Aethlon Medical CEO Jim Joyce Discusses CTE Research Being Conducted by Aethlon's Exosome Sciences Subsidiary

Exosome Sciences, a majority-owned subsidiary of Aethlon Medical Inc. (AEMD:NASDAQ), is pioneering the potential use of an exosome-based biomarker to diagnose chronic traumatic encephalopathy (CTE), a condition that otherwise can only be identified postmortem. As James "Jim" Joyce, executive chairman, tells ***The Life Sciences Report***, other companies are exploring this approach in oncology, but Exosome Sciences is the only company advancing an exosome-based candidate to diagnose CTE.

Management Q&A: View From the Top

The Life Sciences Report: How did Exosome Sciences, a majority-owned subsidiary of **Aethlon Medical Inc. (AEMD:NASDAQ)**, come to be?

James Joyce: Exosome Sciences grew out of our scientific advances at Aethlon Medical, where we have pioneered the development of affinity biofiltration therapies that eliminate life-threatening disease targets from the circulatory system. We formed Exosome Sciences to evolve exosome isolation techniques that we developed at Aethlon Medical for therapeutic purposes into a diagnostic setting. Exosomes are very stable nanometer-size vesicles that transport disease-specific cargos throughout the body.

"Exosomes are very stable nanometer-size vesicles that transport disease-specific cargos throughout the body."

In the case of neurological disorders, we pursued a belief that it might be able to isolate disease-specific exosomes that crossed through the blood-brain barrier and into the blood, thus establishing the possibility of liquid biopsy that could detect and monitor CTE, Alzheimer's disease and perhaps other neurological disorders. We have since translated this belief into the discovery of a biomarker known as a TauSome™, which is sometimes referred to as exosomal tau.

TLSR: What is CTE, and why did you choose it as your lead indication?

JJ: CTE is a progressive neurological disorder that is often found in the brains of athletes, military personnel and other individuals who have suffered from repetitive head impacts. The hallmark of the disease is the excessive buildup of tau protein in the brain. Postmortem autopsies conducted by researchers at the Boston University CTE Center have identified CTE in 87 of 91 examined brains of former National Football League (NFL) players. Not a very encouraging statistic.

CTE can lead to progressive reduction in neural functions, depression, confusion and severe headaches. At present, the diagnosis can only be made through postmortem autopsy of brain tissue. We hope to change that unfortunate reality.

TLSR: If it can't be diagnosed accurately, it can't be treated accurately. Correct?

JJ: That's correct. You have to understand the pathogenesis of the disease, which first starts with diagnosing the underlying condition. We think targeting the TauSome as a biomarker will unlock the potential to diagnose CTE in living individuals, and, at the same time, TauSomes could also evolve to become a therapeutic target in the future.

TLSR: Could other biomarkers do this as well?

JJ: At present, the only other CTE biomarker we're familiar with is tau protein itself. Unfortunately, tau protein is not very stable and is very difficult to find in the circulatory system. Inversely, our TauSome biomarker is quite stable and can be readily found in the circulatory system. As a result, we are able to quantify changes in TauSome levels.

At present, our TauSome biomarker is being studied as the basis for a blood-based test to identify CTE in a clinical study called "Diagnosing and Evaluating Traumatic Encephalopathy using Clinical Tests" (DETECT). The DETECT study is being conducted by the Boston University CTE Center, and it is the first CTE project ever funded by the National Institutes of Health, with additional support coming from a number of other government agencies.

The DETECT study enrolled former NFL players and same-age control athletes who played noncontact sports. The goal is to establish a test that can identify CTE in living individuals. To date, preliminary observations indicate that the former NFL group has significantly higher TauSome levels as compared to the control subjects. A manuscript that fully details the study results is pending potential publication.

TLSR: What is the next step in developing TauSome?

JJ: The next step is to continue our work in the DETECT study. We plan to continue following and testing TauSome levels in the former NFL players who were enrolled in the study. Then, we plan to work with our collaborators to establish further validation studies. After that, we would like to apply what we have learned in CTE to Alzheimer's disease and other neurological conditions.

TLSR: Are there any other companies working with exosomes for diagnostics?

JJ: A lot of exosome-related research is occurring at the academic level, and there are some companies that are investigating exosomes as potential biomarkers for a variety of oncology indications. However, to our knowledge, there's no other company looking for an exosome-based biomarker to detect and monitor CTE. In the meantime, we have filed multiple patents to protect our discoveries.

TLSR: When and how did you first become involved in this research?

JJ: We first got involved when Tom McHale, a former high school and college teammate of mine at the University of Maryland, died in 2008. Not long after his death, the research team at the Boston University (BU) CTE Center presented data at the 2009 Super Bowl that indicated Tom had suffered from CTE. The

integrity of the scientific research advanced by the BU team would define CTE as a disease and forever change the way the NFL and other sports franchises treat head injury.

"At present, the diagnosis of CTE can only be made through postmortem autopsy of brain tissue."

Immediately after Tom's postmortem diagnosis, I reached out to the folks at BU and applauded their efforts to identify CTE, but pointed out that we needed to find a biomarker to identify those who might have a predisposition to suffer from CTE.

This led to a project where we sought to isolate certain markers directly from brain tissue of former players. We didn't have initial success. But then, based on exosome-related studies that we were conducting at Aethlon, we began to understand the possibility that exosomes might be moving across the blood-brain barrier, carrying a biomarker for CTE. Then, we had the good fortune of being invited by the BU team to conduct tests as part of the DETECT study. This gave us access to a unique patient population that's at high risk for developing CTE.

