

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **February 10, 2020**

TRACON Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36818

(Commission File Number)

34-2037594

(IRS Employer Identification No.)

**4350 La Jolla Village Drive, Suite 800
San Diego, California**

(Address of principal executive offices)

92122

(Zip Code)

Registrant's telephone number, including area code: (858) 550-0780

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☒

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

Item 7.01 Regulation FD Disclosure.

Charles P. Theuer, M.D., Ph.D., President and Chief Executive Officer of TRACON Pharmaceuticals, Inc. (“TRACON”), and other executive officers will be presenting the information attached as Exhibit 99.1 to this Current Report on Form 8-K at various upcoming meetings beginning February 10, 2020.

By furnishing this information, TRACON makes no admission as to the materiality of any information in this report. The information contained in this report and the exhibit hereto is intended to be considered in the context of TRACON’s filings with the Securities and Exchange Commission and other public announcements that TRACON makes, by press release or otherwise, from time to time. TRACON undertakes no duty or obligation to publicly update or revise the information contained in this report or the exhibit hereto, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosure.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate Presentation, dated February 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TRACON Pharmaceuticals, Inc.

Dated: February 10, 2020

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

Charles P. Theuer, M.D., Ph.D.

President and Chief Executive Officer

TRACON PHARMACEUTICALS

Investor Presentation

February 2020



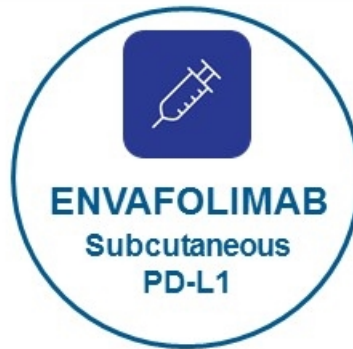
NASDAQ: TCON

Forward-Looking Statements

This presentation contains statements that are, or may be deemed to be, "forward-looking statements." In some cases these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," "potential," or, in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition, business strategy, current and prospective product candidates, planned clinical trials and preclinical activities, potential events and activities under existing collaboration agreements, estimated market opportunities for product candidates, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success of development activities and business strategies, plans and objectives of management for future operations, and future results of anticipated product development efforts, including potential benefits derived therefrom. These statements involve substantial known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risks associated with conducting clinical trials, whether any of our product candidates will be shown to be safe and effective, our ability to finance continued operations, our reliance on third parties for various aspects of our business, the potential early termination of collaboration agreements, competition in our target markets, our ability to protect our intellectual property, our ability to execute our business development strategy and in-license rights to additional pipeline assets, and other risks and uncertainties described in our filings with the Securities and Exchange Commission, including under the heading "Risk Factors". In light of the significant uncertainties in our forward-looking statements, you should not place undue reliance on these statements or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this presentation represent our estimates and assumptions only as of the date of this presentation and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this presentation.

This presentation also contains estimates, projections and other information concerning our industry, our business, and the markets for our drug candidates, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

Investment Highlight #1: Envafolimab



Potential for Near-term U.S. Commercialization of the 1st Subcutaneous Checkpoint Inhibitor

Rapid Execution:

TRACON expects to begin pivotal study in undifferentiated pleomorphic sarcoma (UPS) in 2nd half 2020

Orphan Indication:

Peak revenue estimated at \$200M in UPS alone using parity pricing to approved PD-(L)1 products

Fast to Market Strategy:

Pivotal data expected in 2022
U.S. commercialization potentially in 2023¹

Financial Upside:

Low royalty burden of teens to mid double-digits to partners

Investment Highlight #2: Pipeline of Four Additional Clinical Stage Assets and Access to a Discovery Pipeline

- **Envafolimab Is Lead Product With Expected Pivotal Trial Data in 2022**
- **Large Commercial Opportunity In Wet AMD Supported by Strategic Partnership May Yield Significant Financial Benefit**
- **Potential For Broad Oncology Pipeline Emphasizing Bispecific Antibodies**

Sarcoma Pivotal

→ PD-L1 checkpoint inhibitor envafolimab given by subq route of administration expected to start pivotal study in second half of 2020

Ophthalmology Phase 2

→ Endoglin antibody DE-122 in completed enrolled randomized wet AMD trial with global rights licensed to **Santen**

Mesothelioma Phase 2

→ DNA repair inhibitor TRC102, funded through **NCI** with global rights owned by TRACON

Prostate Cancer Phase 2

→ Androgen Receptor inhibitor TRC253 partnered with **J&J (Janssen)**. J&J opt-in decision expected 1H2020 could trigger \$45M payment to TRACON

Immuno Oncology Phase 1

→ CD73 antibody TJ4309 in combination with Tecentriq® through collaboration with **I-Mab**, TRACON leading US development

Immuno Oncology Bispecifics








→ Access broad Bispecific Antibody Pipeline: Risk and profit share agreement with **I-Mab**, with TRACON leading US commercialization

Investment Highlight #3: Partnering Platform

- **Product Development Platform of CRO-Independent Clinical Research and US Commercialization Experience**

- Built to deliver clinical results rapidly in U.S./E.U. and provide opportunities for U.S. commercialization
- Allows for a risk and cost sharing drug development solution
- Proven ability to leverage platform via BD to expand pipeline without up-front payment
 - Prostate cancer asset from **Johnson & Johnson (Janssen)**
 - CD73 antibody from **I-Mab**
 - Bispecific antibody collaboration with **I-Mab**
 - Subcutaneous PD-L1 antibody envafolimab from **3D Medicines** and **Alphamab Oncology**
- Platform available for any therapeutic area
- Capacity for additional clinical stage asset development

