#### 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): January 5, 2021

(Ex	act name of registrant as specified in its ch	arter)
Delaware	001-36818	34-2037594
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No
4350 La Jolla Villa	ge Drive, Suite 800	
San Diego, C	California	92122
(Address of principal executive offices)		(Zip Code)

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

□ 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:

following provisions:

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  $\square$ 

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.  $\Box$ 

#### Item 2.02 Results of Operations and Financial Condition.

Charles P. Theuer, M.D., Ph.D., President and Chief Executive Officer of TRACON Pharmaceuticals, Inc. ("TRACON"), and other executive officers will be presenting information that includes an estimate of TRACON's December 31, 2020 cash, cash equivalents and short-term investments and outstanding debt principal balances, at various upcoming meetings beginning January 6, 2021. The information is attached as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 7.01 Regulation FD Disclosure.

Charles P. Theuer, M.D., Ph.D., 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 January 6, 2021.

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 January 2021

#### 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: January 5, 2021

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

Charles P. Theuer, M.D., Ph.D. President and Chief Executive Officer

Exhibit 99.1

TRACON PHARMACEUTICALS Investor Presentation January 2021



NASDAQ: TCON

### **Forward-Looking Statements**

This presentation contains statements that are, or may be deemed to be, "forward-looking statements." In some cases these forwardlooking 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, a Potential Best-in-Class Checkpoint Inhibitor

# **ENVAFOLIMAB**

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

Rapid low volume subcutaneous injection without an adjuvant that is more convenient and less invasive than IV therapy, with potential for significant clinical relevance

TRACON (1) Third party estimate sponsored by TRACON (2) Assuming successful pivotal study and BLA approval

#### **Rapid Execution**

ENVASARC pivotal study began dosing in sarcoma in 4Q 2020 following successful FDA meeting

#### **Orphan Indication**

Peak U.S. annual revenue estimated at >\$300M in initial indications using parity pricing to approved PD-(L)1 products<sup>(1)</sup>

#### Fast to Market Strategy

Expect ENVASARC interim data in 2021, endpoint in 2022, and U.S. commercialization in 2023<sup>(2)</sup>

#### **Financial Upside**

ENVASARC pivotal trial cost estimated at <\$20M through TRACON Product Development Platform. Royalty burden of teens to mid double-digits

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# Investment Highlight #2: Pipeline of Clinical Stage Assets

Compound	Indication	Pre- Clinical	Phase 1	Phase 2	Pivotal
Envafolimab	Sarcoma 3DMed 於康宁杰瑞				
TRC102	Lung, Others				
TJ4309	Solid Tumors 🚫 天境生物				
Bispecifics	Solid Tumors 🔇 天境生物				

<sup>1</sup> Partnered with 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab). TRACON does not have rights to Envafolimab outside of North America or for indications other than sarcoma.

<sup>2</sup> TRACON has certain royalty and non-royalty rights with respect to TJ4309; TRACON is responsible for development and commercialization of up to 5 bispecific antibodies in North America and shares profits and losses with I-Mab.

### Investment Highlight #3: Partnering Platform

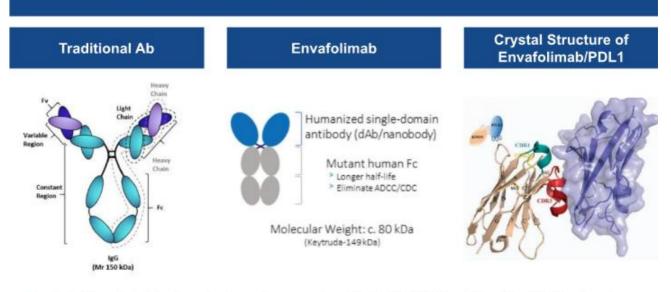
#### Product Development Platform of CRO-Independent Clinical Development and U.S. Commercialization Experience

· 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 with strong collaboration alignment
- · Proven ability to leverage platform via business development sourced pipeline
  - · Subcutaneous PD-L1 antibody envafolimab from 3D Medicines and Alphamab Oncology
  - · Prostate cancer asset from Johnson & Johnson (Janssen)
  - CD73 antibody from I-Mab
  - Bispecific antibody collaboration with I-Mab
- · Platform available for any therapeutic area
- · Capacity for additional clinical stage asset development

