HealthTech Activator

Activating New Zealand Healthtech

Clearing the path to commercialisation

Healthtech sector update 2021

CallaghanInnovation
New Zealand's Innovation Agency

Table of Contents

INTRODUCTION 2

Sector growth 2018-2021 3

SECTOR OVERVIEW 4

NZ healthtech sales 5

Global opportunity 5

Who is founding NZ healthtech businesses? 6

Where are healthtech businesses founded? 6

Potential market size 7

UNDERSTANDING CHALLENGES 8

Regulatory & testing 9

Investment 10

Capability support 10

Expertise 11

Support connections 11

RESOURCES 12

Open resources 12

Workshops 13

CASE STUDIES 14

Aroa Biosurgery 14

Alimetry 15

Heartlab 15

The Insides company 16

REFERENCES 17

Introduction

The New Zealand Health Research Strategy aims for NZ to have a world-leading health research and innovation system by 2027

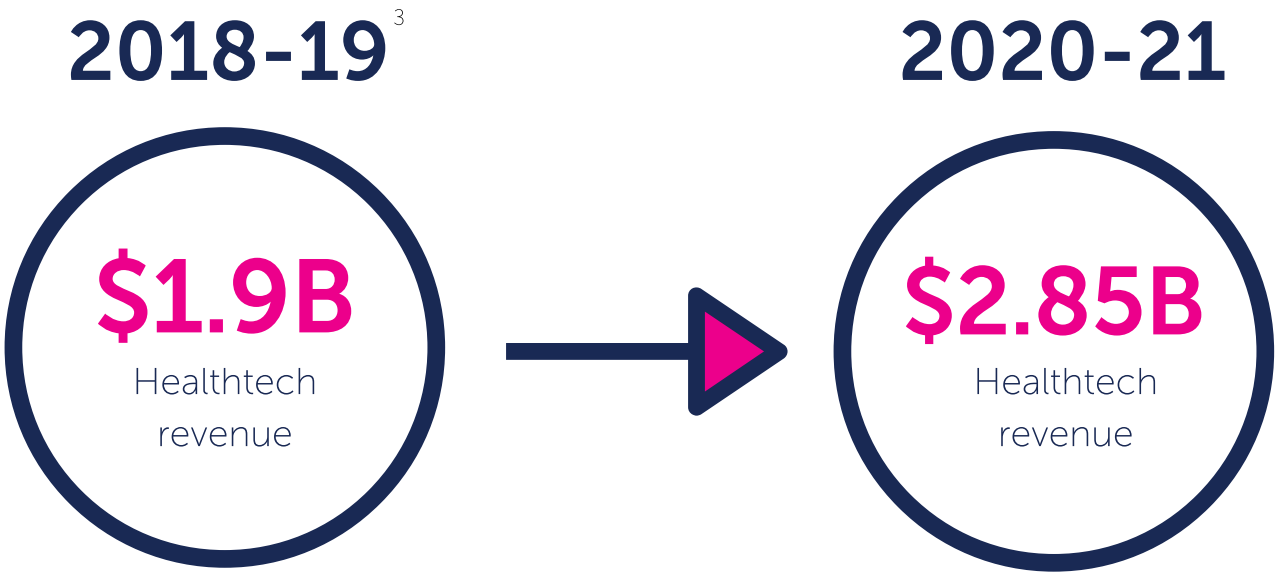
To realise that vision for our 'sunrise' healthtech sector, Kiwi healthtech innovators must overcome a range of unique obstacles. These include stringent regulatory and clinical trial requirements that vary between countries, higher capital needs and longer commercialisation pathways.

To address those obstacles to commercialisation and global recognition, the HealthTech Activator, run by Callaghan Innovation in partnership with the Consortium for Medical Device Technologies (CMDT), is now working to connect NZ's healthtech businesses with required knowledge, expertise and funding.

Sector growth 2018-2021

NZ's healthtech sector shows impressive growth potential. Healthtech businesses generated an estimated $2.85 billion in revenue in the 2020-21 financial year, demonstrating a seven-year Compound Annual Growth Rate (CAGR) of 13%.[1]

Fisher & Paykel Healthcare, New Zealand's first billion-dollar healthtech business, recorded a stunning $1.97 billion revenue for the 2020-21 financial year.[2] This is a 36% CAGR over the past 2 years, with TIN 200 peers AFT Pharmaceuticals and Volpara Health Tech also delivering a 15% and 98% CAGR for the same period respectively. The high performance of many NZ healthtech companies during the coronavirus pandemic has been impressive and demonstrates a global focus on healthcare as the world combats the virus.



