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THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

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Latest Comments

"Those two factors, pricing and innovation, are intertwined closely, because the more pricing you are seeing in your legacy business areas, then the more that company managements have understood that the company needs to innovate."

Vijay Kumar, Evercore ISI

"From a fundamental perspective, everything is intact in many ways. Hospitals, including operating rooms, are busy. Hospitals are spending on new technology via capital equipment and companies are innovating at a rapid pace to increase value offerings to customers."

Ryan Zimmerman, BTIG

"Cancer is now a new area. Initial studies are always done in small numbers of patients, as in 10 or 20, with advanced disease. Initially, we need to get data on safety, which is the FDA's primary concern, and to understand better how the device removes exosomes in humans."

Timothy C. Rodell, Aethlon Medical, Inc.

Medical Devices

Health care innovation and the underlying economics are hot topics in the U.S. today. This issue informs investors on the exciting equity returns available from this important industry.

Vijay Kumar is Managing Director, Healthcare Services & Technology Research Team at Evercore ISI.

"If you look at an Abbott (NYSE:ABT), for example, that is a large-cap, $30 billion revenue company, and for it to grow 7% organically, there is a lot of heavy lifting involved that is mostly driven through innovation.

"They have this phenomenal product called Libre for diabetes that has been a blockbuster. Another heart valve product called MitraClip is also helping them.

"Even when you look at other companies like a Boston Scientific (NYSE:BSX) or a Stryker (NYSE:SYK), most of them have realized the need to innovate, and they are delivering."

Ryan Zimmerman is Director and Medical Technology Analyst of BTIG. Mr. Zimmerman provides coverage across the medical technology sector, focusing primarily on orthopedic and surgical companies.

"You are seeing broad development of robotics, not just in general surgery with companies like Intuitive Surgical (NASDAQ:ISRG), but you are seeing it in musculoskeletal care with Stryker's Mako robot as well as Globus' (NYSE:GMED) ExcelsiusGPS robot. These are trends or products on the forefront of clinical paradigm shifts in terms of the way we treat these cases.

"We are also seeing a lot of interesting technologies coming on board in regenerative medicine, so companies like Vericel that has cell therapy products for the treatment of cartilage or AxoGen (NASDAQ:AXGN) that has products for nerve repair. These are fundamentally changing how these treatments are done or how these patients are treated."

Timothy C. Rodell, M.D., FCCP, is Interim Chief Executive Officer and Director of Aethlon Medical, Inc. Dr. Rodell joined Aethlon in December 2018 as Interim Chief Executive Officer. His new company is a leader in medical technology innovation:

"It has been granted a breakthrough designation by the FDA ... essentially a statement by the FDA that a product, if it turns out to be safe and effective for its targeted indication, will represent a major step forward in treating a life-threatening or life-changing disease. Aethlon has received not one but two breakthrough designations."

Get all the information you need to invest in this and many other medical breakthroughs in this issue of *The Wall Street Transcript*.

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Aethlon Medical, Inc. (NASDAQ:AEMD)

TIMOTHY C. RODELL, M.D., FCCP, is Interim Chief Executive Officer and Director of Aethlon Medical, Inc. Dr. Rodell joined Aethlon in December 2018 as Interim Chief Executive Officer. Previously, he was President, Chief Executive Officer and a member of the board of directors of GlobeImmune, Inc. from 2002 until 2016 prior to a majority acquisition of the company. He remains a member of the GlobeImmune board of directors. During his over 30-year career in the biopharma industry, Dr. Rodell has built a wealth of experience in global product development, operations and financing, including raising over $300 million in domestic and foreign private and public financings. At GlobeImmune, Dr. Rodell led the company through the advancement of five products from the bench into human clinical trials and closed multiple financings, including an IPO and the establishment of two major corporate alliances. Prior to GlobeImmune, Dr. Rodell was President and Chief Executive Officer at RxKinetix, Inc. and has held senior management positions at OXIS International, Inc. and Cortech, Inc. Before moving to industry, Dr. Rodell practiced and taught as a faculty member at the University of Colorado School of Medicine. Dr. Rodell holds an M.D. from the University of North Carolina at Chapel Hill, is board certified in internal medicine and pulmonary medicine, and is a fellow of the American College of Chest Physicians.

SECTOR — HEALTH SERVICES

TWST: What is the Hemopurifier technology that Aethlon Medical is putting forward, and can you comment on its status, including the timeline to commercialization?

