin. No patient demonstrated an objective response. Future clinical trials will focus on enrolling patients with glioblastoma prior to Avastin treatment, when they may be more likely to be responsive to angiogenesis inhibition.
and Avastin or Avastin alone with the goal of demonstrating a 100% increase in progression-free survival. However, an interim analysis performed in September 2014 concluded that the trial was unlikely to achieve the primary endpoint, and enrollment was closed following the accrual of 62 patients. Data reported at the ASCO annual meeting in June 2015 by NCI indicated no statistical difference in progression free survival between patients treated with TRC105 and Avastin compared to patients treated with single agent Avastin.

Other Phase 1 and Phase 2 Clinical Trials of TRC105 in Cancer Patients

A Phase 1, single agent, ascending dose clinical trial sponsored by NCI enrolled 21 patients with metastatic and treatment-resistant prostate cancer and results were published in the British Journal of Urology in 2014. The primary endpoint of the trial was to determine the recommended dose of TRC105 to be used in Phase 2 clinical trials and to assess overall safety and tolerability. Secondary endpoints included analysis of TRC105 distribution in the blood, assessment of whether antibodies were made in response to treatment with TRC105 and assessment of preliminary evidence of improved anti-tumor activity. Given the limited number of patients in this clinical trial, no statistical analyses were performed. TRC105 was tolerated at 20 mg/kg every other week with a safety profile distinct from that of VEGF inhibitors. A significant induction of plasma VEGF was associated with CD105 reduction, suggesting anti-angiogenic activity of TRC105. An exploratory analysis showed a tentative correlation between the reduction of CD105 and a decrease in PSA velocity, suggestive of potential activity of TRC105 in the patients with metastatic castrate resistant prostate cancer. The data from this exploratory analysis suggested that rising VEGF level was a possible compensatory mechanism for TRC105-induced anti-angiogenic activity. A Phase 2 clinical trial of TRC105 sponsored by NCI enrolled 13 patients with advanced or metastatic bladder cancer that had progressed on prior treatment with chemotherapy. Results published in Clinical Genitourinary Cancer indicated TRC105 was well tolerated and did not improve 6-month PFS in heavily pretreated patients with advanced urothelial cell cancer. TRC105 pharmacodynamic effects, including a decreased level of Treg cells among CD4+ T cells, were noted.

A Phase 2 clinical trial sponsored by NCI enrolled 11 patients with advanced or metastatic hepatocellular carcinoma that had progressed on prior treatment with Nexavar. The primary endpoint of the trial was to determine the time to tumor progression. Data published in the United European Gastroenterology Journal indicated no grade 3 or grade 4 treatment-related toxicities. Most frequent toxicities were headache and nosebleeds. A total accrual of 27 patients was planned. However, in accordance with the study design, only 11 patients were enrolled. One patient had a confirmed partial response by RECIST and biologic response on MRI scan but the four-month PFS was insufficient to proceed to the second stage of the study.

Our Phase 2 clinical trial in 23 patients with advanced or metastatic ovarian cancer that had progressed on prior treatment with platinum chemotherapy treated with TRC105 at 10 mg/kg every week indicated limited anti-tumor activity, as evidenced by a minor tumor reduction in one patient and tumor marker reductions in several other patients. However, no patients achieved either of the dual primary endpoints of being free of tumor progression for at least six months or achieving a partial response as assessed by RECIST 1.1. Subsequent data from a Phase 1/2 clinical trial of TRC105 in combination with Avastin suggested advanced ovarian cancer patients were more likely to benefit from the combination treatment. These data are consistent with preclinical findings indicating that inhibition of the VEGF or endoglin pathway individually is less effective than inhibition of the VEGF and endoglin pathways simultaneously. Avastin was recently approved in the United States with chemotherapy for the treatment of ovarian cancer, and we expect to develop TRC105 in combination with Avastin and chemotherapy in this indication.

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

In clinical trials as of December 31, 2016, TRC105 has been administered to more than 500 patients and was generally well tolerated as a single agent and in combination with VEGF inhibitors. The most commonly reported adverse events related to TRC105 therapy, either alone or in combination, include 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, or infusion reaction. 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.

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, and 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
Translational Research

Studies of endoglin biology using choriocarcinoma cell lines indicate that higher levels of endoglin expression are associated with greater degrees of resistance to chemotherapy. Chemotherapy treatment also led to an increase in endoglin expression on choriocarcinoma cell lines. Serum endoglin and BMP levels were higher in pretreatment samples of women who developed GTN that was resistant to chemotherapy, with BMP levels showing a greater ability to predict resistance than the traditional scoring system that is routinely used to assess prognosis in GTN. We plan to assess BMP levels in patients with GTN and other tumor types as part of ongoing Phase 2 studies to determine if serum levels of this activating endoglin ligand will predict which patients are most responsive to TRC105 treatment. 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. Assessment of endoglin expression on archival tumor tissue from patients with soft tissue sarcoma did not indicate that tumor endoglin expression correlated with improved PFS following treatment with TRC105 and Votrient. Circulating tumor cells will be studied in the Phase 3 angiosarcoma trial to assess whether endoglin expression on tumor cells at the time of treatment initiation correlate with efficacy.

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 a drug fragment derived from the same full length antibody from which Avastin was derived. In 2016, 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 1/2 PAVE clinical trial of DE-122 in wet AMD patients and top-line data are expected in 2017. In addition, we expect Santen to initiate the Phase 2 AVANTE clinical trial of DE-122 in wet AMD in 2017 and that this Phase 2 clinical trial will test DE-122 in patients receiving treatment with a VEGF inhibitor.

**Role of Endoglin Antibodies in Fibrotic Disease Treatment**

**Overview of Fibrosis**

Fibrosis is a condition characterized by the harmful buildup of excessive fibrous tissue leading to scarring and ultimately organ failure. It is caused by the abnormal secretion of fibrous proteins, including collagen, by fibroblasts, which are cells that are present in all skin and connective tissue. As a result, fibrosis can affect almost any organ. Endoglin is expressed on fibroblasts, and its expression may be important to cell function. Increased endoglin expression has been demonstrated on fibroblasts from patients with heart failure and may play a role in the development of cardiac fibrosis as well as fibrotic diseases involving other organs. Examples of fibrotic diseases that may be initial target indications for endoglin antibodies include NASH, IPF, and neurofibromatosis.

NASH is a common and serious chronic liver disease caused by excessive fat accumulation in the liver, or steatosis, which induces inflammation and may lead to progressive fibrosis and cirrhosis, followed by eventual liver failure and death. NASH is considered to be the second leading cause of hepatocellular carcinoma, and its prevalence is increasing. NASH is believed to be one of the most common chronic liver diseases worldwide, with an estimated prevalence of 2% to 5% of the general adult population in the United States, and an estimated prevalence of 2% to 3% in Europe and other developed countries. There are currently no therapeutic products approved for the treatment of NASH. Current treatment options are limited to off-label therapies. Given the lack of available treatment options, we believe that there is a significant unmet need for a novel therapy for NASH, particularly in those patients with advanced fibrosis and cirrhosis.

IPF is a disease characterized by progressive fibrosis of the lungs, which leads to their deterioration and destruction. The cause of IPF is unknown. Research suggests that there are between 40,000 and 80,000 diagnosed cases of IPF in the United States, with similar prevalence in the European Union. Esbriet (pirfenidone) is approved for the treatment of mild to moderate IPF in the United States, the European Union and other countries. OFEV (nintedanib) has been approved for the treatment of IPF in the United States and has been submitted for regulatory approval in the European Union.

Cutaneous neurofibromatosis is a rare genetic disorder characterized by tumors of the skin, nervous, system and skeleton, for which there is no approved treatment. The prevalence of the disease in the United States is approximately 100,000 patients and affected patients are predisposed to develop certain cancers.

**The Role of Endoglin in Fibrosis**

Preclinical and clinical data identified increased endoglin expression on fibroblasts in the left ventricle of patients with heart failure and demonstrated that inhibiting endoglin limits TGF-β signaling and production of fibrotic proteins by human cardiac fibroblasts. Inhibiting endoglin function decreased cardiac fibrosis, preserved left ventricular function, and improved survival in mouse models of heart failure. In the figure below, wild-type mice (“WT” in the figure below) that contain both copies of the endoglin gene develop fibrosis, as evidenced by collagen deposition darkly stained in the figure below, at four and ten weeks following the induction of heart failure. However, in endoglin-deficient mice fibrosis was decreased at four and ten weeks, as evidenced by the lack of dark stain (“Eng +/-” in the figure below). Survival also improved in endoglin-deficient mice. Studies using TRC105 demonstrated that TRC105 reversed cardiac fibrosis in mouse models. These data were published in *Circulation* and the *Journal of the American Heart Association*. Subsequent preclinical research in mouse models indicated that antibodies to endoglin inhibit liver fibrosis. In
Data were presented at the American Association for the Study of Liver Diseases Annual Meeting from two separate liver fibrosis models. The data presented showed treatment with an endoglin antibody significantly decreased the percentage of the liver fibrosis area induced by carbon tetrachloride, and treatment with endoglin antibodies also significantly reduced the non-alcoholic fatty liver disease (NAFLD) activity score in a model of NASH. Endoglin antibodies demonstrated hepatoprotective, anti-inflammatory and anti-fibrotic effects. In addition, an endoglin antibody that competitively inhibited bone morphogenic protein (BMP) binding to endoglin more effectively reduced the NAFLD activity score, suggesting that inhibition of BMP function is an important mechanism of action of endoglin antibodies in models of fibrosis. However, studies to date have not validated BMP signal inhibition as the mechanism of action of TRC105 in these models. Notably, a patient with cutaneous neurofibromatosis treated with TRC105 and a VEGF inhibitor in an oncology trial demonstrated reduction in the cutaneous lesions that characterize the disease.

Cardiac Fibrosis in Wild-Type Mice and Endoglin-Deficient Mice

TRC205 and TRC105 Development in Fibrotic Diseases

We may study TRC105 in additional patients with cutaneous neurofibromatosis. We have also used our knowledge of the endoglin pathway to design and evaluate a fully humanized and deimmunized endoglin antibody called TRC205. We have cloned this antibody and demonstrated high affinity binding to human endoglin. We are currently evaluating options for TRC205 which may include filing an IND or a corporate partnership.

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 antimetabolite 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:

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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 at the American Society of Hematology (ASH) annual meeting in December 2014. Anti-tumor activity, including partial response, was noted in patients with lymphoma and chronic lymphocytic leukemia, including patients treated previously with Fludara. 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:

<table>
<thead>
<tr>
<th>Disease Type</th>
<th>Response</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glioblastoma</td>
<td>Partial</td>
<td>14 months</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>Stable</td>
<td>3 or more</td>
</tr>
<tr>
<td>Head and neck cancer</td>
<td>Stable</td>
<td>3 or more</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>Stable</td>
<td>3 or more</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>Stable</td>
<td>3 or more</td>
</tr>
<tr>
<td>Endometrial cancer</td>
<td>Partial</td>
<td>3 or more</td>
</tr>
<tr>
<td>Epithelial ovarian cancer</td>
<td>Stable</td>
<td>3 or more</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>Stable</td>
<td>3 or more</td>
</tr>
</tbody>
</table>

20
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 2016. There were no pharmacologic interactions between the two drugs and TRC102 target concentrations were achieved. Partial response was noted in patients with ovarian cancer, colorectal cancer, and squamous cell lung cancer. Based on these data, the trial was expanded to enroll 15 patient additional cohorts with ovarian, colorectal and lung cancer. The study includes assessment of biomarkers in tumor tissue that associate with BER activation that may predict which patients are most responsive to treatment with TRC102.

**Our Third Product Candidate - TRC253**

**TRC253 Development**

TRC253 (formerly JNJ-63576253) is a novel, orally bioavailable small molecule discovered and developed by Janssen Pharmaceuticals that is a potent, high affinity competitive inhibitor of the wild type androgen receptor (AR) and multiple AR mutations, including the F876L mutation, and is under development for the treatment of men with prostate cancer. The AR F876L mutation results in an alteration in the ligand binding domain that confers resistance to current AR inhibitors, including Xtandi® (enzalutamide) and ARN-509 (apalutamide). The IND for TRC253 was filed in late 2016 and we expect to initiate dosing in a Phase 1/2 trial in the first half of 2017.

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 will focus 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 F876L. AR mutations will be identified using circulating tumor DNA in a Phase 1/2 trial that will determine the recommended Phase 2 dose of TRC253, and then enroll two 30 patient cohorts in the Phase 2 portion of the study. One of the Phase 2 cohorts will consist of patients with the F876L mutation and one cohort will consist of patients with other mutations conferring resistance to Xtandi or other drugs. 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.

**TRC694 Pre-Clinical Development**

TRC694 (formerly JNJ-6420694) is a novel, potent, orally bioavailable inhibitor of NF-kB inducing kinase (NIK) with the potential to be first-in-class and was discovered by Janssen. Genetic alterations leading to stabilization of NIK are found in a subset of B-cell malignancies: multiple myeloma (approximately 12-20% of cases), mantle-cell lymphoma (approximately 17% of cases), diffuse large B-cell lymphoma (approximately 9-15% of cases), classic Hodgkin’s lymphoma and chronic lymphocytic leukemia. In pre-clinical studies, TRC694 selectively repressed non-canonical NF-kB gene expression and inhibited proliferation of cell lines with NIK dysregulation in vitro and in vivo. We anticipate completing formulation development and development of a companion diagnostic to enable patient-directed therapy and submitting an IND for TRC694 in 2018.

**Product Development Platform**

Our clinical operations, quality assurance and regulatory affairs groups are responsible for significant aspects of our clinical trials, including site selection, site qualification, site initiation, site monitoring, maintenance of the trial master file, regulatory compliance, drug distribution management, contracting and budgeting, database management, edit checks, query resolution, and clinical study report preparation. The use of this internal resource minimizes the cost associated with hiring CROs to manage clinical, regulatory and database aspects of the clinical trials that we sponsor. In our experience, this model has resulted in capital efficiencies and improved communication with clinical trial sites, which expedites patient enrollment and facilitates access to patient data compared to a CRO-managed model. We are leveraging this capital efficient model in our two recently initiated international clinical
trials, the Phase 2 clinical trial in GTN and the Phase 3 clinical trial in angi osarcoma. In addition, we have an experienced chemistry, manufacturing and controls group that complete our product development platform.

We have also been able to advance clinical development of TRC105 and TRC102 in a capital-efficient manner through our collaboration with NCI. TRC105 and TRC102 have been selected by NCI for funding of Phase 1 and Phase 2 development. This highly competitive program is designed to accelerate the development of promising oncology drugs that target novel anti-cancer pathways. Notably the NCI collaborated with Genentech Inc. during the development of Avastin on Phase 3 clinical trials of Avastin in lung cancer, breast cancer, ovarian cancer and renal cell carcinoma that were important elements of the resulting Avastin approval in these indications. Phase 2 clinical trials of both TRC102 and TRC105 are being performed in collaboration with NCI. If merited by Phase 2 data, we expect to fund initial 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.

**Collaboration and License Agreements**

**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 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.

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.