Tom McHale was the second former NFL player who was diagnosed with CTE by the BU team. The presentation of his diagnosis at the Super Bowl became an inflection point for media coverage that would introduce the disease of CTE to the mainstream.

Interestingly enough, the first NFL player to be diagnosed with CTE was Mike Webster, an All-Pro center who played for the Pittsburgh Steelers. In his case, the autopsy was performed by Dr. Bennet Omalu, who was not affiliated with the BU research team. Regardless, Mike's death became the impetus for the forthcoming movie "Concussion," which is scheduled to be released on Christmas day. This movie will no doubt increase the dialogue on the issue of CTE in NFL players.

"We think targeting the TauSome as a biomarker will unlock the potential to diagnose CTE in living individuals, and, at the same time, TauSomes could also evolve to become a therapeutic target in the future."

In 1984, I was a member of a Denver Broncos football team that went 13–3 and was the AFC Western Division Champ. In the first round of the playoffs, we hosted the Pittsburgh Steelers, who unfortunately beat us 24–17. Mike Webster was the starting center, and the guard who played next to Mike was Terry Long, who would also be diagnosed with CTE. He committed suicide by drinking antifreeze. Regardless, it will be interesting to see how they are portrayed in the movie. The list of former players who have been diagnosed with CTE after committing suicide is getting to be quite long.

TLSR: Do you believe that CTE and other neurological conditions eventually will be diagnosed through blood-based liquid biopsy?

JJ: I do. If somebody had asked me that question a few years ago, I'm not sure I could have responded with a significant level of confidence. However, today, based on preliminary observations, I think this is very much a possibility.

While more studies will need to be conducted, I can envision that professional sports franchises, the NCAA (National Collegiate Athletic Association), the military and other organizations would want to know the TauSome levels of participants so they can monitor changes over time.

TLSR: What milestones do you anticipate in the coming year?

JJ: The most significant near-term milestone would be the publication of TauSome data from the DETECT study. We also plan to continue following and testing TauSome levels of the NFL players who were enrolled in the DETECT study. Additionally, we need to work with our collaborators to establish further validation study protocols and then apply what we have learned to Alzheimer's disease and other neurological disorders.

TLSR: Is there anything else investors should know about Exosome Sciences?

JJ: That Exosome Sciences is a majority-owned asset of Aethlon Medical, and that its endeavors might be underappreciated and overshadowed by the therapeutic advances we are making at Aethlon Medical. At this point in time, Exosome Sciences shares members of the management and research teams at Aethlon Medical, but has scientific collaborators who are thought leaders in the neurology field.

TLSR: What should investors know about Exosome Sciences' finances?

JJ: The nice thing about forming Exosome Sciences as an independent asset is that it can be financed independently without burdening Aethlon Medical's balance sheet. Aethlon Medical's focus is therapeutics. We have an ongoing FDA-approved clinical study to demonstrate the safety of our technology as a broad-spectrum countermeasure against viral pathogens, and we are also advancing immuno-oncology studies that we hope to leverage into human trials.

TLSR: If investors are interested in Exosome Sciences, does that mean they should be investing in Aethlon?

JJ: Yes, as we are not presently offering shares of Exosome Sciences to accredited or institutional investors.

TLSR: Thank you very much.

Jim Joyce *is the founder of Exosome Sciences and founder, chairman and CEO of Aethlon Medical (AEMD:NASDAQ), which maintains majority ownership in Exosome Sciences. Under Joyce's leadership, Aethlon pioneered the creation of affinity biofiltration devices to treat life-threatening diseases. Time Magazine recently named the Aethlon Hemopurifier® to be one of the "Top 25 Inventions" and one of "11 Remarkable Advances in Healthcare" based on the Hemopurifier's ability to address a broad-spectrum of viral pathogens, including the successful treatment of Ebola virus. In the field of exosome biology, Joyce has co-authored exosome-related publications and is co-inventor on exosome-specific patent submissions. Prior to founding Exosome Sciences and Aethlon Medical, he was managing director at James Joyce & Associates, founder and CEO of Mission Labs, Inc. and was a member of the Denver Broncos Football Club of the National Football League. Joyce is a graduate of the University of Maryland.*

DISCLOSURE:

1) Gail Dutton conducted this interview for Streetwise Reports LLC, publisher of *The Gold Report*, *The Energy Report* and *The Life Sciences Report*, and provides services to Streetwise Reports as an independent contractor. She owns, or her family owns, shares of the company mentioned in this interview: None.

2) Aethlon Medical Inc. is a sponsor of Streetwise Reports.

3) James Joyce had final approval of the content and is wholly responsible for the validity of the statements. Opinions expressed are the opinions of James Joyce and not of Streetwise Reports or its officers.

4) The interview does not constitute investment advice. Each reader is encouraged to consult with his or her individual financial professional and any action a reader takes as a result of information presented here is his or her own responsibility. By opening this page, each reader accepts and agrees to Streetwise Reports' terms of use and full legal **disclaimer**.

5) From time to time, Streetwise Reports LLC and its directors, officers, employees or members of their families, as well as persons interviewed for articles and interviews on the site, may have a long or short position in securities mentioned. Directors, officers, employees or members of their families are prohibited from making purchases and/or sales of those securities in the open market or otherwise during the up-to-four-week interval from the time of the interview until after it publishes.