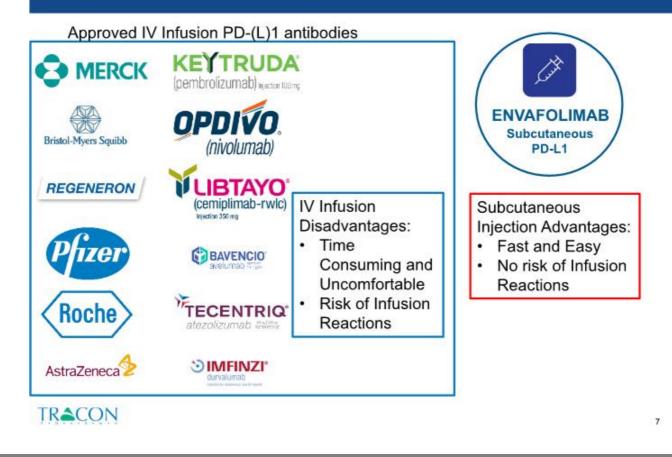


### Envafolimab – Single Domain PD-L1 Antibody



- Single Domain Antibody structure of approved product Cablivi (Ablynx/Sanofi), which is also given subcutaneously
- Stable at room temperature for six months allows rapid low volume subcutaneous injection without an adjuvant (i.e., no need for hyaluronidase)
- High yield (> 7 g/L) and low cost of production by Alphamab Oncology (HKSE: Alphamab Oncology) TRACON 6

# All Approved PD-(L)1 Antibodies are Delivered IV



#### Envafolimab - SubQ Administration with Potential Best-in-Class Profile



- Envafolimab, a much improved subcutaneous formulation:
  - Small injection volume: < 2 mL</li>
  - · Infrequent injection site reactions in clinical trials to date
  - · Fast injection: in seconds
  - · Stable at room temperature for months
  - · Potential for development as a combination therapy



### Envafolimab Global Clinical Development Summary: Submitted for Approval in China and Dosed to > 700 Cancer Patients

Development Country	Pre-Clinical	Phase 1	Phase 1b	Phase 2	Registrational (Phase 2/3)
	Sarcoma Subtypes of Ul	PS/MFS			
*2	Pan-cancer (>15 solid tu Monotherapy – Single-arm,	And the second second second second			
*	Biliary Tract Cancer (BT Combo with chemo – Open		o-arm parallel, OS – 1L		
*2	Gastric Cancer (GC) Combo with chemo – Single-arm, exploratory – 1L				
1. 1.	Hepatocellular carcinom Monotherapy – Safety and	a da anticipada			
	Dose escalation comple	ted			
•	Dose escalation comple	ted			

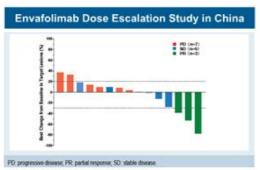
Clinically de-risked through development in China

- Envafolimab has been dosed to >700 Patients and is being studied in two pivotal trials in China
- Positive data from MSI-H cancer pivotal trial presented at ASCO 2020 and CSCO 2020
- NDA accepted for review by the Chinese NMPA in MSI-H cancer in December 2020

### Envafolimab – Safety, PK and Efficacy in Phase 1

#### Highlights

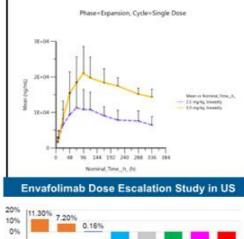
- Safety profile in clinical studies to date similar to approved PD-(L)1 therapies, with elevated transaminases (mainly grade 1 or grade 2) being among the most common adverse events
- Has been dosed up to every 4 weeks. RECIST objective response rates (ORR) in three Phase 1 trials >15% across all dose levels and solid tumors



ASCO 2019 presentations: Xu J et al; Shimizu T et al

#### TRACON

Envafolimab Dose Escalation Study in Japan





ESMO 2018 presentation: Papadopoulos et al

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### Envafolimab - Efficacy in Pivotal Trial in MSI-H/dMMR Cancer Patients Similar to Opdivo and Keytruda Trials