Dr. Rodell: Aethlon Medical is developing a device, the Hemopurifier, a first-in-class blood purification cartridge that can be used to remove toxic products from the blood. While the Hemopurifier has been under development for a number of years in viral disease, we are now focused predominantly in the area of cancer. Those two indications may not seem like they have that much in common, but the characteristics of the Hemopurifier actually tie them together.

The Hemopurifier is hooked into a blood circulating system, like a dialysis system, where it allows blood to pass through its cartridge. The cartridge is made of a series of fibers that have very small holes in them; the holes are too small for blood cells to pass through but will allow blood plasma, which is the liquid part of blood, to pass through, along with anything that is under about 200 nanometers, which includes most if not all viruses. So white blood cells, red blood cells and platelets stay inside the fibers.

Beyond virtually all viruses being removed, the Hemopurifier also clears a set of subcellular membrane-bound particles or vesicles called exosomes that are small particles that are shed from cells. Up until about 10 or 15 years ago, they were thought of as sort of a cellular waste, or cellular dandruff I like to call them. It now turns out that they are one of the most important signaling systems between cells in the body. This is true between normal cells, but more importantly to Aethlon, it is also true for exosomes that are shed from malignant or cancer cells. These particles pass through the holes in the fibers in the filter.

What is unique about the Hemopurifier is that those fibers are surrounded by a matrix of protein called a lectin. Plants use lectins to repel parasitic insects. Lectins bind to a specific sugar called mannose, which is similar to glucose, a sugar that is basically our entire source of energy. Mannose is a similar-sized sugar, but it has slightly different characteristics. Mannoses are a part of a number of biologic membranes, including viral membranes and the membranes of these exosome particles. Any particle of that size that has those sugars on its surface will stick to the lectins and essentially be removed from the blood. The purified blood is then returned to the patient.

The design of this cartridge is, to our knowledge, unique. It has been granted a breakthrough designation by the FDA, which is a new designation that arose as a result of the 21st Century Cures Act from several years ago. It is essentially a statement by the FDA that a product, if it turns out to be safe and effective for its targeted indication, will represent a major step forward in treating a life-threatening or life-changing disease. Aethlon has received not one but two breakthrough designations: one for the treatment of viral disease and one for the treatment of cancer, with the latter one granted in November of 2018.

The focus of the company is to advance the Hemopurifier in clinical trials. We have a lot of data in viral disease, but we are now focused on advancing the Hemopurifier in clinical trials in cancers where there are no or inadequate alternative treatments. A lot of progress has been made in cancer therapy in the last few years. We have made huge strides, but it still remains a major killer. The majority of solid tumors are not adequately treated. We are moving as quickly as we can to get the Hemopurifier into human clinical trials in cancer and to collect safety and efficacy data. That is the primary focus of the company at this point.

"We have shown that the Hemopurifier treatment is very well-tolerated from a safety perspective and that it is extremely effective at removing viruses. That has been shown with hepatitis C. In addition, in one patient, who was on the brink of death with Ebola infection in Germany several years ago, the Hemopurifier treatment enabled subsequent recovery. We have data in viral disease."

TWST: How many patients have been treated for cancer at this time, and what further studies have to be done to get the device cleared by the FDA?

Dr. Rodell: The cancer indication is relatively new for us. We are just moving into that area. We have been working under two different government grants: one for melanoma, which is a deadly skin cancer, and one from the NIH — National Institutes of Health — in breast cancer. These are preclinical studies.

We have safety data and some efficacy data in viral disease, predominantly in hepatitis C. We have tested the Hemopurifier in over 40 patients. There, we have shown that the Hemopurifier treatment is very well-tolerated from a safety perspective and that it is extremely effective at removing viruses. That has been shown with hepatitis C. In addition, in one patient, who was on the brink of death with Ebola infection in Germany several years ago, the Hemopurifier treatment enabled subsequent recovery. We have data in viral disease.

Cancer is now a new area. Initial studies are always done in small numbers of patients, as in 10 or 20, with advanced disease. Initially, we need to get data on safety, which is the FDA's primary concern, and to understand better how the device removes exosomes in humans. Then, we will be moving into multiple midstage studies to show not just safety but also efficacy of the device. What you should be expecting to hear over the course of the rest of this year will be related to our design of these trials in collaboration with the FDA and initiating the clinical trials.

TWST: If all went well, when would be the earliest it could be approved for use with cancer?

Dr. Rodell: It is an excellent question. Now, the initial trials will enroll very small numbers of patients. And while we'll be looking at efficacy in those trials, they won't be large enough for us to get enough data to bring to the FDA and say, "We think we're ready to commercialize this product." That initial trial is probably going to take about a year or more. The trials after that won't necessarily take that much longer. They will simply be done in a lot more patients across more centers.

