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TRACON Pharmaceuticals

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TRACON Pharmaceuticals driving the development of targeted therapies for cancer

- Clinical-stage pipeline includes envafolimab to treat soft-tissue sarcoma
- Awarded Orphan Drug designation for TRC102 to treat brain and spinal cord cancers
- Looking for partnerships to help with regulatory and clinical development of drugs in the US

What TRACON does:

TRACON Pharmaceuticals Inc (NASDAQ:TCON) has positioned itself as a collaboration partner that leads the regulatory filings, clinical trials, as well as US commercialization of best-in-class drug candidates, as an alternative to expensive contract research organization (CRO) based development.

By sharing in the cost and risk of clinical development and leading US commercialization, San Diego, California-based TRACON serves as a solution for companies without clinical and commercial capabilities in the US.

In its early years, TRACON adopted the standard way most biotech companies develop drugs, which is to outsource the work to a CRO. In 2011, after disappointment with the cost, quality and speed of CRO-based drug development, the company internalized all of the clinical development operations that most companies outsource to a CRO.

TRACON boss Charles Theuer has incredible experience and knowledge in the oncology space. He was director of clinical oncology at Pfizer Inc (NYSE:PFE), and led the clinical development of kidney cancer therapy Sutent, which was approved by the US Food and Drug Administration (FDA).

In 2016, Dr Theuer steered TRACON to its first partnership, a collaboration with Johnson & Johnson's (NYSE:JNJ) Janssen Pharmaceutica NV. As part of the deal, TRACON secured the rights to develop a pair of Janssen's oncology drugs. The first is TRC253, a small molecule drug being developed for treating prostate cancer, and the second is TRC694 which addresses blood cancers such as myeloma. Johnson & Johnson Innovation made a $5 million equity investment in TRACON via the purchase of stock at $59.50 per share.

Price: 8.83

Market Cap: $120.84 m

1 Year Share Price Graph

Share Information

Code:	TCON	
Listing:	NASDAQ	
52 week	**High**	**Low**
	10.1	**0.95**
Sector:	**Pharma & Biotech**	
Website:	**www.traconpharma.com**	

Company Synopsis:

TRACON (NASDAQ:TCON) is a U. S. biotech with a product development platform that offers corporate partners CRO-independent clinical development and U. S. commercialization expertise.   TRACON has in-licensed N.

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The company's clinical-stage pipeline also includes envafolimab, which is being developed for the treatment of sarcoma and TRC102, a small molecule drug being developed for the treatment of lung cancer.

How is it doing:

One of TRACON's biggest wins of 2020 came in August when the FDA gave it the go-ahead for a human trial of envafolimab, a novel, single-domain antibody, to treat soft-tissue sarcoma cancer as part of an Investigational New Drug (IND) application.

TRACON said it expects to start enrolling patients in the trial at 25 US sites in the fourth quarter of 2020. The pivotal study is called ENVASARC and it will assess the potential of envafolimab as a single agent and in combination with

monoclonal antibody Yervoy (ipilimumab), which is used to treat late-stage, metastatic melanoma (deadly skin cancer).

The trial will be a multi-center, open-label, randomized, non-comparative, parallel cohort study. Eligible patients will receive one or two prior cancer therapies, but no prior immune checkpoint inhibitor therapy. Planned total enrollment is 160 patients -- with 80 patients enrolled into cohort A of treatment with envafolimab and 80 patients enrolled in cohort B of treatment with envafolimab and Yervoy.

Recent studies of envafolimab also show the therapy may have promise in treating colorectal cancer. Data have demonstrated its tolerability and safety in patients, while TRACON's corporate partners, 3D Medicines and Alphamab Oncology, have presented the findings at peer conferences.

In addition to envafolimab, TRACON is moving ahead with a second cancer-fighting candidate that has earned the FDA's approval.

In October, the agency granted TRC102 its Orphan Drug designation for the treatment of patients with a type of tumor called malignant glioma, including glioblastoma, an aggressive form of cancer that can occur in the brain or spinal cord.

TRC102 is being studied in multiple Phase 1 and Phase 2 clinical trials sponsored by the National Cancer Institute through a Cooperative Research and Development Agreement (CRADA). TRC102 also was evaluated in a Phase 2 trial in combination with Temodar chemotherapy in 19 patients with progressive or recurrent glioblastoma who progressed following Temodar and external beam radiotherapy. Extended survival was observed in two patients for more than two years.

TRACON is also obtaining Phase 2 proof-of-concept data from a Phase 1/2 trial of TRC253 in patients with metastatic prostate cancer. In other advances, topline data from a Phase 1 study of TJ004309, an antibody being developed in combination with Tecentriq, an antibody being supplied by Roche, are also expected in the second half of the year. TJ004309 is being developed in collaboration with TRACON's partner I-Mab Biopharma.

On the financial front, the biotech has extended its cash runway heading into 2021. As of June 30, 2020, it had cash and equivalents of $14.5 million and it recently launched a $5 million private placement to help fund the ENVASARC study.

Inflection points:

- Launch pivotal ENVASARC study in late 2020
- Move ahead with the study and development of TRC102
- Topline data from Phase 1 study of TJ004309 in 2H 2020

What the boss says:

In a recent interview with Proactive, TRACON CEO Charles Theuer said: "Our product development platform allows us to do trials at lower cost, higher quality and on faster timelines and includes US commercialization expertise."

He added: "By leveraging our platform, we were able to license a potential best-in-class checkpoint inhibitor envafolimab that we expect to approve and commercialize in the US, to dramatically improve the standard of care of sarcoma patients."

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