

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 8, 2018**

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))

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, 2017 cash, cash equivalents and short-term investments and outstanding debt principal balances, at various upcoming meetings beginning January 8, 2018. 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 8, 2018.

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	<u>Corporate Presentation, dated January 2018</u>

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 8, 2018

By: /s/ Charles P. Theuer

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

President and Chief Executive Officer

TRACON PHARMACEUTICALS

January 2018



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, 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, competition in our target markets, our ability to protect our intellectual property, 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 Highlights

Capital efficient Product Development Platform advancing a late stage and diverse pipeline of proprietary as well as pharma partner assets

TRC105

- Endoglin antibody in late stage trials in oncology and wet AMD with VEGF inhibitors, a franchise currently generating > \$18B annually; Immune oncology opportunity

Oncology Phase 3

Dosing Phase 3 TAPPAS trial under SPA in orphan drug indication of angiosarcoma; multiple ongoing Phase 2 trials

Ophthalmology Phase 2

Dosing Phase 2 AVANTE randomized wet AMD trial; partnered with Santen

Immune Oncology Phase 1

Dosing Phase 1 trial of TRC105 and Opdivo

TRC102 Phase 2

- Inhibitor of DNA repair dosing in Phase 2 glioblastoma and mesothelioma trials supported by NCI

TRC253 Phase 1

- Inhibitor of mutated and wild-type Androgen Receptor dosing in Phase 1/2 prostate cancer trial

Capital Efficient Product Development Platform

Internal product development platform allows TRACON to conduct clinical trials without a CRO



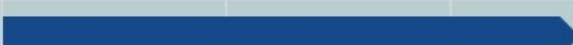








- More efficient access to clinical data at lower cost

Management team with comprehensive CMC, Regulatory and QA expertise

- Development of multiple products through launch

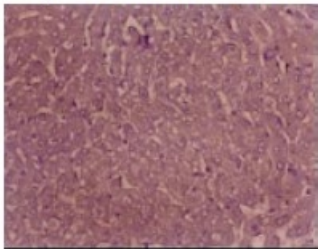
Allows for significant costs savings to TRACON and the opportunity to expand the portfolio through in-licensing of additional programs at no cost (e.g., Janssen transaction)

Broad Pipeline with Multiple Expected Near-term Readouts

	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3
TRC105	Angiosarcoma				
	Renal, Liver  ¹				
	Lung (I/O), Breast				
TRC102	GBM, Mesothelioma				
	Lung, Solid Tumors				
DE-122	Wet AMD  ²				
TRC253	Prostate  ³				
TRC694	Myeloma				

Endoglin: Essential Non-VEGF Angiogenic Target

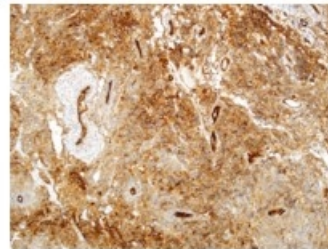
- Endoglin is expressed on endothelial cells and is essential for angiogenesis
 - Selectively expressed on proliferating vessels in cancer and AMD; up-regulated following VEGF inhibition
 - Unfavorable prognostic marker
- Attenuated endoglin expression causes Osler-Weber-Rendu syndrome which is associated with improved cancer survival (31% reduced risk of death)
- Persistent expression on tumor vessels results in progression despite VEGF inhibition, while knockdown of endoglin resensitizes tumors to VEGF inhibition
- Targeting VEGF and endoglin concurrently improves antitumor effects
- Endoglin is also expressed on myeloid derived suppressor cells (MDSCs) and potentiates PD-1/PD-L1 inhibition in preclinical models