We are certainly not talking about approval in the next 12 months, but rather more on the order of two to three years. I am not making a prediction there. I am just saying that traditionally when you're doing these kinds of trials, those are the sorts of time frames you are talking about.

TWST: So we are clear, the use of the Hemopurifier would be an adjuvant therapy for cancer to prevent metastasis, but are you treating the primary tumor?

Dr. Rodell: Yes and no. We are not talking about early-stage breast cancer where there is a single small breast tumor that is removed and basically that is the end of things. We are talking about more advanced disease, not necessarily metastatic disease, although metastatic disease will be included, but also locally advanced disease that cannot be treated with surgery alone.

Now, what I didn't say earlier is that what exosomes do in cancer is actually a number of different things. It is not a single explanation. They are involved in metastasis. The exosome can break off from the primary tumor and move through the bloodstream and initiate metastasis in a distant organ, like the liver for GI cancers or in the lung in the case of breast cancer. They also make distant tissues receptive to metastasis. It is kind of like the exosomes are fertilizing the garden to make it easier for the primary tumor to metastasize.

"Cancer is now a new area. Initial studies are always done in small numbers of patients, as in 10 or 20, with advanced disease. Initially, we need to get data on safety, which is the FDA's primary concern, and to understand better how the device removes exosomes in humans."

Another thing that the exosomes do is they are actually serving as a mechanism of resistance to chemotherapy. Tumors are very smart. One of the things that they do is, when chemotherapy is administered, the tumor cell can actually package that chemotherapy molecule in an exosome and expel it as though it were taking out the garbage, which decreases the efficacy of the chemotherapy.

But probably the most important thing they do, from our perspective at Aethlon, is that they are profoundly immunosuppressive. They block our normal immune system response to tumor cells. Our immune system is capable of recognizing tumor cells in the same way it recognizes bacteria and viruses. Tumors have generated multiple different mechanisms of suppressing the tumor immune response. One of the places that we are looking to use the Hemopurifier is to

remove those immunosuppressive exosomes to make therapies that use the immune system more effective.

There are a number of therapies I am talking about, but some of the most important ones are the so-called checkpoint inhibitors. These are the molecules that actually unleash the immune system. For diseases like melanoma and lung cancer and a number of others, this therapy has shown a remarkable ability to control the tumor and allow patients to live, in some cases, years with very advanced disease.

What is striking about those agents, such as pembrolizumab and nivolumab, in patients who respond, the impact can be miraculous. Unfortunately, 70% to 80% of patients do not respond to therapy at all. Our hypothesis is that if we can use the Hemopurifier to remove those immunosuppressive exosomes that have been shown in multiple labs to block the efficacy of those checkpoint inhibitors, then we will be able to increase the percentage of patients who respond and potentially extend the duration of those responses.

TWST: I see on your website a lot of information, including a white paper on the science behind the exosomes and what's known about them. Is this still considered a controversial topic, meaning the scientific community does not fully agree on what these are and what they do?

Dr. Rodell: No, it is not at all controversial. If you did a web search on exosomes in the scientific literature, there would probably be more new papers being published on that than potentially any other topic. It is one of the hottest topics in cancer today. It was a subject of a major symposium at the American Association for Cancer Research meeting a couple of months ago in Atlanta. As you may know, ASCO is going on as we speak. There will be a huge number of papers published there.

It is interesting that having a device like the Hemopurifier is not only potentially an important therapy, but it is also a tool that we can use to better understand things; we are really the only ones who can clear exosomes out and then look at them and look at the characteristics of the specific exosomes that have been taken out. Our operating principle at this point is that we will be able to remove all types of exosomes efficiently, independent of exactly what they are carrying, because the fundamental characteristic of exosomes is having these mannose sugars on the surface.

TWST: This device attaches to a dialysis or a continuous renal replacement therapy — CRRT — machine, correct?

Dr. Rodell: It does, but it is not necessarily going to need that in the future. Since there is such a large established installed infrastructure of CRRTs, as you pointed out, and dialysis systems in hospitals and clinics, then that is the easiest workplace for us to look to put them initially. It will not ultimately require those. We are looking into a complete self-contained system that will not have to involve a dialysis or a CRRT unit.

TWST: What thoughts are there on the patient protocol? What I mean by that is, are there any considerations for use of this with cancer patients given that they are likely to be fatigued from the disease process and other treatments or medications?