Sector overview

TIN Healthtech - Insights Report 2020

11%

of New Zealand's top 200 technology businesses

12.1%

The percentage of revenue spent on research and development by healthtech companies

87.5%

of healthtech sales were global exports

It's not just businesses that benefit from NZ's growing healthtech sector.

7,636

7,636 staff globally. Of these, over half (4,296) were based in New Zealand.

$85k

The sector's average wage per annum, more than 40% higher than NZ's average

This highlighted the need to identify what was holding back healthtech businesses from bringing their innovations forward in such a potentially lucrative market and spurred the launch of the HealthTech Activator discovery project. Since then, COVID-19 has brought even more attention to the potential of NZ's health technologies, and the importance of supporting those businesses in their journey to commercialisation.

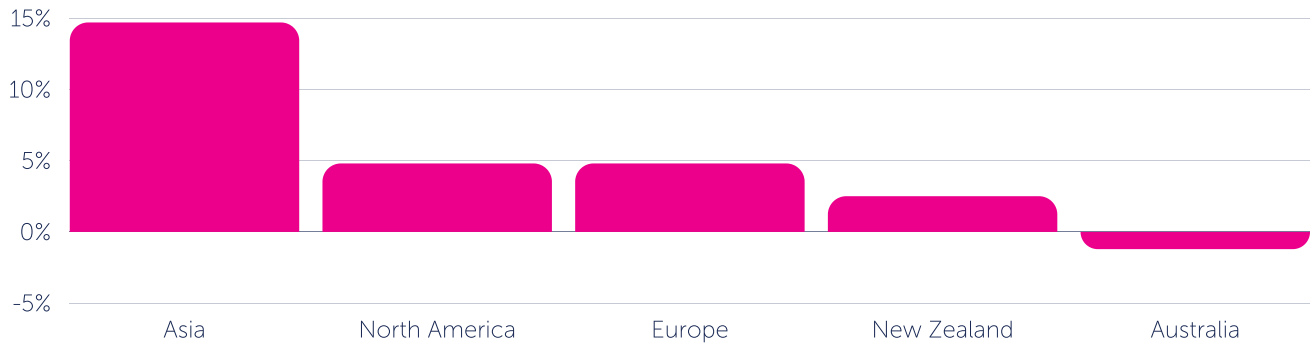
It's important to note that the full impact of COVID-19 on NZ's, and the world's, healthtech sectors is still unfolding.

In mid 2020, the HealthTech Activator (HTA) was created to meet that need and smooth the road to commercialisation for Kiwi healthtech businesses. The goal is to enable NZ to develop a growing, high-paid, global-focused, innovative sector that helps people live healthier, happier lives.

The HTA is a result of collaboration between Callaghan Innovation and the Consortium for Medical Device Technologies (CMDT), an alliance of five NZ universities engaged in health technology research.The HTA is being delivered by Callaghan Innovation, NZ's innovation agency, and is initially funded until 2023 by the Ministry for Business, Innovation and Employment (MBIE).

The HTA is a core pillar of the NZ Health Research Strategy, which set a vision that by 2027 NZ will have a world-leading health research and innovation system. The HTA is currently the only commercialisation support activity under the National Health Strategy.

New Zealand healthtech sales: Growth by region



ASIA
+$35 Million

NORTH AMERICA
+ $32.3 Million

EUROPE
+ $20.5 Million

The global opportunity

TIN Healthtech - Insights Report 2020

In NZ, healthtech is primarily an export based business with most startups targeting overseas markets from the outset. Healthtech businesses received 87.5% of their revenue from outside NZ in 2019[3].

