

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): **October 8, 2021**

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 1.01 Entry into a Material Definitive Agreement.

On October 8, 2021, TRACON Pharmaceuticals, Inc. (the “Company”), Eucure (Beijing) Biopharma Co., Ltd. (“Eucure”) and Biocytogen Pharmaceuticals (Beijing) Co., Ltd., Eucure’s controlling affiliate, entered into a collaborative development and commercialization agreement (the “Collaboration Agreement”) for the development of YH001, a monospecific investigational anti-CTLA-4 antibody.

Pursuant to the Collaboration Agreement, the Company was granted an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment, through administration of YH001 by intravenous or subcutaneous means, of multiple human indications, including sarcoma, microsatellite stable colorectal cancer, renal cell carcinoma (“RCC”), and K-ras positive non-small cell lung cancer (collectively the “Initial Indications”) or one or more of bladder cancer, endometrial cancer, and melanoma as substitute indications, which may be substituted for Initial Indications at the Company’s discretion (each upon such substitution, a “Substitute Indication”). The Company is responsible for, and will bear the costs of, preparing and filing all regulatory submissions and conducting any Phase 1, Phase 2, Phase 3, or post-approval clinical trials in North America for YH001 in the Initial Indications and potentially the Substitute Indications, while Eucure is responsible for conducting, and will bear the costs of, the preparation of chemistry, manufacturing and controls activities for YH001. Eucure has agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, YH001 to the Company for clinical trials pursuant to the terms of a clinical supply and quality agreement to be separately negotiated.

Eucure may pursue clinical trials for YH001 in North America outside of the Initial Indications or Substitute Indications, and also within the Initial Indications or Substitute Indications as part of a combination therapy of YH001 and an additional Eucure product. During a specified period, the Company has the option, subject to Eucure’s prior written approval, to expand the license to include the development and commercialization of YH001 for the treatment, through administration by intravenous or subcutaneous means, of all human and veterinary therapeutic indications in North America for a payment to Eucure in the low single digit millions (the “Company Option”).

Pursuant to the Collaboration Agreement, the Company granted Eucure an irrevocable, perpetual, royalty-free, exclusive license, with the right to grant sublicenses to develop, register, sell, offer to sell, have sold, market and distribute YH001 in all territories outside of North America as well as within North America for all indications other than the Initial Indications and the Substitute Indications.

The Company will be responsible for commercializing YH001 in North America, including booking of sales revenue in the Initial and Substitute Indications. The Company will owe Eucure escalating double digit royalties on net sales of YH001 in North America ranging from the mid-twenties to mid-double digits; provided that until the end of the first full calendar year following the first commercial sale of YH001, royalties will range from the low double digits to the mid-double digits. If sales of YH001 exceed a pre-determined sales threshold in the first full year of sales following first commercial sale, the Company will owe a milestone to Eucure in the high single digit millions. Payment obligations under the Collaboration Agreement continue on a country-by-country basis until the latest of (i) expiration of the last to expire licensed patent covering YH001, (ii) expiration of marketing or regulatory exclusivity covering YH001 and (iii) 10 years from the first commercial sale of YH001 in such country in North America. Eucure has agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, YH001 to the Company at cost plus a low double digit markup for commercial sales pursuant to the terms of a commercial supply and quality agreement to be separately negotiated.

Pursuant to the Collaboration Agreement, each party agreed that during the term of the Collaboration Agreement, it would not develop, manufacture, commercialize or license from any third party a monospecific inhibitor to CTLA-4 administered by intravenous or subcutaneous means in the Initial and Substitute Indications in North America.

The term of the Collaboration Agreement continues until the earlier of (i) the date that the parties cease further development and commercialization of YH001 in North America or (ii) on a country-by-country basis, the expiration of the royalty obligations in such country. The Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety