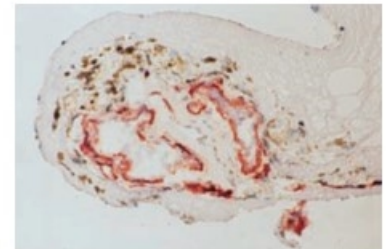
Normal Human Liver



Human Liver Cancer



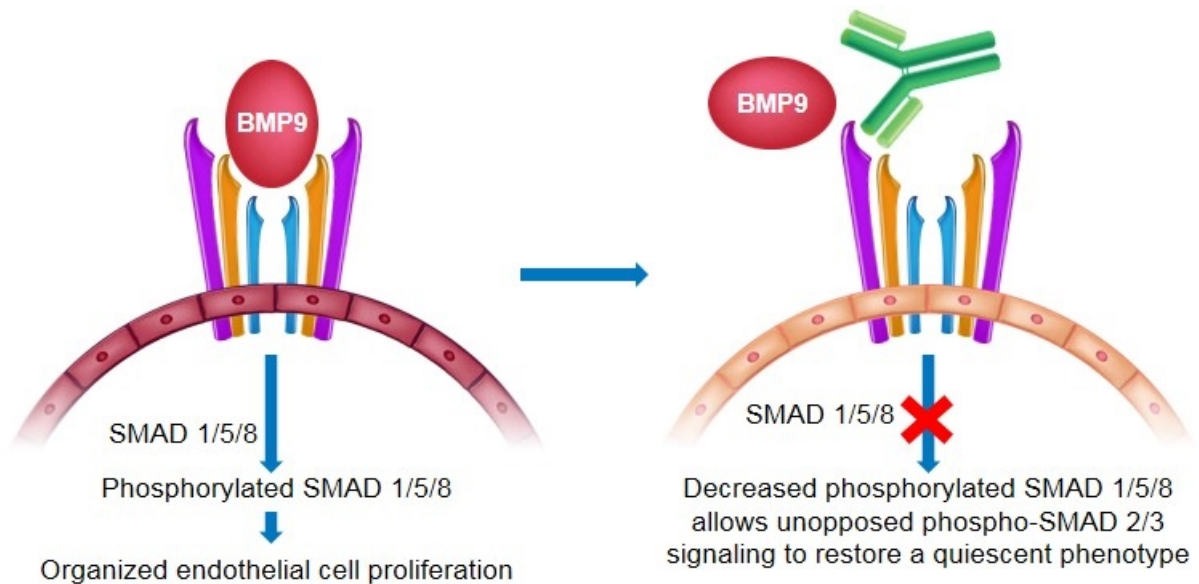
Angiosarcoma



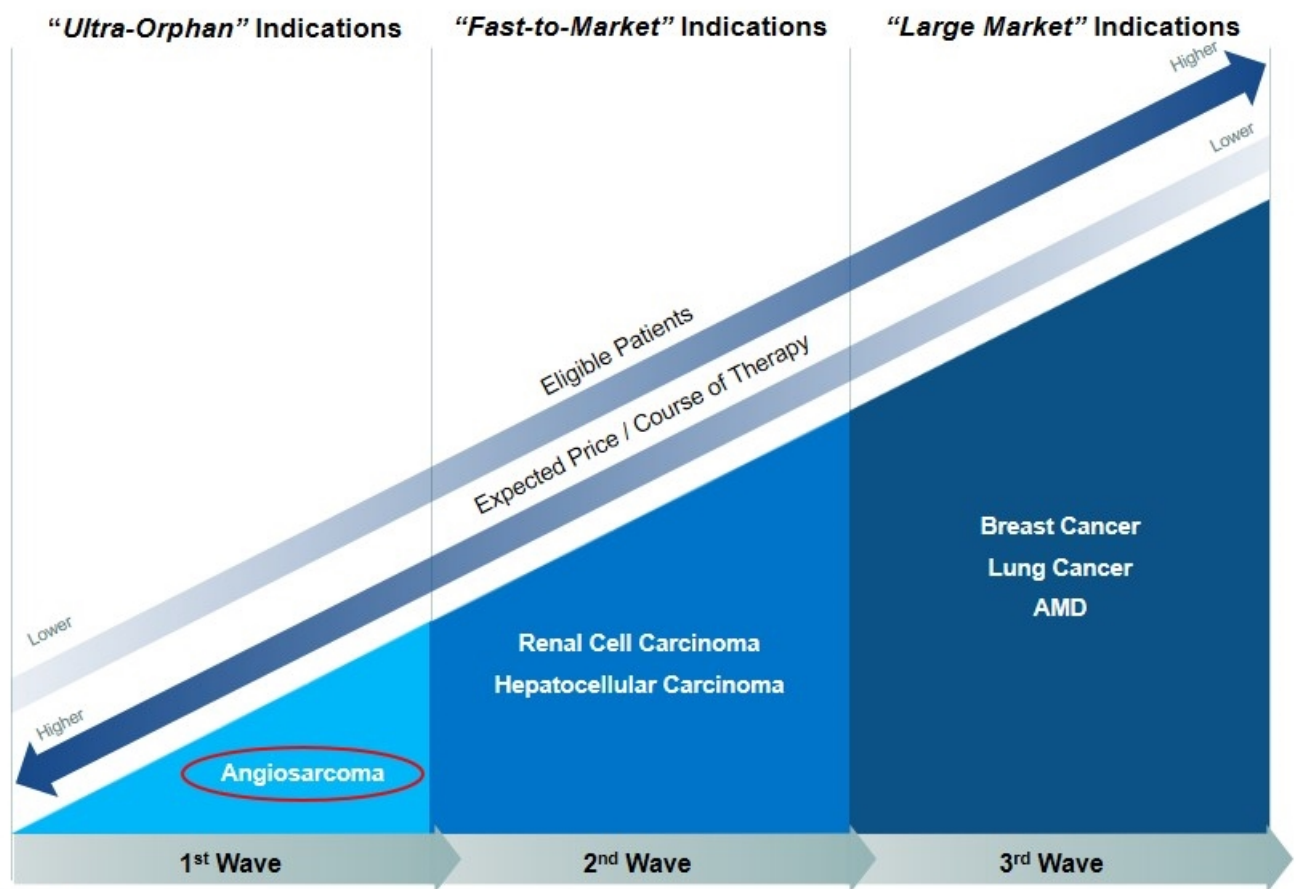
Human AMD Membrane

TRC105: Our Lead Endoglin Antibody

- TRC105 binds a precise endoglin epitope to inhibit BMP binding and angiogenesis
- TRC105 also potently mediates antibody-dependent cell mediated cytotoxicity (ADCC)



Endoglin Antibody Tiered Clinical Development



Lead Indication: Angiosarcoma

- Angiosarcoma has a 5-year survival rate of less than 12%, which highlights the aggressive nature of the tumor when compared to a 5-year survival rate of approximately 56% for all soft tissue sarcoma¹
- Approximately 600 cases annually in the US and 1,200 in Europe, with a greater incidence in Asia²
- Angiosarcoma can arise in any soft-tissue structure or viscera. About half of patients present with a primary cutaneous lesion. Risk factors include prior radiation exposure and chronic sun exposure.
- Treatment with chemotherapy (taxanes or doxorubicin) in the front line setting is associated with PFS of ~ 5 months and OS of less than 1 year³
- Treatment with VEGF inhibitors in the second line setting is associated with PFS of 1.8 - 3.8 months and OS of less than 1 year

