

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, 2022**

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 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, 2021 cash, cash equivalents and short-term investments and outstanding debt principal balances, at various upcoming meetings beginning January 5, 2022. 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 5, 2022.

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.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation, dated January 2022
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

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.

Date: January 5, 2022

TRACON Pharmaceuticals, Inc.

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

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

TRACON PHARMACEUTICALS

Investor Presentation

January 2022



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.

TRACON Pharmaceuticals Summary

- Potential best-in-class checkpoint inhibitor envafolimab dosing in ENVASARC pivotal trial in sarcoma in US is now approved in China
- Clinical stage pipeline includes
 - CTLA-4 antibody in P1
 - DNA repair inhibitor in P2 in collaboration with NCI
 - CD73 antibody in P1 in combination with Tecentriq®
- Business Development engine driven by TRACON's CRO-independent clinical development and commercialization capabilities in the U.S./E.U. that serves as a solution for ex-U.S. companies
 - Five collaborations since 2016 (J&J, Alkermes, 3D Medicines, Eucare and I-Mab)
 - Capacity and appetite for more deals now
- Low financial burn rate and current capital provide runway into 2023 past expected interim ENVASARC pivotal trial data

Investment Highlight #1: Envafolimab, a Potential Best-in-Class Checkpoint Inhibitor

ENVAFOLIMAB

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

Rapid low volume subcutaneous injection without an adjuvant that is more convenient, less invasive and safer than IV therapy



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

Rapid Execution

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

Orphan Drug Designation in Sarcoma

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


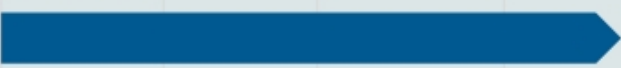

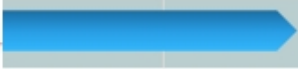

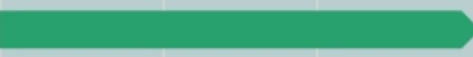

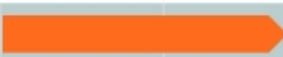


Fast to Market Strategy

Expect ENVASARC interim data in 2022, endpoint in 2023, and U.S. commercialization in 2024⁽²⁾

Financial Upside

ENVASARC pivotal trial cost estimated at <\$25M through TRACON Product Development Platform. Royalty burden of teens to mid double-digits

Investment Highlight #2: Pipeline of Clinical Stage Assets

Compound	Indication		Pre-Clinical	Phase 1	Phase 2	Pivotal
Envafolimab ¹	Sarcoma					
YH001 ²	Sarcoma Others					
TRC102	Lung Others					
TJ4309 ³	Solid Tumors					
Bispecifics ³	Solid Tumors					

¹ 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.

² Partnered with Eucure Biopharma. TRACON has rights in North America in sarcoma and multiple other indications.

³ 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

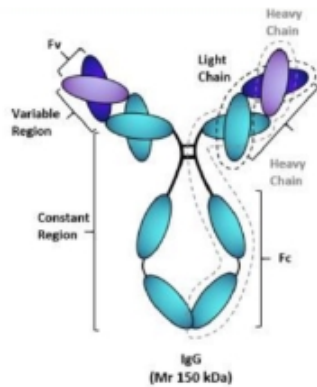
Product Development Platform of CRO-Independent Clinical Development and U.S. Commercialization Experience

- 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 envafolelimab from **3D Medicines** and **Alphamab Oncology**
 - CTLA-4 antibody from **Eucure Biopharma**
 - Prostate cancer asset from **Johnson & Johnson (Janssen)**¹
 - CD73 antibody from **I-Mab**
 - Bispecific antibody collaboration with **I-Mab**
- Platform available for any therapeutic area
- Capacity for additional clinical stage asset development

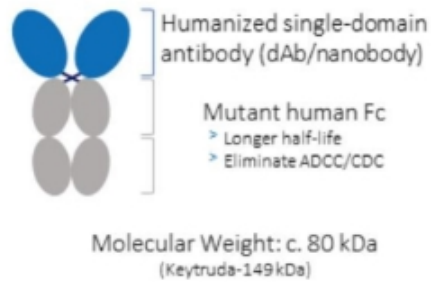
1: License was terminated by TRACON and assets have been returned to Janssen.

Envafolelimab – Single Domain PD-L1 Antibody

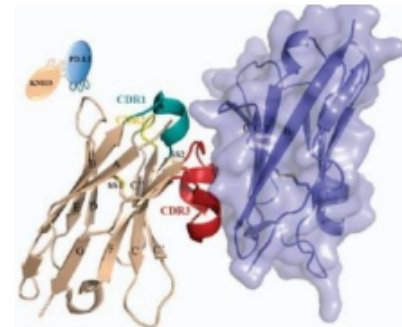
Traditional Ab



Envafolelimab



Crystal Structure of Envafolelimab/PDL1



- 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: 9966 Alphamab Oncology)

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



KEYTRUDA
(pembrolizumab) injection 100 mg



Bristol-Myers Squibb

OPDIVO
(nivolumab)

