

RefleXion Medical Company and Technology Background

RefleXion Medical is a privately held therapeutic oncology company headquartered in Hayward, California. The company was founded in 2009 by Sam Mazin, Ph.D., and Akshay Nanduri to create a new cancer treatment modality through biological guidance.

The two founders first met in high school in Toronto and maintained contact through college and graduate school. In 2008, Mazin contacted Nanduri with an idea he had about a new approach to seeing and treating cancerous tumors at the same time. The two developed a business plan and submitted it to the Massachusetts Institute of Technology (MIT) business plan competition. Although Mazin and Nanduri didn't win the competition, they were semi-finalists, and the work led to the co-founding of RefleXion Medical and a new way to use the established gold standard for cancer diagnostic imaging as a means to deliver cancer treatment to patients.

Specifically, RefleXion is developing a biology-guided radiotherapy (BgRT)* system that is the first to utilize the unique biology of the cancer itself to guide radiotherapy delivery, even in tumors that are moving. The patented technology incorporates a well-established modality for cancer staging and imaging, positron-emission tomography (PET), which enables multiple tumors to continuously signal their location, one day enabling treatment of multiple tumors in the same session. Using the anatomic data from computed tomography (CT) and functional imaging data from PET to guide personalized radiotherapy, the RefleXion machine detects the emissions and immediately sends beamlets of radiation directly to the tumor to destroy it.

RefleXion's approach offers a significant change in strategy from single tumor therapy to the ability to one day treat multiple targets in the same treatment session in cancers that have metastasized. This is a difficult target for conventional radiotherapy because of the logistical patient treatment setup barriers and the amount of radiation that would be delivered to healthy cells. The RefleXion machine also improves upon the delivery of conventional radiotherapy for single-site cancers.

Currently, the RefleXion machine is cleared by the U.S. Food and Drug Administration (FDA) for the delivery of stereotactic body radiotherapy (SBRT), stereotactic radiosurgery (SRS) and intensity modulated radiotherapy (IMRT).

Use of PET

PET makes use of a small amount of a radioactive drug, called a tracer, to highlight the differences between healthy cells and cancer cells. The most commonly used tracer is FDG, a glucose-based compound, which BgRT uses to determine where the tumor is located. Cancer cells rapidly consume the FDG, which breaks down and instantly produces emissions, thereby signaling their location. Real-time response to these detected emissions is the fundamental principle of BgRT and the RefleXion platform.

Combining PET and Radiotherapy

RefleXion combines PET imaging with stereotactic radiotherapy for real-time tracking and treatment. Current radiotherapy systems require a margin of healthy tissue around the tumor to account for positional uncertainties such as involuntary patient movements and breathing. In many cases, this extra margin results in a significant amount of additional radiation delivered to

the patient's healthy tissue. If too much healthy tissue receives radiation and the patient nears threshold toxicity levels, less therapeutic radiation is available to ensure efficacy of treatment or to treat additional tumors. By using the tumor's own emissions to track delivery of the radiation dose, treatment margins and the subsequent radiation dose to healthy tissue may potentially be reduced.

Traditionally, PET is used to form a complete image that takes up to an hour, during which time the tumor can change location. However, as the FDG tracer is consumed, the emissions generated are instantly available and reveal the cancer's location. The RefleXion machine senses the emissions and rapidly responds by sending a beamlet of radiation toward the originating tumor to destroy it.

RefleXion's approach may represent a significant advance for patients by leveraging a proven modality for visualizing cancer with one of the most effective ways to treat cancer, thereby fundamentally altering the treatment model for cancer care.

Funding, Investors and the Team

RefleXion has raised \$350M in debt and equity funding. The company is backed by premier investment firms PSP Investments, Ally Bridge Group, TPG Growth/The Rise Fund, KCK Group, Sofinnova Partners, Venrock, T. Rowe Price, and global pharmaceutical leaders Pfizer Ventures, and Johnson & Johnson Innovation – JJDC, Inc. The company has also received grant funding from the National Cancer Institute (NCI) Small Business Innovation Research (SBIR) Program.

Since the company's founding in 2009, the co-founders have assembled an impressive internal team and advisory boards made up of KOLs and renowned industry veterans. Todd Powell assumed the roles of president and CEO in 2017 after a successful leadership tenure with Elekta, one of the industry's largest manufacturer of radiotherapy systems. In 2018, Martyn Webster joined the team as CFO bringing specific expertise in medical device startups and fundraising, and Thorsten Melcher, a top-tier oncology industry leader with business development experience in both the radiotherapy and biopharmaceutical industries, joined the company as CBO in 2019. Additionally, Sean Shirvani, M.D., who joined RefleXion in 2018, assumed the role of Chief Medical Officer in December 2020. Dr. Shirvani contributes over 15 years of clinical and industry experience, including as a faculty radiation oncologist and medical director at MD Anderson Cancer Center's Arizona affiliate.

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*The RefleXion™ X1 BgRT capability requires 510(k) clearance; this feature is not available for sale.