Five Clinical Stage Assets with Multiple Expected Readouts in 2020

Compound	Indication		Pre-Clinical	Phase 1	Phase 2	Phase 3
Envafoлимab ¹	Sarcoma	 	In United States		In China	
DE-122 ²	Wet AMD					
TRC102	Lung, Others					
TRC253 ³	Prostate					
TJ004309 ⁴	Solid Tumors					
Bispecifics ⁴	Solid Tumors					

¹ Partnered with 3D Medicines (Beijing) Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab). TRACON does not have rights to Envafoлимab outside of North America.

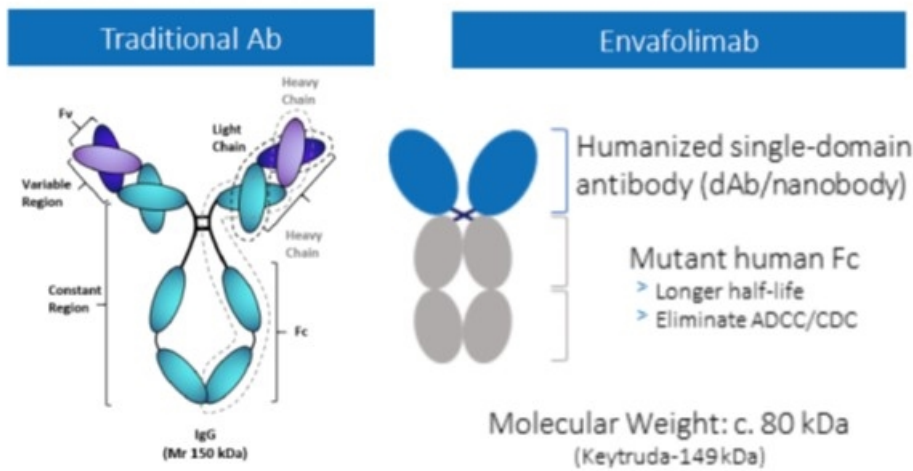
² Partnered with Santen Pharmaceutical Co., Ltd. (Santen)

³ Janssen Pharmaceutica N.V. (Janssen) has a buyback option

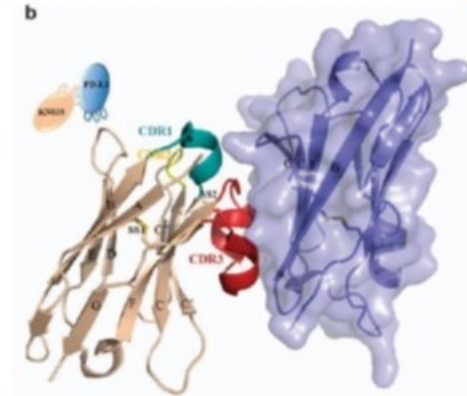
⁴ Part of a broad co-development and co-commercialization immune oncology partnership with I-Mab BioPharma Co. Ltd. (Shanghai). TRACON has certain royalty and non-royalty rights with respect to TJ004309; TRACON is responsible for development and commercialization of up to 5 bispecific antibodies in North America and shares profits and losses with I-Mab.

Background on Envafolelimab

- Single Domain Antibody



Crystal Structural of envafolelimab/PDL1



- Stable at room temperature for six months allows subcutaneous injection without an adjuvant
- High yield (> 7 g/L) and low cost of production by Alphamab (HKSE: Alphamab Oncology)

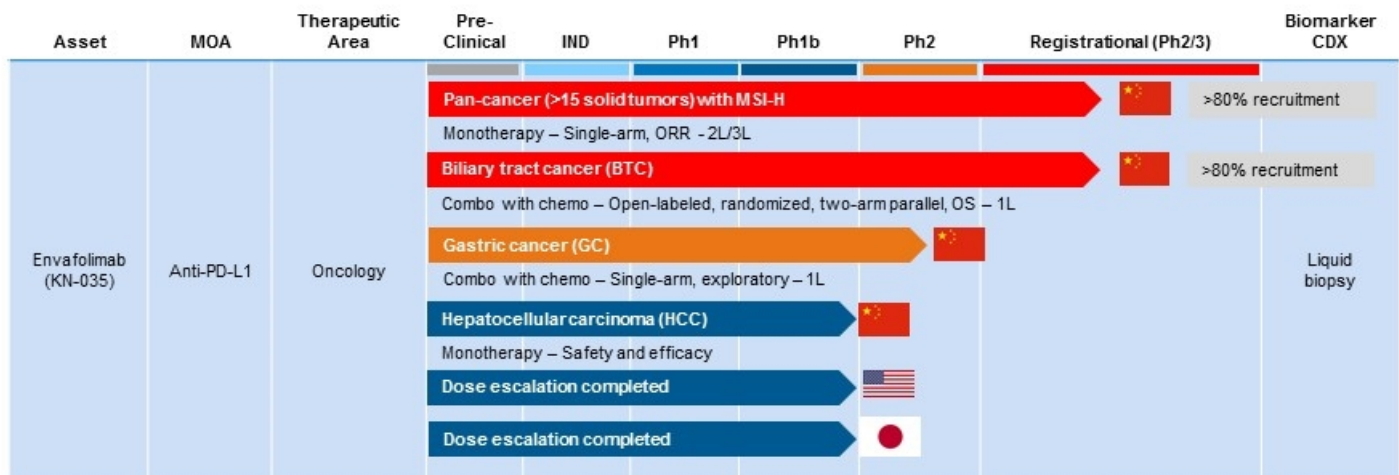
Envafolimab Subcutaneous Administration Does Not Require an Adjuvant: Potential Best-in-Class Profile