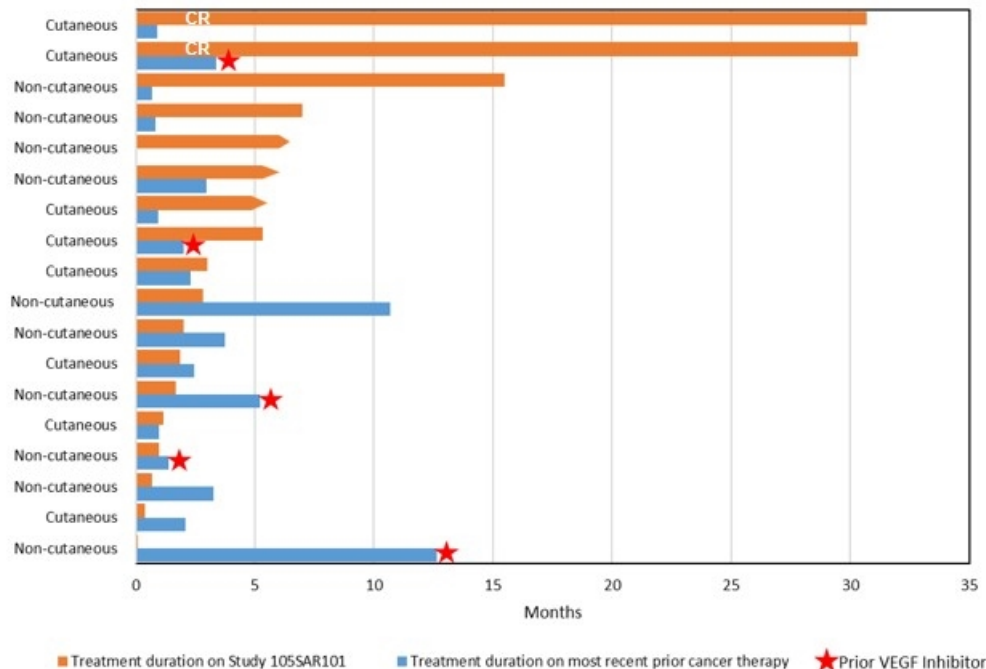
Profile of Unmet Need in Initial Pivotal Indication: VEGF Inhibitors Have Limited Activity in Angiosarcoma

VEGF Inhibitor	Study	Patient Population	Activity
Votrient® ¹	Retrospective analysis (CTOS 2016)	Angiosarcoma (n = 40)	<ul style="list-style-type: none"> • ORR = 20% (No CRs) • PFS = 3.0 months • OS = 9.9 months
Votrient	Retrospective analysis (ASCO 2014)	Soft tissue sarcoma, including 6 angiosarcoma patients	<ul style="list-style-type: none"> • No CR's
Nexavar®	Single agent study (Maki 2009)	Angiosarcoma (n = 37)	<ul style="list-style-type: none"> • ORR = 14% (1/37 CR) • PFS = 3.8 months
Nexavar	Single agent study (French sarcoma group)	Angiosarcoma (n = 41)	<u>Cutaneous angiosarcoma</u> <ul style="list-style-type: none"> • ORR = 15% (2/26 CR) • PFS = 1.8 months <u>Visceral angiosarcoma</u> <ul style="list-style-type: none"> • ORR = 13% (No CRs) • PFS = 3.8 months
Avastin®	Single agent study (Agulnik 2013)	Angiosarcoma (n = 23)	<ul style="list-style-type: none"> • ORR = 9% (No CRs) • PFS = 3.0 months

TRC105 + Votrient is Active in Angiosarcoma in Phase 1b/2 Trial

- mPFS in 13 VEGF inhibitor-naïve patients is 7.8 months, which compares favorably to the mPFS of single agent Votrient of 3.0 months in angiosarcoma patients
- Combination well-tolerated; data presented at CTOS 2017

Study Duration of 9 Angiosarcoma Patients Treated with TRC105 + Pazopanib in the Original Phase 1b/2 Trial and 9 Patients in the Expansion Cohort