With respect to the NIK Program, Janssen maintains a right, which is exercisable within 90 days following the date on which we demonstrate clinical proof of concept with respect to the NIK Program, to negotiate for a period of six months for a reversion of the related rights in the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the NIK Program. If Janssen does not exercise its right of first negotiation, or, if after exercise of such right, Janssen and we are unable to reach an agreement on the terms of a reversion and exclusive license, and, in either case, we continue the development of the NIK Program, then we would be obligated to pay Janssen (i) development and regulatory based milestone payments totaling up to $60.0 million upon achievement of specified events, and (ii) royalties in the low single digits based on annual net sales of NIK 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 (a) 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, and (b) with respect to the NIK Program, upon us and Janssen entering into an exclusive license agreement following Janssen’s exercise of its right of first negotiation or, if Janssen’s right of first negotiation with respect to the NIK Program expires and we do not enter into an exclusive license agreement, upon the expiration of all our payment obligations to Janssen with respect of the NIK Program. We may also terminate a Program or 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 co-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, 2016, $3.0 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 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, 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

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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 an additional $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 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 three 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 two CRADAs governing the development of TRC105 in December 2010, or the 2010 CRADA, and January 2011, or the 2011 CRADA, respectively. The 2010 CRADA is with the Division of Cancer Treatment and Diagnosis of NCI, and the 2011 CRADA is 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 2010 CRADA, we are required to pay NCI $20,000 per clinical trial per year as well as expenses incurred by NCI in connection with carrying out its responsibilities under the 2010 CRADA, up to an aggregate maximum of $500,000 per year, as well as up to $5,000 per year for personnel-related expenses. At our discretion, we may also provide additional funding to support assays and other studies. In addition, we made a one-time payment of $20,000 to support regulatory filings. Under 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 2010 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 2010 CRADA and the 2011 CRADA, both agreements as amended, expiring on December 22, 2018 and January 28, 2021, respectively, and the TRC102 CRADA expiring on August 7, 2017. 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, the Company’s lead drug product candidate. Lonza has previously been providing TRC105 for clinical development on a batch by batch basis.

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. The TRC105 drug substance will be manufactured at a Lonza facility that has not previously manufactured TRC105, and we and Lonza are obligated to cooperate to transfer the TRC105 manufacturing process to the facility. 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, due to a force majeure event that prevents performance under the Manufacturing Agreement for at least six months, or if the parties fail to enter into an initial project plan within 90 days of the date of the Manufacturing Agreement (which period may be extended by mutual agreement of the parties). 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.

TRC205 drug substance and product is currently produced at research scale using standard antibody production methods. We expect to contract with a third-party manufacturer to prepare production-grade cell lines for the cGMP manufacture of TRC205 prior to initiating clinical trials.

TRC253 and TRC694 drug substance and product are currently produced at research scale manufactured through a standard chemical synthesis and may be obtained from multiple manufacturers.

**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 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. Acceleron Pharma Inc., Amgen, Inc., MedImmune LLC, OncoMed Pharmaceuticals Inc., Pfizer Inc., Regeneron Pharmaceuticals, Inc. and Roche AG are each developing non-VEGF angiogenesis inhibitors, which are in various phases of clinical development. Pfizer’s product candidate targets the endoglin co-receptor ALK1 and is in a Phase 1b clinical trial in combination with Stivarga in patients with colorectal carcinoma. Acceleron’s product candidate targets the endoglin ligand BMP and is in a Phase 2b
clinical trial in combination with Inlyta in patients with renal cell carcinoma and a Phase 1b clinical trial in combination with Nexavar in patients with hepatocellular carcinoma. 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. and AstraZeneca 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 castrate resistant prostate cancer. If TRC253 is approved, it could compete with other androgen receptor inhibitors such as Xtandi, ODM-201 and apalutamide. In addition to the therapies mentioned above, there are many generic chemotherapeutics and other agents commonly used to treat prostate cancer.

We are developing TRC694 for the treatment of multiple myeloma. If TRC694 is approved, it could compete with other NIK inhibitors that may be developed, as well as agents targeting other pathways in hematologic malignancies.

**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, which is in Phase 2 clinical development for administration in a single intraocular injection. If approved in combination with VEGF inhibitor treatment, DE-122 could compete with other angiogenesis inhibitors in development including Regeneron's antibody to Ang2, which entered Phase 2 development in 2016 in combination with Eylea.

**Fibrotic Disease Therapies**

If TRC205 is approved for the treatment of diseases characterized by fibrosis, including NASH, IPF, and neurofibromatosis (NF), we anticipate that TRC205 could compete with other therapies being developed for the same or similar indications. In addition, TRC205 would compete with therapies currently used off-label to treat fibrotic diseases.

**NASH**

There are currently no therapeutic products approved by the FDA for the treatment of NASH. Several marketed therapeutics are currently used off-label for this indication, such as insulin sensitizers (including metformin), antihyperlipidemic agents (including gemfibrozil), pentoxifylline and Ursodeoxycholic acid (ursodiol), but they have not been proven effective in the treatment of NASH. We are aware of several companies that have product candidates in Phase 3 clinical development for the treatment of NASH, including Genfit Corp. and Intercept Pharmaceuticals, Inc. In addition, we are aware of companies in Phase 2 clinical development for the treatment of NASH, including Conatus Pharmaceuticals Inc., Galmed Medical Research Ltd., Gilead Sciences, Inc., Immuron Ltd., Shire plc, Mochida Pharmaceutical Co., Ltd., NasVax Ltd., and Takeda Pharmaceutical Company Limited, and there are other companies with candidates in earlier stage programs.

**IPF**

Esbriet, which is marketed by InterMune, Inc., is approved for the treatment of mild to moderate IPF in the United States, the European Union and other countries. OFEV, which is marketed by Boehringer Ingelheim, is a VEGF inhibitor that is approved for the treatment of IPF in the United States and the European Union. There are at least eight product candidates in various stages of Phase 2 development being pursued by Biogen Idec., Bristol-Myers Squibb, Celgene Corporation, Fibrogen, Inc., Gilead, Janssen Pharmaceuticals Inc., Novartis AG and Sanofi S.A.

**NF**

There are no approved drugs for NF. MEK inhibitors are being studied in ongoing clinical trials.
Commercialization

We hold worldwide commercialization rights for our oncology and fibrotic disease product candidates (subject to certain rights held by Janssen for TRC253), 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, 2016, on a worldwide basis, includes 13 issued patents and allowed applications and 11 pending patent applications in the United States and 37 issued patents and allowed applications and 92 pending patent applications outside the United States with pending and issued claims relating to our product candidates. 22 of our issued US and foreign patents 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 2016 to 2035, 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 the TRC105 composition of matter in the United States, Japan, and Canada. The expected expiration date for these composition of matter patents is 2016, plus any extensions of term available under the applicable national law.

We hold issued patents covering the combination therapy of cancer with TRC105 and VEGF inhibitors in Australia, China, Eurasia, South Korea and Japan, an allowed application in Israel, and similar patent applications are pending in many other major jurisdictions worldwide, including the United States, Europe, Canada, Israel and India. The expected expiration date for these method-of-use patents is 2030, exclusive of possible patent term extensions.

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

We have filed an international application and a US utility application directed to uses of anti-endoglin antibodies for treating fibrosis. The expected expiration date for any patent that may arise from these applications is 2035, 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, Japan, South Korea, Mexico, Russia, Singapore, South Africa, Ukraine and the United Kingdom. We also have pending applications in other jurisdictions, including Brazil, China, Europe, Hong Kong, India, Israel and Norway. The expected expiration date for these patents is 2027, plus any extensions of term available under national law.

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 have filed a patent application on further combinations of TRC102 that is pending in the United States and Europe. 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 PCT application and US patent application 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 extension. We also hold a license to patent applications, filed in various jurisdictions, which are directed to methods for determining resistance to androgen receptor therapy. The expected expiration date for patents issuing from these applications is 2033.

TRC694 Patent Coverage

We hold an exclusive license to a PCT application as well as various non-PCT applications covering TRC694 and methods of using TRC694. The expected expiration date for patents issuing from these applications is 2036. We also hold a license to provisional applications covering analogs of TRC694 and their uses. These applications, if issued, are expected to expire in 2037.
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
Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations. Phase 1 clinical trials may be conducted in a limited number of patients, but are usually conducted in healthy volunteer subjects for indications other than oncology. The drug candidate is initially tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics.

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

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

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a 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 fees for commercial manufacturing establishments and 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.
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.

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, 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.
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. We cannot predict the effect of any healthcare reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.
Adoption of new legislation at the federal or state level could further limit reimbursement for pharmaceuticals, including our product candidates if approved.

Foreign Regulation

In addition to regulations in the United States, we 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 obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we 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.

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, 2016, we had 26 full-time employees and one part-time employee, 20 of whom are involved in research, development or manufacturing, and five 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 8910 University Center Lane, Suite 700, 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 $27.0 million and $24.4 million for the years ended December 31, 2016 and 2015, respectively. At December 31, 2016, we had an accumulated deficit of $85.6 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 planned 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.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, including our planned and future clinical trials of TRC105 and TRC253.

At December 31, 2016, we had cash, cash equivalents and short-term investments totaling $44.4 million. Based upon our current operating plan, we believe that our existing cash will enable us to fund our operating expenses and capital requirements for at least the next 12 months. 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 trial in angiosarcoma and Phase 2 trial in GTN. In addition, we recently licensed two early-stage oncology programs from Janssen Pharmaceutica N.V. (Janssen) and are subject to obligations to develop the programs through clinical proof of concept. While we concurrently received a $5.0 million equity investment from an affiliate of Janssen that will help fund the costs of the development activities, we anticipate that we will need additional funds to complete clinical proof of concept for the programs and, to the extent we retain the programs afterwards, to advance the programs through later stages of development.
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.

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 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.*

In January 2017, we entered into an amended loan and security agreement with SVB to borrow up to $8.0 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. In addition, while we have the right to terminate our long-term manufacturing agreement with 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, enrollment was closed for two of our Phase 2 clinical trials sponsored by NCI following interim analyses that did not meet the requirements for continuing enrollment. 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 the 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 inherent safety and efficacy traits 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. 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 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.

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 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 has never been tested in humans, and it is possible that we could observe AEs in our planned Phase 1 study of TRC253 that would preclude further development or cause Janssen to not exercise its option to regain rights to the program.

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
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, such as angiosarcoma and GTN, that express high levels of endoglin. 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. 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 TR253 and TRC694 and expect to develop companion diagnostic tests in prostate cancer and myeloma, respectively, to improve selection of susceptible patients. 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.

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.

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 US and EU 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 have withdrawn our previously filed application for orphan drug designation in gestational trophoblastic neoplasia (GTN). However, we may refile the application in the future. 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. 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 and TRC694, is highly cyclical, with periods of relatively abundant capacity alternating with periods in which there is little available capacity. If any need we have 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 Sales AG, or 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, 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 to proof of concept for TRC253.

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 will need to transfer 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, due to a force majeure event that prevents performance under the agreement for at least six months, or if we and Lonza fail to enter into an initial project plan within 90 days of executing the agreement (which period may be extended by agreement of the parties).

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 one ongoing clinical trial involving TRC105 and four clinical trials involving TRC102. The University of Alabama, Birmingham Cancer Center, or UAB, is also funding a trial with TRC105 in breast 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 there is a failure in a clinical trial sponsored by a third party sponsor due to poor design of the trial, errors in the way the clinical trial is executed or any other reason, or if the sponsor fails to comply with applicable regulatory requirements or 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. The failure to maintain our agreement with Santen or the failure of Santen to perform its obligations under the agreement, 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 have limited control over the amount and timing of resources that Santen will dedicate to these 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, including:

• Santen may not comply with applicable regulatory requirements with respect to developing or commercializing products under the license agreement, which could adversely impact development, regulatory approval and eventual commercialization of such products;
• we and Santen could disagree as to future development plans and Santen may delay initiation of clinical trials or stop a future clinical trial;
• there may be disputes between us and Santen, 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 endoglin antibodies using our technology in the field of ophthalmology, and/or costly litigation or arbitration that diverts our management’s attention and resources;
• Santen 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 our endoglin antibodies, including TRC105, in non-ophthalmology indications;
• business combinations or significant changes in Santen’s business strategy may adversely affect Santen’s ability or willingness to perform its obligations under the license agreement;
• Santen may not properly maintain or defend our intellectual property rights in the field of ophthalmology 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 may be reduced or eliminated based upon Santen’s and our ability to maintain or defend our intellectual property rights.

The license agreement is subject to early termination, including through Santen’s right to terminate without cause upon advance notice to us. If the agreement is terminated early, we may not be able to find another collaborator for the commercialization and further development of our endoglin antibodies for ophthalmology indications on acceptable terms, or at all, and we may otherwise be unable to pursue continued development on our own for these 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.

We may not be successful in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize our 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. 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, 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 impacted 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, 2016, we are the exclusive licensee of six issued U.S. patents, one pending U.S. patent application, and ten issued non-U.S patents and four pending non-U.S. patent applications relating to “Anti-Endoglin Monoclonal Antibodies and their use
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 by patents exclusively in-licensed from Roswell Park Cancer Institute. TRC102 is protected by patents exclusively licensed from Case Western. TRC253 and TRC694 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 and pricing 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. and Acceleron Pharma 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. For example, the recent approval of Opdivo (nivolumab) and Cabometyx (cabozantinib) have decreased the use of Inlyta as a second line treatment in renal cell carcinoma.
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 obsolesent, 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 an 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 new 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 January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law, however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act 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 will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama 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. 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. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels-directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. 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.

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;
- 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 United States are unable to successfully manage these risks associated with international operations, the market potential for our product candidates outside the United 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. 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. In addition, Janssen has an option to negotiate with us to reacquire rights to TRC694 following the completion of clinical proof of concept, which may or may not result in an out-license of the product candidate back to Janssen. If we are unable to retain existing product candidates and add additional product candidates to our pipeline, 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, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, 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.

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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, and its implementing regulations, 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, 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 Affordable Care Act, 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; 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, amends 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 False Claims Act.

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/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational

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harm, exclusion from governmental health care programs, 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, 2016, we had federal and California net operating loss carryforwards, or NOLs, of approximately $69.1 million and $44.0 million, respectively, which expire in various years beginning in 2030, if not utilized. As of December 31, 2016, we had federal and California research and development and Orphan Drug tax credit carryforwards of approximately $3.6 million and $1.1 million, respectively. The federal research and development 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 that it is determined that we have in the past experienced additional ownership changes, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

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

Despite the implementation of security measures, our internal computer systems and those of our current or future contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, third parties that are also sponsoring clinical trials involving our product candidates, such as NCI and Case Western, could experience similar events relating to their computer systems, which could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

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.

Prior to our initial public offering which was completed in 2015, there was no public market for our common stock. 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 is likely 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;
- 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.

**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, 2016, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned over 50% 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 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 8910 University Center Lane, Suite 700, San Diego, California 92122, in a facility we lease encompassing 9,339 square feet of office space. Our lease expires in April 2017. On December 12, 2016, we entered into a new lease with respect to the property located at 4350 La Jolla Village Drive, Suite 800, in San Diego, California. The new lease covers approximately 10,458 square feet of general office space and has an initial term of five years, with an option for an additional five-year term. We anticipate that the new lease will commence on or about May 1, 2017, at which point the associated office space will serve as our principal executive offices.

Item 3. Legal Proceedings.

We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. 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.
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on The NASDAQ Global Market on January 30, 2015 under the symbol “TCON”. Prior to January 30, 2015, there was no public market for our common stock. The following table presents the high and low per share prices for our common stock during the periods indicated as reported on The NASDAQ Global Market.

<table>
<thead>
<tr>
<th>Year</th>
<th>Period</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>First quarter</td>
<td>$9.24</td>
<td>$5.88</td>
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<tr>
<td></td>
<td>Second quarter</td>
<td>7.90</td>
<td>4.26</td>
</tr>
<tr>
<td></td>
<td>Third quarter</td>
<td>7.00</td>
<td>4.00</td>
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<tr>
<td></td>
<td>Fourth quarter</td>
<td>7.30</td>
<td>4.15</td>
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<table>
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<tr>
<th>Year</th>
<th>Period</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>First quarter, beginning January 30, 2015</td>
<td>$21.00</td>
<td>$9.02</td>
</tr>
<tr>
<td></td>
<td>Second quarter</td>
<td>14.90</td>
<td>10.00</td>
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<tr>
<td></td>
<td>Third quarter</td>
<td>18.35</td>
<td>8.46</td>
</tr>
<tr>
<td></td>
<td>Fourth quarter</td>
<td>12.50</td>
<td>8.35</td>
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Holders of Record

As of February 12, 2017, there were approximately 149 stockholders of record of our common stock. Certain shares are held in “street” name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

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.

