RETISPEC: KEEPING AN EYE ON ALZHEIMER'S DISEASE[1]

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> Currently, there are no available tests for the definitive diagnosis of
> Alzheimer's disease in vivo, and the clinical diagnosis of AD remains a
> behavioural diagnosis after the exclusion of other causes. This greatly
> limits the potential for early intervention and prevention research.

- Mistur et al, *Journal of Clinical Neurology*, 2009, p. 153

Sixteen years since this article was published, the diagnosis of Alzheimer's disease still remains complicated and challenging. Other than extremely expensive and inaccessible amyloid PET scans, no conclusive blood test, brain scans or other physical exams can provide a definitive diagnosis of the disease; and given that a large number of conditions can produce symptoms resembling those in the early stages of Alzheimer's, reaching a diagnosis with any degree of certainty is challenging and complicated.

This is precisely the medical challenge that RetiSpec (https://www.retispec.com/), a 26-team startup organisation based in Toronto was looking to address with their AI driven retinal imaging product. Their mission was to enable the widespread early and accurate detection of neuro degenerative disease markers with accessible, affordable, and scalable AI driven retinal imaging. In particular, their hope was to provide biomarker data that could supplement existing diagnosis techniques and result in an earlier diagnosis, thereby allowing patients to be funnelled into a care pathway much sooner than what happens currently, and ideally well before the onset of symptoms. Their most advanced solution aims to enable point of care and AI driven early detection of Alzheimer's pathology through a simple eye exam that could be administered at a local optometrist or ophthalmologist and would take as little as five to 10 minutes (https://www.youtube.com/watch?v=P4I8-_PTq_I).

Alzheimer's and related cognitive disorders are rapidly increasing in incidence all across the world[2]. It is estimated that they affect over 400 million people globally and are poised to place an immense strain on healthcare systems worldwide. Some estimates place the associated costs at about $20 trillion by 2050. From the perspective of clinicians, data suggests that dementia

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[1] This case has been prepared by Professor Dilip Soman (Rotman School of Management, University of Toronto; dilip.soman@rotman.utoronto.ca) for the purpose of classroom discussion, and to illustrate the going-to-market issues facing a healthcare startup. This version: 17 March 2025.

[2] See Gustavsson A, Norton N, Fast T, et al. Global estimates on the number of persons across the Alzheimer's disease continuum. *Alzheimer's Dement*. 2023; 19: 658–670. https://doi.org/10.1002/alz.12694 and Nandi A, Counts N, Chen S, Seligman B, Tortorice D, Vigo D, Bloom DE. Global and regional projections of the economic burden of Alzheimer's disease and related dementias from 2019 to 2050: A value of statistical life approach. EClinicalMedicine. 2022 Jul 22;51:101580. doi: 10.1016/j.eclinm.2022.101580. PMID: 35898316; PMCID: PMC9310134

specialist caseloads are rapidly increasing to a point of being unsustainable. In the United States, for example, the estimated average wait time of 19 months between seeking diagnosis and initiating Alzheimer's therapy is alarming to healthcare providers and patients alike[3].

The company and its origins

Eliav Shaked, CEO and co-founder of RetiSpec distinctly remembered the beginning of the journey. In 2015, Eliav attended Singularity University's (http://www.su.org) Global Solutions Programme in which participants were challenged to start a company that will impact a billion people over the next decade. For Eliav, the trigger to finding a business solution was a family friend that had been diagnosed with Alzheimer's, and hearing stories about the challenges associated with the diagnosis and finding care. This personal pain point in the healthcare system, coupled with the combination of hyperspectral imaging and retinal imaging that was developing around that time (and the advent of AI in the years to come) coalesced together and eventually became RetiSpec. He found an ally in co-founder Roy Kirshon, a biomedical engineer with an MBA. Roy's previous experience with new product introductions for medical technology companies made him a great complement to Eliav.