TRC105 + Votrient Phase 1b/2 Observations

**Patient #1 off study (due to AE)
after 30+ months with ongoing CR**



Data as of November 2017

Patient #2 maintained a CR for 28+ months



Patient #3 remained on treatment for 16 months



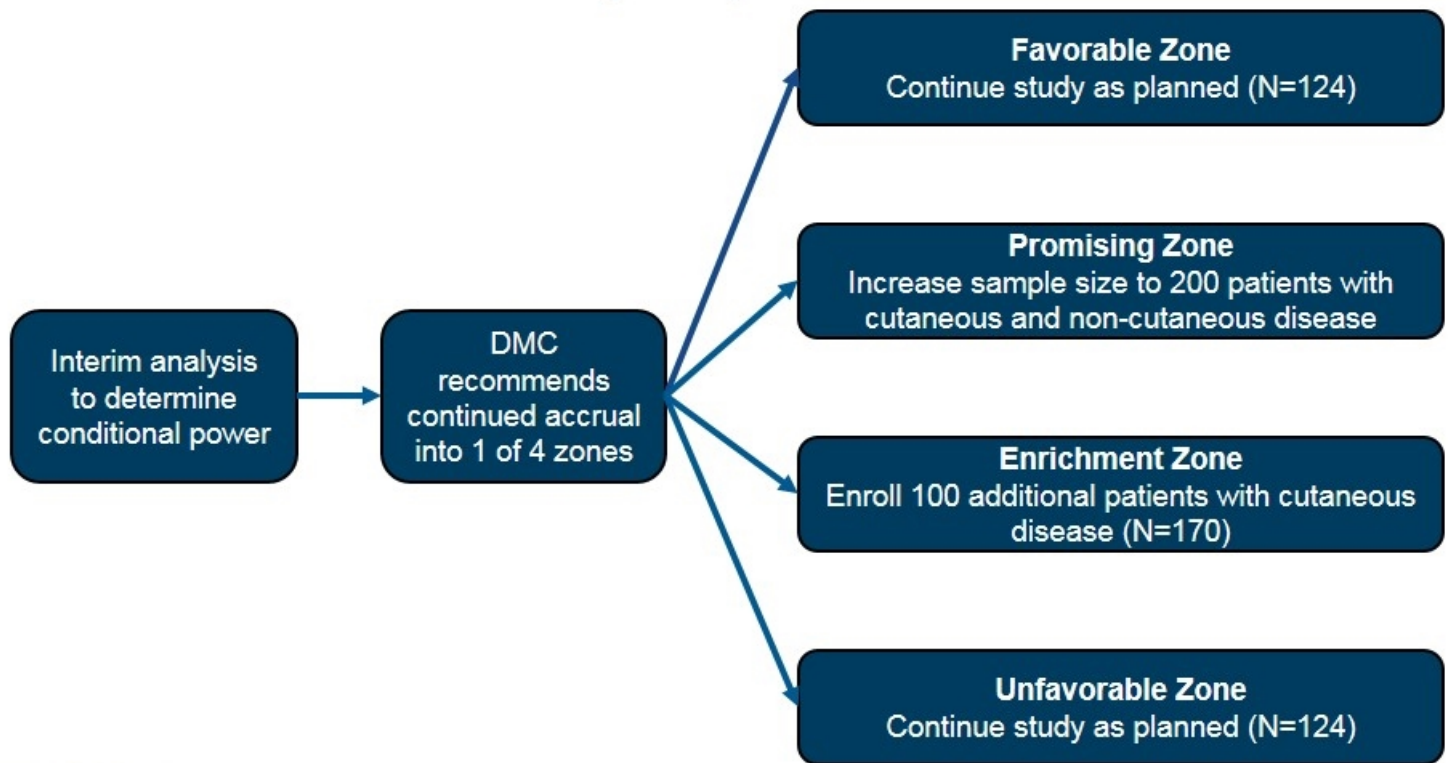
Phase 3 TAPPAS Trial in Angiosarcoma

- Primary Endpoint: PFS
- Independent blinded central review
- Key Secondary Endpoints: ORR, OS
- Key eligibility
 - Age ≥ 12
 - Unresectable angiosarcoma
 - Measurable disease by RECIST 1.1
 - No prior treatment with VEGF inhibitor
 - No more than 2 prior lines of treatment
 - ECOG PS 0-1
- Strata
 - Cutaneous vs Non-cutaneous
 - Prior chemotherapy: 0 vs 1 or 2
- N=124-200 (Adaptive design)



Phase 3 TAPPAS Trial in Angiosarcoma

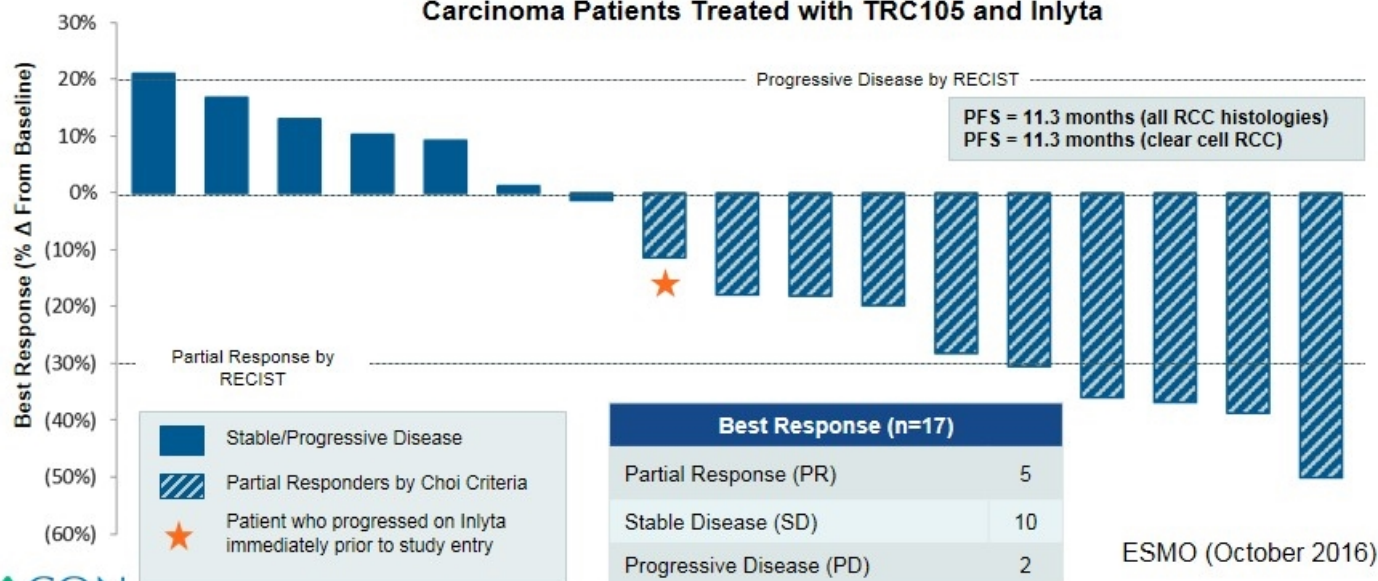
Adaptive design recognized as most innovative clinical trial of 2017. Allows for sample size re-estimation or enrichment of cutaneous disease at the time of the interim analysis expected in 2H 2018.