REGENERON

LIBTAYO
(cemiplimab-rwlc)
injection 350 mg



BAVENCIO
avelumab injection



TECENTRIQ
atezolizumab
injection 1200 mg

AstraZeneca

IMFINZI
durvalumab
injection 500 mg



JEMPERLI

IV Infusion

Disadvantages:

- Time Consuming and Uncomfortable
- Risk of Infusion Reactions



Subcutaneous

Injection Advantages:








- Fast and Easy
- No risk of Infusion Reactions

Envafolimab Rapid SubQ Administration: Potential Best-in-Class Profile



- Envafolimab, much improved subcutaneous dosing
 - Small injection volume: < 2 mL
 - 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

Envafolelimab Global Clinical Development Summary: Approved 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 UPS/MFS				
	Pan-cancer (>15 solid tumors) with MSI-H <i>Monotherapy – Single-arm, ORR - 2L/3L</i>				
	Biliary Tract Cancer (BTC) <i>Combo with chemo – Open-labeled, randomized, two-arm parallel, OS – 1L</i>				
	Gastric Cancer (GC) <i>Combo with chemo – Single-arm, exploratory – 1L</i>				
	Phase 1 <i>Monotherapy – Safety and efficacy</i>				
	Phase 1 <i>Monotherapy – Safety and efficacy</i>				
	Phase 1 <i>Monotherapy – Safety and efficacy</i>				

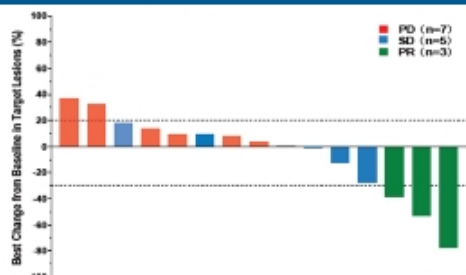
- Approved in microsatellite instability-high/mismatch repair-deficient (MSI-H/dMMR) cancer in China in 2021
- Dosed to >700 Patients and is being studied in additional pivotal trials including ENVASARC

Envafoimab – 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
- **Confirmed ORR in Alveolar Soft Part Sarcoma (ASPS) of 40% (2/5 patients, both durable responses beyond 6 months) similar to Tecentriq confirmed ORR in ASPS (16/43 patients, 37%)¹**

Envafoimab Dose Escalation Study in China

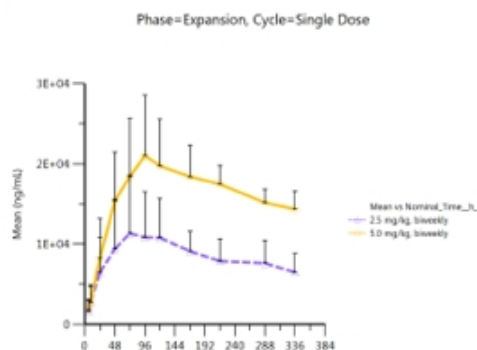


ASCO 2019 presentations: Xu J et al; Shimizu T et al; ESMO 2018 presentation: Papadopoulos et al
CTOS 2018 presentation: Coyne et al.

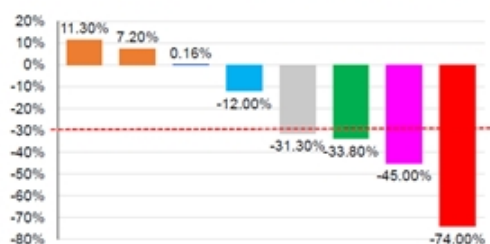


¹: Data from Phase 1 trial in China conducted by 3D Medicines

Envafoimab Dose Escalation Study in Japan



Envafoimab Dose Escalation Study in US



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

- Envafohimab was approved in China in November 2021 in patients with advanced microsatellite instability-high/mismatch repair-deficient (MSI-H/dMMR) cancer
- Objective response rate (ORR) by blinded independent radiographic review of 44.7%, including 12 (11.7%) cases of complete response with duration of response at 12 months of 89%.
- 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
- Safety profile similar to other PD-(L)1 antibodies but without infusion reactions; no cases of colitis or pneumonitis were reported

	Envafohimab	Opdivo (CHECKMATE-142)	Keytruda (KEYNOTE-164)
Indication	MSI-H/dMMR colorectal cancer that progressed following treatment with fluoropyrimidine, oxaliplatin and irinotecan		
Sample Size	41	53	61
ORR by independent radiographic review	32%	28%	33%
Duration of Response \geq 12 months	75%	40%	NA

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% and in refractory cervical cancer with response rate of 14%
 - 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)	PD-L1+ Cervical (Keytruda)
ORR	13%	15%	12%	14%
CDX in label	Yes	No	No	Yes

- Tazemetostat was approved in January 2020 in epithelioid sarcoma with response rate of 11% and 15% in separate trials