Catherine Bornbaum (Chief Business Officer) joined the journey a few years later when RetiSpec was part of the Creative Destruction Laboratory at the University of Toronto's Rotman School. Catherine had enrolled in the Executive MBA program at the Rotman School after an undergraduate and doctoral degrees in Health and Rehabilitation Sciences. Her MBA journey led her to RetiSpec, and more generally towards an entrepreneurial mindset that, in her words, "changed my life." Eliav and Catherine now had to think about the next few years and what it would bring for the company.

RetiSpec's goal is for its product to be used during a routine eye examination. The AI-based software analyses data-rich images of the retina (which are routinely captured during an eye exam with existing imaging cameras available in most eye clinics and an external sensor). From a patient's perspective, this means that the experience is familiar and comfortable (even though somewhat unexpected in an eye exam setting). The automated Alzheimer detection uses artificial intelligence to enable clinicians to detect Alzheimer's years before the emergence of clinical symptoms. Future iterations of the algorithms could potentially assist clinicians in identifying other conditions and diseases.

RetiSpec had currently raised approximately 17 million US dollars to date and developed a valuable range of partnerships and networks. They have attracted the top clinical and research centres in North America and have worked with commercially available fundus camera

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[3] Mattke S, Hanson M. Expected wait times for access to a disease-modifying Alzheimer's treatment in the United States. Alzheimers Dement. 2022 May;18(5):1071-1074. doi: 10.1002/alz.12470. Epub 2021 Sep 27. PMID: 34569686.

manufacturers as well as eyecare partners to better understand how their product will be distributed and used.

The Product

The product uses off the shelf components and provides an AI algorithm as the unifying glue that adds value to existing solutions. RetiSpec has a partnership focused business model. They partner with Topcon Healthcare (a leading digital solutions company in eyecare) who manufactures the fundus cameras that are widely available in eyecare settings today. They also have existing partnerships with a Hyperspectral camera manufacturer in Europe. As Catherine explained, "our value add, or the secret sauce, is in how we process the data that we get out of this combined device; the external sensors attached to the Fundus camera. I'll say that the quality of the data is absolutely critical. I think the unique competitive advantage that we have is that we can offer our technology in a novel setting. The diagnosis of Alzheimer's disease, if done appropriately, often happens in either a primary care or a memory specialist office."

As outlined earlier, it is extremely difficult to find a neurologist who can do a definitive diagnosis. As some experts have commented, the healthcare system is only about 50% accurate with diagnoses because it does not commonly use biomarkers. So, one way of thinking about RetiSpec's value add is that simplifies the process of getting access to biomarker information. Eliav was particularly passionate about the impact that this product would have on the healthcare system as a whole. In his words, "The healthcare system is reactive in many ways, so a patient needs to have a confirmation of cognitive impairment or suspected cognitive impairment in order to be prescribed any one of the disease modifying drugs that are currently available, but the process of diagnosis only kicks off when there are clearly visible symptoms such as memory loss. Our product could allow for the detection of potential Alzheimer's at a presymptomatic stage and the extra time that this gives both the patient and a clinician can be extremely helpful in order to try therapies to block or slow down the onset of the most fearful aspects of Alzheimer's disease, like cognitive impairment."

In this sense, RetiSpec's AI solution allows us to detect things like amyloid burden, which were previously unseen and only inferred when symptoms are first seen. These new eyes on Alzheimer's also allowed Eliav and Roy to imagine a world in which a technology like RetiSpec's had been fully adopted, integrated and embraced by healthcare system, the eyecare world and patients alike. Eliav and his team believed that this world would look significantly different from today's world. In particular, the new world would ideally have fewer instances of the unmanaged version of the disease. Of course, this also relied on the therapeutic pipeline fulfilling its potential of being able to be involved earlier and treat Alzheimer's as a chronic condition. They also believed that this new world would be particularly impactful in regions or geographies in which there was a relatively weak infrastructure to deal with neurodegenerative conditions like Alzheimer's. Catherine recalled a case study from her marketing class during her

MBA, which spoke of mobile ambulance and a mobile research centre diagnostic lab that was outfitted in a truck that went to rural parts of the country to treat and test difficult to reach populations. She could foresee a future world in which a similar mobile eye-exam unit could be deployed in rural geographies to bring in a larger population to the Alzheimer's treatment fold. Of course, both she and Eliav recognised that to move from the current world to the new one would take a lot of steps and potentially missteps on the way.