<table>
<thead>
<tr>
<th>Years Ended December 31,</th>
<th>2016</th>
<th>2015</th>
<th>2014</th>
</tr>
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<tr>
<td>(in thousands, except share and per share data)</td>
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</table>

**Statement of Operations Data:**

- **Collaboration revenue**: $3,449 $7,904 $3,598
- **Operating expenses:**
  - **Research and development**: 21,566 25,680 7,652
  - **General and administrative**: 7,859 5,691 2,125
- **Total operating expenses**: 29,425 31,371 9,777
- **Loss from operations**: (25,976) (23,467) (6,179)
- **Other income (expense)**: (1,032) (943) (630)
- **Net loss**: (27,008) (24,410) (6,809)
- **Accretion to redemption value of redeemable convertible preferred stock**: - (31) (297)
- **Net loss attributable to common stockholders**: $ (27,008) $ (24,441) $ (7,106)
- **Net loss per share attributable to common stockholders, basic and diluted (1)**: $ (2.13) $ (2.20) $ (4.40)
- **Weighted-average shares outstanding, basic and diluted (1)**: 12,677,910 11,115,651 1,615,044

(1) See Note 1 to our consolidated financial statements included elsewhere in this Annual Report for an explanation of the methods used to calculate the net loss per share attributable to common stockholders, basic and diluted, and the number of shares used in the computation of these per share amounts.

**Balance Sheet Data:**

<table>
<thead>
<tr>
<th>As of December 31,</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>(in thousands)</td>
<td></td>
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</tbody>
</table>

- **Cash and cash equivalents**: $35,710 $41,373
- **Short-term investments**: 8,703 10,783
- **Working capital**: 35,405 39,131
- **Total assets**: 45,730 53,522
- **Long-term debt, less current portion**: 7,130 7,464
- **Accumulated deficit**: (85,598) (58,590)
- **Total stockholders’ equity**: 28,336 30,978

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

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration, or wet AMD, and fibrotic diseases. 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, and a key contributor to the development of fibrosis, or tissue scarring. We are developing our lead product candidate, TRC105 (INN 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. The VEGF pathway regulates vascular development in the embryo, or vasculogenesis, and angiogenesis. We believe treatment with TRC105 in combination with VEGF inhibitors may improve survival in cancer patients when compared to treatment with a VEGF inhibitor alone. TRC105 has been studied in eight completed Phase 2 clinical trials and three completed Phase 1 clinical trials, and is currently being dosed in one Phase 3 clinical trial, four Phase 2 clinical trials and three Phase 1 clinical trials. Our TRC105 oncology clinical development plan is broad and involves a tiered approach. We are initially focused on two indications, angiosarcoma and gestational trophoblastic neoplasia, or GTN, both of which are tumors that highly express endoglin, the target of TRC105, and therefore may be more responsive to treatment with TRC105. We have seen complete ongoing responses in these tumor types and have initiated dosing in an international multicenter Phase 3 trial in angiosarcoma and an international multicenter Phase 2 trial in GTN. We obtained Special Protocol Assessment (SPA) agreement from the US 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.

Our other product candidates are TRC205, an endoglin antibody that is in preclinical development for the treatment of fibrotic diseases, TRC102, which is a small molecule that is in clinical development for the treatment of mesothelioma, lung cancer and glioblastoma, and two compounds that we licensed from Janssen Pharmaceutica N.V. (Janssen) in September 2016: TRC253, which is a small molecule that is in pre-clinical development, with the IND allowed by the FDA, for the treatment of castrate resistant prostate cancer, and TRC694, a small molecule in pre-clinical development for the treatment of myeloma. In March 2014, Santen licensed from us exclusive worldwide rights to develop and commercialize our endoglin antibodies for ophthalmology indications.

We have collaborated with the National Cancer Institute (NCI), which has selected TRC105 and TRC102 for federal funding of clinical development, as well as Case Western Cancer Center (Case Western). Under these collaborations, NCI has sponsored or is sponsoring nine completed or ongoing clinical trials of TRC105 and TRC102, and Case Western sponsored two clinical trials of TRC102. We anticipate that NCI will complete ongoing Phase 2 clinical trials of TRC105 and may initiate other Phase 2 clinical trials in addition to the Phase 2 clinical trials of TRC105 that we are sponsoring. In addition, we expect that Phase 2 clinical trials of TRC102 will be completed with NCI funding. If merited by Phase 2 data, we expect to fund initial 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 and planned development of our product candidates:

<table>
<thead>
<tr>
<th></th>
<th>Phase</th>
<th>Data Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TRC105</strong> Ongoing trials:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angiosarcoma</td>
<td>Phase 3</td>
<td>Interim analysis first half 2018</td>
</tr>
<tr>
<td>Renal Cell Carcinoma</td>
<td>Randomized Phase 2</td>
<td>Second half 2017</td>
</tr>
<tr>
<td>Angiosarcoma</td>
<td>Phase 2</td>
<td>Second half 2017</td>
</tr>
<tr>
<td>Gestational Trophoblastic Neoplasia (GTN)</td>
<td>Phase 2</td>
<td>Interim data second half 2017</td>
</tr>
<tr>
<td>Hepatocellular Carcinoma</td>
<td>Phase 1/2</td>
<td>2018</td>
</tr>
<tr>
<td>Hepatocellular Carcinoma (NCI Sponsored)</td>
<td>Phase 1/2</td>
<td>2017</td>
</tr>
<tr>
<td>Lung Cancer</td>
<td>Phase 1</td>
<td>2017</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>Phase 1/2</td>
<td>2017</td>
</tr>
<tr>
<td>Wet AMD (Santen) (DE-122)</td>
<td>Phase 1/2</td>
<td>2017</td>
</tr>
<tr>
<td><strong>TRC102</strong> Ongoing trials:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesothelioma</td>
<td>Phase 2</td>
<td>2018</td>
</tr>
<tr>
<td>Glioblastoma</td>
<td>Phase 2</td>
<td>2018</td>
</tr>
<tr>
<td>Solid tumors</td>
<td>Phase 1</td>
<td>2017</td>
</tr>
<tr>
<td>Solid tumors (Oral) and Lymphomas</td>
<td>Phase 1</td>
<td>2018</td>
</tr>
<tr>
<td>Lung Cancer</td>
<td>Phase 1</td>
<td>2018</td>
</tr>
<tr>
<td><strong>TRC253</strong> Planned trials:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prostate Cancer</td>
<td>Phase 1/2</td>
<td>2018</td>
</tr>
</tbody>
</table>

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 capital stock, a $10.0 million one-time upfront fee and a $3.0 million payment received in connection with our collaboration with Santen and commercial bank debt under our credit facilities with Silicon Valley Bank (SVB). At December 31, 2016, we had cash, cash equivalents and short-term investments totaling $44.4 million.

We do not own or operate, nor do we expect to own or operate, facilities 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 $27.0 million, $24.4 million, and $7.1 million for the years ended December 31, 2016, 2015, and 2014, respectively. At December 31, 2016, we had an accumulated deficit of $85.6 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 will increase substantially in connection with our ongoing activities as we:

- continue to conduct clinical trials of our product candidates;
- continue our research and development efforts;
- manufacture preclinical study and clinical trial materials and prepare for potential commercial manufacture of TRC105;
- 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

Janssen Pharmaceutica N.V.

During 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 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.

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.

With respect to the NIK Program, Janssen maintains a right, which is exercisable within 90 days following the date on which we demonstrate clinical proof of concept with respect to the NIK Program, to negotiate for a period of six months for a reversion of the related rights in the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the NIK Program. If Janssen does not exercise its right of first negotiation, or, if after exercise of such right, Janssen and we are unable to reach an agreement on the terms of a reversion and exclusive license, and, in either case, we continue the development of the NIK Program, then we would be obligated to pay Janssen (i) development and regulatory based milestone payments totaling up to $60.0 million upon achievement of specified events, and (ii) royalties in the low single digits based on annual net sales of NIK Program products, subject to certain specified reductions.

Santen Pharmaceutical Co., Ltd.

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, 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. Santen has sole responsibility for funding, developing, seeking regulatory approval for and commercializing TRC105 products in the field of ophthalmology.

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. As of December 31, 2016, we had received $3.0 million in milestones related to development activities. 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.
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 solely from our March 2014 collaboration with Santen. The terms of this arrangement contain multiple deliverables, which include at inception: (1) a license to patents, information and know-how related to TRC105; (2) technology transfer; (3) collaboration, including technical and regulatory support provided by us; (4) manufacturing and supply obligations; and (5) shared CMC development activities. The license agreement provides that we may receive various types of payments, including an upfront payment, payment for various technical and regulatory support, payments for delivery of drug substance, reimbursement of certain development costs, milestone payments, and royalties on net product sales. In accordance with our revenue recognition policy described in detail below, we have identified one single unit of accounting for all the deliverables under the agreement and are recognizing revenue for the fixed or determinable collaboration consideration on a straight-line basis over the estimated development period.

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, whether and when Janssen reacquires rights to the AR Mutant Program and/or NIK Program and the extent to which any of our products are approved and successfully commercialized by us or Santen. If we or Santen 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.

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

<table>
<thead>
<tr>
<th>Product</th>
<th>2016 (in thousands)</th>
<th>2015 (in thousands)</th>
<th>2014 (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Third-party research and development expenses:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRC105</td>
<td>$14,240</td>
<td>$20,031</td>
<td>$4,730</td>
</tr>
<tr>
<td>TRC253</td>
<td>266</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>TRC102</td>
<td>523</td>
<td>122</td>
<td>25</td>
</tr>
<tr>
<td>TRC694</td>
<td>144</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>TRC205</td>
<td>71</td>
<td>277</td>
<td>98</td>
</tr>
<tr>
<td>Total third-party research and development expenses</td>
<td>15,244</td>
<td>20,430</td>
<td>4,853</td>
</tr>
<tr>
<td>Unallocated expenses</td>
<td>6,322</td>
<td>5,250</td>
<td>2,799</td>
</tr>
<tr>
<td>Total research and development expenses</td>
<td>$21,566</td>
<td>$25,680</td>
<td>$7,652</td>
</tr>
</tbody>
</table>

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

We expect our current level of research and development expenses to continue to increase for the foreseeable future as we continue development of TRC105, including our Phase 3 clinical trial in angiosarcoma, an orphan indication, our Phase 2 clinical trial in GTN, initiate manufacturing activities required for regulatory approval, and begin development of our licensed compounds, TRC253 and TRC694.

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 drug 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 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 income (expense) primarily consists of interest related to our loan agreements with SVB offset 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, stock-based compensation and preferred stock warrant liabilities are most critical to understanding and evaluating our reported financial results.

Revenue Recognition

We recognize revenues when all four of the following criteria are met: (1) there is persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectibility is reasonably assured. Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in our balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as long-term deferred revenue.

We evaluate multiple-element arrangements, such as our collaboration with Santen, to determine: (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires us to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (a) the delivered items have value to the customer on a standalone basis and (b) if the arrangement includes a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and substantially in our control. In assessing whether an item has standalone value, we consider factors such as the research, manufacturing and commercialization capabilities of the partner and the availability of the associated expertise in the general marketplace. In addition, we consider whether the partner can use the delivered items for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered elements.

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. We use the following hierarchy of values to estimate the selling price of each deliverable: (1) vendor-specific objective evidence of fair value; (2) third-party evidence of selling price; and (3) best estimate of selling price, or BESP. The BESP reflects our best estimate of what the selling price would be if we regularly sold the deliverable on a standalone basis. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, we consider applicable market conditions and relevant entity-specific factors, including factors that are contemplated in negotiating an arrangement and estimated costs. We validate the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

We then apply the applicable revenue recognition criteria to each of the separate units of accounting in determining the appropriate period and pattern of recognition. If there is no discernible pattern of performance and/or objectively measurable
performance measures do not exist, then we recognize revenue under the arrangement on a straight-line basis over the period we expect to complete our performance obligations.

With respect to revenues derived from reimbursement of direct, out-of-pocket expenses for research and development costs associated with collaborations, where we act as a principal with discretion to choose suppliers, bear credit risk, and perform part of the services required in the transaction, we record revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the statements of operations.

**Milestones**

We use the milestone method of accounting and revenue is recognized when earned, as evidenced by written acknowledgement from the collaborator or other persuasive evidence that the milestone has been achieved and the payment is non-refundable, provided that the milestone event is substantive. A milestone event is defined as an event (1) that can only be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance; (2) for which there is substantive uncertainty at the inception of the arrangement that the event will be achieved; and (3) that would result in additional payments being due to us. Events for which the occurrence is either contingent solely upon the passage of time or the result of a counterparty’s performance are not considered to be milestone events. A milestone event is substantive if all of the following conditions are met: (a) the consideration is commensurate with either our performance to achieve the milestone, or the enhancement of the value to the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone; (b) the consideration relates solely to past performance; and (c) the consideration is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement. We assess whether a milestone is substantive at the inception of each arrangement. If a milestone is deemed non-substantive, we will account for that milestone payment in accordance with the multiple element arrangements guidance and recognize it consistent with the related units of accounting for the arrangement over the related performance period.

**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 CRO 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, 2016, 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 estimated 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:

<table>
<thead>
<tr>
<th>Years Ended December 31,</th>
<th>2016</th>
<th>2015</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>(in thousands)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>$1,090</td>
<td>$1,038</td>
<td>$178</td>
</tr>
<tr>
<td>General and administrative</td>
<td>1,993</td>
<td>1,050</td>
<td>93</td>
</tr>
<tr>
<td>Total stock-based compensation expense</td>
<td>$3,083</td>
<td>$2,088</td>
<td>$271</td>
</tr>
</tbody>
</table>

As of December 31, 2016, the unrecognized stock-based compensation expense related to outstanding employee stock options and awards was $5.7 million and is expected to be recognized as expense over a weighted-average period of approximately 2.3 years.

**Determination of the fair value of common stock**

Prior to our initial public offering, the fair value of the common stock underlying our stock-based awards was determined on each grant date by our board of directors, with input from management. All options to purchase shares of our common stock were intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, determined in good faith and based on the information known to us on the date of grant.

Following the closing of our initial public offering, our board of directors determines the fair value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

**Other Company Information**

**Net Operating Loss and Research and Development Tax Credit Carryforwards**

At December 31, 2016, we had federal and California net operating loss, or NOL, carryforwards, of approximately $69.1 million and $44.0 million, respectively. The federal and California NOL carryforwards will begin expiring in 2030, unless previously utilized. At December 31, 2016, we had federal and California research and development and Orphan Drug credit carryforwards of approximately $3.6 million and $1.1 million, respectively. The federal research and development credit carryforwards will begin expiring in 2031, unless previously utilized. The California research and development credit carryforwards do not expire unless limited by Section 382 as discussed below.

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, 2015 and as a result of the analysis, an ownership change was determined to have occurred at the time of our initial public offering. Future ownership changes may further limit our ability to utilize our remaining NOL and research and development tax credit carryforwards. As of December 31, 2016, 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, (b) in which we have total annual gross revenue of at least $1.0 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

In May 2014, the Financial Accounting Standard Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers, which converges the FASB and the International Accounting Standards Board standard on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2017. We plan on adopting the ASU prospectively and are continuing to evaluate the potential impact that this standard will have on our financial position and results of operations.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, Compensation – Stock Compensation. ASU 2016-09 includes an update which simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. The adoption of ASU 2016-09 is not expected to have a material impact on our financial statements and related disclosures.

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 are currently evaluating the impact that the adoption of ASU 2016-02 will have on our financial statements and related disclosures.