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

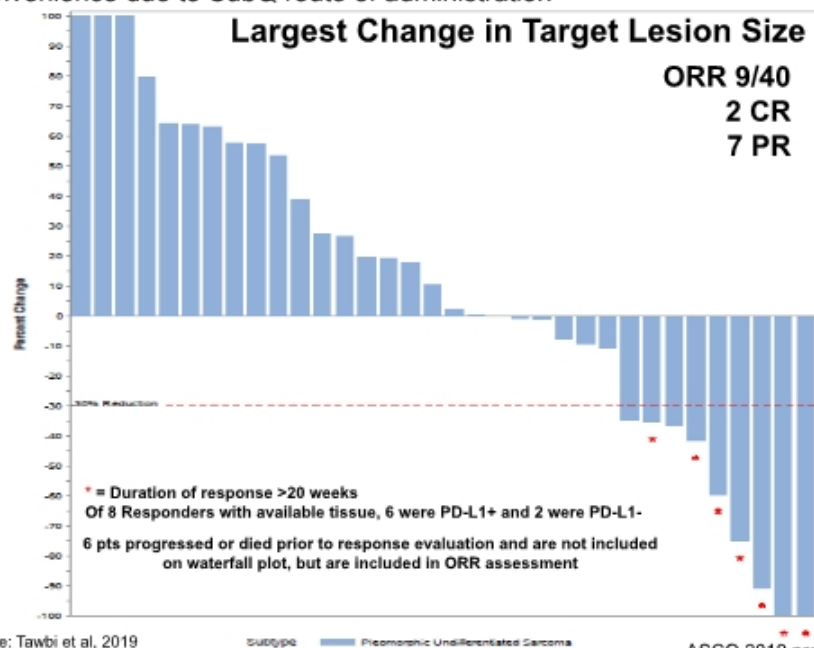
- Common soft tissue sarcomas (formerly contained within the category of malignant fibrous histiocytoma or MFH)
 - ~2,000 cases of UPS in the US annually (Western world incidence: 0.8-1.0/100,000)
 - Myxofibrosarcoma (MFS) half as common as UPS with ~1,000 cases annually in US
- **First line chemotherapy 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%

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 conducting 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

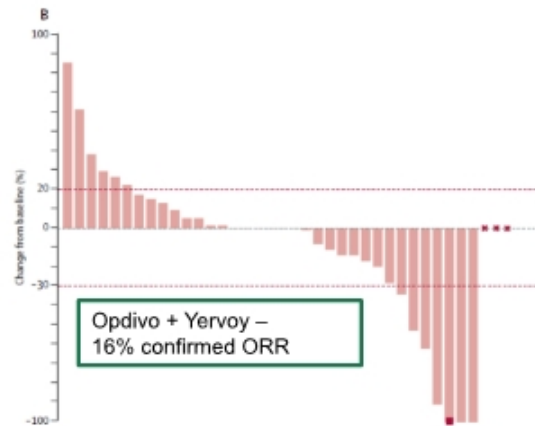
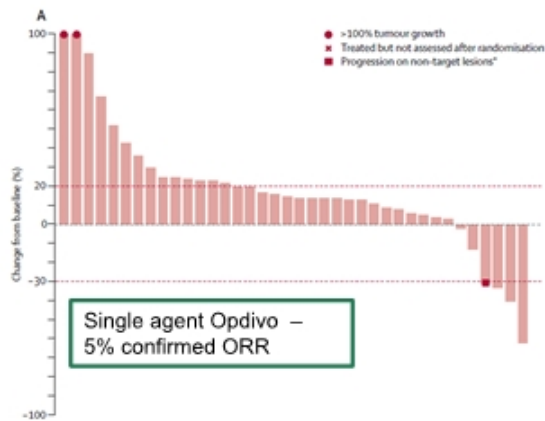
Keytruda Trial in Refractory UPS: 23% ORR

- Keytruda (pembrolizumab), a checkpoint inhibitor targeting PD-1, has shown promising response rate in UPS with 23% ORR
- We expect Envafohimab 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

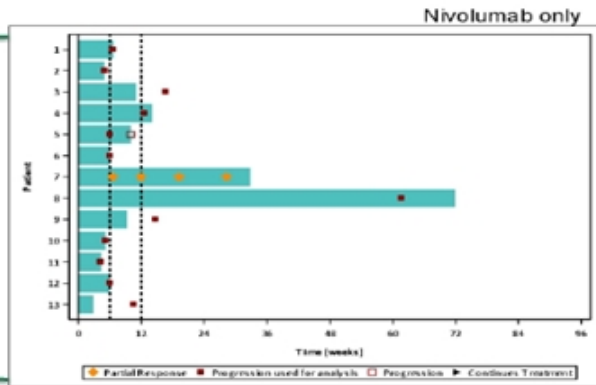
- Randomized trial of multiple soft tissue sarcoma subtypes
 - Parallel, open label, non-comparative cohorts
 - Single agent Opdivo (PD-1 antibody) and Opdivo in combination with Yervoy (CTLA-4 antibody)
- **Opdivo in combination with Yervoy tripled the ORR**



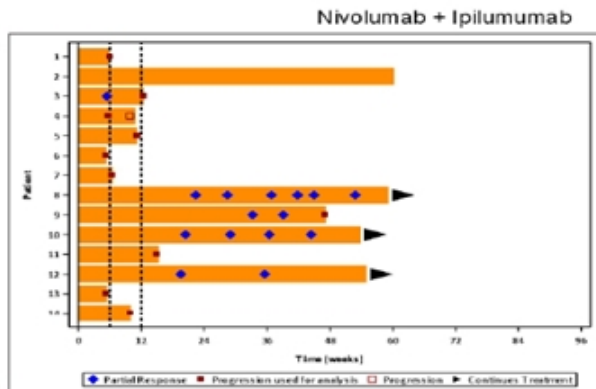
Alliance Trial in Sarcoma (Expanded Cohorts in UPS): Benefit of Dual Checkpoint Inhibition with Opdivo + Yervoy