TRC105 + Inlyta® in Renal Cell Carcinoma

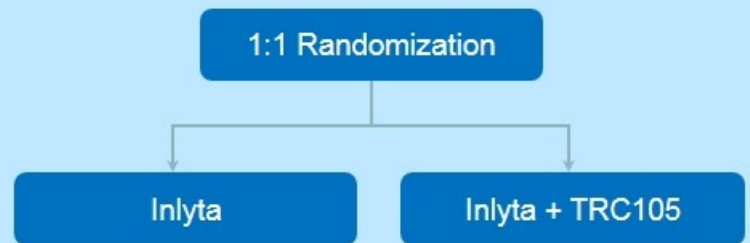
- 18 patients treated in a Phase 1b clinical trial who failed at least one VEGF inhibitor
- Partial response rate by RECIST of 29% (4 of which were in the fourth line setting)
 - Exceeded partial response rate of Inlyta following VEGFR TKI treatment in the Inlyta Phase 3 AXIS trial of 11%
- Improved activity in clear cell (including 4 RECIST PRs) and exploratory analysis indicated two biomarkers (baseline TGF- β R3 and osteopontin) correlated with activity
- Median PFS in clear cell RCC of 11.3 months
 - Exceeded PFS of Inlyta following VEGFR TKI treatment in the Inlyta Phase 3 AXIS trial of 4.8 months

Maximum Percentage Change in Target Lesion Size in Renal Cell Carcinoma Patients Treated with TRC105 and Inlyta



Phase 2 TRAXAR Trial in Renal Cell Carcinoma

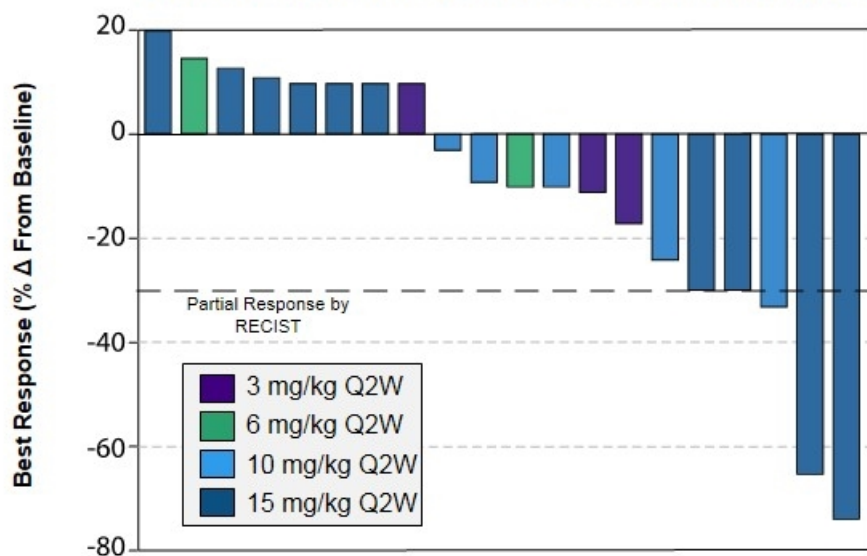
- Primary Endpoint: PFS by RECIST 1.1
- Independent blinded central review
- Key eligibility
 - Advanced or metastatic clear cell RCC
 - Measurable disease by RECIST 1.1
 - Progression following 1 prior VEGF inhibitor
 - 1 prior mTOR inhibitor allowed
 - 1 prior immunotherapy allowed
- Fully enrolled (N=150) event driven trial with data expected 1H 2018



TRC105 + Nexavar in Hepatocellular Carcinoma

- Final data from NCI Phase 1/2 study published in Clinical Cancer Research in May 2017 - partial response rate by RECIST of 25% across all 4 dose levels; partial response rate of 33% for patients treated at two highest doses (10 or 15 mg/kg TRC105)
 - Exceed partial response rate of Nexavar in Phase 3 pivotal studies of 2 - 3%
 - Median OS of 15.5 months exceeded median OS of Nexavar in its pivotal Phase 3 of 10.7 months
- Multicenter Phase 2 trial in hepatocellular carcinoma of up to 33 patients is enrolling to confirm response rate and to potentially justify a randomized Phase 3 trial
- Late stage development in HCC to be led by Ambrx in China

Maximum Percentage Change in Target Lesion Size in Hepatocellular Carcinoma Patients Treated with TRC105 and Nexavar



Clinical Cancer Research (May 2017)