Recently Adopted Accounting Standards

In April 2015, the FASB issued ASU 2015-03, Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. ASU 2015-03 requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying value of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 was effective for interim and annual periods beginning on January 1, 2016. We applied the amended presentation requirements in the first quarter of 2016, which resulted in no change to our financial statements.

In August 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management’s plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. We adopted ASU 2014-15 in the fourth quarter of 2016, which resulted in no change to our financial statements.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

The following table summarizes our results of operations for the years ended December 31, 2016 and 2015:

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2016 (in thousands)</th>
<th>2015 (in thousands)</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaboration revenue</td>
<td>$3,449</td>
<td>$7,904</td>
<td>$(4,455)</td>
</tr>
<tr>
<td>Research and development expenses</td>
<td>21,566</td>
<td>25,680</td>
<td>$(4,114)</td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>7,859</td>
<td>5,691</td>
<td>2,168</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td>(1,032)</td>
<td>(943)</td>
<td>(89)</td>
</tr>
</tbody>
</table>

Collaboration revenue. Collaboration revenue was $3.4 million and $7.9 million for the years ended December 31, 2016 and 2015, respectively. The decrease in revenue was due to the achievement of a $3.0 million development milestone by Santen in June 2015 for which there was no comparable milestone in 2016, and the increase in 2016 in the expected term over which we expect to provide technical and regulatory support to Santen.
Research and development expenses. Research and development expenses were $21.6 million and $25.7 million for the years ended December 31, 2016 and 2015, respectively. The decrease of $4.1 million was due to a decrease in manufacturing activities, partially offset by increased clinical study expenses related to the continued development of TRC105, as well as increased compensation related expenses due to increased headcount and stock-based compensation expenses, and expenses related to our recently acquired assets, TRC253 and TRC694.

General and administrative expenses. General and administrative expenses were $7.9 million and $5.7 million for the years ended December 31, 2016 and 2015, respectively. The increase of $2.2 million was due primarily to increased compensation related expenses due to increased headcount and stock-based compensation expenses.

Other income (expense). Other income (expense) was $(1.0) million and $(0.9) million for the years ended December 31, 2016 and 2015, respectively.

Comparison of the Years Ended December 31, 2015 and 2014

The following table summarizes our results of operations for the years ended December 31, 2015 and 2014:

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2015 (in thousands)</td>
<td>2014</td>
</tr>
<tr>
<td>Collaboration revenue</td>
<td>$7,904</td>
<td>$3,598</td>
</tr>
<tr>
<td>Research and development expenses</td>
<td>25,680</td>
<td>7,652</td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>5,691</td>
<td>2,125</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td>(943)</td>
<td>(630)</td>
</tr>
</tbody>
</table>

Collaboration revenue. Collaboration revenue was $7.9 million and $3.6 million for the years ended December 31, 2015 and 2014, respectively. The increase in revenue was due to the achievement of a development milestone by Santen in June 2015 in connection with our collaboration, which triggered a $3.0 million milestone payment, 12 months of the up-front payment from the license agreement being recognized in 2015 compared with ten months in 2014, and additional development activities being performed in 2015 under the license agreement.

Research and development expenses. Research and development expenses were $25.7 million and $7.7 million for the years ended December 31, 2015 and 2014, respectively. The increase of $18.0 million was due primarily to an increase in manufacturing activities and clinical study expenses related to the continued development of TRC105, as well as increased compensation related expenses due to increased headcount and stock-based compensation expenses.

General and administrative expenses. General and administrative expenses were $5.7 million and $2.1 million for the years ended December 31, 2015 and 2014, respectively. The increase of $3.6 million was due primarily to increased compensation related expenses due to increased headcount and stock-based compensation expenses, and expenses related to becoming a public company in January 2015, such as insurance, accounting and legal expenses.

Other income (expense). Other income (expense) was $(0.9) million and $(0.6) million for the years ended December 31, 2015 and 2014, respectively. The increase of $0.3 million in other income (expense) was primarily the result of interest expense related to the aggregate borrowings under our credit facility with SVB.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception. As of December 31, 2016, we had an accumulated deficit of $85.6 million, and we expect to continue to incur net losses for the foreseeable future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, 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 the 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 to us of approximately $5.0 million and in November 2016, we completed an underwritten public offering which resulted in net proceeds to us of approximately $16.1 million. We anticipate that our existing cash, cash equivalents and short-term investments will fund our operations for at least the next 12 months. 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 January 2017, we entered into a second amendment to our Amended and Restated Loan and Security Agreement with SVB (the 2017 Amended SVB Loan) under which we borrowed $8.0 million, all of which was used to refinance previously outstanding amounts under the loan and security agreement. In connection with the 2017 Amended SVB Loan, we issued warrants to purchase up to 46,692 shares of common stock at an exercise price of $5.14 per share. The warrants are fully exercisable and expire on January 25, 2024.

The 2017 Amended SVB Loan provides for interest to be paid at a rate of 8.55% per annum, with interest-only payments due monthly through December 31, 2017 which will be extended through June 30, 2018 in the event certain funding and clinical development conditions are met. Thereafter, in addition to interest accrued during such period, the monthly payments include an amount equal to the outstanding principal at December 31, 2017 or June 30, 2018, as applicable, divided by 30 months. At maturity (or earlier prepayment), we are also required to make a final payment equal to 4.0% of the original principal amounts borrowed. The 2017 Amended SVB Loan provides for prepayment fees of 3.0% of the amount prepaid if the prepayment occurs prior to January 26, 2018, 2.0% of the amount prepaid if the prepayment occurs after January 26, 2018 but prior to January 25, 2019, and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The 2017 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 2017 Amended SVB Loan.

ATM Facility

In February 2016, we entered into an At-the-Market Equity Offering Sales Agreement, or the Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, pursuant to which we may sell from time to time, at our option, up to an aggregate of $25.0 million of our shares of our common stock through Stifel, 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 Stifel, on the Nasdaq Global Market or otherwise, at negotiated prices or at prices related to the prevailing market price. Stifel 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 obligated to pay Stifel an aggregate sales agent commission equal to 2.5% of the gross proceeds of the sales price for common stock sold under the Sales Agreement. As of December 31, 2016, no shares of our common stock have been sold under the Sales Agreement and the full $25.0 million of common stock remains available to be sold.

Cash Flows

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

<table>
<thead>
<tr>
<th>Years Ended December 31,</th>
<th>2016</th>
<th>2015</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>(in thousands)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net cash provided by (used in):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating activities</td>
<td>$ (27,150)</td>
<td>$(19,163)</td>
<td>$1,758</td>
</tr>
<tr>
<td>Investing activities</td>
<td>2,073</td>
<td>(10,917)</td>
<td>(70)</td>
</tr>
<tr>
<td>Financing activities</td>
<td>19,414</td>
<td>36,453</td>
<td>31,036</td>
</tr>
<tr>
<td>(Decrease) increase in cash and cash equivalents</td>
<td>$(5,663)</td>
<td>$6,373</td>
<td>$32,724</td>
</tr>
</tbody>
</table>

Operating activities. Net cash used in operating activities was $27.2 million for the year ended December 31, 2016, and was primarily due to our net loss, adjusted for noncash items, offset by changes in our working capital. Net cash used in operating activities was $19.2 million for the year ended December 31, 2015, and was primarily due to our net loss, adjusted for noncash items, offset by changes in our working capital. Net cash provided by operating activities was $1.8 million for the year ended December 31, 2014 and was primarily the result of $6.9 million of deferred revenue related to the $10.0 million one-time upfront payment received in conjunction with our collaboration with Santen, offset by our net loss for the period.

Investing activities. Net cash provided by investing activities was $2.1 million for the year ended December 31, 2016, and was related to proceeds from the maturities of short-term investments, offset by the purchases of those investments. Net cash used in
investing activities was $10.9 million for the year ended December 31, 2015, and was related to purchases of short-term investments, offset by maturities of those investments, and purchases of property and equipment. Net cash used in investing activities for the year ending December 31, 2014 was due to purchases of property and equipment.

Financing activities. 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. Net cash provided by financing activities was $36.5 million for the year ended December 31, 2015 and resulted primarily from net proceeds received totaling $36.2 million from our initial public offering and concurrent private placement. Net cash provided by financing activities was $31.0 million for the year ended December 31, 2014 and resulted from $25.7 million of net proceeds from our sale of Series B redeemable convertible preferred stock in September 2014 and net borrowings from a prior credit facility with SVB, offset in part by costs paid in connection with our initial public offering which closed in February 2015.

Funding Requirements

At December 31, 2016, we had cash, cash equivalents and short-term investments totaling $44.4 million. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements for at least the next 12 months. 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 and Phase 2 trial in GTN. 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, including our strategic licensing transaction with Janssen, will likely increase our future funding requirements. However, 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 of TRC105;
• Santen’s ability and willingness to continue clinical development of DE-122;
• 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 and/or the NIK 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, 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.
Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2016:

<table>
<thead>
<tr>
<th>Payments Due by Period</th>
<th>Total</th>
<th>Less than 1 Year</th>
<th>1-3 Years</th>
<th>3-5 Years</th>
<th>More than 5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term debt obligations, including interest and final payment (1)</td>
<td>$11,062</td>
<td>$1,847</td>
<td>$7,255</td>
<td>$1,960</td>
<td>—</td>
</tr>
<tr>
<td>Operating lease obligations (2)</td>
<td>2,230</td>
<td>343</td>
<td>828</td>
<td>903</td>
<td>156</td>
</tr>
<tr>
<td>Purchase obligations (3)</td>
<td>5,755</td>
<td>5,755</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>$19,047</td>
<td>$7,945</td>
<td>$8,083</td>
<td>$2,863</td>
<td>$156</td>
</tr>
</tbody>
</table>

(1) Principal and interest payments to SVB are shown in accordance with the second amendment to the amended and restated loan and security agreement with SVB, executed in January 2017.
(2) Our operating lease obligations relate to our corporate headquarters in San Diego, California. We lease 9,339 square feet of office space under an operating lease that expires in April 2017, and have entered into a lease for 10,458 square feet of office space under an operating lease that commences in May 2017 and expires in April 2022, which will become our corporate headquarters in May 2017.
(3) The purchase obligations are comprised of our non-cancellable purchase commitments under our 2008 master services agreement with Lonza Sales AG (Lonza), and amounts include estimates based on forecasts which may differ from actual amounts we pay.

Under our long-term manufacturing agreement with Lonza Biologics Tuas Pte Ltd (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 $15.0 million. The timing of payments for preapproval batches will be in accordance with a project plan to be agreed to by us and Lonza Biologics. If the parties are unable to agree to a project plan either party may terminate the manufacturing agreement as described below, and our obligations to purchase the pre-approval batches would be cancelled without penalty to us. Following regulatory approval, we will be required to purchase a specified minimum number of batches annually with a total annual estimated cost of approximately $22.0 million. If we cancel any purchase orders, we may be obligated to pay certain cancellation fees. In addition, we will be obligated to pay a milestone fee to Lonza Biologics upon the earlier of the first approval of TRC105 by the U.S. Food and Drug Administration (FDA) or European Medicines Agency (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 Biologics' facility, the manufacturing process or services performed by Lonza Biologics.

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, due to a force majeure event that prevents performance under the agreement for at least six months, or if we and Lonza Biologics fail to enter into an initial project plan within ninety days of executing the agreement (which period may be extended by agreement of the parties). 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, 2016, 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 ($0.4 million of which has been paid and $1.0 million of which became payable in February 2017 and is not included in the table above) upon the achievement
of certain milestones for products utilizing certain intellectual property licensed from RPCI, or the RPCI Technology, including TRC105, of which approximatel y $1.4 million ($0.4 million which has been paid and $1.0 million of which became payable in February 2017 and is not included in the table above) 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. 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 and TRC694, we may be required to pay up to an aggregate of $105.0 million in milestone payments, of which $45.0 million relates to the initiation of certain development activities and $60.0 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals. If TRC253 or TRC694 are 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 SEC.

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

Interest Rate Risk

Our cash and cash equivalents consist of cash, money market funds and certificates of deposit. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes. Our long-term debt bears interest at a fixed rate.
Foreign Currency Exchange Risk

We incur significant expenses, including for manufacturing of clinical trial materials, outside the United States based on contractual obligations denominated in currencies other than the U.S. dollar, including 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 2016 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 Statements and Other Supplementary Information.

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The Board of Directors and Stockholders of TRACON Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of TRACON Pharmaceuticals, Inc., as of December 31, 2016 and 2015, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders’ equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company’s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of TRACON Pharmaceuticals, Inc. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP
San Diego, California
February 28, 2017
<table>
<thead>
<tr>
<th>Assets</th>
<th>December 31, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$35,710</td>
<td>$41,373</td>
</tr>
<tr>
<td>Short-term investments</td>
<td>8,703</td>
<td>10,783</td>
</tr>
<tr>
<td>Prepaid and other assets</td>
<td>1,235</td>
<td>1,150</td>
</tr>
<tr>
<td>Total current assets</td>
<td>45,648</td>
<td>53,306</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>82</td>
<td>173</td>
</tr>
<tr>
<td>Other assets</td>
<td>—</td>
<td>43</td>
</tr>
<tr>
<td>Total assets</td>
<td>$45,730</td>
<td>$53,522</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Liabilities and Stockholders’ Equity</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Current liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable and accrued expenses</td>
<td>$6,213</td>
<td>$8,281</td>
</tr>
<tr>
<td>Accrued compensation and related expenses</td>
<td>1,588</td>
<td>1,163</td>
</tr>
<tr>
<td>Current portion of deferred revenue</td>
<td>1,259</td>
<td>3,353</td>
</tr>
<tr>
<td>Long-term debt, current portion</td>
<td>333</td>
<td>1,378</td>
</tr>
<tr>
<td>Final payment due bank</td>
<td>850</td>
<td>—</td>
</tr>
<tr>
<td>Total current liabilities</td>
<td>10,243</td>
<td>14,175</td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>21</td>
<td>905</td>
</tr>
<tr>
<td>Long-term debt, less current portion</td>
<td>7,130</td>
<td>7,464</td>
</tr>
<tr>
<td>Stockholders’ equity:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred stock, $0.001 par value, authorized shares — 10,000,000 at December 31, 2016 and December 31, 2015; issued and outstanding shares—none</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Common stock, $0.001 par value; authorized shares — 200,000,000 at December 31, 2016 and December 31, 2015; issued and outstanding shares — 16,084,721 and 12,175,942 at December 31, 2016 and December 31, 2015, respectively</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>113,918</td>
<td>89,556</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(85,598)</td>
<td>(58,590)</td>
</tr>
<tr>
<td>Total stockholders’ equity</td>
<td>28,336</td>
<td>30,978</td>
</tr>
<tr>
<td>Total liabilities and stockholders’ equity</td>
<td>$45,730</td>
<td>$53,522</td>
</tr>
</tbody>
</table>

See accompanying notes.
<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaboration revenue</td>
<td>$3,449</td>
<td>$7,904</td>
<td>$3,598</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>21,566</td>
<td>25,680</td>
<td>7,652</td>
</tr>
<tr>
<td>General and administrative</td>
<td>7,859</td>
<td>5,691</td>
<td>2,125</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>29,425</td>
<td>31,371</td>
<td>9,777</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(25,976)</td>
<td>(23,467)</td>
<td>(6,179)</td>
</tr>
<tr>
<td>Other income (expense):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(1,119)</td>
<td>(923)</td>
<td>(667)</td>
</tr>
<tr>
<td>Other income (expense), net</td>
<td>87</td>
<td>(20)</td>
<td>37</td>
</tr>
<tr>
<td>Total other income (expense)</td>
<td>(1,032)</td>
<td>(943)</td>
<td>(630)</td>
</tr>
<tr>
<td>Net loss</td>
<td>(27,008)</td>
<td>(24,410)</td>
<td>(6,809)</td>
</tr>
<tr>
<td>Accretion to redemption value of redeemable convertible preferred stock</td>
<td>—</td>
<td>(31)</td>
<td>(297)</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders</td>
<td>$27,008</td>
<td>$24,441</td>
<td>$7,106</td>
</tr>
<tr>
<td>Net loss per share attributable to common stockholders, basic and diluted</td>
<td>$2.13</td>
<td>$2.20</td>
<td>$4.40</td>
</tr>
<tr>
<td>Weighted-average shares outstanding, basic and diluted</td>
<td>12,677,910</td>
<td>11,115,651</td>
<td>1,615,044</td>
</tr>
</tbody>
</table>

See accompanying notes.
## TRACON Pharmaceuticals, Inc.

### Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except share and per share data)

<table>
<thead>
<tr>
<th>Redeemable Convertible Preferred Stock</th>
<th>Common Stock</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Deficit</th>
<th>Total Stockholders' Equity (Deficit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
<td>Amount</td>
<td>Capital</td>
</tr>
<tr>
<td>Balance at December 31, 2013</td>
<td>12,249,999</td>
<td>$23,929</td>
<td>1,614,851</td>
<td>$2</td>
</tr>
</tbody>
</table>

- Issuance of Series B redeemable convertible preferred stock in September for cash of $2.1935 per share, net of offering costs of $1,546
- Accretion to redemption value of redeemable convertible preferred stock
- Exercise of common stock options
- Vested shares related to repurchase liability
- Stock-based compensation expense
- Net loss

Balance at December 31, 2014 | 24,650,273 | 49,880 | 1,633,854 | 2 | 2,004 | $(34,180) | $(32,174) |

Initial public offering and private placement of common stock for cash of $10 per share, net of offering costs
Conversion of redeemable convertible preferred stock into common stock at initial public offering
Reclassification of redeemable convertible preferred stock warrant
Accretion to redemption value of redeemable convertible preferred stock
Issuance of common stock under equity plans
Stock-based compensation expense
Vested shares related to repurchase liability
Issuance of common stock warrants in connection with debt financing
Net loss

Balance at December 31, 2015 | 12,175,942 | 12 | 89,556 | (58,590) | 30,978 |

Issuance of common stock under equity plans
Stock-based compensation expense
Vested shares related to repurchase liability
Issuance of common stock in a public offering, net of offering costs
Other issuances of common stock, net
Issuance of common stock in exchange for services
Net loss

Balance at December 31, 2016 | $16,084,721 | $16 | $113,918 | $(85,598) | $28,336 |

See accompanying notes.
TRACON Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
</tr>
<tr>
<td><strong>Cash flows from operating activities</strong></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (27,008)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash (used in) provided by operating activities:</td>
<td></td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>3,083</td>
</tr>
<tr>
<td>Common stock issued for services</td>
<td>23</td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>94</td>
</tr>
<tr>
<td>Amortization of debt discount</td>
<td>100</td>
</tr>
<tr>
<td>Amortization of premium/discount on short-term investments</td>
<td>3</td>
</tr>
<tr>
<td>Noncash interest</td>
<td>522</td>
</tr>
<tr>
<td>Change in fair value of preferred stock warrant liability</td>
<td>—</td>
</tr>
<tr>
<td>Deferred rent</td>
<td>(53)</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>(2,094)</td>
</tr>
<tr>
<td>Changes in assets and liabilities:</td>
<td></td>
</tr>
<tr>
<td>Prepaid expenses and other assets</td>
<td>(42)</td>
</tr>
<tr>
<td>Accounts payable and accrued expenses</td>
<td>(2,203)</td>
</tr>
<tr>
<td>Accrued compensation and related expenses</td>
<td>425</td>
</tr>
<tr>
<td>Net cash (used in) provided by operating activities</td>
<td>(27,150)</td>
</tr>
<tr>
<td><strong>Cash flows from investing activities</strong></td>
<td></td>
</tr>
<tr>
<td>Purchase of property and equipment</td>
<td>(3)</td>
</tr>
<tr>
<td>Purchases of available-for-sale short-term investments</td>
<td>(17,506)</td>
</tr>
<tr>
<td>Proceeds from the maturity of available-for-sale short-term investments</td>
<td>19,582</td>
</tr>
<tr>
<td>Net cash provided by (used in) investing activities</td>
<td>2,073</td>
</tr>
<tr>
<td><strong>Cash flows from financing activities</strong></td>
<td></td>
</tr>
<tr>
<td>Proceeds from long-term debt</td>
<td>—</td>
</tr>
<tr>
<td>Repayment of long-term debt</td>
<td>(2,000)</td>
</tr>
<tr>
<td>Proceeds from sale of common stock, net of offering costs paid in the current period</td>
<td>21,236</td>
</tr>
<tr>
<td>Proceeds from sale of preferred stock, net of offering costs</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from issuance of common stock under equity plans</td>
<td>178</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>19,414</td>
</tr>
<tr>
<td>(Decrease) increase in cash and cash equivalents</td>
<td>(5,663)</td>
</tr>
<tr>
<td>Cash and cash equivalents at beginning of period</td>
<td>41,373</td>
</tr>
<tr>
<td>Cash and cash equivalents at end of period</td>
<td>$35,710</td>
</tr>
<tr>
<td><strong>Supplemental disclosure of cash flow information</strong></td>
<td></td>
</tr>
<tr>
<td>Interest paid</td>
<td>$ 622</td>
</tr>
<tr>
<td><strong>Supplemental schedule of noncash investing and financing activities</strong></td>
<td></td>
</tr>
<tr>
<td>Issuance of preferred stock warrants in connection with long-term debt</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of common stock warrants in connection with long-term debt</td>
<td>—</td>
</tr>
</tbody>
</table>

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, age-related macular degeneration and fibrotic diseases. The Company’s research focuses on antibodies that bind to the endoglin receptor, which is essential to angiogenesis (the process of new blood vessel formation) and a key contributor to fibrosis (tissue scarring).

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, 2016, 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, 2016, the Company had an accumulated deficit of $85.6 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, 2016, the Company had cash, cash equivalents and short-term investments of $44.4 million. Based on the Company’s current business plan, management believes that existing cash, cash equivalents and short-term investments will be sufficient to fund the Company’s obligations for at least the next twelve months. The Company plans to continue to fund its losses from operations and capital funding needs through cash and investments on hand, as well as future debt and equity financing and potential collaboration arrangements. If the Company is not able to secure adequate additional funding, it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or delay or reduce the scope of its planned development programs. 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 and the disclosure of contingent assets and liabilities in the Company’s financial statements and accompanying notes. The most significant estimates in the Company’s financial statements relate to revenue recognition 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, as well as certificates of deposit.

Concentration of Credit Risk

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

Property and Equipment

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

Preferred Stock Warrant Liabilities

Prior to the completion of the Company’s initial public offering in February 2015, the Company had outstanding freestanding warrants to purchase shares of its Series A redeemable convertible preferred stock. Since the underlying Series A redeemable convertible preferred stock was classified outside of permanent equity, these preferred stock warrants were classified as liabilities in the December 31, 2014 balance sheet. The Company adjusted the carrying value of such preferred stock warrants to their estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as an increase or decrease to other income (expense) in the consolidated statements of operations. Upon the completion of the Company’s initial public offering, the warrants no longer require liability accounting and the then fair value of the warrant liability was reclassified into stockholders’ equity.

The Company performed the final remeasurement of the warrant liability as of the initial public offering date and recorded the $65,000 change in fair value into other income (expense) for the year ended December 31, 2015.

Revenue Recognition

The Company’s revenue is derived from its license agreement with Santen Pharmaceutical Co., Ltd. (Santen) as described in Note 7. The Company recognizes revenue when all four of the following criteria are met: (1) there is persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured. Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as long-term deferred revenue.

The Company evaluates multiple-element arrangements to determine: (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. Deliverables are considered separate units of accounting provided that: (a) the delivered items have value to the customer on a standalone basis and (b) if the arrangement includes a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and substantially in the Company’s control. In assessing whether an item has standalone value, the Company considers factors such as the research, manufacturing and commercialization capabilities of the partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the partner can use the other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered elements.

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. The Company uses the following hierarchy of values to estimate the selling price of each deliverable: (1) vendor-specific objective evidence of fair value; (2) third-party evidence of selling price; and (3) best estimate of selling price (BESP). The BESP reflects the Company’s best estimate of what the selling price would be if the Company regularly sold the deliverable on a standalone basis. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and relevant entity-specific factors, including factors that are contemplated in negotiating an arrangement and estimated costs. The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

The Company then applies the applicable revenue recognition criteria to each of the separate units of accounting in determining the appropriate period and pattern of recognition. If there is no discernible pattern of performance and/or objectively measurable performance measures do not exist, then the Company recognizes revenue under the arrangement on a straight-line basis over the period the Company expects to complete its performance obligations.

With respect to revenue derived from reimbursement of direct, out-of-pocket expenses for research and development costs associated with collaborations, where the Company acts as a principal with discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, the Company records revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the consolidated statements of operations.
Milestones

The Company uses the milestone method of accounting and revenue is recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved and the payment is non-refundable, provided that the milestone event is substantive. A milestone event is defined as an event: (1) that can only be achieved based in whole or in part on either the Company’s performance or on the occurrence of a specific outcome resulting from the Company’s performance; (2) for which there is substantive uncertainty at the inception of the arrangement that the event will be achieved; and (3) that would result in additional payments being due to the Company. Events for which the occurrence is either contingent solely upon the passage of time or the result of a counterparty’s performance are not considered to be milestone events. A milestone event is substantive if all of the following conditions are met: (a) the consideration is commensurate with either the Company’s performance to achieve the milestone, or the enhancement of the value to the delivered item(s) as a result of a specific outcome resulting from the Company’s performance to achieve the milestone; (b) the consideration relates solely to past performance; and (c) the consideration is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

The Company assesses whether a milestone is substantive at the inception of each arrangement. If a milestone is deemed non-substantive, the Company will account for that milestone payment in accordance with the multiple element arrangements guidance and recognize it consistent with the related units of accounting for the arrangement over the related performance period.

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, contract research organizations (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.

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 trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through 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, 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 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 in the period ended December 31, 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, net of estimated forfeitures. 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.

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. The Company has excluded 7,878, 6,555, and 2,863 weighted-average shares subject to repurchase or forfeiture from the weighted-average number of common shares outstanding for the years ended December 31, 2016, 2015, and 2014 respectively. 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):

<table>
<thead>
<tr>
<th>Security Description</th>
<th>2016</th>
<th>2015</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redeemable convertible preferred stock outstanding</td>
<td></td>
<td></td>
<td>6,369,567</td>
</tr>
<tr>
<td>Warrants to purchase redeemable convertible preferred stock</td>
<td></td>
<td></td>
<td>38,758</td>
</tr>
<tr>
<td>Warrants to purchase common stock</td>
<td>57,173</td>
<td>57,173</td>
<td></td>
</tr>
<tr>
<td>Common stock options and restricted stock units</td>
<td>2,023,478</td>
<td>1,788,149</td>
<td>1,023,847</td>
</tr>
<tr>
<td>ESPP shares</td>
<td>2,857</td>
<td>143</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2,083,508</td>
<td>1,845,465</td>
<td>7,432,172</td>
</tr>
</tbody>
</table>

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.
Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers, which converges the FASB and the International Accounting Standards Board standard on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2017. The Company plans on adopting the ASU prospectively and is continuing to evaluate the potential impact that this standard will have on its financial position and results of operations.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, Compensation – Stock Compensation. ASU 2016-09 includes an update which simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. The Company does not expect the adoption of ASU 2016-09 to have a material impact on its financial statements and related disclosures.

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 is currently evaluating the impact that the adoption of ASU 2016-02 will have on its financial statements and related disclosures.

Recently Adopted Accounting Standards

In April 2015, the FASB issued ASU 2015-03, Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. ASU 2015-03 requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying value of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 was effective for interim and annual periods beginning on January 1, 2016. The Company applied the amended presentation requirements in the first quarter of 2016, which resulted in no change on its financial statements.

In August 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management’s plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. The Company adopted ASU 2014-15 in the fourth quarter of 2016, which resulted in no change on its financial statements.

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

At December 31, 2016, short-term investments consist of certificates of deposit and U.S. treasury securities. The Company classifies all investments as available-for-sale, 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, with the unrealized gains and losses reported as a component of other comprehensive income in equity until realized. 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. At December 31, 2016, 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 and short-term investments, all of which are classified as available-for-sale securities, consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost</td>
</tr>
<tr>
<td>Money market funds</td>
<td>$    3,188</td>
</tr>
<tr>
<td>Certificates of deposit</td>
<td>3,655</td>
</tr>
<tr>
<td>U.S. treasury securities</td>
<td>16,503</td>
</tr>
<tr>
<td></td>
<td>$ 23,346</td>
</tr>
</tbody>
</table>

Classified as:

- Cash equivalents $ 14,643
- Short-term investments $ 8,703
- Total Cash equivalents and Short-term investments $ 23,346

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):

<table>
<thead>
<tr>
<th>Fair Value Measurements at Reporting Date Using</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quoted Prices in Active Markets for Identical Assets (Level 1)</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

At December 31, 2016

Certificates of deposit, money market funds and U.S. treasury securities, included in Cash equivalents and Short-term investments $ 23,346 $ — $ 23,346 $ —

At December 31, 2015

Certificates of deposit, money market funds and U.S. treasury securities, included in Cash equivalents and Short-term investments $ 14,996 $ — $ 14,996 $ —
3. Property and Equipment

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

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer and office equipment</td>
<td>$115</td>
<td>$112</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>124</td>
<td>99</td>
</tr>
<tr>
<td>Construction in process</td>
<td>—</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>258</td>
<td>255</td>
</tr>
<tr>
<td>Less accumulated depreciation and amortization</td>
<td>(176)</td>
<td>(82)</td>
</tr>
<tr>
<td></td>
<td>$82</td>
<td>$173</td>
</tr>
</tbody>
</table>

Depreciation expense related to property and equipment totaled approximately $94,000, $51,000 and $15,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

4. Long-Term Debt

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

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term debt</td>
<td>$8,000</td>
<td>$10,000</td>
</tr>
<tr>
<td>Less debt discount, net of current portion</td>
<td>(537)</td>
<td>(536)</td>
</tr>
<tr>
<td>Long-term debt, net of debt discount</td>
<td>7,463</td>
<td>9,464</td>
</tr>
<tr>
<td>Less current portion of long-term debt</td>
<td>(333)</td>
<td>(2,000)</td>
</tr>
<tr>
<td>Long-term debt, net of current portion</td>
<td>$7,130</td>
<td>$7,464</td>
</tr>
<tr>
<td>Current portion of long-term debt</td>
<td>$333</td>
<td>$2,000</td>
</tr>
<tr>
<td>Current portion of debt discount</td>
<td>—</td>
<td>(622)</td>
</tr>
<tr>
<td>Current portion of long-term debt, net</td>
<td>$333</td>
<td>$1,378</td>
</tr>
</tbody>
</table>

In January 2017, the Company entered into a second amendment to its Amended and Restated Loan and Security Agreement with Silicon Valley Bank (the 2017 Amended SVB Loan) under which the Company borrowed $8 million all of which was immediately used to repay the Company’s existing loan with SVB (the 2015 Amended SVB Loan). In accordance with the terms of the 2015 Amended SVB Loan, the Company paid a final payment of $0.9 million associated with the pay off of the 2015 Amended SVB Loan.

The 2017 Amended SVB Loan provides for interest to be paid at a rate of 8.55% per annum. Interest-only payments are due monthly through December 2017, which will be extended through June 2018 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 December 31, 2017 (or June 30, 2018, 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 2017 Amended SVB Loan provides for prepayment fees of 3% of the outstanding balance of the loan if the loan is repaid prior to January 26, 2018, 2.0% of the amount prepaid if the prepayment occurs after January 25, 2018 but prior to January 25, 2019 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

Except as described above, the 2017 Amended SVB Loan is subject to the same material terms set forth in the 2015 Amended SVB Loan Agreement. In connection with the second amendment, the Company issued SVB a warrant to purchase 46,692 shares of its common stock at an exercise price of $5.14 per share. The warrant is fully exercisable and expires on January 25, 2024.