- Envafolimab, a much improved subcutaneous formulation:
 - Small injection volume: starting from 0.75ml
 - Infrequent injection site reactions in clinical trials
 - Fast injection: in seconds
 - Stable at room temperature for months
 - Potential for development as a combination therapy with oral drugs

Envafolimab has been Dosed to > 650 Patients and is being Studied in Two Registrational Trials in China

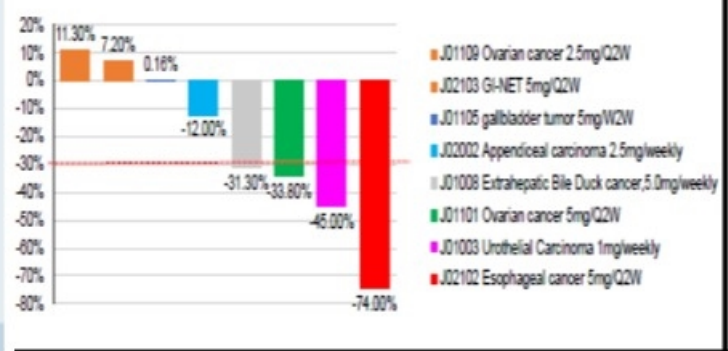
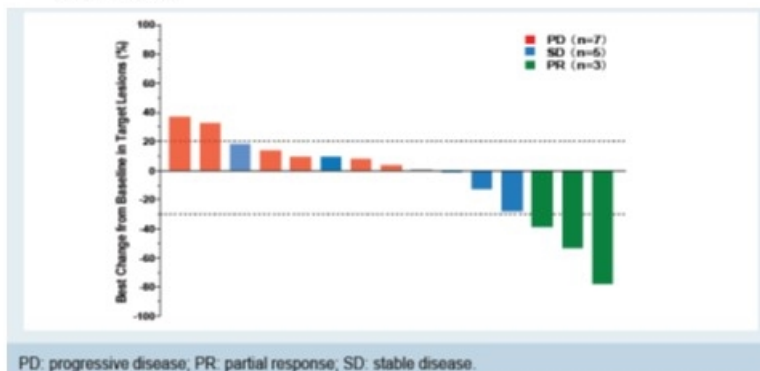
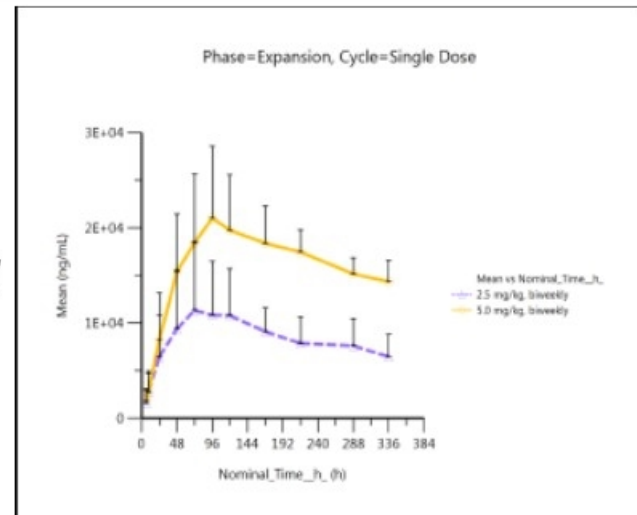
*3D Medicines retains global rights
other than in the field of sarcoma in North America*



Filing for approval in China in MSI-H cancer is expected in the first half of 2020 assuming registration trial demonstrates an objective response rate similar to the ~30-35% response rate demonstrated by Keytruda and Opdivo in MSI-H trials, that were the basis for approval of these drugs by the U.S. FDA

Envafolimab Safety and Efficacy

- Safety profile in clinical studies to date similar to approved PD-(L)1 therapies, with elevated transaminases (mainly grade 1 or grade 2) being the most common adverse events
- Dosed every 2 weeks—*every 4 week dosing is being explored in ongoing Phase 1 trials in the US and Japan*
- RECIST response rates in Phase 1 trials >15% across all dose levels and solid tumors



PD-(L)1 Accelerated Approval in Refractory Solid Tumors has been Based on ~15% Overall Response Rates

- FDA has been supportive of therapeutics that address unmet needs, with the bar for accelerated approval being $\geq 15\%$ response rate in those indications
 - Keytruda was approved in refractory gastric cancer with a 13% response rate
 - Tecentriq and Imfinzi were approved in refractory urothelial cancer with response rates of 15% and 17%, respectively
 - Recent FDA approval for tazemetostat for epithelioid sarcoma with response rate of 11-15%

	Gastric (Keytruda)	Urothelial (Tecentriq)	Urothelial (Imfinzi)
ORR	11.6%	14.8%	17%
ORR in PD-L1 +	13.3%	26%	26%
ORR in PD-L1 -	6.4%	9.5%	4%
CDX in label	Yes	No	No

Keytruda package insert 2019; Tecentriq package insert 2019; Imfinzi package insert 2019

Tazemetostat Approved in Epithelioid Sarcoma in January 2020 Following Overall Response Rate of 11-15%

- ODAC voted 11-0 on December 18, 2019 that the drug's benefits outweighed the risks, despite low risk of patients potentially developing secondary cancers (T cell lymphoma, MDS and AML), following clinical trials in epithelioid sarcoma demonstrating an overall response rate of 11-15%; FDA approved Tazemetostat on January 23, 2020.

