



BIO & HEALTH

RON LEUTY covers biotech, life sciences and medicine

rleuty@bizjournals.com

415-288-4939

@rleuty_biotech



FRESH \$80M ROUND AIMS TO HELP EAST BAY COMPANY ZAP CANCER

Sam Mazin wandered into a lecture at Stanford University 15 years ago, and today his company said it walked away with \$80 million for a machine aimed at zapping tough-to-treat, late-stage cancers.

RefleXion Medical Inc. of Hayward said the equity financing came from existing investors as well as new investors Ascension Ventures, Catalio Capital Management, Sixty Degree Capital and Hillenbrand Capital Partners.

In all, it has raised more than \$400 million from the likes of TPG, Sofinnova Partners, Venrock, T. Rowe Prize and the venture capital arms of drug giants Pfizer Inc. (NYSE: PFE) and Johnson & Johnson (NYSE: JNJ).

The idea behind the 250-plus-employee company is that its machine, called X1, can zero in on cancer in a way unlike conventional radiation therapy.

RefleXion (pronounced “reflection”) received Food and Drug Administration clearance two years ago to use X1 for conventional CT-guided therapy. But the company now is incorporating positron emission tomography, or PET, that doctors have used for years to spot cancer. It essentially reflects the tracer’s light signal into a realtime guide for radiation to be fired at the tumor.

It is called biology-guided radiotherapy, or BgRT.

“Literally, the cancer is talking to the machine, and the machine can localize (therapy) in sub-second periods,” said Mazin, the company’s co-founder and chief technology officer. “So you improve treatment of not only one tumor but you could treat many tumors in the same session.”

Traditionally, radiation treatment or surgery has been used to target a tumor at a time. But when there is metastatic disease, where cancer has spread beyond the original organ to various parts of the body, there’s too much cancer, so doctors instead must use chemotherapy or immunotherapy drugs to slow tumor progression.

If RefleXion is successful in getting FDA clearance, BgRT would allow radiation therapy to be coupled with drugs to take a one-two

