

New Blood Test for Autoantibody Signature Detection and Signaling the Presence of Prostate, Lung and Breast Cancer



David A. Esposito
President & CEO
Armune BioScience, Inc.

CEOCFO: *Mr. Esposito, what is the concept behind Armune BioScience?*

Mr. Esposito: The intent of Armune is twofold; one, to improve cancer detection and two, to enhance the outcome of therapeutics in oncology. Therefore, our business is focused on developing and commercializing blood tests that leverage the body's immune system as an early warning signal to improve the early detection of cancer and improve survival rates. With our technology, we also look to identify cancer progression from indolent or non-aggressive to aggressive disease. In addition, our autoantibodies are able to play a role in monitoring the effectiveness of therapeutic interventions.

CEOCFO: *What have you developed to provide a new approach?*

Mr. Esposito: Armune BioScience licensed technology that was discovered at the University of Michigan where researchers identified the body's immune system response to cancer antigens. We licensed a library of these, what would be called auto antibodies or protein signatures, in prostate, lung and breast cancer. Through several years of research and work in our laboratory, we developed a blood test that will be able to capture and identify the presence of these autoantibodies in a patient's blood that would signal the presence of cancer.

CEOCFO: *How early would it be able to detect and would it work for virtually everyone?*

Mr. Esposito: Like any diagnostic test dealing with the complexity of cancer, there really is no single perfect solution for all cases. However, we launched our first product, APIFINY, in April of this year. APIFINY is the only cancer specific, non-PSA blood test available in the world. With APIFINY, if your immune system detects a cancer antigen, it releases autoantibodies to the prostate cancer antigens. Our test, APIFINY, measures the presence of those autoantibodies and that would signify to a clinician a potential high risk of prostate cancer. In addition to the other diagnostic tools that a clinician has available, whether it is a rectal exam, a PSA level or family history, to further assess your risk for prostate cancer.

CEOCFO: *Can your tests be used for other types of cancer?*

Mr. Esposito: Our first product on the market is for the detection of prostate cancer. However, we have licensed this library of auto antibodies in addition to prostate for lung and breast cancer. Therefore, part of our research and development effort is to develop blood tests similar to the one we have for prostate cancer in the market for lung and breast cancer. We are probably a few years away from that, but we anticipate having similar products available for those other types of cancers.

CEOCFO: *Why prostate first?*

Mr. Esposito: It is a two-fold answer. First, prostate cancer was where the researchers at Michigan had moved the research furthest along in their laboratories at the time of the licensing agreement we signed, In addition, prostate cancer is the number one non-skin cancer among men. Therefore, it is a very large market and has a significant unmet need that we fill. We believe we can fill that need with our product APIFINY.

CEOCFO: *Have blood tests been used in the past to detect cancer? What are you looking at and how are you able to assess it when we have not been able to do it before?*

Mr. Esposito: Currently, the standard blood test to assess prostate cancer risk is the PSA blood test, which is Prostate Specific Antigen. The challenge with the PSA blood test is that it is not cancer specific. It is basically identifying that some abnormality is happening in the prostate. It could be prostatitis; an infection in the prostate, it could be prostate cancer or a number of conditions. Therefore, the challenge with today's available blood tests that are PSA based is that they are not cancer specific. Our test APIFINY is cancer specific in that it is measuring the immune system's response to a prostate cancer antigen. Just like in the common cold, your immune system will kick off a series of signals to fight that cold. We are

identifying that signal that your immune system kicks off in the presence of prostate cancer antigens. Therefore, we are measuring cancer specific auto antibodies and that is what is unique to APIFINY, compared to the other blood tests that are PSA based available on the market.

CEOCFO: *What has been the reception from people who have learned about your solution so far?*

Mr. Esposito: From physicians in the community; both urologists and primary care clinicians, there has been a broad base of support amongst those clinicians that we have begun to make aware of APIFINY. We launched the product and made it commercially available in April of this year. We are being used in over twenty states by over two hundred clinicians. Just about two thousand tests have been ordered so far. Clinicians have seen a real need to move beyond PSA based testing to tests like Apifiny that are cancer specific. Therefore, there has been a very strong uptake of clinicians in support of APIFINY to be able to provide them additional diagnostic information to help support their improved detection of prostate cancer.

CEOCFO: *Where are we today in using the PSA test to detect cancer?*

Mr. Esposito: The US Preventive Services Taskforce in 2012 issued guidance that PSA should not be used as a screening tool for prostate cancer for men, because of the high false positive rate, which creates a fair amount of unnecessary referrals from primary care clinicians and a fair amount of unnecessary procedures within urology. Therefore, ever since the US Preventative Services Task Force released those guidelines, it has increased the pressure to identify additional biological markers beyond PSA that can make a difference in prostate cancer risk.

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CEOCFO: *You recently added Dr. Robert Reinhardt, MD as your Chief Medical Officer. How will he be helping Armune move forward?*

Mr. Esposito: Dr. Reinhardt is a practicing clinician and teacher at the Western Michigan University Medical School. He has also been an industry veteran in terms of the diagnostics industry. Dr. Reinhardt is going to help us in terms of expanding our physician education efforts, and make more clinicians aware of APIFINY and how to use it in clinical practice. In addition, he is going to help us continue our clinical development program for APIFINY and the various other products that we have coming into our R&D pipeline.

