

Commercialising
a first-in-market, low cost saliva-based
Companion Diagnostic Device (CDx) for
the rapid detection of early heart failure risk



Information Memorandum

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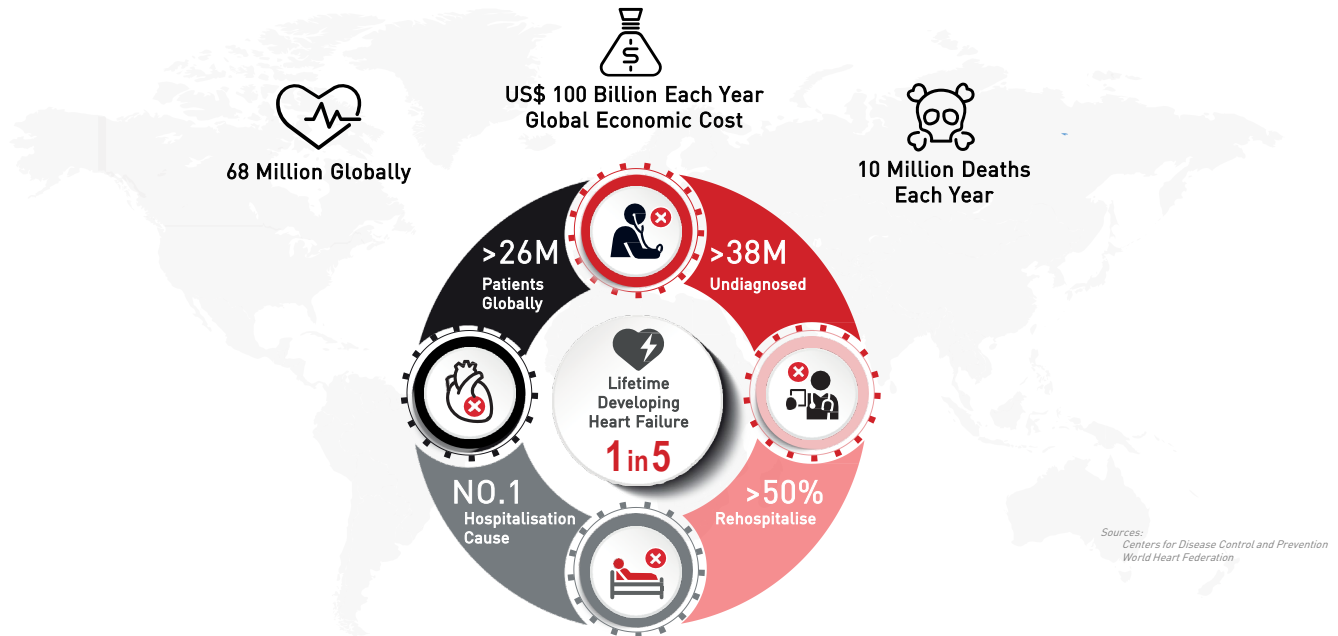
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Problem: No Early Detection of Heart Failure

Heart failure is a significant health risk affecting 68 million people globally. In the U.S., approximately 6.5 million people suffer heart failure. It is one of the largest causes of death with 1 in 8 deaths attributed to the disease and up to 2/3rds of people diagnosed with heart failure die within 5 years.

Tragically, most cases of heart failure are not detected until symptoms appear and it is often too late. In addition to reductions in the quality of life and early loss of life, total health care services, medications and other costs relating to heart failure are over US\$30 billion in the U.S. alone and growing each year.



Solution: Detecting Early Risk of Heart Failure – Companion Diagnostic Devices (CDx)

ESN Cleer’s platform incorporates patent protected novel biomarkers, coupled with established nano-technology, producing highly accurate early risk of heart failure detection applications. Our platform is based on patented novel biomarkers that have been peer-review tested showing over 90% accuracy.

Our CDx applications include *EHF-Test Kit* and *EHF-ESwab*, saliva-based in vitro diagnostic devices for qualitative detection. The *EHF-Test Kit* in-lab test kit is expecting to gain FDA approval by early 2021, while the digital *EHF-ESwab* is targeted for FDA approval by 2022. Together with current-proven effective drugs such as SGLT2i, it is envisaged that our CDx applications will significantly reduce the risk of developing heart failure, minimising the global social and economic burden of the disease.