Consistent with the terms of the 2015 Amended SVB Loan agreements the 2017 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 2017 Amended SVB Loan.
The 2015 Amended SVB Loan provided for in interest to be paid at a rate of 6.5% per annum. Interest-only payments were due monthly through June 2016. Thereafter, in addition to interest accrued during such period, the monthly payments included an amount equal to the outstanding principal at July 1, 2016 divided by 30 months. At maturity (or earlier prepayment), the Company was also required to make a final payment equal to 8.5% of the original $10.0 million principal amount borrowed.

The fair value of the warrants and the final payment related to the 2015 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 SVB Loan and the Amended SVB Loan Agreements.

At December 31, 2016, the Company has the following exercisable outstanding warrants for the purchase of common stock issued in connection with the Company’s loan agreements with SVB:

<table>
<thead>
<tr>
<th>Expiration</th>
<th>Number of shares</th>
<th>Exercise price</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 14, 2023 through June 4, 2024</td>
<td>38,758</td>
<td>$7.74</td>
</tr>
<tr>
<td>May 13, 2022</td>
<td>18,415</td>
<td>$10.86</td>
</tr>
<tr>
<td></td>
<td>57,173</td>
<td></td>
</tr>
</tbody>
</table>

The fair value of the warrants and the final payment related to the 2015 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 SVB Loan and the Amended SVB Loan Agreements.

Future minimum principal and interest payments under the 2015 and 2017 Amended SVB Loans, including the final payments, are as follows (in thousands):

<table>
<thead>
<tr>
<th>Debt instrument</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>Less interest and final payment</th>
<th>Long-term debt including current portion</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 Amended SVB Loan</td>
<td>$1,269</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>$ (936)</td>
<td>$ 333</td>
</tr>
<tr>
<td>2017 Amended SVB Loan</td>
<td>578</td>
<td>3,766</td>
<td>3,489</td>
<td>1,960</td>
<td>(1,793)</td>
<td>8,000</td>
</tr>
</tbody>
</table>

5. Commitments and Contingencies

Facility Lease

The Company leases its office space under a non-cancelable operating lease that expires in April 2017, and has entered into a separate lease for office space that expires April 2022, which will become its corporate headquarters in May 2017. The leases are 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, 2016, 2015 and 2014 was $0.4 million, $0.2 million and $0.1 million, respectively.

Under the terms of the lease agreement for its new corporate headquarters, the Company provided the lessor with an irrevocable letter of credit in the amount of $175,000. The lessor shall be 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, 2016 are as follows (in thousands):

<table>
<thead>
<tr>
<th>Year</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>$343</td>
</tr>
<tr>
<td>2018</td>
<td>$405</td>
</tr>
<tr>
<td>2019</td>
<td>$423</td>
</tr>
<tr>
<td>2020</td>
<td>$442</td>
</tr>
<tr>
<td>2021</td>
<td>$461</td>
</tr>
<tr>
<td></td>
<td>$2,074</td>
</tr>
</tbody>
</table>

90
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, 2016, potential future milestone payments under these agreements totaled an aggregate of approximately $127.0 million.

6. Stockholders’ Equity (Deficit)

Redeemable Convertible Preferred Stock

In connection with the completion of the Company’s initial public offering on February 4, 2015, all of the outstanding shares of redeemable convertible preferred stock were converted into 6,369,567 shares of the Company’s common stock; outstanding warrants to purchase 150,000 shares of Series A redeemable convertible preferred stock were converted into warrants to purchase 38,758 shares of the Company’s common stock, and the Company’s certificate of incorporation was amended and restated to authorize 200,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock. No preferred stock dividends were paid or declared by the Company.

Sales of Common Stock

During November 2016, the Company completed an underwritten public offering of 3,018,750 shares of its common stock at an offering price of $5.75 per share. The Company received net proceeds from this offering of approximately $16.1 million, after deducting underwriting discounts, commissions and offering-related expenses of $1.3 million.

In September 2016, concurrent with its License and Option Agreement with Janssen Pharmaceutica N.V. (Janssen) and its affiliate, Johnson & Johnson Innovation-JJDC, Inc. (JJDC) (see Note 7), the Company issued and sold 840,022 shares of its common stock at a purchase price of $5.95 per share (determined by the average of the daily volume weighted average closing prices of the common stock as reported on NASDAQ for the five days prior to the date of the purchase) to JJDC for gross proceeds of $5.0 million. The Company also entered into an Investor Rights Agreement, pursuant to which the Company granted JJDC certain rights to require the Company to register the shares for resale under the Securities Act.

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 fair value of RSUs that vested during the year ended December 31, 2016 was $0. The aggregate intrinsic value of outstanding RSUs at December 31, 2016 was $1.5 million and is based on the Company’s closing market price per share on December 31, 2016 of $4.90. As of December 31, 2016, there was approximately $1.7 million of unrecognized compensation costs related to outstanding RSUs, which is expected to be recognized over a weighted average remaining period of 2.8 years.

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

<table>
<thead>
<tr>
<th></th>
<th>Number of Shares</th>
<th>Weighted Average Grant Date Fair Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding at Dec 31, 2015</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granted</td>
<td>306,780</td>
<td>$ 7.70</td>
</tr>
<tr>
<td>Forfeited</td>
<td></td>
<td>$ 7.70</td>
</tr>
<tr>
<td>Outstanding at Dec 31, 2016</td>
<td>306,780</td>
<td></td>
</tr>
</tbody>
</table>

Stock Options

Stock option activity under all Plans is summarized as follows:

<table>
<thead>
<tr>
<th></th>
<th>Number of Options</th>
<th>Weighted-Average Exercise Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at Dec 31, 2015</td>
<td>1,788,149</td>
<td>$ 7.76</td>
</tr>
<tr>
<td>Granted</td>
<td>107,747</td>
<td>$ 6.68</td>
</tr>
<tr>
<td>Exercised</td>
<td>(9,300)</td>
<td>$ 0.70</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(169,898)</td>
<td>$ 9.71</td>
</tr>
<tr>
<td>Balance at Dec 31, 2016</td>
<td>1,716,698</td>
<td>$ 7.54</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Number of Shares</th>
<th>Weighted-Average Exercise Price</th>
<th>Weighted-Average Remaining Contractual Term (in years)</th>
<th>Aggregate Intrinsic Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 31, 2016:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Options outstanding</td>
<td>1,716,698</td>
<td>$ 7.54</td>
<td>7.34</td>
<td>$ 2,241</td>
</tr>
<tr>
<td>Options vested and expected to vest</td>
<td>1,716,698</td>
<td>$ 7.54</td>
<td>7.34</td>
<td>$ 2,241</td>
</tr>
<tr>
<td>Options exercisable</td>
<td>1,115,178</td>
<td>$ 6.04</td>
<td>6.84</td>
<td>$ 2,162</td>
</tr>
</tbody>
</table>

The weighted-average grant date fair value per share of employee option grants during the years ended December 31, 2016, 2015 and 2014 was $6.68, $12.97 and $4.70, respectively. The aggregate intrinsic value used in the above table of options at December 31, 2016 is based on the Company’s closing market price per common share on December 31, 2016 of $4.90. The Company received approximately $6,500, $54,200 and $52,300 in proceeds from the exercise of stock options during the years ended December 31, 2016, 2015 and 2014, respectively. The total intrinsic value of options exercised was approximately $78,000, $0.8 million and $84,000 during the years ended December 31, 2016, 2015 and 2014, respectively. The total fair value of options that vested during the year ended December 31, 2016, 2015 and 2014 was $3.4 million, $0.8 million and $1.2 million, respectively.

Employee Stock Purchase Plan

On January 1, 2015, the Company’s board of directors adopted the Employee Stock Purchase Plan (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 lesser 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, 2016 and 2015 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:

<table>
<thead>
<tr>
<th>Years Ended December 31,</th>
<th>2016</th>
<th>2015</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>1.6 %</td>
<td>1.7 %</td>
<td>1.9 %</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>80.0 %</td>
<td>74.0 %</td>
<td>76.0 %</td>
</tr>
<tr>
<td>Expected term (in years)</td>
<td>6.3</td>
<td>6.3</td>
<td>6.3</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>— %</td>
<td>— %</td>
<td>— %</td>
</tr>
</tbody>
</table>

**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 is as follows (in thousands):

<table>
<thead>
<tr>
<th>Years Ended December 31,</th>
<th>2016</th>
<th>2015</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development</td>
<td>$1,090</td>
<td>$1,038</td>
<td>$178</td>
</tr>
<tr>
<td>General and administrative</td>
<td>1,993</td>
<td>1,050</td>
<td>93</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$3,083</strong></td>
<td><strong>$2,088</strong></td>
<td><strong>$271</strong></td>
</tr>
</tbody>
</table>

As of December 31, 2016 and 2015, the unrecognized compensation cost related to outstanding time-based employee options was $4.0 million and $7.0 million, respectively, and is expected to be recognized as expense over approximately 2.1 years and 3.0 years, respectively.

**Common Stock Reserved for Future Issuance**

Common stock reserved for future issuance is as follows:

<table>
<thead>
<tr>
<th>December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Common stock warrants</td>
</tr>
<tr>
<td>Common stock options and restricted stock units granted and outstanding</td>
</tr>
<tr>
<td>Awards available under the 2015 Plan</td>
</tr>
<tr>
<td>Shares available under the Employee Stock Purchase Plan</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>
7. Collaboration

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. The license agreement provides for various types of payments, including the upfront payment, payment for various technical and regulatory support, payments for delivery of drug substance, reimbursement of certain development costs, milestone payments, and royalties on net product sales. The Company has identified multiple deliverables, which include at inception: (1) a license to patents, information and know-how related to TRC105, (2) technology transfer, (3) collaboration, including technical and regulatory support provided by the Company, (4) manufacturing and supply obligations, and (5) shared chemistry, manufacturing and controls (CMC) development activities. Deliverables 1 and 2 above were substantially delivered at the inception of the agreement, and deliverables 3 through 5 are expected to be delivered during the estimated 31-month period over which the Company will provide technical and regulatory support to Santen. At inception and through December 31, 2016, the Company has identified one single unit of accounting for all the deliverables under the agreement since the delivered elements do not have standalone value. The Company’s technical and regulatory expertise, including manufacturing and CMC activities, in the development of biologic therapeutics, specifically TRC105, is a significant component of Santen’s ability to utilize the license and know-how related to TRC105. Given the early stage of development of TRC105 for ophthalmology, the Company is the only party capable of performing the level and type of technical and regulatory collaboration services required by Santen under the agreement. As a result, the Company has determined that the license, including the ability to sublicense, and know-how related to TRC105 do not have standalone value to a licensee. As such, the Company is recognizing revenue for the fixed or determinable collaboration consideration on a straight-line basis over the estimated 43-month period over which it will deliver its technical and regulatory support.

During the year ended December 31, 2016, the expected term over which the Company will provide technical and regulatory support to Santen was extended from 31 to 43 months. The changes in the estimated term decreased net loss by $0.6 million, or $0.04 per share for the three months ended December 31, 2016, and increased net loss by $1.3 million, or $0.10 per share, for the twelve months ended December 31, 2016.

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. The Company has determined that $10.0 million related to the initiation of certain clinical development activities will be based upon its efforts and meet the criteria of substantive milestones and therefore will be recognized as revenue upon achievement of the milestone in accordance with the milestone method of accounting. The remaining $145.0 million of potential milestone payments are not substantive milestones as they do not require the efforts of the Company. During the year ended December 31, 2015, a development milestone that was deemed a substantive milestone at the inception of the arrangement was achieved, and accordingly, the milestone payment of $3.0 million was recognized as revenue.

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.

In connection with the collaboration with Santen, the Company recognized revenue of $3.4 and $7.9 million for the years ended December 31, 2016 and 2015, respectively, and had deferred revenue of $1.3 million and $3.4 million as of December 31, 2016 and 2015, 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, and, together with the AR Mutant Program, the Programs).

With respect to the AR Mutant Program, Janssen maintains an option, which is exercisable until 90 days after the Company demonstrates clinical proof of concept, 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.

With respect to the NIK Program, Janssen maintains a right, which is exercisable within 90 days following the date on which the Company demonstrates clinical proof of concept with respect to the NIK Program, to negotiate exclusively for a period of six months for a reversion of the related rights in the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the NIK Program. If Janssen does not exercise its right of first negotiation, or, if after exercise of such right, the Company and Janssen are unable to reach an agreement on the terms of a reversion and exclusive license, and, in either case, the Company continues the development of the NIK Program, then the Company would be obligated to pay Janssen (i) development and regulatory based milestone payments totaling up to $60.0 million upon achievement of specified events, and (ii) royalties in the low single digits based on annual net sales of NIK 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, no value has been assigned to these assets in the accompanying consolidated balance sheet.

The Company is obligated to use diligent efforts to develop the Programs 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 or the NIK Program, as applicable, 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 or the NIK Program, as applicable, 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 (a) 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, and (b) with respect to the NIK Program, upon the Company and Janssen entering into an exclusive license agreement following Janssen’s exercise of its right of first negotiation or, if Janssen’s right of first negotiation with respect to the NIK Program expires and the Company and Janssen have not entered into an exclusive license agreement, upon the expiration of all payment obligations of the Company to Janssen with respect of the NIK Program. The Company may also terminate a Program or the Agreement in its entirety without cause, subject to specified conditions.
8. Income Taxes

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

<table>
<thead>
<tr>
<th>Years Ended December 31,</th>
<th>2016</th>
<th>2015</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal income taxes</td>
<td>$ (9,453)</td>
<td>$ (8,300)</td>
<td>$ (2,315)</td>
</tr>
<tr>
<td>State income taxes, net of federal benefit</td>
<td>—</td>
<td>—</td>
<td>(381)</td>
</tr>
<tr>
<td>Permanent items</td>
<td>717</td>
<td>277</td>
<td>59</td>
</tr>
<tr>
<td>Uncertain tax positions</td>
<td>1,644</td>
<td>749</td>
<td>—</td>
</tr>
<tr>
<td>Research and development credits</td>
<td>(2,078)</td>
<td>(881)</td>
<td>(252)</td>
</tr>
<tr>
<td>California net operating loss carryforwards</td>
<td>(1,054)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Rate change</td>
<td>(489)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Other, net</td>
<td>5</td>
<td>82</td>
<td>18</td>
</tr>
<tr>
<td>Change in valuation allowance</td>
<td>10,708</td>
<td>8,073</td>
<td>2,871</td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>December 31,</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred tax assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net operating loss carryforwards</td>
<td>$ 24,484</td>
<td>$ 14,950</td>
</tr>
<tr>
<td>Research and development credits</td>
<td>3,262</td>
<td>1,606</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>441</td>
<td>1,140</td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>229</td>
<td>121</td>
</tr>
<tr>
<td>Other, net</td>
<td>1,753</td>
<td>818</td>
</tr>
<tr>
<td>Total deferred tax assets</td>
<td>30,169</td>
<td>18,635</td>
</tr>
<tr>
<td>Valuation allowance</td>
<td>(30,169)</td>
<td>(18,635)</td>
</tr>
<tr>
<td>Net deferred tax assets</td>
<td>$ —</td>
<td>$ —</td>
</tr>
</tbody>
</table>

The Company has net deferred tax assets relating primarily to net operating loss (NOL) carryforwards and research and development 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, 2016, 2015 and 2014 was $10.7 million, $8.1 million and $2.9 million, respectively.