CEOCFO: *Is there a range of possible outcomes of the test?*

Mr. Esposito: The test provides a risk assessment, so you will see the score from zero to one hundred. Along that continuum of zero to one hundred is the assessment of lower risk to higher risk. Closer to zero range is lower risk and closer to the one hundred range is higher risk. Therefore, the Apifiny score, combined with other tools that a clinician would have at his or her disposal; whether it is PSA, rectal exam, family history or urinary symptoms, will help a clinician determine what to do next with the APIFINY results.

CEOCFO: *You have a long history in the industry and your bio indicates that you have a military background; in fact, you received a Bronze Star for Combat Action in Iraq. What did you learn in the military that translates into your business and the medical business?*

Mr. Esposito: That is a great question! We could probably talk for a long time on that. However, I think that perhaps the two things around my military service or my experience that has helped transition is first and foremost the importance of setting a very clear mission so that you and your team can rally the strength to achieve. Therefore, clarity of mission is critically important. Then the second piece is around setting the example. Executing in a manner that we need the whole team to execute on is an important part for me as a leader to be able to lead that way. Therefore, I really think the importance of clarity in a mission, so everybody knows what they are working towards and then being able to set the example for others to follow in that we are all in this together are some of the learnings I took away from my time in the military.

CEOCFO: *How are you going about the commercialization? How do you gain attention? Are you going directly to doctors? Are you working through distributors? What is the strategy?*

Mr. Esposito: Our commercial strategy has five key areas. One is around educating health care providers. Ultimately, it is a physician that orders this test, so we do that in a manner of direct promotion to clinicians, done by employees of Armune

and we use distributors in the market place. In addition, we utilize our laboratory partners to help educate clinicians. So that is the second part of our strategy, where clinicians order APIFINY through their normal laboratory service. The third part of our strategy and part of our market is to insure adequate reimbursement for the test. Therefore, we also provide education to clinicians through commercial payers to be able to educate clinicians on the appropriate use of the test. Then the fourth piece of our strategy is around educating patients. Therefore, we do see, as you mentioned, that PSA is widely known to have certain shortcomings in the assessment of prostate cancer risk and educating patients is an important part of our effort. We do most of that through our online and social media presence. Then the fifth part of our work is around research and development. However, those first four areas around health care provider education, patient education, laboratory partnerships, working with reimbursement authorities to ensure we hit the right utilization of the product. Those are the four tenets of how we spread the word, so to speak.

CEOCFO: *What is next?*

Mr. Esposito: There are probably three areas of what is next. First and foremost, we are an early stage business, so we are continuing to raise money. We have a series A round of financing of four million dollars out there now. We hope to close that round before the end of this year and embark on a series B round of twenty five million dollars which will carry us to positive free cash flow, break even to become a self-sustaining business. Therefore, raising growth equity capital is an important priority for us now in the business. The second piece is to continue to execute on our commercial plans to grow APIFINY. As I mentioned, with upwards of almost two thousands tests ordered by over two hundred clinicians and we continue to expand our commercial efforts. That is really what is next as we continue to grow. Then, the third part of what is next is around continuing to expand our research and development work, so that we continue to launch other products in prostate cancer and we continue to launch products in lung and breast cancer. Those are the three big areas of what is next. We are excited to report that we continue to make positive progress on all three of those areas.

CEOCFO: *Interest in different diseases or tests tends to be somewhat cyclical. Is your area in favor today with investors?*

Mr. Esposito: I think in terms of material investment and community, innovative tools in healthcare are still highly valued and highly sought after. We are seeing that reception with regards to investors on the innovation that our autoantibody technology is having in the marketplace. Innovation always attracts investors. However, in the current healthcare space the diagnostics industry is probably not viewed in the best light. With regard to investors; some of the recent guidance from CMS with regards to reimbursement processes and the move towards a value based pricing model is sometimes unpredictable and that is a source of concern for investors. Therefore, although investors do significantly move behind innovative technologies like ours, I think the reimbursement transition from a fee for service based model to a value based pricing model has some investors concerned. The way we address that is that we have a credible price point with APIFINY in terms of its impact to improve care and reduce the cost of care, which is a significant upside to health systems to physicians and patients, and that is attracting the investment dollars to grow the business.

CEOCFO: *You are testing and you are looking at the blood. Do you find as this is a simple concept it becomes a little easier gain acceptance and interest?*

Mr. Esposito: I think that type of understanding is very helpful. I think that the technology and how you would view these auto antibodies in blood and the results of a test, I think is relatively straightforward; I think where it gets complicated is what the ultimate positioning of the product is in the mind of a clinician. Do we see primary care clinicians adopting this technology very early on in their assessment of prostate cancer risk or do we see the urology community then adopting APIFINY in a much later place in their diagnostic tools to assess prostate cancer risk. I think that is where it is important for us as a company and certainly as we talk to, not only investors, but clinicians, to be very clear that the positioning of APIFINY in the mind of a physician to where they ultimately could see a benefit to improve patient care. I think that is the heavy lifting for us, with regards to communicating that positioning of the product.

CEOCFO: *Why take note of Armune BioScience today?*

Esposito: Armune BioScience is on a mission to improve the detection of cancer and we have unique technology that is poised to improve the detection of cancer to improve long term survival. We all know the toll that cancer has in the world on patients and loved ones and we have the ability with Armune's technology to improve the detection, ultimately improve survival rates and, at the same time, improving care while we reduce the cost of care. That is what is exciting about what we are seeing from clinicians and what we are hearing from investors.



Armune BioScience, Inc.

For more information visit:

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