Table 21: Summary of Objective Response Rate, Best Overall Response, and Duration of Response per Blinded Radiology Review in Study 202 (Cohort 5)

Response Measure Category/Statistic	Primary ES Population (N = 62)
Objective Response Rate (CR + PR, Confirmed)	
n (%)	9 (15)
95% CI (%)	(6.9, 25.8)
Best Overall Response, n (%)	
Complete Response (CR)	1 (2)
Partial Response (PR)	8 (13)
Stable Disease (SD)	30 (48)
Progressive Disease (PD)	19 (31)
Not Estimable (NE)	0 (0)
Missing/Unknown	4 (6)

Abbreviations: CI = confidence interval; ES = epithelioid sarcoma
ORR, per investigator assessment provided in Appendix 10.3.

Table 25: Summary of Efficacy Results from Study 202 (Cohort 6)

	Study 202 (Cohort 6) N = 44
Best Overall Response at Any Time	
ORR (95% CI) ¹	11% (3.8, 24.6)
DOR, Weeks (Range) ¹	NE (15.3, 79.1+)
DCR _{32 weeks} (95% CI) ¹	14% (5.2, 27.4)
OS, Median Weeks (95% CI)	71.9 (41.1, NE)

Abbreviations: CI = confidence interval; DCR₃₂ = disease control rate through 32 weeks; DOR = duration of response; NE = not estimated; ORR = objective response rate; OS = overall survival

¹ Data based on blinded radiology review.

Current Treatment and Unmet Need in Undifferentiated Pleomorphic Sarcoma (UPS)

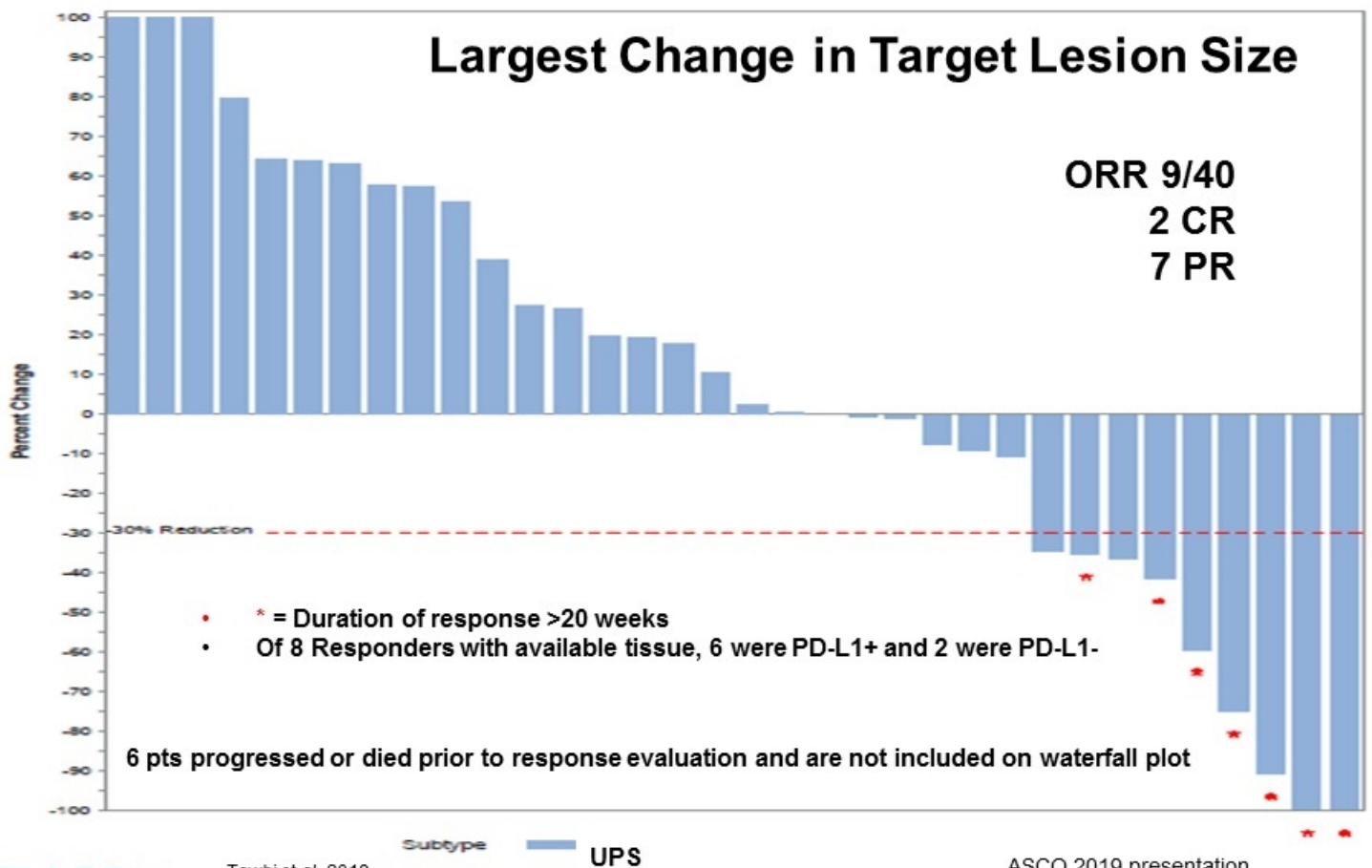
- Fourth most common soft tissue sarcoma (formerly contained within the category of malignant fibrous histiocytoma or MFH), with ~3,000 cases in the US annually (Western world incidence: 0.8-1.0/100,000)
- First line chemotherapy with doxorubicin is typical with objective response rate of ~20%
- Approved second line agent pazopanib has low response rate (4% objective response rate)
- Treatment of refractory disease with chemotherapy (e.g., gemcitabine) is associated with response rate of < 5%
- Advanced or metastatic UPS has 5 year overall survival of < 5%