TRC105 + Opdivo® in Lung Cancer

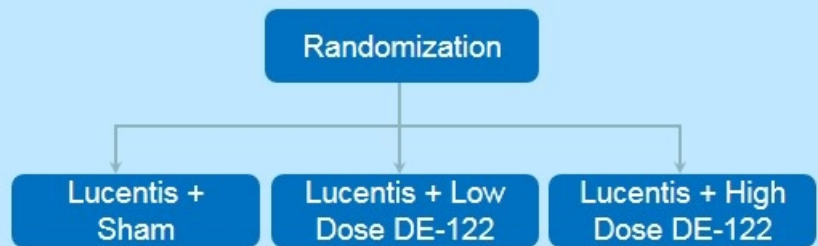
- Endoglin is expressed on myeloid derived suppressor cells (MDSCs), a cell type not addressed by checkpoint inhibition
- TRC105 mediates ADCC of endoglin expressing cells
- TRC105 potentiates the activity of PD-1 inhibition in syngeneic mouse tumor models
 - Publication in preparation from Leiden University
- TRC105 is being studied with Opdivo in second line non-small cell lung cancer in a Phase 1 trial
 - Opdivo single agent response rate¹ in this setting is 20%
 - Correlation between response and MDSC content of tumors will be assessed

Development in AMD Partnered with Santen

- Failed Phase 2 and 3 studies from Ophthotech and Regeneron leaves substantial opportunity for a superior MOA to build on VEGF inhibition in wet AMD; regulatory path confirmed; substantial commercial opportunity
- Santen, a global ophthalmology company with \$1.8 billion in annual revenue, leads global development and commercialization efforts for DE-122 (ophthalmic formulation of TRC105) in wet AMD and other eye diseases
- Deal terms
 - \$20 million received thus far
 - Santen pays all development costs
 - Up to \$145 million in additional milestone payments
 - Royalties in the high single digits to low teens
- Phase 1/2 PAVE trial results to be presented February 10, 2018 at the Angiogenesis, Exudation and Degeneration meeting at Bascom Palmer Eye Institute
- Dosing randomized Phase 2 AVANTE trial

Phase 2 AVANTE Trial in Wet AMD

- Primary Endpoint: Best Corrected Visual Acuity following six monthly intravitreal injections
- Double masked
- N=51



TRC102: Reversing Resistance to Chemotherapy

- Small molecule designed to reverse resistance to chemotherapy and complement poly ADP-ribose polymerase (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®)
- Ongoing clinical development funded by NCI

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 some 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 some patients previously treated with Fludara	
TRC102 + Temodar (Presented at ASCO 2017)	✓	Partial responses in some 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 lung, colorectal, and ovarian cancer; Phase 2 trial with Temodar in glioblastoma

Deal with Janssen

- TRC253 and TRC694 in-licensed from Janssen
 - TRC253 is an antagonist of the F877L and other AR mutations that are resistance mechanisms for Xtandi® and ARN-509 (apalutamide)
 - TRC694 is a selective inhibitor of NF-kB-inducing kinase (NIK)
- TRACON was chosen because of our efficient product development platform
- \$5M equity investment made by JJDC

TRC253

- Janssen has rights to re-acquire TRC253 following Phase 1/2 for \$45M
 - Additional potential milestones of \$137.5M and low single digit royalty
- If kept by TRACON, we would owe regulatory and commercial milestones of up to \$45M and a low single digit royalty to Janssen

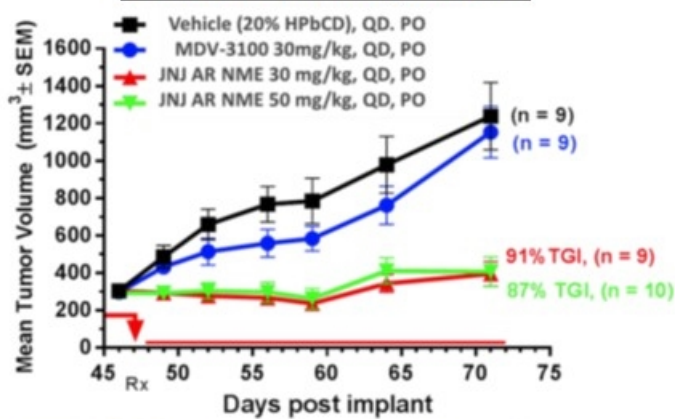
TRC694

- Janssen has a right of first negotiation for TRC694 following Phase 1
- TRACON will owe development and regulatory milestones of up to \$60M and low single digit royalty

TRC253: Novel Androgen Receptor (AR) Mutant Inhibitor

- Designed to treat AR resistant prostate cancer
 - Occurs in ~10% of mCRPC cases
- Active against wild-type AR and many clinically relevant ligand binding domain mutants
- Clear path to POC in targeted population using a companion diagnostic
- Phase 1/2 trial enrolling

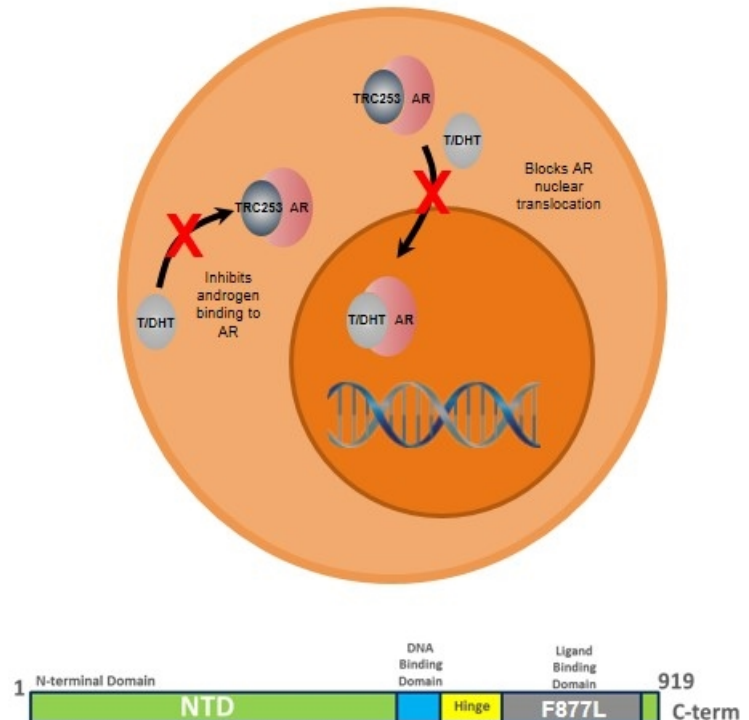
AR F877L-driven xenograft model



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Hickson, I. AACR 2016 Annual Meeting.
Joseph, JD, et al. Cancer Discovery 2013.