Opdivo in combination with Yervoy tripled the ORR in UPS

ORR of 8% (1/13) with single agent Opdivo

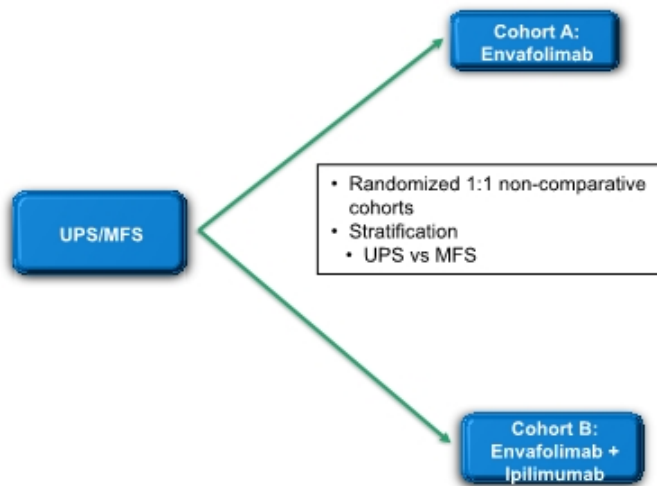


ORR of 29% (4/14) with Opdivo in combination with Yervoy



ENVASARC Pivotal Trial Design

Envafolelimab: 600 mg Q3weeks subQ
Ipilimumab (cohort B only): 1 mg/kg Q3weeks i.v. x 4

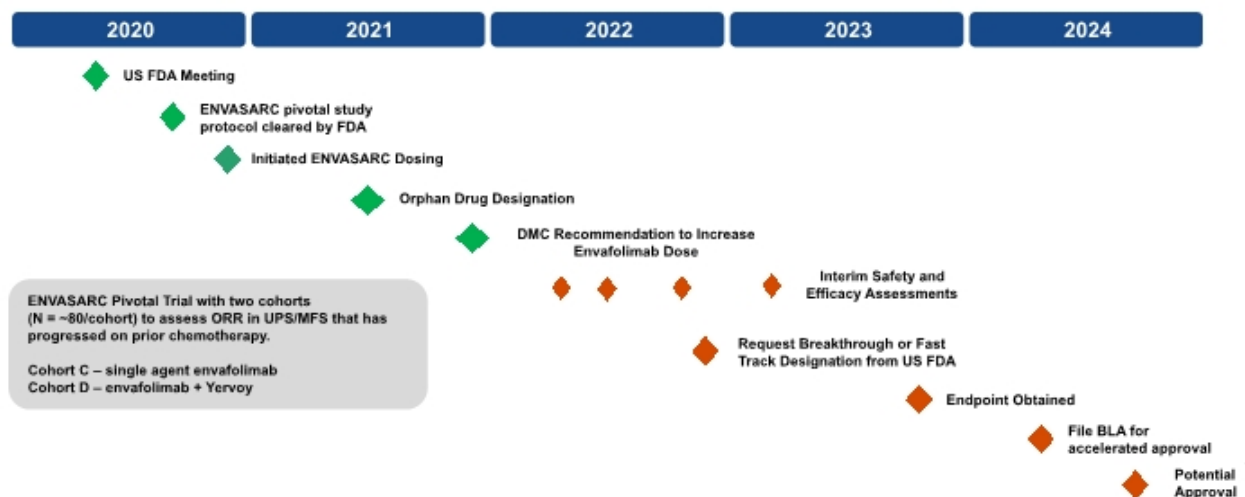


- **Primary Endpoint:** ORR by blinded central review; 9/80 responses in either cohort (11.25% ORR) will produce a lower bound of the 95% confidence interval that excludes the documented Votrient ORR of 4%
- Key Secondary Endpoints: DOR, PFS, OS, safety
- Key eligibility
 - Age ≥ 12
 - Advanced or metastatic UPS/MFS
 - Measurable disease by RECIST 1.1
 - No prior treatment with immune therapy
 - No more than 2 prior lines of treatment
 - ECOG PS 0-1
- Independent blinded central review
 - Imaging every 6 wks x 24 wks then every 12 weeks
- Futility rules: 0/18 or $\leq 2/46$ ORR

DMC Review of Safety and Efficacy in December 2021

- Envafolelimab was safe as a single agent and when combined with Yervoy with only a single grade 3 related SAE reported in 36 patients and has shown to be safe at doses 8-fold higher than the dose of envafolimab used initially in ENVASARC
- Objective responses by central review were noted in cohort A and cohort B that satisfied the futility analysis
- Activity was significantly higher in lighter weight patients
- DMC recommended increasing the envafolimab dose to 600 mg every 3 weeks from the current dose of 300 mg every 3 weeks to increase exposure and maximize benefit in all patients
- We plan to propose enrollment of up to 80 patients into each cohort at the higher dose recommended by the DMC to the FDA in a protocol amendment

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



Envafolelimab Target Product Profile:

Dual approval based on single agent ORR of ~15% and combination agent ORR of ~30% in refractory UPS/MFS with majority of patients having duration of response > 6 months, with a similar or superior safety profile compared to other approved PD-(L)1 therapies. Note Opdivo is approved as a single agent and in combination with Yervoy in MSI-H cancer.