- Envafolimab is being evaluated in patients with advanced microsatellite instability-high/mismatch repair-deficient (MSI-H/dMMR) cancer in a pivotal study in China
- Data from a planned interim analysis performed after the first 50 patients had at least two on-study tumor assessments were presented at ASCO 2020 and CSCO 2020
- Confirmed ORR in MSI-H/dMMR colorectal patients who failed fluoropyrimidine, oxaliplatin and irinotecan is nearly identical to ORR reported for Opdivo and Keytruda in separate trials in that patient population
- Twelve month duration of response (DOR) of 75%
- Safety profile similar to other PD-(L)1 antibodies but without infusion reactions; no cases of colitis or pneumonitis were
  reported
- The study concluded that envalorimab demonstrated durable anti-tumor activity with a manageable safety profile in patients with previously treated advanced MSI-H/dMMR cancer

	Envafolimab	Opdivo (CHECKMATE-142)	Keytruda (KEYNOTE-164)
Indication	MSI-H/dMMR colorecta	l cancer that progressed following trea oxaliplatin and irinotecan	tment with fluoropyrimidine,
Sample Size	39	53	61
ORR by independent radiographic review	32%	28%	33%
Duration of Response ≥ 12 months	75%	40%	NA

TRACON (1) Data from separate clinical trials may not be directly comparable due to differences in trial protocols, conditions and patient populations.

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### PD-(L)1 Accelerated Approvals in Refractory Solid Tumors have been Based on ~15% Objective Response Rates

- FDA has been supportive of therapeutics that address unmet needs, with the bar for accelerated approval being ~ 15% response rate in those indications
  - Keytruda was approved in refractory gastric cancer with response rate of 13%
  - Tecentriq was approved in refractory urothelial cancer with response rate of 15%
  - · Opdivo was approved in refractory small cell lung cancer with response rate of 12%

	PD-L1+ Gastric (Keytruda)	Urothelial (Tecentriq)	Small Cell Lung (Opdivo
ORR	13%	15%	12%
CDX in label	Yes	No	No

Tazemetostat was approved in January 2020 in epithelioid sarcoma with response rates of 11-15%

TRACON Keytruda package insert 2019; Tecentriq package insert 2019; Opdivo package insert 2019

# High Unmet Need in Undifferentiated Pleomorphic Sarcoma (UPS) and High-grade Myxofibrosarcoma (MFS)

- Common soft tissue sarcomas (formerly contained within the category of malignant fibrous histiocytoma or MFH)
  - · ~3,000 cases of UPS in the US annually (Western world incidence: 0.8-1.0/100,000)
  - · Myxofibrosarcoma (MFS) half as common as UPS with ~1,500 cases annually in US
- First line chemotherapy with doxorubicin is typical with objective response rate of ~17%
- · Only approved agent for refractory UPS, Votrient, has 4% objective response rate
- Advanced or metastatic UPS/MFS has 5-year overall survival of < 5%</li>

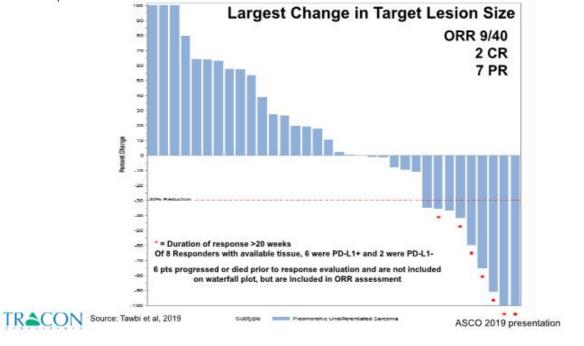
#### PD-(L)1 Could Address the Unmet Needs in Sarcoma