Dr. Rodell: Our early studies are looking at patients with later-stage disease who have failed other therapies or who have completed another therapy and then their disease has come back or has advanced. Usually, you move from late-stage disease into earlier-stage disease. But there is nothing about the Hemopurifier treatment that would require that a patient be in perfect physical condition in order to be treated with it.

"Our early studies are looking at patients with later-stage disease who have failed other therapies or who have completed another therapy and then their disease has come back or has advanced. Usually, you move from late-stage disease into earlier-stage disease."

Exosomes are critically important in the pathogenesis and the advancement of cancer. However, having said that, it is very early on, and we are just learning how important they are. We are just learning the new mechanisms by which they cause the advancement of cancer. We are just starting to make the kinds of hypotheses I have been talking about how we can use the clearance of exosomes to improve cancer therapy. Nobody would argue that they are critically important. That's not controversial at all. It is just we are still pretty early on in this and learning very, very rapidly.

TWST: Is the Hemopurifier's capturability in any way correlated with the type of exosome depending on the cancer involved?

Dr. Rodell: The short answer is that all exosomes so far have been described to be mannosylated, meaning that they have the mannoses on the surface, which is the primary biophysical characteristic that is required for the Hemopurifier to remove them. But there are hundreds, if not thousands, of different kinds of exosomes. Whether one particular subtype of those will be removed more efficiently than another, we don't yet know because we haven't used it in humans with cancer yet. We will be starting to get those data points very shortly. That is part of the reason why we do these early-stage studies.

Many dialysis patients have very chronic disease, have low blood counts and a whole bunch of other things, and they tolerate dialysis quite well. So the patient is not going to have to be in perfect shape to be treated with the Hemopurifier. But we will be treating later-stage and more advanced patients initially.

TWST: Aethlon Medical owns a majority stake in Exosome Sciences. What is the point of this decision? Are you doing this in part to advance the use of biomarkers that would stratify and help to prepare patients for the use of adjuvant therapy like the Hemopurifier? How does this company marry with what you are doing at Aethlon?

Dr. Rodell: Exosome Sciences is primarily involved in the diagnostic side of exosomes. It was founded around technology for separating and identifying exosomes. Think about it as being the diagnostic wing, if you will, of Aethlon. There are several implications to that. We expect to be developing, as we advance the Hemopurifier, the ability to characterize the exosomes that are being removed and better understanding, number one, whether they predict the response to the Hemopurifier, but number two, what they tell us about the underlying tumor and the biology of the underlying tumor.

But Exosome Sciences is also not only limited to working on diagnostics in cancer but also heavily involved in looking at the diagnosis of chronic traumatic encephalopathy, or CTE, which is a disease that is seen predominantly in football players, but also boxers and hockey players. CTE results from repeated head trauma. Exosome Sciences is also looking at the diagnosis and evaluation of other neurodegenerative diseases like Alzheimer's and Parkinson's disease.

At the moment, it should be viewed as sort of the diagnostic arm, but there are a number of potential applications, not only in characterizing patients for use of the Hemopurifier but also characterizing them more generally, such as being able to, for instance, predict the likelihood that a patient might have cancer recur when he or she has completed definitive therapy for cancer. There is a lot of work happening in that area using other diagnostic markers.

TWST: In regard to the Hemopurifier's application with viruses, what would you consider to be the most significant outcomes to date? Would it be the curing of the Ebola patient?

Dr. Rodell: The curing of the Ebola patient certainly received a lot of attention, mine included. I took over the company in December of 2018, so just this past year, but that was a really striking response. You cannot build a product or a business around a single individual though.

The strongest data set we have is in hepatitis C, where we have treated over 40 patients, and we have shown that the Hemopurifier is very good at clearing hepatitis C out of the blood. When those studies were done, it was before the era of the direct-acting antivirals like the Gilead product and others that have essentially made hepatitis C a curable disease in almost 100% of patients with oral therapy. Hepatitis C no longer represents a commercial opportunity for the Hemopurifier. It is a proof of concept at this point.

What we know from our hepatitis C data, but also from in vitro data with multiple other viruses, is that any virus that has sugars on its surface, which is almost all viruses, can be cleared with the Hemopurifier very effectively. The question then becomes where to best apply the device in the clinic. We have what used to be called compassionate use and are now called expanded access approved protocols with the FDA in the U.S. for Ebola and a similar approval in Canada for use with any Ebola patient. Those tend to be people who were infected very recently or health care workers who are involved in the care of Ebola patients. We are prepared to supply Hemopurifiers for those patients if we are asked to.