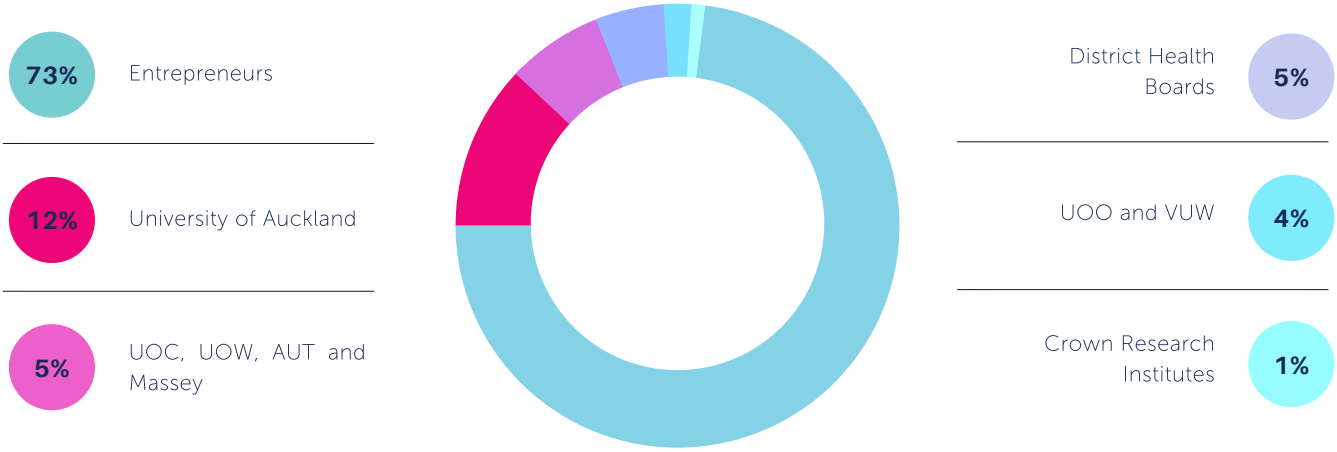
As a country of only five million people, overseas markets offer NZ healthtech businesses a chance to scale up all aspects of their products, follow appropriate regulatory pathways and raise capital.

North America and Europe were the two largest markets for NZ healthtech exports, accounting for $707.5 million (38%) and $444.4 million (24%) of sales respectively.

However, Asia far outpaced other regions in terms of sales growth in 2019, with $272 million in sales and 14.7 % growth when compared with the same period in 2018.

Domestic markets delivered $234.8 million in sales while Australia generated $131.2 million.

Who is founding New Zealand's healthtech businesses?



Where do healthtech businesses come from?

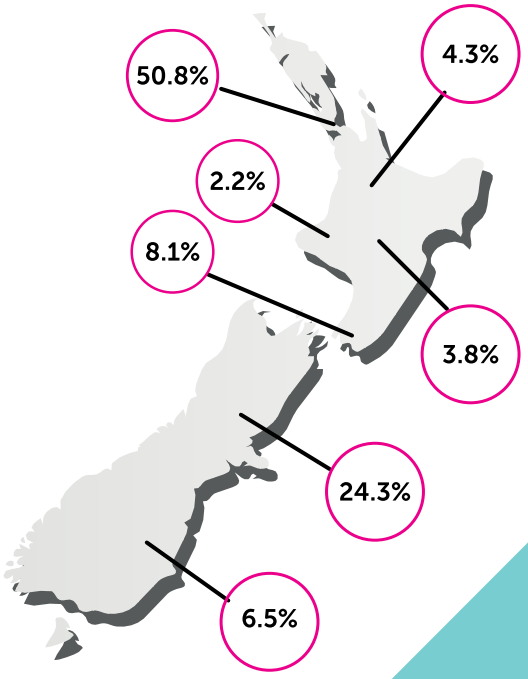
The HealthTech Activator estimates that there are more than 180 healthtech businesses in NZ, with most being early to late stage startups.

It is important for the HTA to understand where these healthtech companies are emanating from to best address their needs. The majority of healthtech businesses are founded by entrepreneurs — as opposed to researchers based at learning or research institutes.

In NZ, 73% of healthtech businesses were founded by entrepreneurs, 12% through The University of Auckland, 5% through District Health Boards, 4% by the University of Otago and Victoria University of Wellington, 1% by Crown Research Institutes, and the remaining 5% between Canterbury, Waikato, AUT, and Massey universities .

Based on the 2019 TIN figures, most healthtech businesses were based in Auckland (50.8 %) and in Canterbury/Upper South Island (24.3%). This is followed by 8.1% in Wellington, 6.5% in Otago, 4.3% in Hamilton, 3.8% in Central North Island/Bay of Plenty, and 2.2 % in New Plymouth.

Device businesses, such as Fisher & Paykel Healthcare, generate over two thirds of the healthtech sector's revenue. Diagnostics and therapeutics businesses, such as AFT Pharmaceuticals, account for around a quarter of the sector's revenue. Digital health and IT health led by Orion Health, round out the remaining categories.