- Data were presented at ASCO 2019 that Keytruda, a PD-1 inhibitor, demonstrated a 23% objective response rate in refractory UPS/MFS
- Data were presented at ASCO 2020 that the combination of Opdivo, a PD-1 inhibitor, and Yervoy, a CTLA-4 inhibitor, tripled the objective response rate to 29% in refractory UPS/MFS compared to Opdivo alone
- To our knowledge, no company is currently running a pivotal trial in sarcoma with a PD-(L)1
- An approved subcutaneous PD-(L)1 would have the potential advantage of physician preference and market access/reimbursement in sarcoma

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

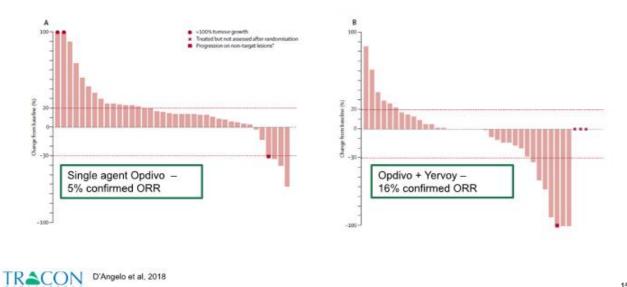
### Keytruda Trial in Refractory UPS: 23% ORR

- Keytruda (pembrolizumab), a checkpoint inhibitor targeting PD-1, has shown promising response rate in UPS with 23% ORR
- We expect Envafolimab to perform in line with Keytruda in UPS with a better safety profile and superior convenience due to SubQ route of administration

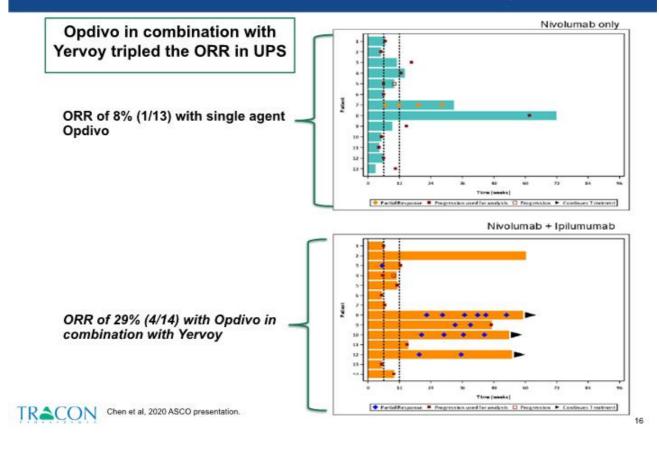


### Alliance Trial in Sarcoma (not just UPS): Benefit of Dual Checkpoint Inhibition with Opdivo + Yervoy

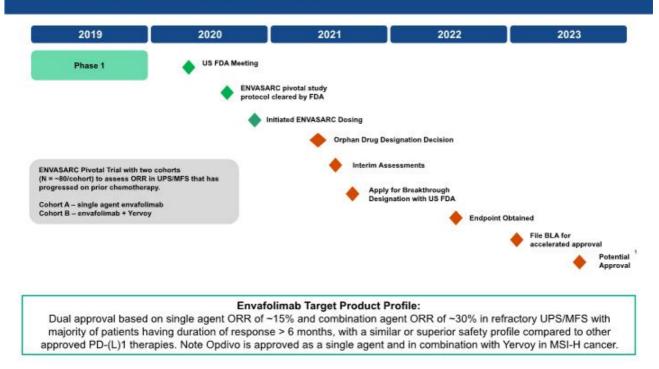
- Randomized trial of multiple soft tissue sarcoma subtypes
  - · Parallel, open label, non-comparative cohorts
  - · Single agent Opdivo (PD-1 antibody) and Opdivo in combination with Yervoy (CTLA-4 antibody)
- Opdivo in combination with Yervoy tripled the ORR