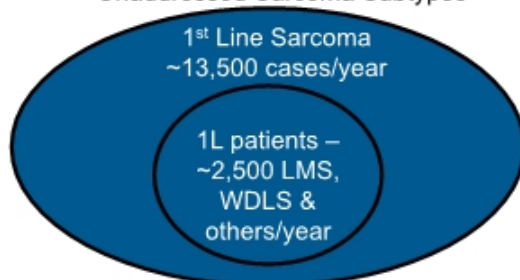
U.S. Market Size in Sarcoma Estimated at >\$1B Assuming Parity Pricing

Significant 2L Opportunities

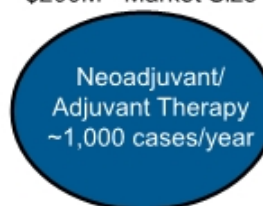


Label Expansion Opportunities – 1L & Adjuvant

\$400M Increase in Market Size in Unaddressed Sarcoma Subtypes



\$200M+ Market Size

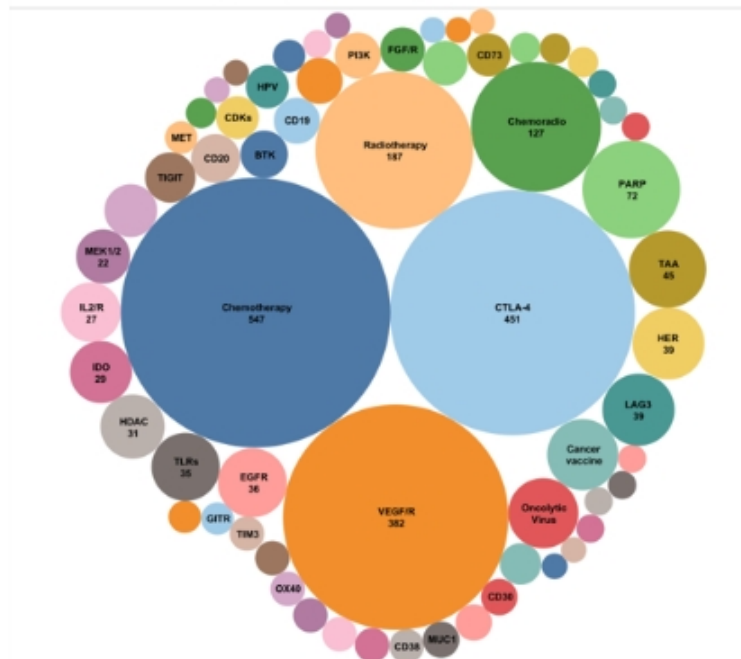


UPS – Undifferentiated pleomorphic sarcoma; MFS – myxofibrosarcoma; AS – Angiosarcoma; ASPS – Alveolar soft part sarcoma; DDLS – Dedifferentiated Liposarcoma; GIST – Gastrointestinal stromal tumors; WDLS – Well Differentiated Liposarcoma; LMS – leiomyosarcoma
1: UPS estimate from Orpha.net (.8 cases per 100K); unless otherwise noted, all figures are TRACON estimates

Envafohimab 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 Envafohimab and sell to TRACON at pre-negotiated prices
- TRACON to commercialize Envafohimab 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 Envafohimab 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