Orpha.net; Widemann and Italiano, 2018; Pazopanib package insert 2019; Savina et al 2017; Tap et al, 2017

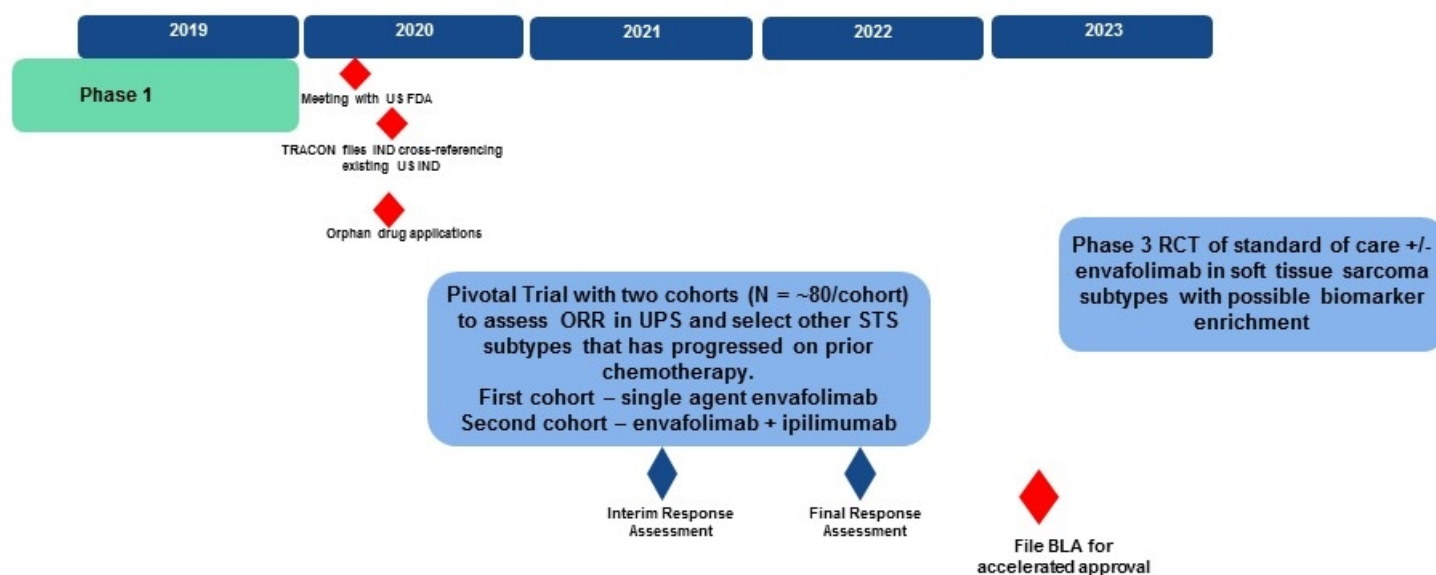
PD-(L)1 Overview in Sarcoma

- Refractory sarcoma of any subtype represents a very high unmet need population
- Data were presented at ASCO 2019 that Keytruda, a PD-1 inhibitor, demonstrated a 23% response rate in Undifferentiated Pleomorphic Sarcoma (UPS)
- Other PD-(L)1 antibodies have also demonstrated > 40% response rate in cutaneous angiosarcoma (CAS) and alveolar soft part sarcoma (ASPS)
- To our knowledge, no company is currently running a pivotal trial in sarcoma with a PD-(L)1

Keytruda in UPS: SARC 028 Study



Envafolimab Development Plan in United States in Sarcoma



A two cohort non-comparative pivotal trial is proposed in refractory UPS and select other soft tissue sarcoma (STS) subtypes, with each cohort targeting ORR of 15% as the primary endpoint for accelerated approval based on high unmet need.

