

Q&A with Eric Mayer, CEO of EDP Biotech Corporation developing a Blood Based Diagnostic for the Early Detection of Colorectal Cancer



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CEOCFO: *Mr. Mayer, what is idea behind EDP biotech?*

Mr. Mayer: The idea is early detection products. We are a company dedicated to early detection of disease, with a primary focus on colorectal cancer. We feel this is an unmet need in the marketplace and can truly help change healthcare, save people's lives and reduce costs.

CEOCFO: *What is the process today of early detection and what do you add to the mix?*

Mr. Mayer: Right now the gold standard is colonoscopy and that will most likely remain the gold standard. There are other screening tests out there, including fecal tests and DNA based test. Those have a wide range of accuracy and a wide price point as well. We are developing a blood based diagnostic, which will be very simple for the patient to have their blood drawn at a physical. The blood will be sent off to the reference laboratory and analyzed with our ColoMarker diagnostic.



CEOCFO: *What is the challenge with detection through blood?*

Mr. Mayer: Right now, liquid biopsy is the hot topic. We are looking for very small biochemical changes in people's blood. It is very difficult to detect these changes and we need very sensitive components in our test in order to detect these very small variations. Many people are trying to work on this throughout the world, and they have been met with varying degrees of success. We feel that we have a long history and track record and preclinical data, showing that our diagnostic could be one of the first blood based tests for colorectal cancer early detection.

CEOCFO: *How are you able to get to the minute material that needs to be read or to allow the material to be read?*

Mr. Mayer: We have discovered some proteins that are in all of our blood but tend to be elevated in people's blood that have colon cancer and potentially precancerous polyps as well. We have built very sensitive components to detect that proprietary protein that we have discovered. There have been many years of work going into surveying patients' blood, surveying tumor tissues, and years of interrogation went into developing that discovery.

CEOCFO: *How early on might you be able to detect?*

Mr. Mayer: The goal is to be looking for precancerous polyps before they turn into colon cancer. If we can find the precancerous polyps, the physician or gastroenterologist can confirm with colonoscopy and then cut those polyps out, preventing cancer from ever happening. There is also a huge need to detect Stage I cancer and our tests seem to be picking up those early stage cancers with a very high accuracy rate.

CEOCFO: *Would you tell us about the cancer you are working on and the statistics?*

Mr. Mayer: In the United States in 2017, there will be about 120,000 new cases of colon or rectal cancer diagnosed this year. It is the number two or three cancer killer in America and in the world, depending on country. It is one of those cancers that people do not really like to talk about but it is one of the worst ones behind lung cancer in the United States. An estimate of 50,000 people will die of it every year in the US, mostly because it is caught late in Stage IV when there are other symptoms presented. An individual may have GI symptoms for several weeks and maybe they have some blood in their stool. They know something is wrong. They will go to the physician's office and by that point, when there are other symptoms, prognosis is very poor. There are surgical ways to treat. There are other therapies that can be used, but the best treatment is prevention, so finding the polyps and cutting them out before they ever turn into cancer or at very least, trying to detect early Stage I and Stage II cancer when it can be much more effectively treated.

CEOCFO: *What do you see as the potential for usage compared to colonoscopy and to the test where you send stool away for analysis?*

Mr. Mayer: We are not going to be competitive with colonoscopy; we want to be complimentary to colonoscopy. We want to be the tool that physicians use to aid in the diagnosis of colorectal cancer, to get the right people to colonoscopy. That would mean making sure that we have very low false positive rates and very high sensitivity to the cancer itself. Compared to some of the tests that are already out there, some of the fecal tests, they have varying degrees of accuracy. Some of them are not quite as good. Some of the DNA tests out there do have high accuracy. They are quite good tests, but they are expensive and people do not always send them back and follow through with the screening. We believe that the best screening tool is a test that someone is willing to take and is the easiest, most convenient way for the patient is to just have a little tube of blood drawn during their annual physical. That is where we would like to be.

CEOCFO: *This would be part of regular blood tests you take or could be added on by the doctor?*

Mr. Mayer: Exactly. That is entire goal.

CEOCFO: *Where are you in the process?*

Mr. Mayer: We are still in research and development but we are in the final stages of developing this test. We have undone many years of preclinical work. And we are preparing for clinical research in the near future. This is not yet FDA approved, so it is not for use in the United States right now. A lot of the work that we are doing in order to be prepared to approach the FDA, we will begin performing research in European countries at the end of this year or early 2018.

CEOCFO: *Why would someone not go for the test? Do you see the medical community being on board with so many things to test for today?*

Mr. Mayer: We sure think so. We are finding as we talk to physicians, GI doctors and oncologists, they want a tool that they can use conveniently for the patient that is cost effective. We do not see many barriers at all to get this into the hands of the right doctors so they can effectively screen or detect cancer early in their patients. Healthcare costs are a big topic right now, so we feel that we meet the need perfectly. We do not plan to be as expensive as DNA tests, because ours is not a complex test. I think there are very few barriers presently towards adoption. You always have to be mindful of false positives and that reimbursement goes through with the insurance companies, but those are all topics that we have strategies to tackle and manage.

CEOCFO: *Is cost a factor?*

Mr. Mayer: Our goal and target would to be less than \$100 to the patients. We would love to be in the \$50 range for the patient. Just for comparison, some of the fecal tests run from \$10 up to \$35. The DNA tests run in the \$350 up to \$455 range. We want to be in the middle of the road in terms of price point to help reduce healthcare costs for people.

CEOCFO: *Are you funded for the steps you would like to take? Are you seeking partnership or investment?*

Mr. Mayer: As a small company, we are always seeking strategic partners and investment partners to help not only accelerate this development, but to be a reliable source of growth capital so that we can take advantage of where we are planning to be positioned in the marketplace.

CEOCFO: *What has been the interest from the investment community?*

Mr. Mayer: We have received very positive feedback, but most of the professional investors, venture capital and private equity groups are moving perhaps away from the early stage, development stage companies, towards more of the growth stage companies. The feedback we have received is they are certainly interested and this is a great concept that they want to get involved in when we are a little further along. We have been doing everything through angel, seed, founders and friends and families of the founders. This has been a home grown effort right here in Knoxville, Tennessee, which we are very proud of.

CEOCFO: *What other challenges do you see ahead?*

Mr. Mayer: There are a lot of challenges always in this field. Medical devices are a federally regulated field, so there are challenges there with approvals. There is IP, intellectual property, to make sure we are protected, pursuing the right patents and the correct rights to use licensed technologies. There are competitors out there in the marketplace, some big companies and some small companies like us. We keep tabs on all of this. We have strategies to manage it all and I would say those are some of the bigger challenges.

CEOCFO: *Why should EDP Biotech stand out?*

Mr. Mayer: I think EDP Biotech should stand out because we are going to offer the market a cost effective, accurate and convenient solution for detecting early stage colorectal cancer. It is a huge unmet need and we have years of proprietary work that have gone into our discoveries and we are relatively close to the finish line to get this out to the physicians and patients that need it the most.

CEOCFO: *What, if anything, might people miss when they first look at the company?*

Mr. Mayer: I think what a lot of people miss is the fact that we are a sophisticated, ISO compliant medical device developer in Knoxville, Tennessee. I think most people tend to think that you have to be in Silicon Valley or in Boston, Massachusetts in order to be a player in the biotech industry. We want people to know there are many good companies throughout the country, ours especially right here in the middle of Appalachian country.



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