### Alliance Trial in Sarcoma (Expanded Cohorts in UPS): Benefit of Dual Checkpoint Inhibition with Opdivo + Yervoy

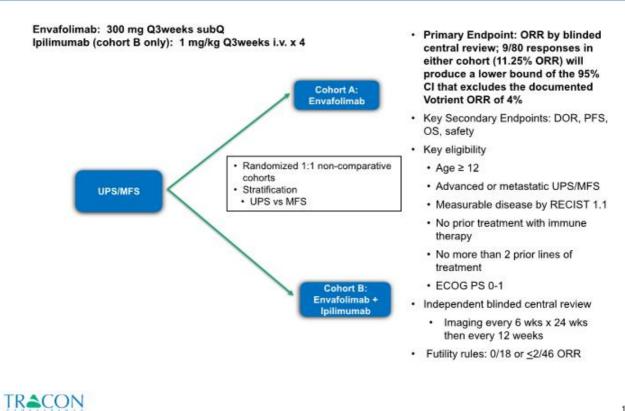


#### Envafolimab Development Plan in Sarcoma Following Successful Type B Meeting with US FDA on May 8, 2020

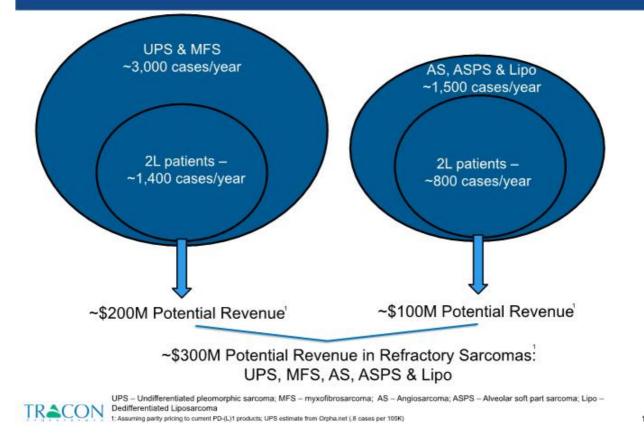


TRACON 1: Assuming positive data from ENVASARC trial

## ENVASARC Pivotal Trial Design



# Initial U.S. Market Size in Refractory Sarcoma Subtypes Known to Respond to Single Agent Checkpoint Inhibition (~25% of all Sarcoma)



### **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 in U.S. 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 books sales in Sarcoma, will owe double digit royalties to 3D Medicines and Alphamab ranging from teens to mid-double digits.
- If 3D Medicines and Alphamab books sales 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 a waiver from TRACON, and the parties will negotiate fair compensation

# **TRC102: Multiple Clinic Trials Funded by the NCI**

Companion Therapy	2019	2020	2021
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 DNA base excision repair, a dominant pathway of DNA repair that allows for resistance to alkylating chemotherapy (e.g., Temodar<sup>®</sup>) and antimetabolite chemotherapy (e.g., Alimta<sup>®</sup>)
- Orphan Drug Designation granted by FDA for malignant glioma, including glioblastoma in 2020
- Updated clinical data presented at ASCO 2020 and published in Cancer Cell in 2020

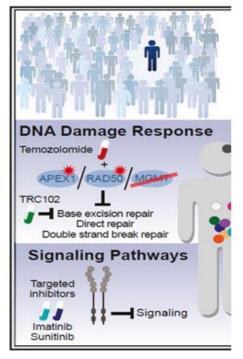
# TRC102 Profiled in Cancer Cell

- TRC102 designed to reverse resistance to chemotherapy by inhibiting the Base Excision Repair pathway
- Cancer Cell article highlighted a durable near complete response in a colorectal cancer patient treated with Temodar + TRC102
  - Detailed molecular analyses of the patient's tumor showed silencing of alternative DNA repair pathways that may have resulted in sensitivity to the inhibition of DNA base excision repair pathway by TRC102
  - MGMT expression was also assessed in biopsies from 11 colorectal patients who subsequently enrolled in an expansion cohort, one of which demonstrated a partial response. The one patient with a tumor that did not express MGMT had a partial response, whereas each of the 10 tumors that did not respond to therapy expressed MGMT robustly.