reasons related to YH001. In the event of a termination of the Collaboration Agreement, other than by the Company as a result of Eucure's material uncured breach or bankruptcy, (i) the Company's license shall terminate and (ii) the Company is obligated to grant Eucure an irrevocable, perpetual, royalty-free, non-exclusive license with the right to grant sublicenses under its rights in all development data and intellectual property to develop, register, sell, offer to sell, have sold, market and distribute YH001 in North America. In the event of a termination of the Collaboration Agreement by the Company as a result of Eucure's material uncured breach or bankruptcy, the license shall continue in the Initial Indications in North America, provided that (i) such license shall remain exclusive during the royalty term and non-exclusive thereafter; (ii) the Company shall have the right to have YH001 manufactured for its development and commercialization requirements in the Initial Indications in North America; and (iii) the license shall terminate in the event of an uncured material breach by the Company of any provision (including payment obligations) that survives termination of the Collaboration Agreement. In the event that the Collaboration Agreement terminates for safety reasons related to YH001, by mutual agreement of the parties or by Eucure in the event of an uncured material breach or bankruptcy by the Company, then the Company's rights and obligations under the Collaboration Agreement will revert to Eucure. In the event that Eucure does not approve the Company Option, the Company may terminate the Collaboration Agreement for convenience with a 30-day notice to Eucure, provided that such termination is given within 12 months of the effective date of the Collaboration Agreement (the "Company Option Termination"). In the event of a Company Option Termination, Eucure shall reimburse the Company for all costs and expenses that it incurred in performing the development activities.

The description of the Collaboration Agreement above is qualified in its entirety by reference to the text of the Collaboration Agreement, a copy of which the Company intends to file, with certain confidential terms redacted, with the Securities and Exchange Commission (the "SEC") as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021.

On October 11, 2021, the Company issued a press release with respect to entering into the Collaboration Agreement. A copy of the press release is attached hereto as Exhibit 99.1.

Item 8.01 Other Events

YH001 is an investigational humanized anti-CTLA-4 IgG1 monoclonal antibody. YH001 is being developed by Eucure for the treatment of various cancer indications.

Cytotoxic T-lymphocyte-associated protein 4, or CTLA-4, is a protein expressed on all T-cells but which is expressed at the highest level on regulatory T-cells ("Treg") and contributes to the suppressor function of Treg and acts as an off-switch to T-cell immune response to cancer cells. A CTLA-4 inhibitor has been approved as a single agent in melanoma and approved in combination with other therapies in multiple indications including non-small cell lung cancer, RCC and microsatellite instability high colorectal cancer.

Clinical Development of YH001

As of August 9, 2021, YH001 had been dosed to more than 34 patients in China and Australia.

Phase I Dose Escalation Clinical Trial in Australia

An open-label, single-arm Phase 1 dose escalation clinical trial of YH001 in combination with the PD-1 antibody, toripalimab, is ongoing in Australia. The safety and efficacy data from this trial were presented at the 2021 Chinese Society of Clinical Oncology ("CSCO") Annual Meeting in September 2021. Based on the data presented in the CSCO Annual Meeting ("CSCO Presentation"), 21 subjects were enrolled in this trial as of August 9, 2021.

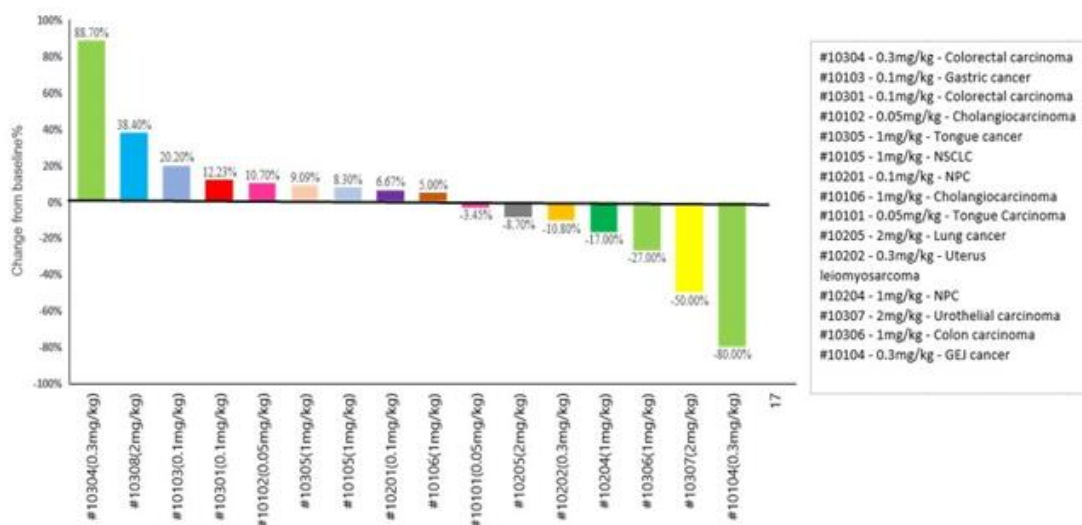
Study purpose. The primary objectives of the Phase 1 dose escalation clinical trial were to assess the safety and tolerability profile and maximum tolerated dose of YH001 in combination with the PD-1 inhibitor toripalimab in subjects with advanced solid tumors. The secondary objectives were to evaluate the PK profile and anti-tumor activity.