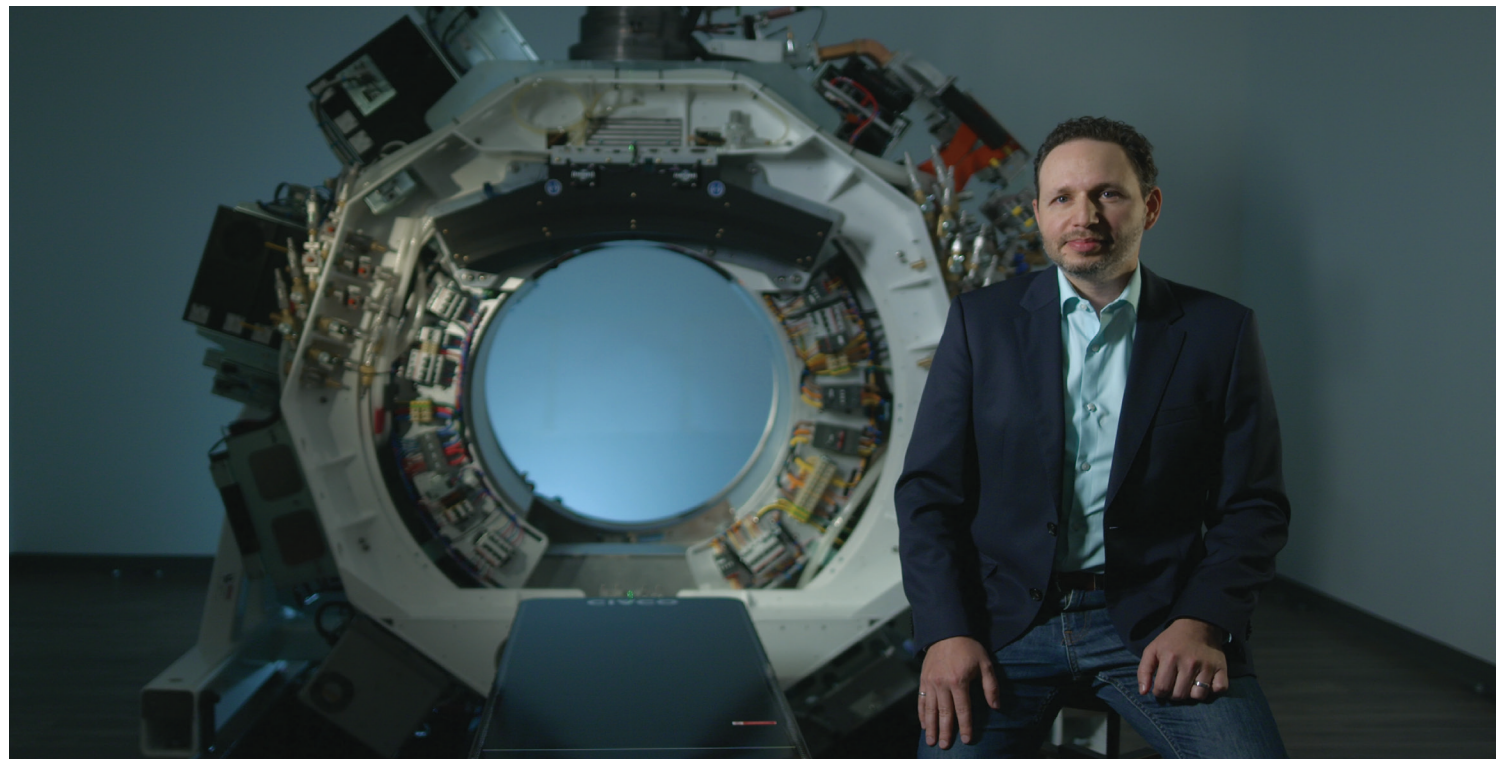


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*Samuel Mazin,
Founder
and CTO of
RefleXion
Medical.*

punch at cancer.

“The bulky disease is handled by BgRT while drugs mop up the rest,” Mazin said.

Mazin came up with the idea behind RefleXion in 2007, while he was doing postdoctoral work at Stanford focused on medical imaging in the radiological sciences lab of Norbert Pelc. He “chanced” into a lecture by radiation physics professor Lei Xing that talked about PET imaging algorithms and the difficulty in seeing tumors during cancer treatment.

“I started thinking, ‘If a cancer cell sends a photon to a (PET) scanner, why not send a photon right back,’” Mazin said. “But I didn’t know that would be an actual company.”

It would take two more years before Mazin hooked up with childhood friend Akshay Nanduri, now the CEO of Onc.AI of San Carlos, to found RefleXion Medical.

The company won its FDA clearance for imaging guidance radiotherapy centered on traditional computerized tomography, or CT, scans. That allowed it to sell its X1 unit into academic-based cancer centers at Stanford, City of Hope in Duarte, the UT Southwestern Medical Center in Dallas and the University of Pittsburgh

Medical Center, among others.

RefleXion submitted paperwork earlier this quarter for FDA clearance with BgRT. The agency late last year granted it “breakthrough” designation for treating lung cancer, which gives the company greater access to the FDA and priority review.

The hefty, Hayward-built machine, which fits into a standard radiation therapy vault, already includes the PET system hardware that makes it ready for BgRT, Mazin said. “So, really, it’s just a software upgrade,” he said.

The combination of targeted radiation and drugs could particularly improve the prognosis of late-stage cancer patients, Mazin said. Although RefleXion’s machine is aimed initially at treating one, two or three tumors at a time, he said, it is gathering more evidence that treating many more tumors could have a “remarkable improvement” in progression-free survival and overall survival.

Progression-free survival is the length of time after treatment that a disease does not worsen; overall survival is the time after diagnosis or treatment that patients are still alive.

The X1, like most radiotherapy machines, costs multi-millions

of dollars, but Mazin said the price is flexible to keep the technology affordable for community cancer clinics as well.

Meanwhile, RefleXion is working with Merck & Co. Inc. (NYSE: MRK) to evaluate the drug maker’s cancer immunotherapy Keytruda in combination with BgRT in multiple late-stage cancers, including non-small cell lung cancer in two clinical trials.

The standard tracer used in PET monitors the uptake of glucose, which tumors gobble up. But the best-known marker, called fluorodeoxyglucose, or FDG, is a commodity now, so RefleXion is working with tracer makers that can shine a light on specific cancers or elements of cancer. In prostate cancer, in particular, highlighting certain lesions would allow BgRT to be more targeted so radiation doesn’t damage nearby healthy tissue, Mazin said.

Meanwhile, RefleXion is building a clinical program of its own to see if BgRT can be used against some of the most difficult to treat cancers, such as ovarian and pancreatic cancer.

“It’s more of a biotech-type of program to unlock new applications,” Mazin said. “We’re likely to start with the big indications that are killing the most people.” ❗