# **Cancer Cell**

# Molecular Featu Exceptional Res

**Graphical Abstract** 



# **Clinical Trial Summary**

Combination	Well Tolerated	Signs of Activity in Phase 1b/2
TRC102 + Alimta (Published in Investigational New Drugs, 2012)	$\checkmark$	Stable disease in patients with squamous cell lung cancer, a tumor type where Alimta is inactive
TRC102 + Fludara (Published in Oncotarget, 2017)	$\checkmark$	Partial response and stable disease in patients previously treated with Fludara
TRC102 + Temodar (Presented at ASCO 2017 and AACR 2019; published in <i>Cancer Cell</i> 2020)	$\checkmark$	Partial responses in patients with lung, KRAS+ colorectal and ovarian cancer; exception responder with MGMT methylation and double strand break repair pathway mutation/LOH
TRC102 + Temodar in GBM (Presented at SNO 2018)	$\checkmark$	PFS of 11+ months in 2/19 patients with recurrent GBM was associated with glycosylase expression and MGMT methylation
TRC102 + Chemoradiation in Advanced Lung Cancer (presented at ASCO 2020)	$\checkmark$	Of 15 evaluable patients, 3 had CR (20%) and 12 had PR (80%). 2-year PFS rate was 49%.
TRC102 + Alimta in Alimta refractory mesothelioma (presented at ASCO 2020)	$\checkmark$	Of 14 patients, 2 had PR (both epithelioid cancer) meeting the pre-specified criteria for continued interest (>0/14). Median PFS = 4.3 mos.
TRC102 + Alimta and cisplatin (presented at ASCO 2020)	V	Of 9 evaluable patients, 3 had 3 PR (all parotid salivary gland tumors). Median PFS = 7.1 mos.

Efforts continue to focus on identifying biomarkers (e.g., MGMT methylation, glycosylase expression, gene expression profile) that correlate with response to treatment with chemotherapy + TRC102



### I-Mab Corporate Collaboration: TJ4309 a CD73 antibody

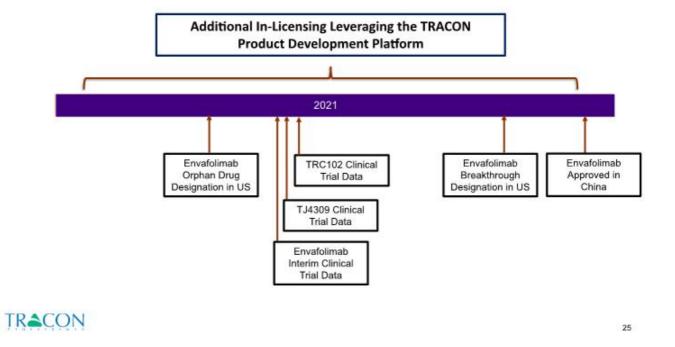
	2019	2020	2021
TJ4309	Ph	ase 1 Solid Tumors with Teo	centriq

#### 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 TJ4309, 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
- U.S. IND filed by TRACON in Dec 2018, cleared in Jan 2019, and dosing commenced in July 2019
- Dispute notice issued to I-Mab in April 2020 following I-Mab disclosure of TJ4309 strategic partnership with KG Bio in March 2020 that TRACON believes triggered a milestone payment to TRACON



# **Expected 2021 Key Milestones**





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.
- · 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 representative populations that could facilitate global approval
- · Industry recognition for clinical trial design (Clinical Research Excellence Award)
- · Proven ability to leverage platform to expand pipeline and build value
  - Subcutaneous PD-L1 antibody envafolimab from 3D Medicines and Alphamab Oncology (HKSE: ALPHAMAB ONCOLOGY)
  - Prostate cancer asset from Johnson & Johnson, included equity investment
  - CD73 antibody from I-Mab (NASDAQ: IMAB)
  - Bispecific antibody collaboration with I-Mab (NASDAQ: IMAB)



# Financial Overview (as of December 31, 2020)

Ticker	TCON (NASDAQ)
Cash, Cash Equivalents and Short-term Investments	\$36.1 million
Debt – Outstanding Principal	\$4.2 million
Common Shares O/S	15.5 million
Covering Analysts	Jim Birchenough (Wells Fargo) Bert Hazlett (BTIG) Maury Raycroft (Jefferies) Ed White (H.C. Wainwright)

Completed Registered Direct Offerings for ~\$14M at the market without warrants with new and existing investors in December; 2020 cash burn was ~\$4-5M/quarter

# Investment Highlights: Pipeline of Clinical Stage Assets and Partnering Platform