Potential market size

13%

Seven-year compound annual growth rate

With a seven-year CAGR of 13% to 2021, the healthtech sector has been steadily building momentum, but there are global factors at play which open up even greater opportunities.

GROWING WORLD POPULATION

A UN estimate puts the world population at about 11.2 billion by 2100[4]. This will increase the demand and the need for healthtech innovation around the world.

POST COVID-19 WORLD

The global pandemic has brought health — and how technology can impact and improve it — to the forefront of people's attention. Greater interest in, and curiosity about how healthtech can improve quality of life, has the potential to open doors for NZ healthtech businesses.

ACCESS TO MARKETS

With the growth of sales into the vast Asian market as well as Europe and North America, NZ healthtech businesses are well positioned to be significant players in meeting the world's growing healthtech needs.

Understanding the challenges: What's holding New Zealand back?

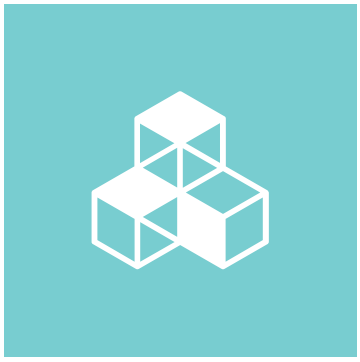
Callaghan Innovation wanted to identify the best way to respond to the needs of NZ healthtech businesses and the broader ecosystem to help unlock potential within the sector.

The foundational research upon which the HTA was built highlighted clear barriers preventing NZ's healthtech sector from achieving its true potential.

It indicated a need to create a mechanism that could work with individual businesses to overcome those obstacles and unlock the potential of the whole sector to meet the global opportunity.

Regulatory and testing

- Complex regulatory requirements
- Lengthy clinical trial processes



Capability Support

- Lack of access to pre-seed funding
- Confusion around available support

Investment

- High risk of early stage healthtech
- Longer return on investment timeframe

Regulatory and testing

Healthtech businesses face more challenges in bringing their products to market than many other innovative ventures or sectors.

These include two core aspects of a healthtech business:

- The clinical trial process
- Regulatory requirements

Both of these present even more complex challenges when taking a product to an international market. Different countries have different regulatory requirements and reimbursement processes. Understanding and progressing these can be complex, costly, and time consuming.

For example, with the vast majority of NZ healthtech businesses focussed on the US, there is a need to understand that country's complex regulatory and reimbursement system. Understanding this from the outset will often determine how a company chooses to classify itself and how it will enter the US.

There is also potential to establish better trial opportunities in NZ.

A recent report by the NZ Productivity Commission found that opportunities are limited for healthtech firms to collaborate with District Health Boards to trial and develop innovative new products and services.[5]

This is despite the commission listing a number of benefits for DHBs including innovation leading to gains in efficiency, effectiveness and access to health services. Collaboration also created draw cards for recruitment, could enhance a DHBs national and international profile, and potentially create a source of revenue through partnerships.

Reform of the public health system, with the replacement of DHBs, offers an opportunity to address some of the hurdles healthtech businesses face when looking to run clinical trials in NZ.

Investment

The complexity of healthtech, and the longer return on investment timeframe (market entry may take up to 10 years) means the sector appeals to only a limited group of investors. There is also a higher risk that the product will not meet regulatory requirements, and there can be higher capital needs than other sectors.

All of these factors require healthtech businesses to present a compelling case to secure funding.

The significant time horizons, and high risk nature of early stage healthtech investment, also mean publically funded support is important. The majority of public funding for healthtech innovation is currently directed to university researchers rather than to commercialisation.

Despite the need for greater publically funded investment into the early-stage healthtech ecosystem, a challenge for NZ businesses is that they often need to grow in scale internationally before they can afford to offer their technology to the NZ health system.

There is an opportunity to incentivise those in the healthtech ecosystem to not only produce world class research but ensure, where possible, that research is commercialised.

Capability support

The HTA discovery project found healthtech businesses had difficulty accessing certain types of funding (such as pre-seed) and had difficulty accessing the educational support needed for taking products to market.

The discovery project also found healthtech innovators needed to be well connected to experts and investors to succeed, but there was confusion about what support is available to help facilitate that.

The Healthtech Activator: Addressing the gaps

The HTA has been created to support the commercialisation of healthtech and growth of emerging NZ healthtech businesses. It is a coordinated, ecosystem-wide support mechanism for early-stage founders and businesses in NZ's healthtech sector.