At December 31, 2016, the Company had federal and California NOL carryforwards of approximately $69.1 million and $44.0 million, respectively. The federal and California NOL carryforwards will begin to expire in 2030, unless previously utilized. At December 31, 2016, the Company also had federal and California research and development and Orphan Drug credit carryforwards of approximately $3.6 million and $1.1 million, respectively. The federal research and development credit carryforwards will begin expiring in 2031 unless previously utilized. The California research credit carryforward does not expire.

Pursuant to Sections 382 and 383 of the Code, 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, 2015 and as a result of the analysis, ownership changes were determined to have occurred and certain deferred tax assets were written off. The Company will continue to consider changes in ownership that may cause losses of tax attributes in the future.

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

<table>
<thead>
<tr>
<th></th>
<th>First Quarter</th>
<th>Second Quarter</th>
<th>Third Quarter</th>
<th>Fourth Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016 Revenue</td>
<td>$1,210</td>
<td>$807</td>
<td>$815</td>
<td>$617</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>$7,504</td>
<td>$8,817</td>
<td>$6,412</td>
<td>$6,692</td>
</tr>
<tr>
<td>Consolidated net loss</td>
<td>$(6,526)</td>
<td>$(8,297)</td>
<td>$(5,871)</td>
<td>$(6,314)</td>
</tr>
<tr>
<td>Basic and diluted net loss</td>
<td>$(0.54)</td>
<td>$(0.68)</td>
<td>$(0.48)</td>
<td>$(0.45)</td>
</tr>
<tr>
<td>attributable to common stockholders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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, 2016, 2015 and 2014 totaled approximately $172,000, $107,000 and $73,000, 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, 2016 and 2015 are as follows (in thousands, except per share data):
11. Subsequent Event

On February 22, 2017, the Company entered into a long-term 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, 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 $15.0 million. The timing of payments for pre-approval batches will be in accordance with a project plan to be agreed to by the Company and Lonza Biologics. If the parties are unable to agree to a project plan either party may terminate the manufacturing agreement as described below, and the Company’s obligations to purchase the pre-approval batches would be cancelled without penalty to the Company. 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 $22.0 million. 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 Biologics 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 Biologics’ facility, the manufacturing process or services performed by Lonza Biologics.

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, due to a force majeure event that prevents performance under the Manufacturing Agreement for at least six months, or if the parties fail to enter into an initial project plan within 90 days of the date of the Manufacturing Agreement (which period may be extended by mutual agreement of the parties). 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.

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 and Chief Financial 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 and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of December 31, 2016, the end of the period covered by this report. Based upon the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2016.

Management’s Report on Internal Control Over Financial Reporting

Our Management is responsible for establishing and maintaining adequate internal control over 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, 2016. 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, 2016, 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, 2016, 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.

Manufacturing Agreement

On February 22, 2017, we entered into 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. Lonza has previously been providing TRC105 for clinical development on a batch-by-batch basis.

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. The TRC105 drug substance will be manufactured at a Lonza facility that has not previously manufactured TRC105, and we and Lonza are obligated to cooperate to transfer the TRC105 manufacturing process to the facility. 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, due to a force majeure event that prevents performance under the Manufacturing Agreement for at least six months, or if the parties fail to enter into an initial project plan within 90 days of the date of the Manufacturing Agreement (which period may be extended by mutual agreement of the parties). 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.

The foregoing is only a summary of certain provisions of the Manufacturing Agreement and is qualified in its entirety by the terms of the Manufacturing Agreement, a copy of which will be filed as an exhibit to our quarterly report on Form 10-Q for the quarter ending March 31, 2017.

Amended and Restated Employment Agreement – Dr. Theuer

On February 27, 2017, we entered into an Amended and Restated Employment Agreement with Charles P. Theuer, our President and Chief Executive Officer, which amends, restates and supersedes in its entirety Dr. Theuer’s employment agreement entered into in May 2015. Pursuant to the amended employment agreement, Dr. Theuer is entitled to an annual base salary of $532,400 and is eligible to receive an annual performance bonus of up to 50% of his base salary, as determined by our board of directors.

Pursuant to the amended employment agreement, Dr. Theuer is also entitled to certain severance benefits and other payments upon the occurrence of certain events. If Dr. Theuer’s employment is terminated without cause or he resigns for good reason, in each case, other than in connection with a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for 12 months, employee benefit coverage for up to 12 months and 100% automatic vesting of any unvested time-based stock option awards. If Dr. Theuer’s employment is terminated without cause or he resigns for good reason within 12 months following a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for 18 months, 150% of his annual performance bonus, employee benefit coverage for up to 18 months and 100% automatic vesting of any unvested time-based stock option awards. In addition, if Dr. Theuer’s employment is terminated as a result of his death, his estate would be entitled to a one-time lump-sum payment equal to his base salary for 12 months and his stock option.
awards would vest on an accelerated basis as if his termination occurred 6 months later. If Dr. Theuer’s employment is terminated as a result of disability, his stock option awards would vest on an accelerated basis as if his termination occurred 6 months later. If Dr. Theuer’s employment is terminated for cause or if he resigns without good reason, he would be entitled to his base salary owed to him, any expense reimbursement owed to him, and any other benefits accrued, in each case, as of the date of his termination.

Amended and Restated Employment Agreement and Severance Agreement – Mr. Logan

On February 27, 2017, we entered into an Amended and Restated Employment Agreement with H. Casey Logan, our Chief Business Officer, which amends, restates and supersedes in its entirety Mr. Logan’s employment agreement entered into in February 2013. Pursuant to the amended employment agreement, Mr. Logan is entitled to an annual base salary of $324,400 and is eligible to receive an annual performance bonus of up to 35% of his base salary, as determined by our board of directors. Upon termination of Mr. Logan’s employment for any reason, he would be entitled to his base salary owed to him, any expense reimbursement owed to him, and any other benefits accrued, in each case, as of the date of his termination.

On February 27, 2017, we also entered into a Severance Agreement with Mr. Logan. Pursuant to the severance agreement, Mr. Logan is entitled to certain severance benefits and other payments upon the occurrence of certain events. If Mr. Logan’s employment is terminated without cause or he resigns for good reason, in each case, other than in connection with a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for 9 months, employee benefit coverage for up to 9 months and 100% automatic vesting of any unvested time-based stock option awards. If Mr. Logan’s employment is terminated without cause or he resigns for good reason within 12 months following a change in control, he would be entitled to receive severance payments equal to continued payment of his base salary for 12 months, 100% of his annual performance bonus, employee benefit coverage for up to 12 months and 100% automatic vesting of any unvested time-based stock option awards.

Employment Agreement and Amended and Restated Severance Agreement – Ms. Bitar

On February 27, 2017, we entered into an Employment Agreement with Patricia Bitar, our Chief Financial Officer, which supersedes in its entirety our prior employment offer letter with Ms. Bitar. Pursuant to the employment agreement, Ms. Bitar is entitled to an annual base salary of $342,125 and is eligible to receive an annual performance bonus of up to 35% of her base salary, as determined by our board of directors. Upon termination of Ms. Bitar’s employment for any reason, she would be entitled to her base salary owed to her, any expense reimbursement owed to her, and any other benefits accrued, in each case, as of the date of her termination.

On February 27, 2017, we also entered into an Amended and Restated Severance Agreement with Ms. Bitar, which amends, restates and supersedes in its entirety Ms. Bitar’s severance agreement entered into in September 2014. Pursuant to the amended severance agreement, Ms. Bitar is entitled to certain severance benefits and other payments upon the occurrence of certain events. If Ms. Bitar’s employment is terminated without cause or she resigns for good reason, in each case, other than in connection with a change in control, she would be entitled to receive severance payments equal to continued payment of her base salary for 9 months, employee benefit coverage for up to 9 months and 100% automatic vesting of any unvested time-based stock option awards. If Ms. Bitar’s employment is terminated without cause or she resigns for good reason within 12 months following a change in control, she would be entitled to receive severance payments equal to continued payment of her base salary for 12 months, 100% of her annual performance bonus, employee benefit coverage for up to 12 months and 100% automatic vesting of any unvested time-based stock option awards.

The foregoing summaries of the employment and severance agreements do not purport to be complete and are qualified in their entirety by reference to the complete agreements, copies of which are attached to this Annual Report as Exhibits 10.7, 10.8, 10.12, 10.9 and 10.10, respectively, and are incorporated herein by reference.
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 2017 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, 2016, 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.


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


(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, 2016:

- Report of Independent Registered Public Accounting Firm
- Balance Sheets
- Statements of Operations
- Statements of Redeemable Convertible Preferred Stock and Stockholders’ Equity (Deficit)
- Statements of Cash Flows
- Notes to Financial Statements

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

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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.

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 Patricia L. Bitar, CPA, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his 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

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<td>/s/ Patricia L. Bitar, CPA</td>
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(13) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on December 13, 2016.
The TRACON Pharmaceuticals, Inc. ("TRACON" or the "Company") Bonus Plan (the "Plan") is designed to reward eligible employees for the achievement of corporate objectives, as well as measured individual objectives that are consistent with and support the overall corporate objectives.

ELIGIBILITY

All regular employees are eligible to participate in the Plan. In order to be eligible, a participant must have been in an eligible position for at least three (3) full months prior to the end of the Plan year, and the participant must remain employed through the end of the Plan year and until awards are paid. If the participant is not employed on the date awards are paid, the participant will not have earned any bonus. If the participant has been subject to any performance improvement plan or other disciplinary procedure during the Plan year, any award to such individual will be at the discretion of the President/CEO or the Compensation Committee of the Board of Directors (the "Compensation Committee"), and may be reduced or withheld regardless of corporate performance as outlined below.

Change in Status During the Plan Period:

a. Participants hired during the Plan year:
   • Participants hired during the Plan year are eligible for a prorated award based on the number of calendar days employed in an eligible position.
   • Participants hired during the months of October through December are not eligible to participate for the Plan year.
   • If an employee has worked in a temporary or consulting capacity for TRACON, this time will NOT impact the eligibility start date which is the date of hire. Only as an exception and with approval by the Compensation Committee or the Board of Directors will time worked as a consultant be considered when determining the bonus award proration for an employee.

b. Promotion/change in level:
   • Participants promoted during the Plan year with a change to bonus target and/or bonus corporate and individual performance factor percentages are eligible for an award that will be prorated based on the number of calendar days employed in each eligible position.

c. Termination of employment:
   • If a participant’s employment is terminated voluntarily prior to the date awards are paid, the participant will not be eligible to receive an award.
   • If a participant’s employment is terminated involuntarily prior to the date awards are paid, it will be at the absolute discretion of the Company whether or not an award payment is made.

d. Leave of absence:
   • Bonus award will be prorated to reflect the calendar days on a leave of absence that exceed 60 calendar days in the Plan year.

AWARD CALCULATION

Awards will be determined by applying a “bonus percentage” to the participant’s base salary that is in effect at the end of the Plan year, regardless if the salary has changed at any point during the calendar year.

The President/CEO will present to the Compensation Committee/Board of Directors a list of the overall corporate objectives for the applicable Plan year, which are subject to approval by the Compensation Committee/Board of Directors. All participants in the Plan whose performance is measured in part based on individual performance factors will then develop a list of key individual objectives, which must be approved by the responsible Vice President, Senior Vice President, Chief Officer, or President/CEO.
The relative weight between “corporate and individual performance factors” varies based on the individual’s assigned level within the organization. The bonus percentage and/or the weighting may be reviewed periodically and may be adjusted for any Plan year by the Compensation Committee. The bonus percentages and weighting for the performance factors will initially be as follows:

<table>
<thead>
<tr>
<th>LEVEL/POSITION</th>
<th>Bonus Percentage</th>
<th>Corporate Factor</th>
<th>Core Competency</th>
<th>Individual Goal Achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>President and CEO</td>
<td>50%</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chief Officer</td>
<td>35%</td>
<td>75%</td>
<td>10%</td>
<td>15%</td>
</tr>
<tr>
<td>Senior Vice President</td>
<td>35%</td>
<td>75%</td>
<td>10%</td>
<td>15%</td>
</tr>
<tr>
<td>Vice President</td>
<td>30%</td>
<td>60%</td>
<td>16%</td>
<td>24%</td>
</tr>
<tr>
<td>Senior Director</td>
<td>20%</td>
<td>40%</td>
<td>24%</td>
<td>36%</td>
</tr>
<tr>
<td>Director</td>
<td>20%</td>
<td>40%</td>
<td>24%</td>
<td>36%</td>
</tr>
<tr>
<td>Associate Director</td>
<td>20%</td>
<td>40%</td>
<td>24%</td>
<td>36%</td>
</tr>
<tr>
<td>Senior Manager II, I</td>
<td>20%</td>
<td>25%</td>
<td>30%</td>
<td>45%</td>
</tr>
<tr>
<td>Manager II, I</td>
<td>20%</td>
<td>25%</td>
<td>30%</td>
<td>45%</td>
</tr>
<tr>
<td>Individual Contributor II, I</td>
<td>20%</td>
<td>25%</td>
<td>30%</td>
<td>45%</td>
</tr>
<tr>
<td>Support</td>
<td>20%</td>
<td>25%</td>
<td>30%</td>
<td>45%</td>
</tr>
</tbody>
</table>

**Performance Award Multiplier**

Separate award multipliers will be established for both the corporate and the individual components of each award. The award multiplier for the corporate component will be determined by the Compensation Committee/Board of Directors each Plan year, in its sole discretion, based on the achievement of the approved corporate objectives for the Plan year. The same award multiplier for the corporate component of the award shall be used for all such Plan participants.

The award multiplier for the individual component shall be approved by the responsible Chief Officer or President/CEO and consists of the Core Competency Assessment and the achievement of Individual goals, each weighted 40% and 60%, respectively.
The ratings used for the Annual Performance Core Competency Assessment is as follows:

5 = Exceptional; Far exceeds all goals and objectives on a consistent basis
4 = Exceeds; Consistently exceeds goals and objectives
3 = Meets; Consistently meets goals and objectives
2 = Marginal; Met some goals and objectives but requires improvement
1 = Unsatisfactory

<table>
<thead>
<tr>
<th>Numerical Rating Scale</th>
<th>Multiplier for Core Competency Individual Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>120.00%</td>
</tr>
<tr>
<td>4.9</td>
<td>118.37%</td>
</tr>
<tr>
<td>4.8</td>
<td>116.70%</td>
</tr>
<tr>
<td>4.7</td>
<td>115.03%</td>
</tr>
<tr>
<td>4.6</td>
<td>113.36%</td>
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<tr>
<td>4.5</td>
<td>111.69%</td>
</tr>
<tr>
<td>4.4</td>
<td>110.02%</td>
</tr>
<tr>
<td>4.3</td>
<td>108.35%</td>
</tr>
<tr>
<td>4.2</td>
<td>106.68%</td>
</tr>
<tr>
<td>4.1</td>
<td>105.01%</td>
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<tr>
<td>4</td>
<td>103.34%</td>
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<tr>
<td>3.9</td>
<td>101.67%</td>
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<td>3.8</td>
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<td>3.3</td>
<td>87.50%</td>
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<td>85.00%</td>
</tr>
<tr>
<td>3.1</td>
<td>82.50%</td>
</tr>
<tr>
<td>3</td>
<td>80.00%</td>
</tr>
<tr>
<td>2.9</td>
<td>72.00%</td>
</tr>
<tr>
<td>2.8</td>
<td>64.00%</td>
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<tr>
<td>2.7</td>
<td>56.00%</td>
</tr>
<tr>
<td>2.6</td>
<td>48.00%</td>
</tr>
<tr>
<td>2.5</td>
<td>40.00%</td>
</tr>
<tr>
<td>2.4</td>
<td>32.00%</td>
</tr>
<tr>
<td>2.3</td>
<td>24.00%</td>
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<tr>
<td>2.2</td>
<td>16.00%</td>
</tr>
<tr>
<td>2.1</td>
<td>8.00%</td>
</tr>
<tr>
<td>2</td>
<td>0.00%</td>
</tr>
</tbody>
</table>
For Executives (Vice President level and above): The actual performance bonus awarded in any year, if any, may be more or less than the applicable target, depending primarily on the Compensation Committee’s determination of the award multiplier for the corporate component and the executive’s individual performance with respect to the corporate objectives. Whether or not performance bonus is paid for any year is within the discretion of the Compensation Committee/Board of Directors based on such achievement.