Envafolimab License Terms

- License for indication of Sarcoma in North America
- TRACON to conduct and bear costs of clinical trials in Sarcoma
- 3D Medicines and Alphamab to manufacture Envafolimab and sell to TRACON at pre-negotiated prices
- TRACON to commercialize Envafolimab in Sarcoma in North America
 - TRACON will lead commercialization if first launch is in Sarcoma
 - TRACON has option to co-market if first launch is by 3D Medicines or approval occurs in a non-orphan indication after approval in Sarcoma
- If TRACON is leading commercialization in Sarcoma, will owe double digit royalties to 3D Medicines and Alphamab ranging from teens to mid-double digits.
- If 3D Medicines and Alphamab are leading commercialization they will owe TRACON double digit royalties ranging from teens to mid-double digits if TRACON does not co-market, and a 50% royalty on Sarcoma sales if TRACON does co-market
- 3D Medicines and Alphamab are able to reacquire Envafolimab if the product is sold to a third party, provided the sale will not occur prior to the completion of the pivotal trial in Sarcoma without TRACON's written consent, and the parties will negotiate fair compensation

Santen License for DE-122

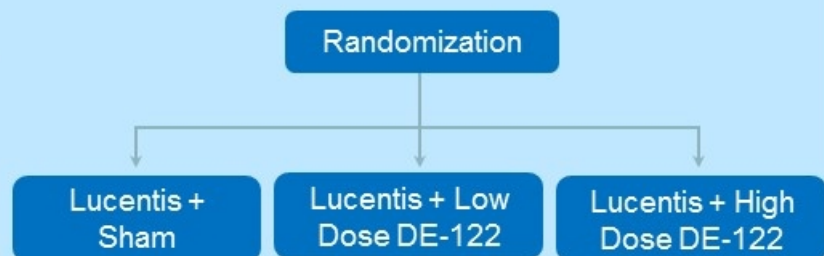
	2019	2020
DE-122	Phase 2 AVANTE Trial in Wet/Neovascular AMD	

- Global ophthalmology company with \$1.8 billion in annual revenue leading global development and commercialization for DE-122 (ophthalmic formulation of endoglin antibody) in wet AMD and other eye diseases
- DE-122 in lead for VEGF inhibitor companion drug due to failed Phase 2 and 3 studies from Ophthotech and Regeneron; could be VEGF companion product to Eylea® and Lucentis® products (~\$10B market for wet AMD); high unmet need
- Regulatory path is well defined
- Deal terms
 - Santen pays all development and commercialization costs.
 - Up to \$145M in remaining milestones; royalties in high single digits to low teens.

Santen Development of DE-122 in wet AMD

- Phase 1/2 PAVE trial results presented February 10, 2018 at the Angiogenesis, Exudation and Degeneration meeting at Bascom Palmer Eye Institute
 - 8 out of 12 subjects demonstrated bioactivity: improved macular edema or visual acuity
 - Safe with no serious adverse events
- Phase 2 AVANTE randomized trial has completed enrollment - data expected first half 2020

- Primary Endpoint: Best Corrected Visual Acuity following six monthly intravitreal injections
- Double masked
- N = 76



TRC102: Expected Value Inflection Points

Companion Therapy	2019	2020
Alimta	Phase 2 Mesothelioma	
Alimta/cisplatin	Phase 1b Solid Tumors	
Temodar	Phase 1b Solid Tumors	
Chemoradiation	Phase 1b Lung	

- Small molecule designed to reverse resistance to chemotherapy and complement PARP inhibitors
- Inhibits base excision repair, a dominant pathway of DNA repair that allows for resistance to alkylating chemotherapy (e.g., Temodar®) and antimetabolite chemotherapy (e.g., Alimta®)
- Current clinical development funded by National Cancer Institute

TRC102: Reversing Resistance to Chemotherapy

Combination	Well Tolerated	Signs of Activity in Phase 1b/2	Ongoing Development
TRC102 + Alimta (Published in <i>Investigational New Drugs</i> , 2012)	√	Stable disease in patients with squamous cell lung cancer, a tumor type where Alimta is inactive	Phase 2 trial with Alimta in mesothelioma
TRC102 + Fludara (Published in <i>Oncotarget</i> , 2017)	√	Partial response and stable disease in patients previously treated with Fludara	
TRC102 + Temodar (Presented at ASCO 2017 and AACR 2019)	√	Partial responses in patients with lung, KRAS+ colorectal and ovarian cancer; induced biomarkers of DNA damage Rad51, pNbs1, and/or γ-H2AX	Phase 2 expansion cohorts added in colorectal (6% partial response rate), lung and ovarian cancer
TRC102 + Temodar in GBM (Presented at SNO 2018)	√	PFS of 11+ months in 2/19 patients with recurrent GBM was associated with glycosylase expression	

- Efforts are focused on identifying a biomarker (e.g., glycosylase expression) that will correlate with response to treatment with chemotherapy + TRC102

TRC253: Expected Value Inflection Point

	2019	2020
TRC253	Phase 1/2 Prostate Cancer	

- TRC253 is an antagonist of Androgen Receptor mutations that are resistance mechanisms for Xtandi® and Erleada®
 - Phase 1/2 trial completed enrollment in November 2019
- TRACON was chosen because of our innovative product development platform
- JJDC made equity investment in TRACON

Janssen Right to Re-Acquire upon Phase 2 Data

- If Janssen opts-in: \$45M opt-in payment and additional potential milestones of \$137.5M and a low single digit royalty to TRACON
- If Janssen does not opt-in: TRACON retains all rights and will owe development and regulatory milestones of up to \$45M and a low single digit royalty to Janssen