Led by Callaghan Innovation, the HTA is being delivered in partnership with the MedTech Centre of Research Excellence (CoRE) and The Consortium for Medical Device Technologies. It is supported by MBIE and has strength in its cross-sector participation & guidance.

Expertise

The HTA's aim is to address key knowledge gaps in the sector by connecting Kiwi innovators with the healthtech sector and business expertise they need to succeed. Supported by a team of sector professionals, the HTA provides resources, training, networking and advice to NZ healthtech businesses at no or minimal cost to the business.

The HTA is completely agnostic, assisting healthtech businesses no matter where in the ecosystem they come from; they might be entrepreneur-led, university originated, or spin-outs from the health service.

It makes it easier for healthtech businesses to find and access the support they need to turn their health innovations into successful businesses. In doing so, it aims to advance, de-risk and accelerate the commercialisation of innovation in NZ's healthtech ecosystem.

Supporting connections

While the HTA does not provide investment capital, it does provide a highly valuable in-depth education in this area and is well connected with other avenues and entities, such as NZ Trade & Enterprise. The HTA provides and subsidises an ongoing programme of workshops and seminars with world-class experts on all aspects of healthtech commercialisation.

One of the HTA's goals is to drive better engagement between emerging health technology businesses and the NZ healthcare delivery system to enable product and service validation locally as businesses look to scale internationally.

With the Government beginning its proposed health reforms, there could be an opportunity to make regulatory pathways easier for Kiwi healthtech businesses by better integrating them into NZ's health system

Open resources

The HealthTech Activator website is a free, open resource. It includes information on other resources already available elsewhere, details on how to connect to the ecosystem, funding options, whom to speak with, as well as touchpoint maps around how to potentially navigate a regulatory pathway. It provides ecosystem and funding maps with focused areas of support in the following areas.

Market validation

Capital education

Clinical trials

Regulatory planning

Reimbursement

In-depth workshops and resources

The HTA offers a programme of workshops to address the challenges healthtech businesses face, such as better understanding and adapting to their markets.

A key database used by the HTA is the worldwide market data website, Global Data, which includes information on market size, competitors, deals done, pipelines and marketed products within different searchable sectors.

The HTA also uses Callaghan Innovation's library archives to support businesses through their market research and data sourcing.

The HTA is trialling GLG, an insights company that assists with market validation by putting businesses in touch with an industry insider in their market.

For example, if a NZ healthtech company is targeting the US software as a medical device (SaMD) market, they can have a conversation about how healthtech procurement works in a large private hospital network and what the key strategy considerations are for market entry.

The HTA programme of workshops is designed to help businesses build their capabilities. The workshops are offered at varying levels of depth depending on the stage of the businesses. Courses are already offered in market validation, capital planning, company valuation, and will soon also cover reimbursement and regulation.

Case studies

F&P Healthcare and it's $1.97b in revenue for the year ended March 2021 remain a flagship for what is achievable in NZ healthtech.

However, other, smaller innovative businesses provide excellent examples of how tapping into the ecosystem to overcome obstacles such as expertise and funding have helped clear their way to commercialisation.

Aroa Biosurgery

Entrepreneur Brian Ward had a great healthtech business idea: to meet growing international interest in using biological materials for soft-tissue repair by creating products based on high-quality source materials readily available through NZ's primary industry sector.

He eventually found a suitable raw material source in sheeps' stomachs, from which a high-quality biomaterial could potentially be made. The problem was that Ward, although trained in science, couldn't develop the material himself.

So, he employed a weightless business model by tapping into the healthtech ecosystem. His firm – Aroa Biosurgery – rented lab space at an IRL (now Callaghan Innovation) facility and contracted scientists from the organisation to do initial development work.

Aroa was also able to secure crucial funding through the ecosystem, attracting early-stage venture capital investment from Movac, Sparkbox, Cure Kids Ventures and K1W1, and accessing Callaghan Innovation grants to fund specific R&D projects.

Twelve years later, Aroa has regulatory approval for its hi-tech wound care products, credible partners in the world's largest healthcare market – the US – and employs more than 100 staff.

Alimetry

Alimetry is a University of Auckland spin-out company developing novel technologies for the non-invasive diagnosis of gastrointestinal disorders such as Irritable Bowel Syndrome (IBS) and Dyspepsia.

The company has developed a lightweight sensor system and algorithms that allow monitoring and analysis of intestinal contractions or gut waves which can be used to predict intestinal disease more quickly. For example, it can take six months for an IBS diagnosis using traditional methods, whereas Alimetry's technology aims to come to a diagnosis in a day.