Study design. This trial adopted a modified "3+3" design. Subjects receive YH001 in six cohorts at 0.05 mg/kg, 0.1 mg/kg, 0.3 mg/kg, 1.0 mg/kg, 2.0 mg/kg, 4.0 mg/kg, and 6.0 mg/kg by IV administration during a three

week run-in period, after which subjects receive YH001 in combination with 240mg of the PD-1 antibody toripalimab every three weeks for four doses.

Safety. At the August 9, 2021 data cutoff, no dose limiting toxicities had occurred and a single serious adverse event of grade 3 colitis was reported, which led to treatment discontinuation. Thirty two YH001 drug-related adverse events (“AEs”) were reported, including 11 cases of grade 2 AEs and 20 cases of grade 1 AEs.

Efficacy. Among 16 patients that had image tumor assessments available at the August 9, 2021 data cut-off, 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. The figure below illustrates the patients with tumor assessments available as of the August 9, 2021 data cutoff.



Conclusion. The authors concluded that YH001 was well tolerated up to 2 mg/kg when combined with toripalimab and demonstrated activity in patients with advanced solid tumors. Dose level cohorts above 2 mg/kg did not have tumor assessments available as of data cutoff at August 9, 2021.

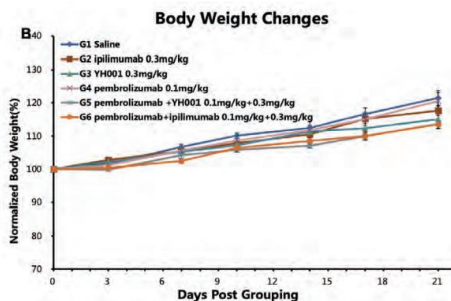
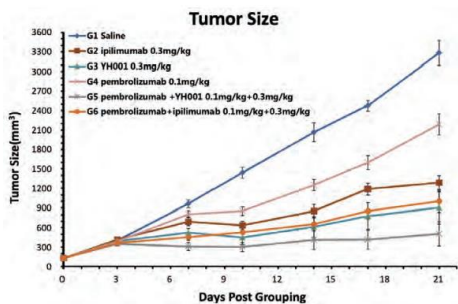
Phase I Dose Escalation Clinical Trial in China

An open-label, single-arm Phase 1 dose escalation clinical trial of YH001 is ongoing in China.

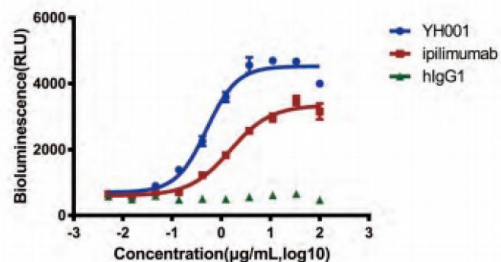
Preclinical Studies

In pre-clinical studies in mice, YH001 was compared with ipilimumab, an approved CTLA-4 inhibitor marketed by Bristol Myers Squibb, and YH001 showed the following potential advantages:

- Superior in vivo activity than ipilimumab as a single agent and when combined with pembrolizumab, a PD-1 antibody marketed by Merck. The following graphs illustrate the tumor size growth and body weight changes in mice.



- *More potent and active than ipilimumab.* YH001 was more potent and active than ipilimumab in blocking hCTLA-4 inhibition of CD80/86 activity. The following graph illustrates an *in vitro* reporter assay demonstrating the ability of YH001 or ipilimumab to induce T-cell proliferation by inhibiting the interaction of hCTLA-4 with CD80/86.



Clinical Development in North America

The Company intends to initiate a Phase 1/2 clinical trial of YH001 in combination with envafolelimab in sarcoma with expanded cohorts in the sarcoma subtypes of angiosarcoma, liposarcoma and alveolar soft part sarcoma in 2022. Additionally, the Company plans to initiate a Phase 1 trial of YH001 in combination with envafolelimab and doxorubicin in 2023 in first line sarcoma in addition to multiple other trials.

Manufacturing

YH001 is manufactured by an experienced contract manufacturer in China.

Competition

There is no CTLA-4 therapy approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of soft tissue sarcoma. If YH001 is approved, it may nevertheless compete with the currently marketed CTLA-4 inhibitor ipilimumab (Yervoy, marketed by Bristol Myers Squibb), which is approved by the FDA in multiple indications other than soft tissue sarcoma. Other antibodies to CTLA-4 are being studied in clinical trials of cancer patients.