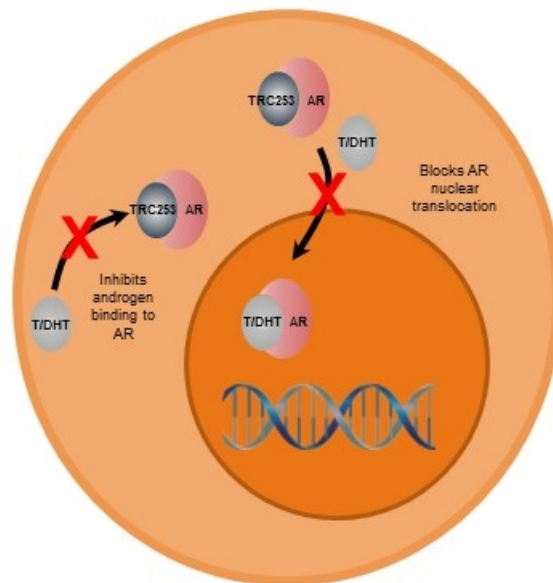
TRC253: Novel Androgen Receptor (AR) Mutant Inhibitor

- Designed to address AR F877L mutation
- Active against wild-type AR
- Phase 1/2 trial completed enrollment in 3 cohorts of Xtandi or Erleada resistant prostate cancer:
 - F877L mutated AR
 - Undisclosed AR point mutation
 - Another basis for acquired resistance to Xtandi or Erleada
- Target PK exposures were achieved consistently with 280 mg oral daily dosing, which was declared the Phase 2 dose based on safety and PK data
- Well tolerated, with grade 1 QTc prolongation the most common adverse event
- Lower than expected response rate in patients with F877L AR mutation and lower than expected prevalence of F877L AR mutation
- Proof of Concept data expected to be available for Janssen in 1H2020, which would trigger their right to reacquire TRC253



Rathkopf D, et al, ASCO Proceedings 2019

Multiple Mechanisms of Action



I-Mab Corporate Collaboration #1: TJ004309 a CD73 antibody



- CD73 Antibody
 - CD73 is a receptor expressed on tumors which generates adenosine which suppresses the immune response to tumors
 - TRACON conducts clinical development in U.S. and E.U. and TRACON and I-Mab share clinical development expenses starting with Phase 2
 - TRACON is entitled to portions of royalty and non-royalty consideration received by I-Mab for territories outside China, ranging from a high-single digit to mid-teen % of non-royalty consideration as well as double digit % of royalty consideration
 - In the event that I-Mab commercializes TJ004309, TRACON is entitled to a royalty percentage on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the E.U. and Japan in the mid-single digits
 - The TJ004309 IND was filed by TRACON in Dec 2018, cleared by FDA in Jan 2019, and dosing commenced in July 2019
 - Phase 1 data expected by year end 2020

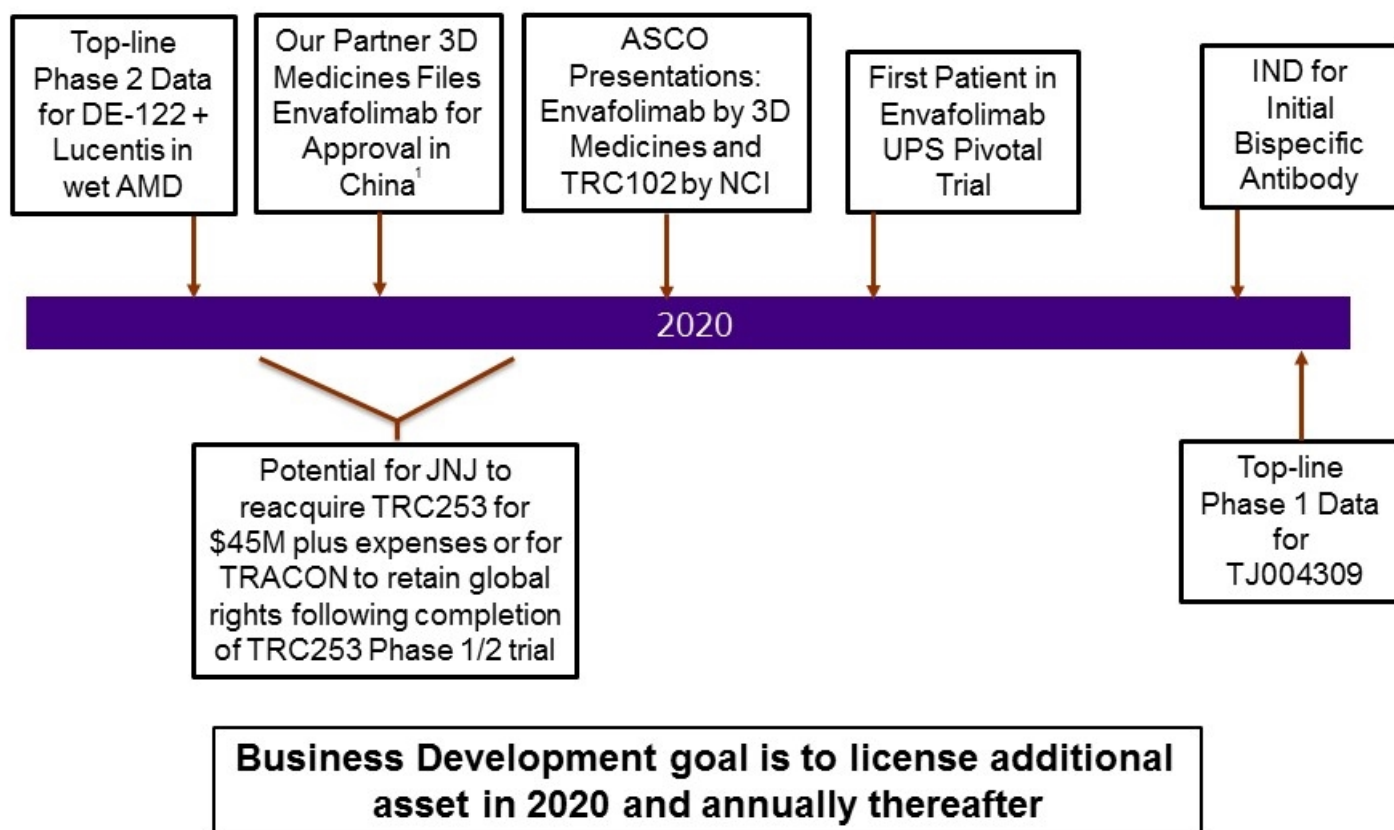
I-Mab Corporate Collaboration #2: Bispecific Antibodies

