

Non-Invasive Blood Test for Detecting Breast Cancer for Women with Dense Breast tissue based on Measuring Protein Released from Tumors



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“The Agkura™ Personal Score uses a tumor specific antibody and a robust repeatable testing process to monitor the effectiveness of the immune system in preventing the growth of transformed or cancer cells.”- Rahul Puri, Ph.D.

CEOCFO: *Dr. Puri, according to your site OncoTAb is improving the quality of cancer care. Would you tell us how so?*

Dr. Puri: The quality of cancer care can be increased tremendously

with early diagnosis and treatments that have minimal side effects. Our technology, a monoclonal antibody, is very cancer specific and we are developing it for both cancer diagnosis and therapies. Scientists have been striving for many years and perhaps decades to have a tumor-specific antibody. Our chief science officer actually happened to create one that so far, looks extremely promising. On the diagnostic side we actually have already launched a product, a simple blood test, the Agkura™ Personal Score, that is an adjunct to mammography. The problem we are trying to solve is for women with dense breast tissue; the tumors are missed by mammography 50% of the time. Our idea is that with this test, which is measuring a protein that is present in 95% of tumors and then is released into circulation, we can aid earlier diagnosis in women with dense breast tissue. We have used the knowledge of how tumors interact with our immune system to come up with a strategy to detect cancer early.

CEOCFO: *Would you explain what is happening in the body?*

Dr. Puri: Our immune system fights off infections as well as cancer. Every day our bodies are producing millions of cells to replace cells that are dying. However that production of new cells is not 100% effective; there are sometimes cells that are produced that are transformed. Our body has mechanisms to cope with this. There are DNA enzymes that do the repairing if there is DNA that is aberrant. If that does not work, our immune system uses killer cells that will take care of the aberrant cells. That is how our immune system keeps the transformed cells in check. However, transformed cells learn how to evade the immune system over time and then they start growing in number. Most cancers are formed from epithelial cells. As soon as a cell is transformed there is a particular protein on most epithelial cells, which gets transformed as well. What our antibody does is recognize this transformed protein. Our strategy is to measure the amount of the transformed protein, which is present even in healthy individuals because our immune systems are keeping the aberrant cells in check. We establish a baseline measurement in every individual and as soon as the levels start increasing we know the cancer has gone to the next phase and this is where they will start growing and eventually show up on an imaging diagnostic. We are aiming to catch the cancer early with an understanding of tumor biology. That is how our test works. It requires a tumor specific antibody, which we have, and it requires us to be very accurate in terms of repeatability and reproducibility. My background is in Six Sigma, which is all about getting rid of variation. Our focus during development was to use this tumor specific antibody and develop a very robust and repeatable test. In summary, the Agkura™ Personal Score uses a tumor specific antibody and a robust repeatable testing process to monitor the effectiveness of the immune system in preventing the growth of transformed or cancer cells.

CEOCFO: *Might it replace mammography at some point?*

Dr. Puri: Mammograms have become the standard of care in the US. If you talk to any woman, their understanding is that at a certain age they need to start getting mammograms. What we are saying is that for certain women mammography works perfectly fine, while for others it does not. The breast is made up of two kinds of tissue: fatty tissue and dense tissue or fibro glandular tissue. If a woman has more and more fibro glandular tissue, a tumor which appears white on a mammogram gets masked by the fibro glandular tissue, which also appears white, making it very difficult for a radiologist to detect the tumor. For these women a tumor can continue growing resulting in late-stage diagnosis, higher treatment costs and increased mortality. Our test is mainly targeted for the women with dense breast tissue. Fatty tissue shows up as black, so even a small tumor will show up as a white spot against a black background and for these women mammography works 98% of the time.

CEOCFO: *Does the community that should be aware know what you are doing?*

Dr. Puri: We are a very small company and are looking to raise capital so we can build out a sales and marketing effort and create more awareness. We have presented at scientific and business conferences. We have about fifteen physician practices that have ordered out test for their patients. We plan to start growing our test volume and believe the key to achieving growth is to publish our data. We have written a manuscript that has taken two years worth of data including a blinded study where we were given samples from healthy volunteer women who gave their blood over the course of ten years. During that time some women developed breast cancer. When we were given those samples, we did not know which sample was from a breast cancer patient and which sample was from a control volunteer that did not have cancer. In this study, our test demonstrated the ability to aid diagnosis of breast cancer up to two years before these women were diagnosed by mammography. Once our manuscript is published, we expect good press coverage and the scientific community and doctors will know about the Agkura™ Personal Score. That is where we expect an inflection point in our growth.