Partnerships with Eyecare Providers

RetiSpec's success would depend largely on the willingness of the eyecare and eye exam industry to embrace their product and integrate it into their workflows. Both Eliav and Catherine were initially expecting resistance to something that could complicate existing workflow of eyecare providers. However, they were both surprised that there was not just acceptance, but enthusiasm, particularly the eyecare providers that worked with an older population.

From an eyecare provider's perspective, the extra work required to do the Alzheimer's scan would take no more than five to 10 minutes. However, there was immense value in doing so. For one, the data that would be generated from the scan could be used by primary care physicians or specialty clinics without having to wait for delayed or expensive lab results. Furthermore, there were existing billing codes in the United States that could be used to cover the cost associated with this extra scan. Furthermore, it is a relatively easy scan that can be done by a technician or a nurse practitioner

Going to Market

While the entire world could possibly be a long-term market for RetiSpec, Eliav and Catherine were initially thinking of the United States and Canada. Their first pivotal study would be in the United States for submission to the FDA (the U.S. Food and Drug Administration); and the pivotal study in Canada would be submitted to Health Canada. Other markets that they had thought about include Japan; given the prevalence of the disease and the fact that the Japanese healthcare system was extremely structured and annual screenings were routine. Similarly, Europe was another attractive market, and they had also received strong interest from potential partners in Latin America, India, the Middle East, and other parts of the global south. The pivotal studies both for the United States and Canada are scheduled to be run in 2025 and completed by the end of the year. RetiSpec expected a decision from the regulatory bodies in the middle of 2026 and would ideally go to the market shortly thereafter.

In anticipation of the fall of 2026, Eliav and Catherine now needed to think about a going to market plan. Thankfully, they still have a bit of time before all of the approvals are expected to be in place. However, both knew about the "illusion of ample time" (the belief that there was plenty of time only for it to vanish and being left with tight deadlines at the end of it all),

especially in a new venture setting. There were several aspects of going to market that Catherine had been mulling over. For instance, she had recently learned through their existing partnerships that the eyecare market is quite nuanced and heterogeneous. There are a number of sole proprietor outlets, then a mid tier group of entities that might have a string of 10 to 50 clinics in a limited geographic region, followed by the larger networks that might have national chains. The kind of integration and support that each of these groups might need would be different given differences in operating models and the nature of relationships they had with their customers and providers. Catherine contemplated whether they should be targeting all of these groups or perhaps focus on some. Of course, this might also depend on which geography they end up targeting.

Eliav and Catherine were also sensitive to the fact that there were deeply entrenched behaviours that might need to be changed in order for their product to be fully integrated into the healthcare systems. For example, patients today were not used to being screened for Alzheimer's at an eye exam. Would there be resistance? Would they trust the technology enough to want to give it a try? Likewise, clinicians have never really relied on this type of data from an eye exam, and that would be another behaviour change that could take time. Hospital administrators, administrators of provincial healthcare systems, insurance companies, clinic managers, and providers would all need some sort of a mindset shift to move us from the old world of Alzheimer's to the new one that they had envisioned.

Catherine looked back at her class notes from Marketing. She had scribbled "What is the value proposition to each ecosystem member? What is the positioning statement? Which market is attractive and why? What is the best segmentation, targeting and positioning approach? What is the optimal revenue model and pricing strategy? What should our communication strategy look like? Who might the early adopters be?" This seemed like a useful checklist of questions to start answering in order to develop a going-to-market plan!