Bispecific Antibodies	2020	2021	2022
#1 of 5	IND		
#2 of 5		IND	
#3 of 5			IND

Timelines are for illustrative purposes only. Actual number of bispecifics, if any, that are subject to the collaboration and the development timing for each is subject to I-Mab nomination and subsequent development efforts.

- TRACON to develop and commercialize up to 5 of I-Mab's bispecific antibodies in the U.S.
- TRACON and I-Mab share clinical development expenses starting with the pivotal trial
- Parties will share commercial profits and losses equally
- TRACON is entitled to tiered low single digit royalties in the E.U. and Japan
- Prior to pivotal trial read-out, TRACON can opt-in to acquire global commercial rights outside of Korea and China for payments that escalate based on phase of development
 - For example, if Opt-In is triggered prior to IND enabling activities, TRACON owes \$10M upfront, up to \$90M development & regulatory milestones, up to \$250M sales milestones, and mid-single digit royalty per bispecific antibody
- I-Mab bispecific candidates include: PD-L1 x IL-7; PD-L1 x CD47, PD-L1 x CD73, PD-L1 x B7-H3, **PD-L1 x 4-1BB, undisclosed Tumor Associated Antigen x 4-1BB**, CD47 x GM-CSF

Expected Key Milestones



TRACON is a Clinical CRO-Independent Company



Expected benefits of CRO-Independence:

- Reduced cost
- Decreased timelines
- Control over development
- Improved quality

Aligned Product Development Solution

- Cost, risk and profit share of partnered assets produces goal alignment
 - Platform can be applied to develop first-in-class, best-in-class or fast-follower oncology and other physician specialist prescribed products.
- Industry recognition for clinical trial design (Clinical Research Excellence Award)
- U.S. NDA/BLA may be leveraged for regulatory filings in all major territories
- Opportunity to add U.S. sites to a regional trial to generate a representative populations that could facilitate global approval
- Proven ability to leverage platform to expand pipeline and build value
 - Prostate cancer asset from Johnson & Johnson, included equity investment
 - CD73 antibody from I-Mab (NASDAQ: IMAB)
 - Bispecific antibody collaboration with I-Mab (NASDAQ: IMAB)
 - Subcutaneous PD-L1 antibody envafolelimab from 3D Medicines and Alphamab Oncology (HKSE: ALPHAMAB-B)

Financial Overview (as of January 31, 2020)

Ticker	TCON (NASDAQ)
Cash, Cash Equivalents and Short-term Investments	\$16.8 million
Debt – Outstanding Principal	\$5.4 million
Common Shares O/S	5.2 million
Covering Analysts	Jim Birchenough (Wells Fargo) Bert Hazlett (BTIG) Maury Raycroft (Jefferies) Ed White (H.C. Wainwright)

Convenience and Uptake of Subcutaneously Administered Antibodies

MabThera/Rituxan SC in hematologic cancers FDA advisory committee recommends approval

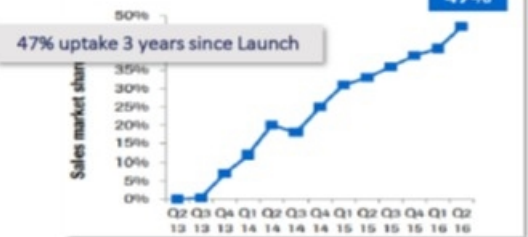


- ODAC voted unanimously (11:0) that the benefit-risk of rituximab/hyaluronidase for SC injection was favorable for the treatment of certain blood cancers
- Approved in the EU in NHL and CLL
- Encouraging initial uptake in the EU markets, comparable to Herceptin SC

MabThera/Rituxan SC partnered with Halesgine; SC=subcutaneous; ODAC=OncoLogic Drug Advisory Committee of the FDA; NHL=non-hodgkin's lymphoma; CLL=chronic lymphoid leukemia

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SC share of Herceptin sales in launched countries*



- Besides Herceptin SC and MabThera/Rituxan SC, Roche is also developing SC versions for other marketed or clinical products:

- > Perjeta+Herceptin SC
- > Gantenerumab (RG1450)
- > IgG-IL2 FP (RG7835)
- > ST2 Mab (RG6149)

Source: Roche; Company analysis