CEOCFO: *What is involved in interpreting the results?*

Dr. Puri: We simplified it. Everybody has a different number of cells that are being generated that are aberrant and the release of this protein from the cell also depends on the cell type and the amount of protein in the cell. The scientific concept of cancer immunoediting explains how the immune system interacts with these aberrant cells. During the equilibrium phase, these cells keep being produced and the killer cells keep destroying them. The cancer grows when these cells evade the immune system in the escape phase. Since everybody will have a different number of aberrant cells in the equilibrium phase, we believe the right way to detect cancer is to look at an individual's protein level over time, which is why our test is called the Agkura™ Personal Score. Once you establish that personal baseline, all we are looking for is an increase from that baseline. We did some studies with healthy women and established a reference change value that would signify that something maybe going on and some imaging diagnostics should be done. It is more like personalized diagnostics.

CEOCFO: *What else are you working on now?*

Dr. Puri: Last year was a great year. We not only launched the Agkura™ Personal Score but we also received two extremely competitive funding awards from the National Cancer Institute. We have been striving hard to win these awards and received two back-to-back in June and September of last year for developing therapies using our technology. We have picked two indications that are recognized as unmet needs. One is pancreatic cancer, which is a very deadly disease and the other is triple negative breast cancer. There are various sub types of breast cancer. They are classified based on the receptor statuses of those cancer cells. Triple negative means that there are three different receptor types that are all absent. Now you must have heard of HER2 therapy where the HER2 is a receptor, which can be targeted with antibodies so there is a targeted treatment for it. But for triple negative because all receptors are missing, there has been no target as yet. However, our antibody recognizes and targets more than 90% of triple negative breast cancer cells. That makes it a very effective strategy to target and kill triple negative breast cancer cells. Under this National Cancer Institute Contract Award, we are developing a targeted radionuclide therapy in which our antibody will deliver a radioisotope to the tumor directly. The other funding award is to develop a combination therapy to treat pancreatic cancer. We are working with a collaborator from MIT to co-administer our antibody along with a drug that they have developed. The combination is expected to kick the immune system into action to start killing the cancer cells.

CEOCFO: *What have you learned as you have been doing research and what surprised you?*

Dr. Puri: One of the biggest surprises for us is that scientists and the diagnostic industry have been striving to develop blood tests for cancer that use a single value to differentiate people who have disease from the ones who are healthy. Leveraging the knowledge of our chief science officer and immunologist, we believe that there does not have to be a single numerical cut off value, especially for cancer. Catching cancer early is not easy, which is why the whole scientific

community is trying to find a simple test and there is no simple blood test as of yet. We believe our test will be that test since we have a very tumor specific antibody and a very robust repeatable process to run the test.

CEO CFO: *Where does price come into play?*

Dr. Puri: We are incentivizing our patients to test repeatedly especially if they are high-risk and have dense breast tissue. For the first test we are offering our service at \$199 and if they sign up for our “Monitor and Save” program, we drop the price of all subsequent tests to \$179. With efficiencies of scale, we should be able to reduce cost further and stay ahead of our competition. If you think about various tests, even at \$200 this test is at the lower end of some new test costs that have been developed. I know of some other tests that are charging \$750. Right now the Agkura™ Personal Score is not covered by insurance but that is our goal. Our publication is going to be key to create widespread awareness of the test. We have a solid value proposition for insurance companies. Women who are diagnosed with late-stage disease, cost US insurance companies \$4.8 billion more in the first two years of treatment alone. The lifetime treatment cost benefit is expected to be much higher.

CEO CFO: *What is next for OncoTAb?*

Dr. Puri: Our vision for OncoTAb is to use its patented technology platform to detect cancers early as well as develop targeted therapies to treat cancer with minimal side effects. We are seeking partnership with pharmaceutical companies to further develop our technology to treat pancreatic and triple negative breast cancer. We are also planning to develop a blood test to detect pancreatic cancer early in high-risk individuals.