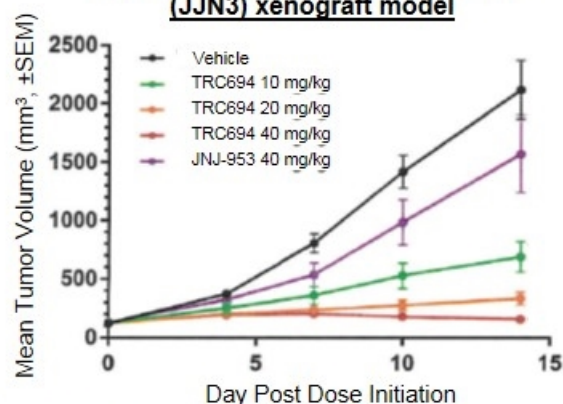
Multiple Mechanisms of Action



TRC694: Novel NF- κ B Inducing Kinase (NIK) Inhibitor

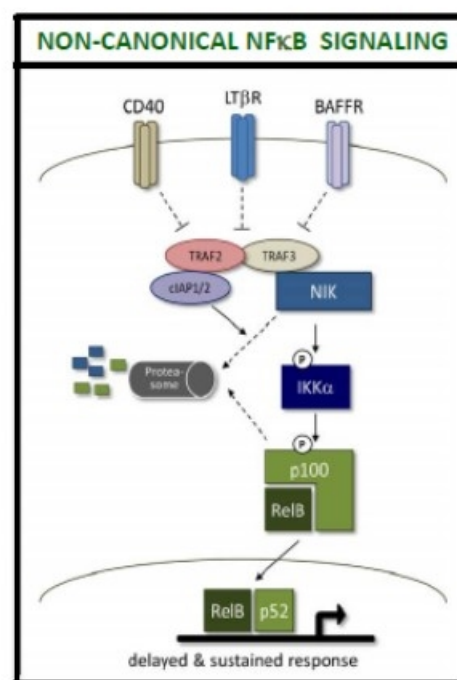
- NIK pathway is dysregulated in hematologic malignancies
 - Multiple myeloma (~12-20% of cases), mantle cell lymphoma (~17%), diffuse large B-cell lymphoma (~9-15%), CLL (~4% at diagnosis, higher later)
- Presented at AACR 2017
- Clear path to POC in targeted population using a precision medicine approach

NIK-translocated myeloma cell line (JJN3) xenograft model



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NIK is Critical for Non-Canonical NF κ B Activation


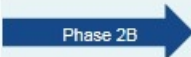













Krappmann & Vincendeau, 2016

Business Development Strategy

- Leverage the TRACON Product Development Platform to develop promising oncology assets while diversifying the TRACON portfolio
- Transactions similar to the Janssen transaction where TRACON develops asset(s) to certain value inflection points in return for substantial economics and/or downstream commercial rights
- For companies with little or no development infrastructure in the US, conduct proof-of-concept clinical trials in the US in exchange for substantial economics and/or product rights in the US

Multiple Expected Near-Term Value Inflection Points

	Companion Therapy	Indication	2018	2019
TRC105 (carotuximab)	Votrient	Angiosarcoma	Phase 3 	
	Inlyta	Renal	Phase 2B  	
	Nexavar	Liver	 Phase 1B/2 	
	Opdivo	Lung	Phase 1B  	
DE-122	Lucentis	Wet AMD	 Phase 2B 	
TRC102	Alimta	Mesothelioma	Phase 2 	
	Temodar	GBM	Phase 2 	
TRC 253		Prostate	 Phase 1/2 	

Expected Milestones Across All Programs

Milestone	Expected Timing
Initial Response Data from TRC105 Phase 2 multicenter trial in HCC	1H 2018
Present DE-122 Phase 1/2 PAVE trial data in wet AMD at Angiogenesis, Exudation and Degeneration Meeting (Santen)	1H 2018
Complete dose escalation in TRC253 Phase 1/2 trial in prostate cancer	1H 2018
Top-line data from TRC105 Phase 2 TRAXAR trial in RCC	1H 2018
Interim Analysis from TRC105 Phase 3 pivotal TAPPAS trial in angiosarcoma	2H 2018
Present data from TRC105 + Opdivo Phase 1 trial	2H 2018

Financial Overview (as of December 31, 2017)

Ticker	TCON (NASDAQ)
Cash, Cash Equivalents and Short-term Investments	\$34.5 million*
Debt – Outstanding Principal	\$8.0 million*
Common Shares O/S	17.7 million*
Covering Analysts	Jim Birchenough (Wells Fargo) Bert Hazlett (BTIG) Chad Messer (Needham) Maury Raycroft (Jefferies) Tom Shrader (Stifel)

*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, 2017.