Intellectual Property

Eucre has filed patent applications on the composition of matter and methods of use of YH001 in China, the European Union and the United States, including international application PCT/CN2017/102816 that was published March 28, 2019. The terms of the patents, if issued, would expire in 2037 or later.

Forward-Looking Statements

Certain statements contained in this report are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include, without limitation, statements regarding, among other things, the efficacy, safety and therapeutic potential of YH001, the results, conduct, progress and timing of clinical trials of YH001, plans regarding future clinical trials and regulatory actions, and potential future payments and activities under the Collaboration Agreement. Words such as “will”, “expect”, “may,” “goal,” “potential” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from our expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, risks and uncertainties that are inherent in clinical trials, including delays in our ability to acquire sufficient supply of clinical trial materials, delays in reaching agreement on acceptable terms with prospective clinical trial sites and disruptions to or delays in ongoing clinical trials caused by the COVID-19 global pandemic, and the possibility that the Collaboration Agreement is terminated early. Additional factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements are disclosed in our filings with the SEC. These forward-looking statements represent our judgment as of the time of this report. We disclaim any intent or obligation to update these forward-looking statements, other than as we may be required under applicable law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by TRACON Pharmaceuticals, Inc. on October 11, 2021.
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: October 11, 2021

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 and Eucure Biopharma, a Subsidiary of Biocytogen, Announce Partnership for Development of Clinical Stage CTLA-4 Antibody YH001

YH001 is a potential best-in-class CTLA-4 antibody with enhanced ADCC and CDC effector functions

YH001 is currently being dosed in multiple Phase 1 oncology trials sponsored by Eucure Biopharma in Australia and China

TRACON intends to initiate a Phase 1 trial of YH001 in combination with envafolelimab in soft tissue sarcoma as well as to study YH001 in multiple other selected tumor types

San Diego, CA – October 11, 2021 – TRACON Pharmaceuticals (NASDAQ: TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted cancer therapeutics and utilizing a cost efficient, CRO-independent product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the U.S., announced today that it has entered into a collaborative partnership agreement with Eucure Biopharma, a subsidiary of Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen), and a China-based clinical stage biopharmaceutical company primarily focused on the research and development of biologics, for the development of YH001, a CTLA-4 antibody with enhanced ADCC and CDC effector functions, for development in multiple oncology indications, including soft tissue sarcoma, in North America.

Under the terms of the agreement, TRACON will be responsible for the clinical development and commercialization of YH001 in multiple oncology indications in North America, with the majority of the development activities expected to occur in the U.S. TRACON will bear the costs of clinical trials and Eucure Biopharma will supply YH001. TRACON will be responsible for commercializing YH001 in multiple oncology indications in North America and will owe Eucure Biopharma escalating double digit royalties on net sales.

YH001 was developed to potently inhibit CTLA-4 binding to the CD80/CD86 receptors and deplete regulatory T cells through enhanced ADCC and CDC effector functions. YH001 demonstrated superior activity *in vitro* and in transgenic syngeneic tumor models compared to ipilimumab (Yervoy®), both as a single agent and when combined with a PD-(L)1 antibody.

“We are focused on advancing a dual checkpoint inhibitor strategy focused on the PD-(L)1 and CTLA-4 pathways, that we expect to leverage in sarcoma by combining YH001 with envafolelimab, our novel, single-domain PD-L1 antibody, in sarcoma. Going forward, we intend to use YH001 rather than Yervoy in our future dual checkpoint inhibition trials in sarcoma, which we anticipate will result in meaningful cost savings from not needing to purchase Yervoy at retail prices.” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “Moreover, we expect to study YH001 in other solid tumors in combination with PD-(L)1 antibodies, including in patients who have progressed on prior PD-(L)1 treatment.”

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 URL: www.traconpharma.com

“We believe that this collaboration with TRACON has potential to provide cancer patients in the United States with a best-in-class CTLA-4 checkpoint inhibitor. YH001 was optimized using Biocytogen’s discovery labs and proprietary transgenic mouse models to inhibit CTLA-4 binding and to deplete regulatory cells. In our ongoing Phase 1 clinical trials, YH001 has been tolerable as a single agent and in combination with the PD-1 antibody toripalimab,” said Dr. Yuelei Shen, CEO of Biocytogen and Eucure Biopharma.