EHF-Test Kit



EHF-ESwab

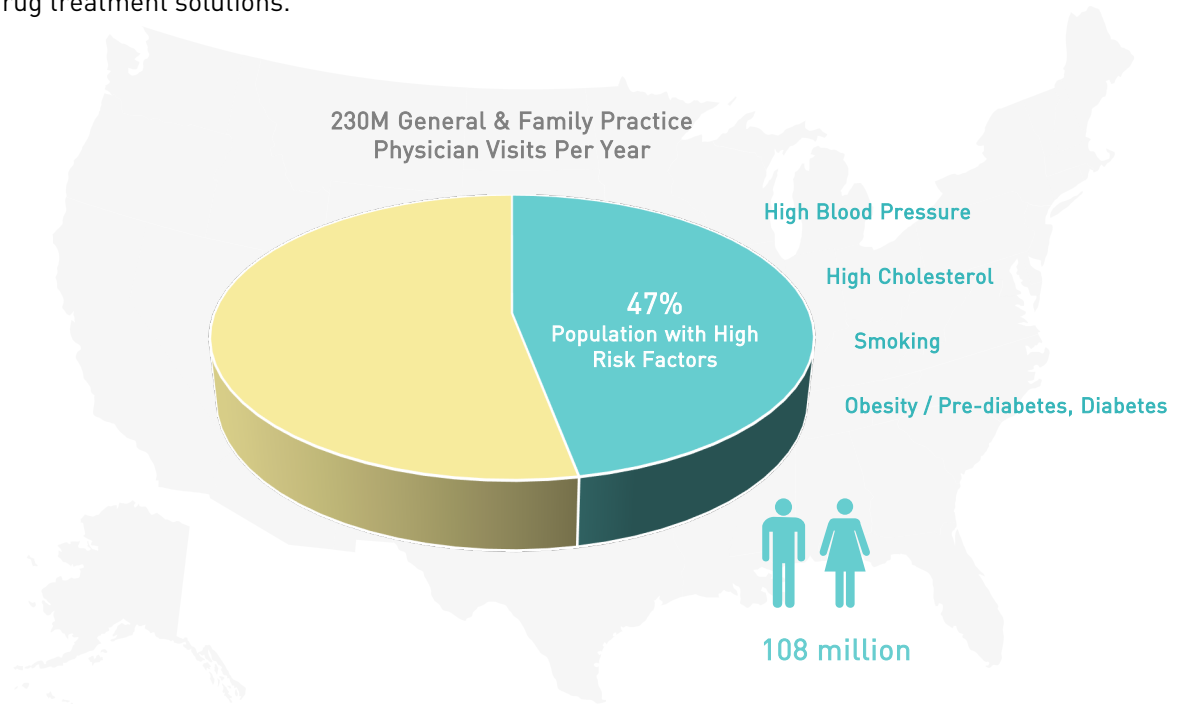
- ✓ Early Detection
- ✓ Confidence
- ✓ Precision Accuracy
- ✓ Affordable
- ✓ Fast Results

The *EHF-Test Kit* deployment by strategic licensing partnership is expected within the next 12 months, providing sustainable revenue, while we anticipate additional Companion Diagnostics Device (CDx) approval with an approved early heart failure drug. The digital *EHF-ESwab* with enhanced features is anticipated for launch by 2022.

Market: Primary Care

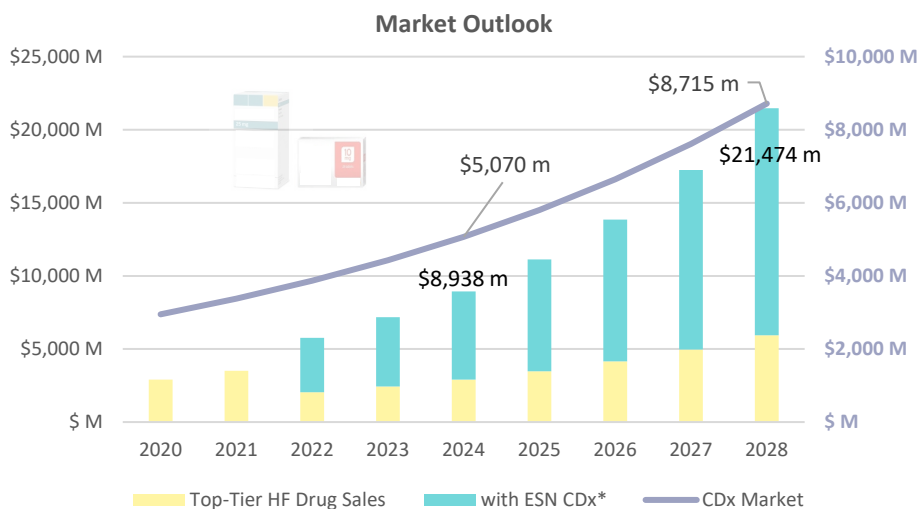
With no comparable early heart failure risk screening test available in the market, the ESN Cleer CDx applications will have large market applications across multiple population segments. There is substantial interest from major global pharmaceutical companies, primary care and mass distribution organizations.

ESN Cleer's current primary focus is collaboration with one or more Pharmaceutical companies developing / marketing a member of the SGLT2i drug class. The targeted market segment is primary care, providing detection – drug treatment solutions.



Market: CDx, Early Heart Failure Drug

In recent years, there has been a significant increase in CDx deployment globally for personalised medicine. Multi-million dollar strategic partnerships continue to rise to provide fully integrated detection-treatment solutions. The CDx model has been a proven detection-treatment mechanism with successful deployment in oncology. ESN Cleer is at the forefront of the next wave of CDx applications in cardiology.