Callaghan Innovation has been working with Greg and the team at Alimetry for the last 2 years with project and student grant funding as well as the innovation skills programme. The company has now connected to Health Tech Activator support, including the in-depth market validation programme.

Heartlab

Healthtech startup HeartLab is using artificial intelligence (AI) to help in the fight against the world's number-one preventable cause of death: heart disease.

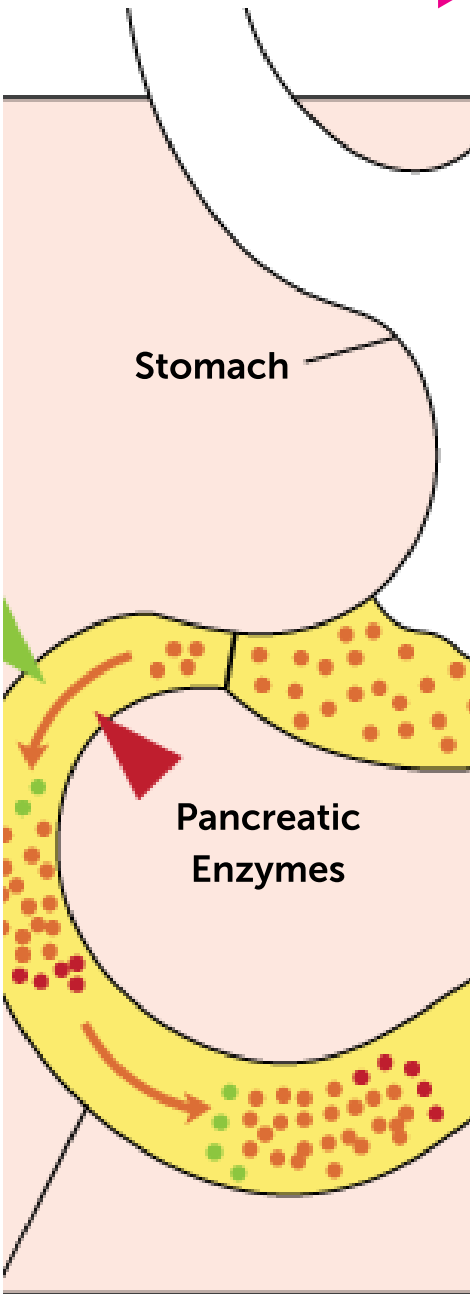
HeartLab is developing AI tools to help doctors with the time-consuming and manual process of reviewing echocardiograms – one of the most common scans used to identify heart problems.

While essentially developing digital tools, HeartLab's technology is classified as a medical device – meaning the business faces a complex and highly regulated commercialisation path.

Co-founded by Dr Patrick Gladding and Will Hewitt, HeartLab has tapped into NZ's healthtech ecosystem, including accessing Callaghan Innovation support, to help it with everything from company incubation, to funding, to market validation.

Members of HeartLab's team recently undertook a workshop through the HTA focused on market validation – an area that Hewitt says is important for the company as it continues at pace on its innovation journey.

The Insides Company



Associate Professor Greg O'Grady is a surgeon, researcher and an entrepreneur. In 2017, O'Grady co-founded The Insides Company – alongside fellow colorectal surgeon Professor Ian Bissett, and engineers Rob and John Davidson – to develop medical devices for bowel cancer surgery and recovery.

The medical devices developed by The Insides Company, of which O'Grady is Chief Scientific Officer, dramatically reduce the time until patients can fully use their guts again following bowel surgery, resulting in significant health benefits and reductions in clinical complications such as dehydration and infection.

In 2019 the firm's commercialisation progress ramped up by tapping into the healthtech ecosystem. It appointed experienced entrepreneur Garth Sutherland as CEO, and its devices gained entry into the US Food and Drug Administration's Breakthrough Devices regulatory pathway – giving it the opportunity to significantly reduce its time to market in the US.

It also successfully gained funding from the NZ angel investment community, raising a total of $4.3 million from the likes of Icehouse Ventures, K1W1, UniServices, Eden Ventures and NZVIF.

That commercialisation momentum created by tapping into the healthtech ecosystem has ultimately advanced the opportunities for human health benefits.

References

1. HealthTech Activator
2. Fisher & Paykel Healthcare 2021 annual report.
3. TIN Healthtech - Insights Report 2020
4. United Nations, Global Issues, Population
5. NZ Productivity Commission, Frontier Firms