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- Endoglin antibody in late stage trials in oncology and wet AMD with VEGF inhibitors, a franchise currently generating > \$18B annually; Immune oncology opportunity

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TRC253 Phase 1

- Inhibitor of mutated and wild-type Androgen Receptor dosing in Phase 1/2 prostate cancer trial

TRACON PHARMACEUTICALS

January 2018



NASDAQ: TCON

Complementing VEGF Inhibition Represents a Substantial Potential Commercial Opportunity for TRC105

Indication	Approved VEGF Inhibitors	2016 VEGF Inhibitor Revenue ¹
2 nd Line Renal Cell Carcinoma	Inlyta	\$401 million
1 st Line Hepatocellular Carcinoma	Nexavar	\$1.0 billion ²
2 nd Line Soft Tissue Sarcoma	Votrient	~\$150 million ³
Colorectal Cancer, Lung Cancer	Avastin, Cyramza, Zaltrap, Stivarga	>\$5 billion ⁴
Wet AMD	Eylea Lucentis	\$5.2 billion \$3.2 billion

Substantial opportunity to build upon multiple established VEGF inhibitor franchises by improving patient outcomes through improved inhibition of angiogenesis

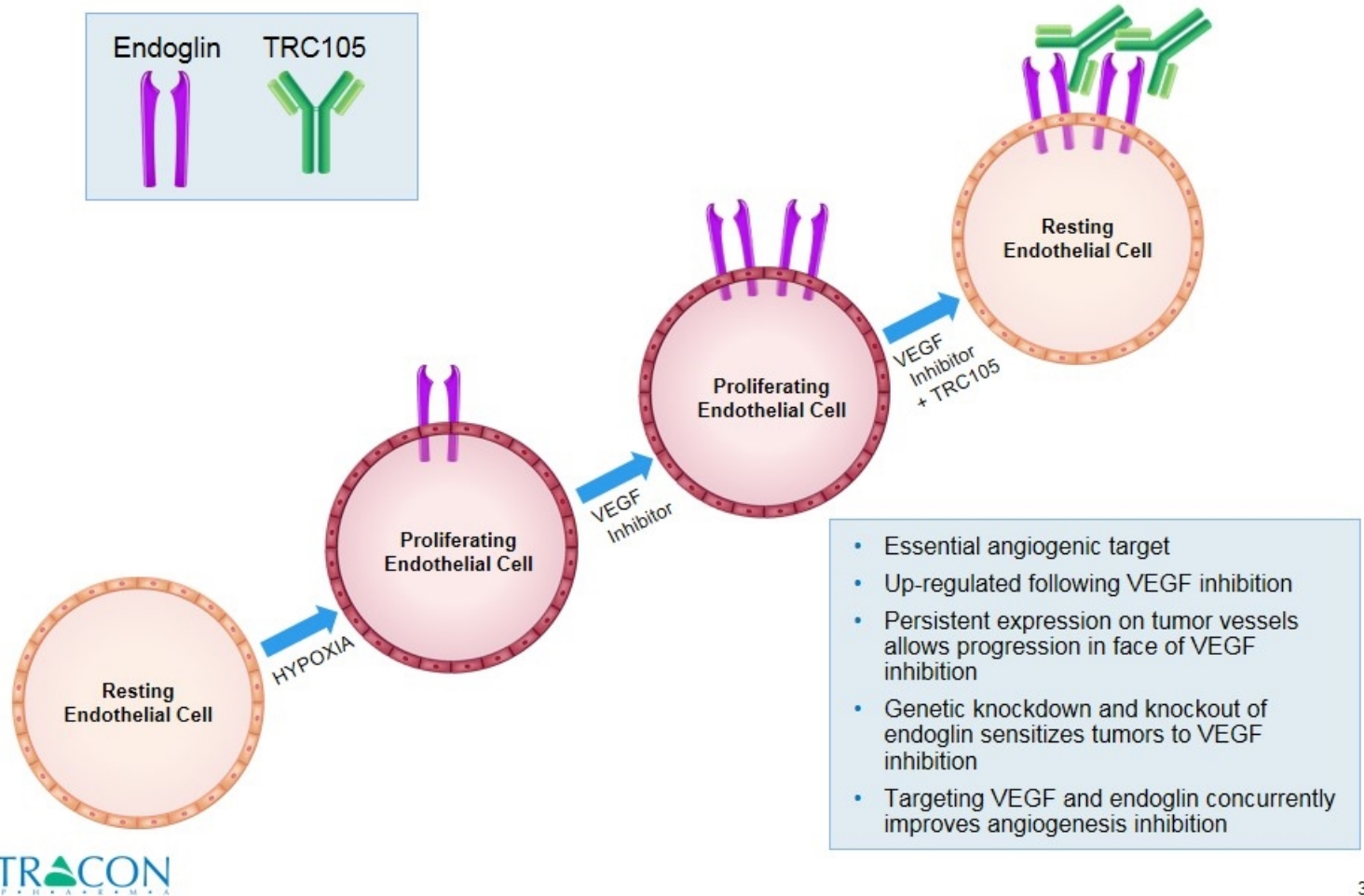
¹ Company reports, SEC filings, DataMonitor.

² Nexavar is approved in HCC, RCC and thyroid cancer. The majority of Nexavar's sales are in HCC.

³ Votrient is approved in both HCC and advanced STS. Estimated sales for Votrient in STS (based on 2014 total sales less DataMonitor estimates in RCC).

⁴ Based on company estimates of sales by indication for Avastin and Cyramza.

Targeting Endoglin Complements VEGF Inhibition



TRC102: Reversing Resistance to Chemotherapy