But you cannot get a device approved based on single cases like those. There are a number of other viral diseases. One that we see fairly frequently in the summer in the southwestern United States is called hantavirus, which is a virus that is very similar to Ebola. It is an absolutely horrendous virus that can kill people in 24 hours from bleeding and respiratory failure. We actually have benchtop data showing that we can clear hantavirus. So there are a number of opportunities there.

Unfortunately, we cannot do a controlled trial in Ebola virus. That is, we cannot do the kind of trial that's being done with Ebola vaccines where the epidemic is happening in the DRC. In fact, in many of the treatment centers, there is no electricity, so there is no established infrastructure for us to hook up the Hemopurifier. However, we are in a position to respond to patients who make it back to the United States. When the single patient was treated in Germany, the health care systems could respond, but it is hard to do a controlled clinical trial in that setting.

TWST: In your latest investor slide deck, it states that Aethlon Medical has shown the in vitro capture validation for 15 high-threat viral pathogens. Did you want to elaborate?

Dr. Rodell: That is correct, so it is a reasonable generalization to say that pretty much any virus that is important to humans, we should be able to clear, and that includes the horrendous ones like Ebola, hantavirus and Marburg agent or those sorts of things. It also includes a number of other viruses that are involved in chronic situations, as in cytomegalovirus, or CMV, which is a primary cause of transplant failure, or Epstein-Barr virus, which causes both infectious mononucleosis but also causes a number of different lymphomas or hematologic malignancies. We intend to continue to look at those.

The reason we are as focused as we are on cancer is because the regulatory and development pathway is much more straightforward at this point and the markets are larger. We are a small company with limited resources, and we are trying to essentially push on the door that's the furthest to open and take the easiest pathway first. Then, we can start to address some of these other ones.

"There is so much need, and the regulatory pathways are very clear here to meet it. We understand exactly what the FDA is looking for. Because of the breakthrough designation, we have very open communication with the FDA."

TWST: You have so many avenues you can go down because there is so much unmet medical need. Even when, say, a cancer has a drug treatment available, as you said, it might work or only work until resistance develops. What are your conversations with the FDA like about these avenues?

Dr. Rodell: There is so much need, and the regulatory pathways are very clear here to meet it. We understand exactly what the FDA is looking for. Because of the breakthrough designation, we have very open communication with the FDA. I think there is a little bit of a misconception out there among some people that a breakthrough designation means the FDA is going to develop a drug for you and approve it without data. That is not the case. It is the same requirement to show safety and efficacy, but the communication channels are much faster and involve much more responsiveness.

TWST: Are you setting up your own manufacturing? Where are you in that process?

Dr. Rodell: We use contract manufacturers, so we control the process, but it is manufactured in contract facilities rather than in our laboratory. That is actively ongoing right now. It is an important point because in order for us to do clinical trials, we have to have product, and at the early stages, the FDA is as interested in how you manufacture as they are in how you develop because their first concern is safety, as is ours.

TWST: Can you provide a quick financing update?

Dr. Rodell: The company has raised money in the last several years. Because we are a public company, it means our finances are public. We have a bit under a year of cash in the bank running at our current rate. We are extremely efficient in terms of how much capital we burn, but we are going to have to finance again to get to the next stages. We are looking at a number of different potential opportunities for that.

TWST: You came on board in December of 2018. Are there any other management changes planned within a year or so? Are you hoping to stay on in this role?

Dr. Rodell: It is a good question, as my formal title is interim and not acting Chief Executive Officer. The board brought me on, number one, because I have 35 years of development experience, and we are predominantly a development-stage company right now and, second, also to assess what the best path forward for the company would be. I expect to be here for the duration. Part of my job is to figure out the best way to move the company forward strategically.

In terms of other planned changes, I am employee number five. As I said, we are very efficient. It is a small company with an efficient operation. My Chief Financial Officer, Jim Frakes, has been in place for about eight years, and he is an extremely experienced individual. We just hired a Director of Quality Systems, Lisa Boswell, so we will be looking at some key positions. We expect to stay small and light on our feet, but I am not going anywhere if that is your question.

TWST: Is there anything else that you wanted to mention that we haven't covered yet?

Dr. Rodell: Just to summarize, the key point here is that the Hemopurifier really is a unique device. We are unaware of anyone else who is doing anything that has the capability of doing what we are doing, which is removing glycosylated viruses and exosomes directly from the blood. We have extensive patents on intellectual property, and we are protecting our ability to continue to do that.

So we have a really unique tool to work with here. It will allow us to answer some very important questions quickly, and potentially, together with the FDA, we can have it approved very quickly. I wouldn't be here if I didn't think it was a huge opportunity and a very important potential advance for patients.

TWST: Thank you. (KJL)

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