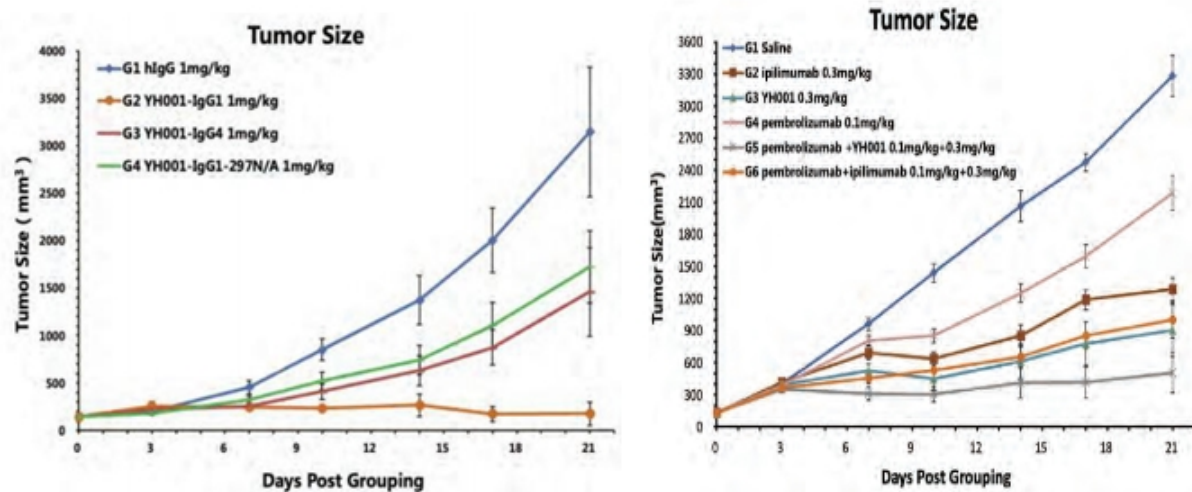
Trials by target - PD-(L)1 Combinations



Source: www.cancerresearch.org

YH001: Potential Best-in-Class CTLA4 Antibody

- Enhanced ADCC and CDC activity and superior *in vitro* and *in vivo* activity compared to ipilimumab in syngeneic MC38/hCTLA4 tumors in hCTLA4 mice or MC38/hPD-L1 tumors in hPD-L1/hCTLA4 mice

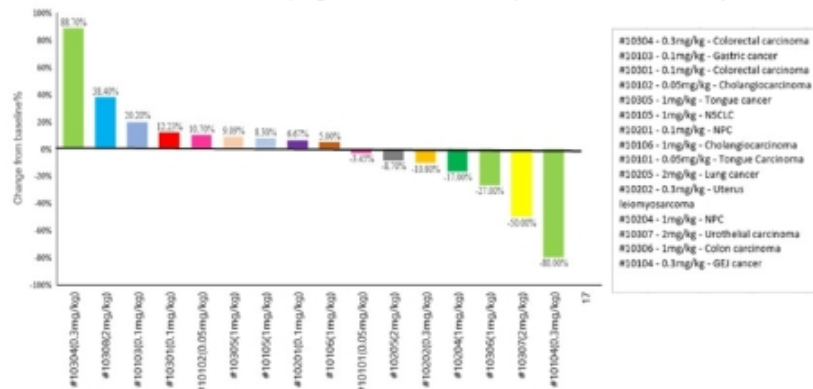


- YH001 treatment decreased T reg content and increased CD8⁺:Treg ratios in tumors
- More potent *in vitro* T cell activation and ADCC activity compared to ipilimumab

YH001 Phase 1 trials

- Single agent dose escalation ongoing in China
- Dose escalation with PD-1 antibody toripalimab ongoing in Australia
- Expect to initiate Phase 1/2 trial of YH001 + Enva + Doxorubicin in 1H 2022 for first-line treatment of sarcoma patients

Data from CSCO 2021 (August 9, 2021 data cutoff) in combination with Toripalimab

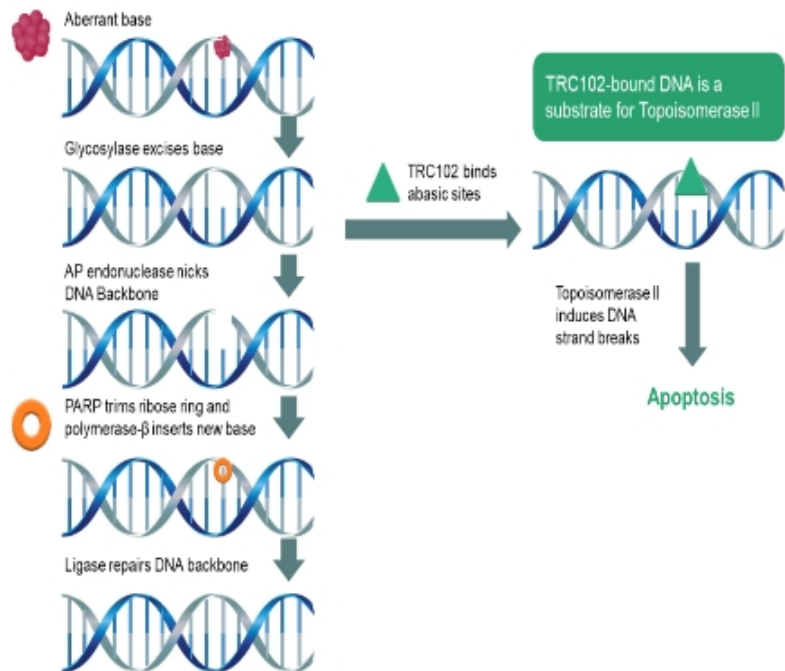


Among 16 patients that had image tumor assessments available two achieved partial response by RECIST, including in one patient with urothelial cancer who had failed prior treatment with a PD-1 antibody, and seven had stable disease.

