



DESTINATION STARTUP

TheraCea Pharma

One-Sentence Summary of What You Do: TheraCea Pharma is developing new diagnostic agents to assess early responses in immunotherapy through PET imaging.

Affiliated Institution: University of Arizona

Have you formed a company yet? Yes

Funding/Financing: Grant Funding

Please describe your company and the problem you are trying to solve: Cancer immunotherapy strategies (cancer vaccines, CAR-T, monoclonal antibodies, and checkpoint inhibitors) are highly effective to those who are responsive to the treatment, which is less than 20% of the total population of the cancer patients. Without a reliable methodology to predict the response to immunotherapy our healthcare systems have created: 1) a life-threatening delay to adopt alternative treatments, 2) significant cost for the patients and the healthcare system, and 3) inconclusive, longer, and more expensive clinical trials for new immunotherapy products. TheraCea has developed a proprietary technology for the assessment of responses to cancer immunotherapy by Positron Emission Tomography (PET) imaging. Our products offer significant technical advantages, access to a large distribution network and adoptability with the current infrastructure in the industry. In partnership with a leading biotechnology company, TheraCea is performing the required preclinical and clinical studies to introduce the new products to this \$117.82B market with a CAGR of 11.0 %. TheraCea will generate \$140M revenue from licensing deals (and royalty fees) with pharmaceutical/biotechnology companies in 2025.

What is/was your go-to-market strategy? The global immunotherapy drugs market is estimated to reach \$258.6B by 2025 from \$163.0B in 2020, at a CAGR of 11.0 % (cancer immunotherapy: \$117.82B by the year 2026). While there are only two products in clinical trials (89Zr-CD8 and 18F-Grmb), there are no products for the assessment of response to immunotherapy in the market yet. There is a huge interest from pharmaceutical companies to use these products. Pharmaceutical companies with immunotherapy products in their pipeline and patients who use immunotherapy treatments are required to know whether their immunotherapy strategy is effective or not. TheraCea's diagnostic products are first-in-the-market type that meet the need of the market in all of the immunotherapy segments based on T Cell activation. TheraCea's technology, adaptation by current suppliers, and customer friendly features encouraged a leading biotechnology company with a product in the Clinical Trials to establish a product co-development partnership with TheraCea.



DESTINATION STARTUP

We continue to form a product co-development partnership with other biotechnology companies that have drugs or biomolecule products in 2021-2022. Later we will form partnerships with groups/ organizations that have access to clinical trial networks (e.g. Society for Nuclear Medicine and Molecular Imaging) in 2022-2023. TheraCea will then form strategic partnerships with the owners of cyclotrons and radiopharmacies (e.g. PETNET or Cardinal Health) where our products are used to prepare the final form of the diagnostic agents for injection into the patients (2024). Finally, we will form development partnerships with larger pharmaceutical companies for the support of clinical trials (2025).

How will/do you generate revenue? There are 3 major milestones to achieve: 1- Completion of preclinical studies and tests, 2- Investigational New Drug (IND) approval by FDA and 3- Completion of Phase I/II clinical trials. Then, TheraCea will license out its products to other pharmaceutical companies. Access to validated marketing and sales channels through our current partner will allow TheraCea to enter 4 non-exclusive deals with pharmaceutical companies in 2025. TheraCea is using the similar-product/company-deal method to provide a benchmark value for the licensing deals. A review of similar deals for the past 5 years (In 2017, Lantheus and GE signed a definitive license agreement for the continued Phase III development and worldwide commercialization of 18F-flurpiridaz for \$5 million cash and, if successful, up to \$60 million in regulatory and sales milestone payments, plus royalties. In 2018, AAA was acquired by Novartis for \$3.9 billion to advance technology related to neuroendocrine tumor imaging and therapy. Also in 2018, AAA entered into an exclusive worldwide license agreement with Cancer Targeted Technology (CTT) to develop and market an investigational new drug (18F-CTT1057) for prostate cancer detection. In 2019, Bracco Imaging acquired all shares (\$475 million total) of BED from Syncona, (the primary investment company for BED) suggesting that \$35M should be a fair license value for a product with our technology.

How will this showcase benefit your company or technology? TheraCea is actively seeking for additional team members for various roles, specifically CFO and COO that are needed to be filled by mid 2022 as operation size increases. Our cost projection indicates that TheraCea will spend ~\$623K, ~\$2.98M, ~\$4.62M, and ~\$8.44M for 2022, 2023, 2024, and 2025, respectively (total of ~\$16.90M in 4 years) to cover all operations, IP, regulatory, clinical trials, and personnel. Hiring personnel for key activities in product development (regulatory and clinical trials) causes a jump in cost 2022 to 2023. Involvement in more expensive and advances Clinical trials and matching key personnel's salary to the market value in 2025 will cause another significant increase in cost (2024 to 2025). Funding Strategy: TheraCea will need a total of \$1.38M investment for the next 18 months to retain positive cash flow with (10% variation), of which \$600K is secured by two SBIR funding and founders' investments. We focus on securing \$4.0M from funding agencies (NIH/NSF) in the next 2 years, and \$12M from Angel Investors in 2022 and Venture Capital group in 2023/2024.



DESTINATION STARTUP[®]

Who are the members of your team, and why is this the right team to get the job done?

TheraCea Team brings technical background, knowledge of the market, and business development skills. Dr. I. Daryaei, CEO and Co-Founder, is an entrepreneur with >10 years of experience in medical imaging and chemistry. Mr. J. Jeffery, CBO, brings over 15 years of experience in medical imaging business development and related entrepreneurial activities. Mr. N. Wright brings expertise in physiology and knowledge of market evaluation and business development. Dr. E. Marinelli, the director of R&D department, has >35 years of experience from biomedical imaging/pharmaceutical industry. Dr. H. Dang, and Mr. N. Doan are the R&D scientists. Dr. Daryaei, Dr. Marinelli, and Mr. Jeffery have the experience of developing several clinical products in industry. As TheraCea operations expand, we will add a COO to the team in mid 2022 and a CFO in 2023. A regulatory affairs, clinical coordinator, and QC chemist will be added to the team in 2023.