



ceocfointerviews.com
© All rights reserved
Issue: November 25, 2019

CEOCFO Magazine

Precipio, Inc. and their Diagnostics Laboratory are providing specialized products and services to Oncologists and Patients that lower the risk of Misdiagnosis in Blood-Related Cancer



Ilan Danieli
CEO

Precipio, Inc. (NasdaqGS: PRPO)

Interview conducted by:
Bud Wayne, Editorial Executive
CEOCFO Magazine

CEOCFO: *Mr. Danieli, you have been there as CEO from the founding of Precipio, Inc. back in 2011. Share with us what it is like to take the company from where it was at its inception to where it is today?*

Mr. Danieli: It has been an exhilarating ride, but not one that I did on my own. It takes a village to build a company, and I'm fortunate to have a wonderful team that helped us get to where we are today. It also helps to be united by a vision which is to eradicate the problem of misdiagnosis.

Everyone on our team has been touched by this problem, so we've built a culture of dedication to the cause. We created a great work environment that values people: our employees, our customers and their patients. Anyone who visits our company sees that our team really cares about what we do. I think those are the key ingredients that it takes to reach where we have today.

CEOCFO: *Let's first look at the industry. Misdiagnosis is a huge consequence to the patient and the healthcare system. Your website points out that 1 in 5 patients are misdiagnosed. How and why does that happen and how do we stop that?*

Mr. Danieli: Like most complicated problems, there's no one simple solution, it is a combination of various factors. Cancer has become an increasingly complex disease. If you look at the number of disease classifications in, for example lymphoma, which is one of the cancers we deal with, 25 years ago there was probably 20-30 classifications of lymphoma, today there are over 100. That indicates the complexity of the disease, and the challenge of being able to diagnose it correctly.

Secondly, pathologists, who are the diagnosticians, are constantly being asked to do more with less, and they are expected to handle multiple areas while often being paid less (which doesn't help). This is a field that requires more and more expertise and specialization and unfortunately the forces within healthcare are pushing more pathologists to work as generalists in multiple different areas, which means they cannot develop the specialized expertise required in order to correctly diagnose the disease.

CEOCFO: *What are the diseases you diagnose for?*

Mr. Danieli: Within cancer, we focus on blood related cancers which are the most complicated types of cancers to diagnose. We routinely diagnose blood related cancers such as leukemia, lymphoma, myeloma, and other types of blood related cancers.

CEOCFO: *Would you tell us about the Precipio Platform and how you are changing things?*

Mr. Danieli: Our products and services are focused on getting the right diagnosis to the patient. It is important to understand that the diagnostic process has two components. The first is the technical work done in the lab; the second is the interpretation done by the pathologist. Each of those areas requires high levels of expertise. In terms of technical work done in the lab, we have created proprietary processes, medias and assays that help arrive at the right answer.

Additionally, our platform aggregates academic experts from various universities that have developed expertise within cancer, and we bring that expertise to every single patient in the community, and worldwide.

CEOCFO: You have 6 services: Primary Diagnostics, SmartPath™, SmartGen™, ARC, ICP Liquid Biopsy Testing, and 3 products: MX-ICP Reagents, HemeScreen™ HRM Reagents and IV Cell™ Cytogenetics Media. Would you briefly tell us what the physicians you service find unique about your company, and how does that benefit their patients?

Mr. Danieli: Our customers know they are getting the highest quality of accuracy in the service we provide. Sadly, diagnostics has become a commodity, with pricing and speed of results being the key factors the industry focuses on. Although we are competitive in both areas, the most important and overarching factor we center on - is accuracy. Without accuracy, even the best oncologist will be misguided by an incorrect diagnosis.

We constantly measure ourselves in terms of the accuracy of our results, benchmarking our outcomes against second opinion evaluations that review the results we provide. Oddly enough, no other company measures their level of accuracy. As a result, our customers know they can count on us to ensure we get the right diagnosis, so that they can proceed to treat the patient.

CEOCFO: Would you tell us about your ICE COLD-PCR technology?

Mr. Danieli: ICE COLD-PCR technology is a very exciting technology with multiple applications, one of them in cancer diagnosis. Essentially the technology enables a lab to enrich a sample's DNA to a level of sensitivity required to analyze patient genetic information. One area that is growing within cancer diagnosis is called liquid biopsies, which is the ability to pick up critical genetic information from shreds of the tumor circulating in the blood, rather than having to biopsy the tumor itself. This is a game-changing field that is going to allow us to both diagnose and monitor patients accurately to see the genetic changes which drive a lot of the treatments today.

“Cancer is the scariest word in healthcare, it touches all of us, and in this day and age nobody should receive anything but a correct diagnosis... We hope that one day, no one will have to say “if only they’d gotten it right the first time”.- Ilan Danieli

CEOCFO: The headline for your September 30th press release reads: First Substantial Customer: Tennessee Oncology Internalizes Precipio's HemeScreen™. That must be great feeling. How did this come about and how will you build on this?

Mr. Danieli: Indeed it was a great feeling; it is always good to have a new and substantial customer after we've been working on this technology for a long time. It's nice to see its adoption by a serious player such as Tennessee Oncology. This is just the start, we have numerous trials and validations both nationwide and internationally. We are getting great feedback on this product and we think it is going to be a substantial contributor to our company's growth.

CEOCFO: How are you reaching out? Are you attending conferences, do you have a sales staff or networking? Are people coming to you for inquiries at this point?

Mr. Danieli: We began mostly through networking. We've been in the business for eight years, but key members of our team have been in the field for much longer. We have been using our network to reach out to various industry players that we know and get them interested in our technology. We have recently seen an increase in incoming inquiries, which is great. The first sale is always the toughest one but I have no doubt that as we proceed and get more customer references, this is going to grow.