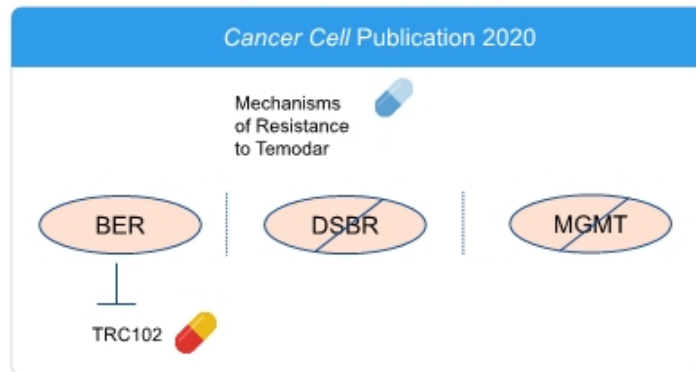
- License for indication of sarcoma and three additional named indications (renal cell carcinoma, Kras mutant lung cancer and colorectal cancer) as well as three substitution indications (endometrial cancer, bladder cancer and melanoma) in North America
- TRACON opt-in opportunity for low single-digit million at Eucure's discretion for all North American indications
- TRACON to conduct and bear costs of clinical trials in North America
- Eucure to manufacture Envafolimab and sell to TRACON at pre-negotiated prices
- TRACON to commercialize Envafolimab in noted indications in North America
- TRACON will owe double digit royalties to Eucure ranging from low double digits to mid-double digits in first year of launch and from mid-twenties to mid-double digits thereafter.

TRC102: Multiple Clinical Trials Funded by the NCI

- Oral 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®) and antimetabolite chemotherapy (e.g., Alimta®)
- 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 + Temodar Induces Synthetic Lethality in MGMT Methylated Cancer



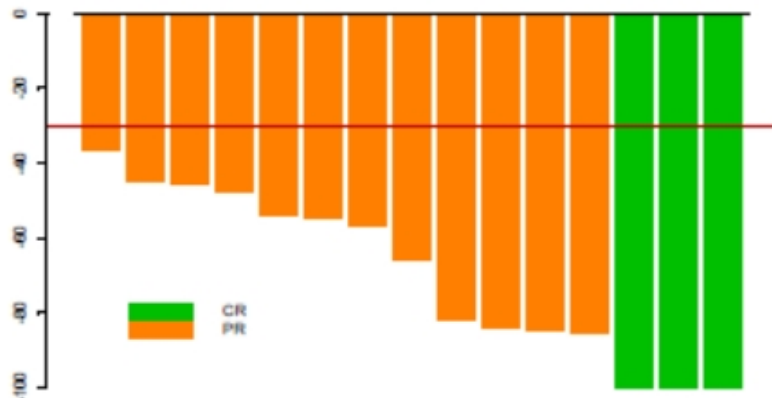
Responses seen in National Cancer Institute funded trials of GBM and colorectal cancer patients with MGMT methylation

Next step: First Line Trial of TRC102 + Temodar + Radiation in GBM patients with MGMT Methylation funded by NCI cooperative group

BER: Base Excision Repair; DSBR: Double Strand Break Repair

TRC102 Improves Response Rate to Chemoradiation in Advanced Localized Lung Cancer

Data reported at ASCO 2020



TRC102 + Alimta/cisplatin
and radiation in Advanced
Localized Lung Cancer

**100% Response rate –
Of 15 evaluable patients:
3 had CR (20%)
12 had PR (80%)
2-year PFS rate was
49%**

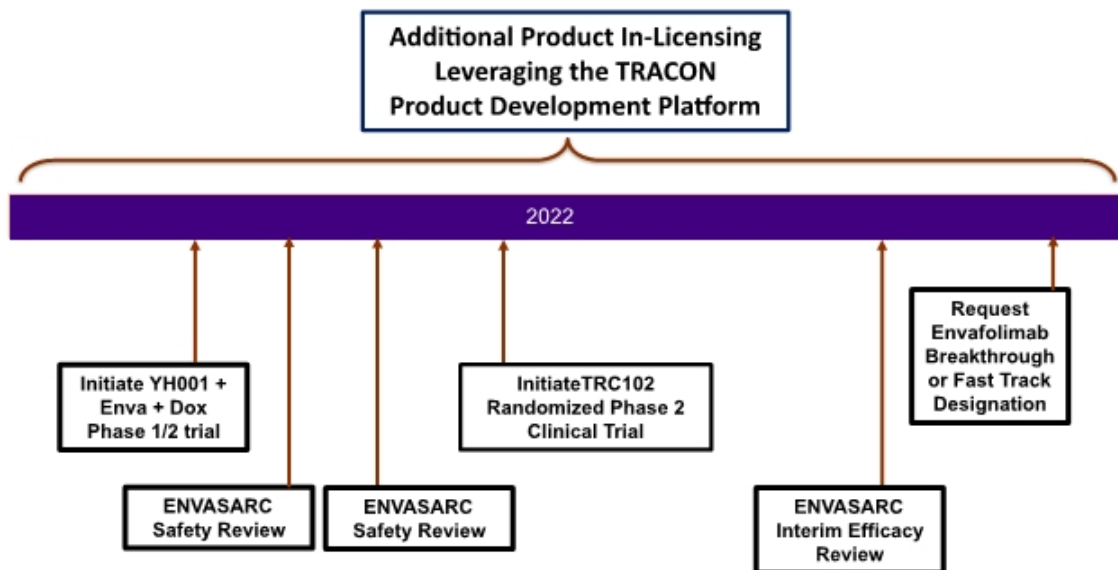
Next step: First Line Randomized Trial Sponsored by NCI in Advanced
Localized Lung Cancer of Chemoradiation +/- TRC102 with Imfinzi maintenance