About YH001

YH001 is an IgG1 antibody against CTLA-4 that has shown enhanced antibody dependent cellular cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC) *in vitro*. In preclinical studies YH001 demonstrated superior T cell activation and superior tumor growth inhibition activity compared to ipilimumab. YH001 also demonstrated superior activity compared to ipilimumab in human transgenic mouse tumor models when combined with a PD-(L)1 antibody. In these models, single agent YH001 depleted regulatory T cells and increased CD8+ T cells in tumor tissue. YH001 is being dosed as a single agent in a Phase 1 trial in China (NCT04699929) and in combination with the PD-1 antibody toripalimab in a Phase 1 trial in Australia (NCT04357756). In July 2021, the U.S. Food and Drug Administration (FDA) approved the Investigational New Drug application to initiate multiple phase II clinical trials for YH001 in the United States.

About Envafolimab

Envafolimab (KN035), a novel, single-domain antibody against PD-L1, is the first subcutaneously injected PD-(L)1 inhibitor to be studied in pivotal trials. Envafolimab is currently being studied in the ENVASARC Phase 2 pivotal trial in the U.S. sponsored by TRACON, as well as in a Phase 2 pivotal trial as a single agent in MSI-H/dMMR advanced solid tumor patients and a Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China sponsored by TRACON’s corporate partners, Alphamab Oncology and 3D Medicines. Alphamab Oncology and 3D Medicines submitted an NDA to the NMPA in China for envafolimab in MSI-H/dMMR cancer that was accepted for review in December 2020 and granted priority review in January 2021. In the Phase 2 MSI-H/dMMR advanced solid tumor trial, the confirmed objective response rate (ORR) by blinded independent central review in MSI-H/dMMR colorectal cancer (CRC) patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan was 32%, which was similar to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan and the 33% confirmed ORR reported for Keytruda in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan in cohort A of KEYNOTE-164.

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient, CRO independent, product development platform. The Company’s clinical-stage pipeline includes: Envafolimab, a PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; TRC102, a Phase 2 small molecule drug candidate for the treatment of lung cancer; and TJ004309, a CD73 antibody in Phase 1 development for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads U.S. regulatory and clinical development and shares in the

cost and risk of clinical development and leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the U.S. To learn more about TRACON and its product pipeline, visit TRACON's website at www.traconpharma.com.

About Eucure Biopharma

Eucure Biopharma, a subsidiary of Biocytogen, is a China based innovative biotechnology company with global vision, specializing in developing innovative antibody drugs with independent intellectual property rights. Relying on a strong clinical development team with extensive experience, the company has established a product pipeline for more than 10 targets. At present, three products have received clinical trial approvals in the US and China including that two products have obtained the phase II clinical approval from the FDA and have initiated the global phase II clinical trial, two products have entered the phase I clinical trial in China, four products have entered Phase I clinical stages in Australia. These lay a solid foundation for the development of Eucure Biopharma. As a wholly owned subsidiary of Biocytogen, Eucure Biopharma is focused on clinical development. Biocytogen is an international biotechnology company driven by innovative technology and committed to becoming the global birthplace of new drugs, with a mission to focus on technological innovation, continuously produce new drugs, and safeguard human health. For more information, please visit www.eucure.com.

About Biocytogen

Biocytogen Pharmaceuticals (Beijing) Co., Ltd. is a global biotech company that drives the research and development of new drugs with innovative technologies. The company is committed to becoming a global headstream of new drugs and bringing the benefits to patients around the world as its mission. Based on the fully human antibody RenMab™ and RenLite™ mice for fully human antibodies production with robust humoral responses, highly diverse antibody repertoire and superior affinity, Biocytogen has integrated its platforms in single-cell antibody discovery, gene editing, large-scale animal model supply, and screening to form a new approach to streamline the entire drug development process. Biocytogen actively promotes the independent and cooperative development of new drugs. For more, please visit <http://en.biocytogen.com.cn/>

Forward-Looking Statements

Statements made in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding TRACON's and Eucure's plans to further develop YH001, potential benefits of the collaboration between TRACON and Eucure, expectations regarding the timing, design and scope of clinical trials, potential payments and activities under the collaboration with Eucure, expected development milestones, and potential benefits of YH001 and TRACON's product candidates. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON or others will be able to complete or initiate clinical trials on TRACON's expected timelines, if at all; the impact of the COVID-19 pandemic; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that the collaboration agreement with Eucure

Biopharma is subject to early termination; potential changes in regulatory requirements in the United States and foreign countries; TRACON's reliance on third parties for the development of its product candidates, including the conduct of its clinical trials and manufacture of its product candidates; whether TRACON will be able to obtain additional financing; and other risks described in TRACON's filings with the Securities and Exchange Commission under the heading "Risk Factors". All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. TRACON undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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