Example:

**Step #1:** Potential bonus award calculation

Position: Manager  
Base salary at end of calendar year: $100,000  
Target bonus percentage: 20%  
Potential base bonus: $20,000

**Step #2:** Split award target amount based on weighting of performance factors

Potential corporate performance bonus (25%): $5,000  
Target individual performance bonus (75%):  
- Core Competency (40% of 75%, or 30%) $6,000  
- Personal Goal Achievement (60% of 75%, or 45%) $9,000  
$20,000

**Step #2:** Actual bonus award calculation

Payment multipliers are determined and approved based on assessment of corporate and individual performance, for example:

- Corporate multiplier: 25.0%
- Core Competency Assessment multiplier: 116.7% - performance assessed at 4.8
- Personal Goal Objective Performance: 85.0%

- Corporate component: $3,750 ($5,000 x 25.0%)
- Individual component:  
  - Core Competency Assessment: $7,002 ($6,000 x 116.7%)
  - Individual Goals Achieved: $7,650 ($9,000 x 85.0%)

Total Award: $18,402

**AWARD PAYMENTS**

Bonus award payments may be made in cash, through the issuance of stock, stock options or another form of equity award, or by a combination of cash, stock, stock options and/or another form of equity award, at the discretion of the Compensation Committee. All bonus award payments are subject to applicable tax withholdings. In the event that the Compensation Committee and/or the Board of Directors elect to pay bonus awards in stock or stock options, the Compensation Committee, in its sole discretion, will make a determination as to the number of shares of stock or stock options to be issued to each Plan participant based, in part, upon the overall corporate performance and each participant’s individual performance, as described. The issuance of stock and stock options may also be subject to the approval of the Company’s stockholders, and any stock options issued will be subject to the terms and conditions of the Company’s equity incentive award plan, as amended from time to time by the Company.

Payment of bonus awards will be made as soon as practicable after the Company’s year-end, but not later than December 31 of the year following the Plan year. Payments will not be impacted by any benefits, with the exception of elected 401(k) contributions which will be applied.
**PLAN PROVISIONS**

**Governance**

The Plan will be governed by the Compensation Committee. The President and/or CEO of TRACON will be responsible for the administration of the Plan. The Compensation Committee will be responsible for recommending to the Board of Directors a bonus amount for the President and/or CEO (unless such compensation is intended to be qualified, performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, as amended). Additionally, the Compensation Committee will be responsible for approving any compensation or incentive awards to other executive officers of the Company and all other officers who are subject to the reporting requirements of Section 16(a) of the Securities Exchange Act of 1934, as amended. All determinations of the Compensation Committee, under the Plan, shall be final and binding on all Plan participants.

**Compensation Committee’s Absolute Right to Alter or Abolish the Plan**

The Compensation Committee reserves the right in its absolute discretion to terminate the Plan, or any portion of the Plan, at any time or to alter the terms and conditions under which a bonus will be paid. In the event of the Plan’s termination prior to the payment of a bonus, such bonus will not be payable under this Plan. Such discretion may be exercised any time before, during, and after the Plan year is completed. No participant shall have any vested right to receive any compensation hereunder until actual delivery of such compensation. Participation in the Plan at any given time does not guarantee ongoing participation.

**Employment Duration/Employment Relationship**

This Plan does not, and TRACON’s policies and practices in administering this Plan do not, constitute an express or implied contract or other agreement concerning the duration of any participant’s employment with the Company. The employment relationship of each participant is “at will” and may be terminated at any time by TRACON or by the participant, with or without cause.

*Any questions pertaining to this Plan should be directed to the Human Resources Department.*

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This Amended and Restated Employment Agreement (the “Agreement”) is made and entered into effective as of February 27, 2017 (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 May 8, 2015 (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 $532,400 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.

3.
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, 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.
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.


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

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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.


16.1 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/ Patricia L. Bitar
Patricia L. Bitar
Chief Financial Officer

EXECUTIVE

/s/ Charles P. Theuer
Charles P. Theuer

12.
TRACON PHARMACEUTICALS, INC.

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

For

H. CASEY LOGAN

This AMENDED AND RESTATED EMPLOYMENT AGREEMENT (the “Agreement”) is made and entered into effective as of February 27, 2017 (the “Effective Date”), by and between TRACON Pharmaceuticals, Inc., a Delaware corporation (the “Company”), and H. Casey Logan (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 along with the Severance Agreement entered into by and between Executive and the Company concurrently with this Agreement (the “Severance Agreement”) shall replace and supersede that certain Employment Agreement between Executive and Company entered into as of February 18, 2013 (the “Prior Agreement”). Certain capitalized terms used in this Agreement are defined in Section 11.

RECEITALS

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

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 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 continue to 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 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 Chief Executive Officer (the “CEO”), and shall have such duties and responsibilities

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as are customary for the positions of Chief Business 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.

2. Compensation.

2.1 Salary. Executive shall receive a base salary at the rate of $324,600 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 35% 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 Company’s Board of Directors (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.

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 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 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 of 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.


9.1 Confidential Information Agreement. As a condition of continued employment, Executive acknowledges and reaffirms Executive’s obligations to the Company under the Employee Proprietary Information and Inventions Agreement Executive executed on or about September 17, 2014 (the “Confidentiality Agreement”).

9.2 Third-Party Agreements and Information. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive’s employment by the Company, except as expressly authorized by that third party. During Executive’s employment by the Company, Executive will use in the performance of Executive’s duties only information which is generally known and used by persons with training and experience comparable to Executive’s own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive’s work for the Company.
10. Outside Activities During Employment.

10.1 Non-Company Business. Except with the prior written consent of the Board, Executive will not during the term of Executive’s employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive’s duties hereunder.

10.2 No Adverse Interests. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

11. Dispute Resolution. To ensure the rapid and economical resolution of disputes that may arise in connection with Executive’s employment and services for the Company, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive’s employment with and services for the Company, or the termination of Executive’s employment with and services for the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §§1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted in San Diego, California (or such other location as mutually agreed by the parties) by JAMS, Inc. (“JAMS”) or its successors by a single arbitrator. Both Executive and the Company acknowledge that by agreeing to this arbitration procedure, they each waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. Any such arbitration proceeding will be governed by JAMS’ then applicable rules and procedures for employment disputes, which can be found at http://www.jamsadr.com/rules-clauses/ and which will be provided to Executive upon request. In any such proceeding, the arbitrator shall (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision including the arbitrator’s essential findings and conclusions and a statement of the award. Executive and the Company each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. Nothing in this Agreement is intended to prevent either the Company or Executive from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. The Company shall pay all filing fees in excess of those that would be required if the dispute were decided in a court of law, and shall pay the arbitrator’s fees and any other fees or costs unique to arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.


12.1 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 Agreement and 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 but not limited to the Prior Agreement). 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 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.

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
Chief Executive Officer

/s/ H. Casey Logan

H. Casey Logan

6.
TRACON PHARMACEUTICALS, INC.

EMPLOYMENT AGREEMENT

For

PATRICIA BITAR

This EMPLOYMENT AGREEMENT (the “Agreement”) is made and entered into effective as of February 27, 2017 (the “Effective Date”), by and between TRACON Pharmaceuticals, Inc., a Delaware corporation (the “Company”), and Patricia Bitar (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 along with the Amended and Restated Severance Agreement entered into by and between Executive and the Company concurrently with this Agreement (the “Amended Severance Agreement”) shall set forth the terms of Executive’s employment and shall supersede the terms of the Severance Agreement between the Company and Executive dated February 15, 2016 (the “Prior Agreement”). Certain capitalized terms used in this Agreement are defined in Section 11.

RECORDALS

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

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 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 continue to serve as the Company’s Chief Financial 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.

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1.2 **Duties and Location.** Executive shall continue to report to the Company’s Chief Executive Officer (the “CEO”), and shall have such duties and responsibilities as are customary for the positions of Chief Financial 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.

2. **Compensation.**

2.1 **Salary.** Executive shall receive a base salary at the rate of $342,125 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 35% 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 Company’s Board of Directors (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 accordance with the terms of the Company’s vacation policy and practices (including but not limited to maximum vacation accrual caps).

5. **Expenses.** The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in furtherance or in connection with the performance of Executive’s duties hereunder, in accordance with the Company’s expense reimbursement policy as in effect from time to time.

6.
Equity.

6.1 Prior Awards. Any stock, stock options, or other equity awards that Executive has already been granted by the Company shall continue to be governed in all respects by the terms of the applicable grant agreements, grant notices, and plan documents, except as otherwise provided in this agreement.

6.2 Additional Awards. The Board (or the Compensation Committee thereof) may grant additional stock, stock options, or other equity awards to Executive in its sole discretion.

7. Termination of Employment.

7.1 At-Will Employment. Executive’s employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without cause or advance notice.

7.2 Termination Benefits. In the event that Executive’s employment terminates for any reason, including due to Executive’s death or disability, no further payments shall be due under this Agreement, except that 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 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 of the Amended 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.


9.1 Confidential Information Agreement. As a condition of continued employment, Executive acknowledges and reaffirms Executive’s obligations to the Company under the Employee Proprietary Information and Inventions Agreement which Executive executed on or about September 23, 2014 (the “Confidentiality Agreement”).

9.2 Third-Party Agreements and Information. Executive represents and warrants that Executive’s employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive’s duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive’s employment by the Company, except as expressly authorized by that third party. During Executive’s employment by the Company, Executive will use in the
performance of Executive’s duties only information which is generally known and used by persons with training and experience comparable to Executive’s own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive’s work for the Company.

10. Outside Activities During Employment.

10.1 Non-Company Business. Except with the prior written consent of the Board, Executive will not during the term of Executive’s employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive’s duties hereunder.

10.2 No Adverse Interests. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

11. Dispute Resolution. To ensure the rapid and economical resolution of disputes that may arise in connection with Executive’s employment and services for the Company, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive’s employment with and services for the Company, or the termination of Executive’s employment with and services for the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §§1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted in San Diego, California (or such other location as mutually agreed by the parties) by JAMS, Inc. (“JAMS”) or its successors by a single arbitrator. Both Executive and the Company acknowledge that by agreeing to this arbitration procedure, they each waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. Any such arbitration proceeding will be governed by JAMS’ then applicable rules and procedures for employment disputes, which can be found at http://www.jamsadr.com/rules-clauses/ and which will be provided to Executive upon request. In any such proceeding, the arbitrator shall (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision including the arbitrator’s essential findings and conclusions and a statement of the award. Executive and the Company each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. Nothing in this Agreement is intended to prevent either the Company or Executive from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. The Company shall pay all filing fees in excess of those that would be required if the dispute were decided in a court of law, and shall pay the arbitrator’s fees and any other fees or costs unique to arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.


4.
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 Agreement and 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 but not limited to the Prior Agreement). 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 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.

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/ Patricia L. Bitar
Patricia L. Bitar

6.
This Amended and Restated Severance Agreement (the “Agreement”) is entered into by and between Patricia Bitar (“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.

This Agreement has an effective date of February 27, 2017 (the “Effective Date”) and as of the Effective Date amends, restates and supersedes in its entirety the Severance Agreement between you and the Company dated September 22, 2014, as amended on February 15, 2016. 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 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;
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) 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;

   -6-
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;

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.

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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.  PATRICIA BITAR

/s/ Charles P. Theuer  /s/ Patricia L. Bitar
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 Amended and Restated Severance Agreement dated [DATE], 2017 (the “Severance Agreement”) entered into by and between Patricia Bitar (“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.]

Exhibit A-1
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 (i i) 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") of the Company's group health plan, the Company shall pay the entire applicable premiums to continue Employee's existing medical and dental benefits through [DATE], which represents [_____] month[s] following the Termination Date. Thereafter, Employee shall be eligible to continue his or her medical and dental benefits at his or her own cost in accordance with COBRA. If at any time subsequent to the Termination Date, Employee obtains medical and dental benefits through another employer, Employee shall immediately notify the Company that he or she has obtained such medical and dental benefits and the Company shall no longer be required to pay any premiums for Employee's medical and dental benefits as of the date that Employee's new medical and dental benefits begin coverage.

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 "Releas...
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.

Exhibit A-3
9. In the event a government agency files or pursues a charge or complaint relating to Employee’s employment with the Company and/or the Disputes, Employee agrees not to accept any monetary or other benefits arising out of the charge or complaint.

10. Employee agrees not to make any derogatory, disparaging or negative comments about the Company, its products, officers, directors, or employees.

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.
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.

Exhibit A-5
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: ____________

PATRICIA BITAR

TRACON Pharmaceuticals, Inc.

Dated: ____________

Name:
Title:

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

This Severance Agreement (the “Agreement”) is entered into by and between H. Casey Logan (“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.

This Agreement has an effective date of February 27, 2017 (the “Effective Date”) and as of the Effective Date, together with your Amended and Restated Employment Agreement with the Company entered into concurrently with this Agreement, amends, restates and supersedes in its entirety the Employment Agreement between you and the Company dated February 18, 2013. You have been designated as a Covered Employee 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 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(m)(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.

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3. **Change in Control Related Termination of Employment.** If your employment is terminated due to a Change in Control, 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 "**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.

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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) 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;

(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.     H. CASEY LOGAN

/s/ Charles P. Theuer               /s/ H. Casey Logan
BY: Charles P. Theuer, President and CEO
This Separation Agreement and General Release, dated [DATE] (the “Agreement”), is made pursuant to that certain Severance Agreement dated [DATE], 2017 (the “Severance Agreement”) entered into by and between H. Casey Logan (“Employee”) on the one hand, and TRACON Pharmaceuticals, Inc. (“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.]

Exhibit A-1
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") of the Company's group health plan, the Company shall pay the entire applicable premiums to continue Employee's existing medical and dental benefits through [DATE], which represents [_____] month[s] following the Termination Date. Thereafter, Employee shall be eligible to continue his or her medical and dental benefits at his or her own cost in accordance with COBRA. If at any time subsequent to the Termination Date, Employee obtains medical and dental benefits through another employer, Employee shall immediately notify the Company that he or she has obtained such medical and dental benefits and the Company shall no longer be required to pay any premiums for Employee's medical and dental benefits as of the date that Employee's new medical and dental benefits begin coverage.

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

Exhibit A-2
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.

Exhibit A-3
9. In the event a government agency files or pursues a charge or complaint relating to Employee’s employment with the Company and/or the Disputes, Employee agrees not to accept any monetary or other benefits arising out of the charge or complaint.

10. Employee agrees not to make any derogatory, disparaging or negative comments about the Company, its products, officers, directors, or employees.

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.

Exhibit A-4
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.

Exhibit A-5
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: ____________

H. CASEY LOGAN

TRACON Pharmaceuticals, Inc.

Dated: ____________

Name:
Title:

[Signature Page to Separation Agreement and General Release of All Claims]
CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the 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., and
(2) Registration Statement (Form S-3 No. 333-209313) of TRACON Pharmaceuticals, Inc.;

of our report dated February 28, 2017, 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, 2016, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2017
CERTIFICATION OF PRINCIPAL EXECUTIVE 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, 2017

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer
CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Patricia L. Bitar, CPA, 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, 2017

/s/ Patricia L. Bitar, CPA
Patricia L. Bitar, CPA
Chief Financial Officer
(Principal Financial Officer)
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., Ph.D., 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, 2017

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive 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.
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Patricia L. Bitar, CPA, Chief Financial 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, 2017

/s/ Patricia L. Bitar, CPA
Patricia L. Bitar, CPA
Chief 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.