I-Mab Corporate Collaboration: CD73 antibody TJ4309

	2019	2020	2021
TJ4309		Phase 1 Solid Tumors with Tecentriq	

- 2021 ESMO randomized Phase 2 data from Astra Zeneca indicated CD73 antibody oleclumab potentiated PD-L1 antibody Imfinzi in lung cancer
- Phase 1 data presented at ASCO:
 - TJ4309 was safe and well-tolerated as a monotherapy and in combination therapy with Tecentriq. No dose limiting toxicity was observed and the maximum tolerated dose was not reached.
 - Full saturation of circulating and cell-bound CD73 was achieved at doses ≥ 10 mg/kg.
 - Linear PK profile was observed at the doses ≥ 10 mg/kg following a single dose and supports Q3W dosing.
 - Evidence of clinical activity following treatment with TJ4309 and Tecentriq.
- TRACON is entitled to revenue sharing 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
- 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. I-Mab indicated their desire to terminate the collaboration in 2021, which would trigger a \$9M payment to TRACON

Expected Key 2022 Milestones



TRACON is a Rare Clinical CRO-Independent Company



Expected benefits of TRACON's
CRO-Independent Product Development Platform:

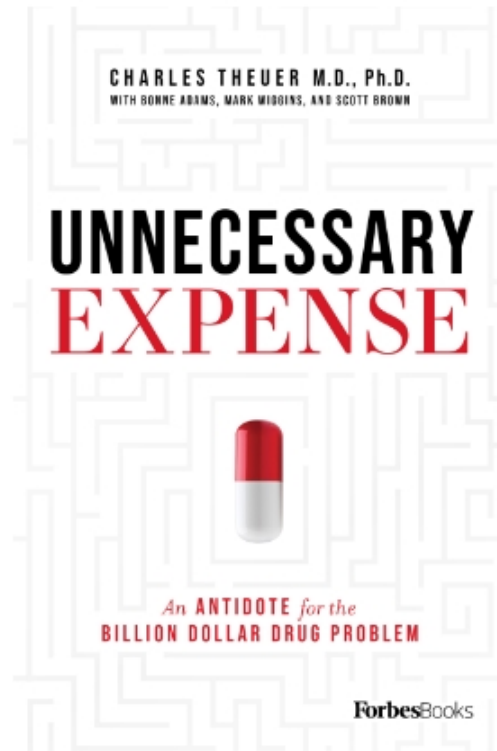
- Reduced trial cost
- Decreased timelines
- Control over development
- Improved quality

Product Development Solution: Aligned Deal Structure Leveraging Our Product Development Platform

- Cost, risk and profit share deal structure of partnered assets produces alignment, with TRACON typically paying U.S. clinical trial costs through initial approval and commercializing in North America
- 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 in ex-U.S. territories by our partner
- Opportunity to add U.S. sites to a regional trial to generate representative populations to facilitate global approval
- Proven ability to leverage platform to expand pipeline and build value without upfront payment
 - Subcutaneous PD-L1 antibody envafolimab from 3D Medicines and Alphamab Oncology (HKSE: 9966 ALPHAMAB ONCOLOGY)
 - CTLA-4 antibody from Eucure Biopharma
 - Prostate cancer asset from Johnson & Johnson, included equity investment¹
 - CD73 antibody from I-Mab (NASDAQ: IMAB)
 - Bispecific antibody collaboration with I-Mab (NASDAQ: IMAB)

Recognition of TRACON's Product Development Platform and Aligned Deal Structure

- Product Development Platform and Aligned Deal Structure Profile profiled in *Unnecessary Expense*, published by Forbes Books and available on Amazon
- Industry recognition for clinical trial design (Clinical Research Excellence Award 2017)



Financial Overview (as of December 31, 2021)

Ticker	TCON (NASDAQ)
Cash, Cash Equivalents and Short-term Investments	\$24.1 million *
Debt – Outstanding Principal	\$1.4 million *
Common Shares O/S	19.4 million *
Cash Runway	Into 2023
Covering Analysts	Nick Abbott (Wells Fargo) Bert Hazlett (BTIG) Maury Raycroft (Jefferies) Ed White (H.C. Wainwright) Jason McCarthy (Maxim) Soumit Roy (JonesTrading) Matt Cross (AGP)

*These amounts are preliminary, have not been audited and are subject to change upon completion of the audit of our consolidated financial statements as of and for the year ended December 31, 2021.

- Potential best-in-class checkpoint inhibitor envafolimab dosing in ENVASARC pivotal trial in sarcoma in US is now approved in China
- Clinical stage pipeline includes
 - CTLA-4 antibody in P1
 - DNA repair inhibitor in P2 in collaboration with NCI
 - CD73 antibody in P1 in combination with Tecentriq®
- Business Development engine driven by TRACON's CRO-independent clinical development and commercialization capabilities in the U.S./E.U. that serves as a solution for ex-U.S. companies
 - Five collaborations since 2016 (J&J, Alkermes, 3D Medicines, Eucare and I-Mab)
 - Capacity and appetite for more deals now
- Low financial burn rate and current capital provide runway into 2023 past expected interim ENVASARC pivotal trial data

