Ischemia Care: Developing a molecular diagnostics test for cause of stroke

Jeff June is CEO, founder, investor, and board member of Ischemia Care, a molecular diagnostics company that commercializes blood tests for cause of stroke across the stroke care continuum, including atrial fibrillation and point of care. Jeff has founded and invested in multiple early-stage companies, including life science and IT companies. His investment experience spans seed stage venture capital and large private equity firms. As a company founder, Jeff has participated in establishing clinical, operational, sales, and financial foundations from seed stage to exit, including a $600 million IPO, and a separate $95 million exit.

Jeff June, CEO
Ischemia Care

Thermo Fisher Scientific: Tell us about Ischemia Care.

Jeff June: At Ischemia Care, we develop blood tests for cause of stroke. We ran the largest, most successful stroke biomarker trial that's ever been conducted. We've recruited over 1,600 patients that have helped us identify distinct signatures.

Thermo Fisher: And can you tell us more about what those signatures are and why that's important?

Jeff June: Absolutely. Stroke is a very big problem. Every year in the US alone, 2 million people report to the emergency room with stroke-like symptoms—800,000 of them have actually had a stroke. Identifying the cause of these strokes and the proper treatment for these patients is a challenging problem. For example, in 40% of cases, the cause is never determined. So, we work with leading clinicians and stroke centers to provide them with better tools to identify the cause of stroke and help prevent secondary recurrence.

> "In 40% of cases, the cause [of stroke] is never determined."

Thermo Fisher: And this ultimately helps with patient care?

Jeff June: Absolutely. Not only does this help with patient care and provide people who have had debilitating events the opportunity to go home, hug their children, and live normal lives, but it can also significantly reduce hospital costs. Every year in the US, about $65 billion is spent triaging, identifying the cause of, and treating stroke. We believe we can significantly reduce that while improving care for patients.

Thermo Fisher: And how close are you to launching a test?

Jeff June: We're very close. We've developed the final version of a blood test for the cause of stroke, the ISCDx test. We'll be piloting that test with the goal of full commercialization later on in the year.

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Thermo Fisher: How did you start developing this biomarker test? Can you walk us through what some of those challenges were and the accomplishments along the way?

Jeff June: The basis of the Ischemia Care testing draws its roots back to about 15 years ago. It is part of major multicenter collaborative research that was performed. Prior to starting our base clinical trial, there were approximately 1,200 patient samples in over 15 years of peer-reviewed, published research. We used the publications as building blocks in terms of creating what Ischemia Care is today. Some of the challenges were that some of the early research was done on the Applied Biosystems™ GeneChip™ Human Genome U133 Plus 2.0 Array. We made the decision to switch to the Applied Biosystems™ GeneChip™ Human Transcriptome Array 2.0 because it provided more robust information, strengthened our signature, and allowed us to look at a variety of different types of RNA (including lncRNA, mRNA, miRNA, and other types that would be considered noncoding).

Thermo Fisher: And how does Thermo Fisher Scientific fit into the development process?

Jeff June: Thermo Fisher has been the ideal partner to help us develop our technology from beginning to end. We started with the GeneChip U133 Plus 2.0 microarray and made a seamless transition to the GeneChip Human Transcriptome Array 2.0. We're using that as an initial commercial platform, and soon, we will be transitioning that to qPCR. What's great about working with Thermo Fisher is that they have provided all of the products and support to take us from the very earliest stages of discovery all the way through developing and launching commercial products. It's been a tremendously beneficial relationship for us, and we wouldn't be where we are today without that type of support, and their breadth and depth of experience.

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Thermo Fisher: Why did you need to look at another technology to actually bring the signature to market?

Jeff June: Ultimately, the goal is to develop the best possible product. We started with the GeneChip Human Transcriptome Array 2.0 microarray, where we've generated really tremendous, strong data. The next goal is to achieve scalability. Our plans are to move to the qPCR products, which will help us increase throughput in the laboratory and reduce turnaround time. For some of the early sites that we worked with, and in generating our early clinical data, turnaround time was not as much of an issue. But as we move into the future where we hope to grow to between 3,000 and 40,000 tests just in this one signature, the goal is to provide scale as well as cost reduction, and to work with our hospitals to have the ideal platform on which to generate these results. Ultimately, if we can move it to a scalable product that can then be reduced to a kit, that could be something that could be used directly by the hospitals to generate results and treat patients more effectively. We don't want the availability of the technology to limit the number of patients it could help.

Thermo Fisher: What are some of the other future tests that you may be working on?

Jeff June: Think about this: There are 2 million patients each year that report to emergency rooms with stroke-like symptoms. The first test that we're working on, [the ISCDx test], is to identify the cause of the stroke. Future tests are going to relate to cardiac causes, such as atrial fibrillation, which is very difficult to detect in the hospital setting. So, think of those first two tests as addressing in-hospital needs. We'll then continue to move upstream, closer to the triaging of patients, where we'll be developing tests that could help clinicians determine whether stroke has occurred or not, and the optimal form of intervention that can be used to save that patient's life.

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Thermo Fisher: Jeff, thank you very much. Is there anything else you'd like to say?

Jeff June: In closing, it's been a great opportunity working with Thermo Fisher. I think what's really kept us on track and put us on a pathway to be very successful in what we do is the combination of outstanding sales support, service, knowledge, and an understanding of our needs as we build the future.

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Here's another example: As we transition from the GeneChip Human Transcriptome Array 2.0 to the qPCR-based product, a lot of the probes that were on the array don't exactly correspond to those of the qPCR-based products. I felt that we worked very diligently to identify 400 of these probes that could transition very efficiently between the two platforms, and that became the basis for what we will do in the future. So, while there may be opportunities to work with other vendors, I think the big difference is that Thermo Fisher was with us from day one when we started developing our products. We have been very thankful for that relationship, and it's propelled us to where we are now.

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