CEOCFO: Are you funded for future growth or will you be reaching out to investors or potential partners?

Mr. Danieli: We are well funded for future growth. I believe that particularly the technology side of the business will be a major contributor, not only to our revenues but also towards getting us to break-even.

CEOCFO: Misdiagnosis must have a tremendous affect on the healthcare industry itself. The magnitude of cost that goes into misdiagnosis is probably astronomical, so what you are doing is actually cost-saving to the healthcare system. Am I correct on that thinking?

Mr. Danieli: Absolutely. If you look at the cost in treating a patient is anywhere from \$100,000 to \$0.25M dollars a year. Considering the number of patients diagnosed with cancer and a proportion of them that are unfortunately misdiagnosed, depending on what publication you read, we have seen sources quoting \$750 billion a year in waste as a result of mistaken diagnosis, not just with cancer but obviously cancer makes up a large part of healthcare dollars. We look at this as a huge contribution to the healthcare industry not only in getting patients the right care but also making sure our precious resources are devoted towards the right treatment of patients.

CEOCFO: *My sister in-law has leukemia, and I just found out a very good friend of mine has leukemia. Everybody knows what a solid tumor is, if you say you have pancreatic cancer or throat cancer, or skin cancer, they know it is a lump somewhere. I think the average person grapples with what a blood cancer is? Why do they say it is cancer?*

Mr. Danieli: That is the reason we chose blood related cancers because your question indicates the complexity of the disease and in fact the biggest problem is that there is no pointed tumor that one can biopsy and reference. Without getting too technical, the blood system begins in the bone-marrow, which is responsible for producing the different blood cells which handle the work of our body and carry nutrients and oxygen around our body.

Like any other organ, when there is a tumor those cells begin to malfunction and grow out of control. What happens with blood cancers is that the marrow that is supposed to be functioning and creating these healthy cells, stops functioning properly and starts to create unhealthy cells that don't do the job they are supposed to do. That is the simple version of what a cancer is, and with blood-based cancers there is no identifiable tumor that can be evaluated and targeted, so they are tougher to diagnose or treat.

CEOCFO: *That is why what you are doing is so crucial and important. I once heard somebody say that when it comes to solid tumors, a lot of misdiagnosis occurs because they cannot tell the difference between a fungal cell and a cancer cell in many cases, they will look at it and they both look the same and there is a lot of misdiagnose because of that. Is there anything similar in blood cancers?*

Mr. Danieli: There are multiple problems. Actually if you think about the diagnosis of a solid tumor, essentially a biopsy is conducted, a piece of the tumor is taken out, put on a slide and sent to the pathologist to look at it under the microscope and identify malignant cells. With blood related cancers there are usually four or five different technologies involved including genetic analysis, cell counting and chromosome evaluation that, in addition to the slides and the stains that the pathologist has to look at, they have to put all those pieces together. So it is a really complicated process; it requires extensive training and expertise and particularly in different types of blood-related cancers, to be able to correctly identify the right type of cancer.

CEOCFO: *We touched on the pains to the healthcare industry, but there is also the pains to the individual who is misdiagnosed and what they go through because they could be put on some heavy chemotherapy or whatever, and they may not even need it.*

Mr. Danieli: Unfortunately we receive those cases too many times. We have actually seen cases where a patient is diagnosed with cancer, put on chemotherapy, the patient was not responding and getting worse. Then another biopsy came to us and we realized the patient doesn't actually have cancer, it was an infection. In a way it is good news for the patient; but to think that someone has gone through the horrors of chemotherapy for six months only to find out that they were misdiagnosed, that's awful. I think it is important to note that pathologists are doing the best job they can. They are sometimes asked to do the impossible. Many pathologists are expected to diagnose cases that they may not have been properly trained for and might not have developed the necessary expertise. I think it is just a situation where the industry is not providing an adequate solution to the problem.

CEOCFO: *Do you work with mostly pathologists, only pathologists, do individuals ever come to you and ask you to check something out for them?*

Mr. Danieli: Absolutely. It is important to understand that cancer is one of the few areas in healthcare where the treating physician and the diagnosing physician are two different people. Our main focus is on oncologists and hospitals that are treating patients. We are a pathology lab and we built a network of pathologists from some of the world class leading universities, Harvard, Yale, University of Pennsylvania, for example. We are the diagnosticians, we are there to support the oncologist in treating their patients.

Ultimately, the oncologist could be the best doctor in the world and the most experienced oncologist, but if they receive the wrong diagnosis for the patient, it does not matter because they are going down the wrong path. It is so critical. We get patients calling us all the time and we arrange for them to get a primary diagnosis or a second opinion on the diagnosis.

CEOCFO: *Are your tests covered by insurance?*

Mr. Danieli: Yes, they are all covered by insurance.

CEOCFO: *Will you take requests from anywhere in the country?*

Mr. Danieli: Certainly. In fact we get second opinion requests from patients worldwide. My personal opinion, I think it is absolutely insane that a patient gets put on a cancer treatment without getting a second opinion. Getting a second opinion

costs less than \$500. If I was an insurance company, I would require every single patient that is diagnosed with cancer to get a second opinion to confirm their diagnosis. That is my personal opinion.

CEOCFO: *In closing, why is what you are doing at Precipio such a difference maker for the industry today?*

Mr. Danieli: I think it is a couple of things. Cancer is the scariest word in healthcare, it touches all of us, and in this day and age nobody should receive anything but a correct diagnosis. We envision a world where patients get the chance to fight the right disease, the disease you actually have. That does not mean that everyone wins the battle, but at least their efforts and people around them and resources are focused on the right battle. We hope that one day, no one will have to say "if only they'd gotten it right the first time".