Total Heart Failure drug market is at 19.5% CAGR, from \$20B in 2018 to \$118B by 2028, with Generic competing Top-Tier heart failure drugs expected by 2022. ESN Cleer CDx solution can support sustainable Top-Tier drug sales with its added IP protection. Total Companion Diagnostic Devices market is at 14.5% CAGR from 2019 to 2025.

Experienced Team

ESN Cleer was established in 2017, lead by Managing Director and Founder, Leopoldt de Bruin, with extensive commercial and industry experience in creation and sustaining long-term value for organizations and its stakeholders. The Chief Operations Officer, Co-Founder, Johnny Feng has more than 20 years of international supply chain experience with global major retailers. The Chief Information Officer, Gustav de Bruin, brings 20 years of corporate industrial electronics and software development and management proficiency.

The board is lead by Non-Executive Chairman, Professor Andrew Coats, renowned academia and cardiologist leader, currently also President of the Heart Failure Association. Professor Coats is also the Head of medicine and pharmaceutical at ESN Cleer. As a Non-Executive Director, Matt McNamara, supports ESN Cleer with his immense Venture Capital, Pharmaceutical, MedTech and corporate governance expertise.

ESN Cleer has an experienced executive team and board, committed to commercialising the world's first affordable, easy-to-use, screening test for early risk of heart failure.



Leopoldt de Bruin
Managing Director
Founder



Johnny Feng
Chief Operations Officer
Executive Director,
Co-Founder



Gustav de Bruin
Chief Information Officer
Solutions Integration,
Regulatory Affairs



Professor Andrew Coats
Non-Executive Chairman
Head of Medicine, Pharmaceutical

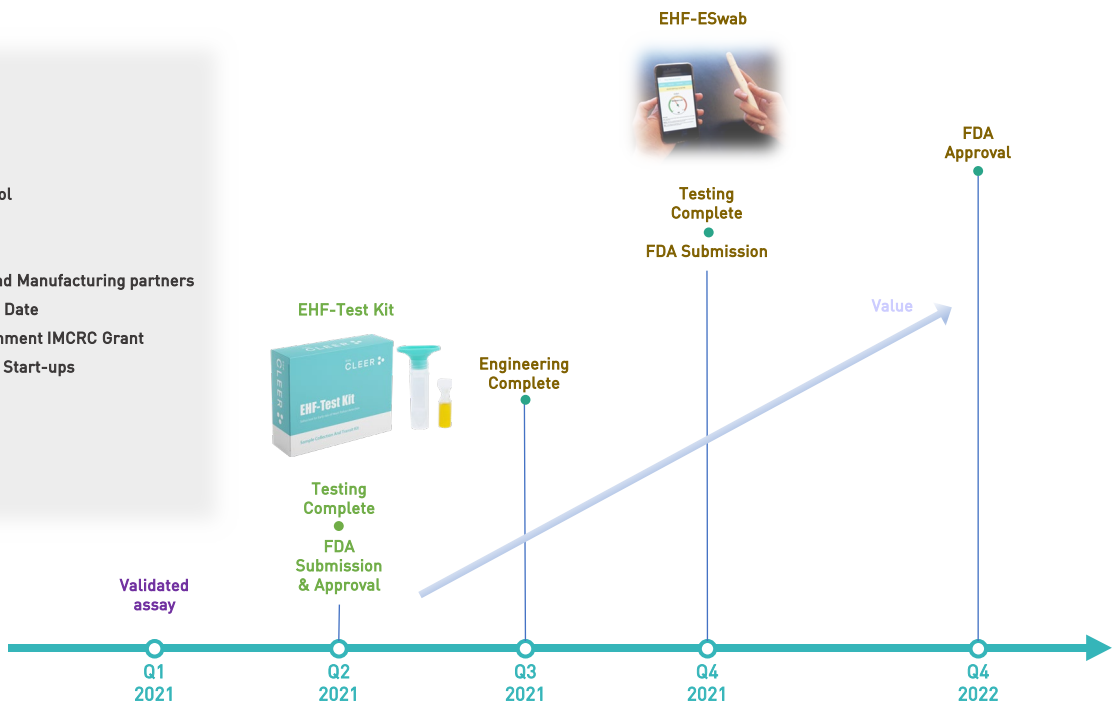


Matt McNamara
Non-Executive Director
MedTech Commercialisation

Achievements, Development & Value Inflection Pathway

Achievements

- Peer-reviewed science
- Engineering prototype
- Clinical Validation Protocol
- Software Platform
- Patents and Licenses
- Science, Technological and Manufacturing partners
- A\$2.5M Capital Raised To Date
- A\$3.5M Australian Government IMCRC Grant
- Named Amongst Top Tier Start-ups



Investment Highlights

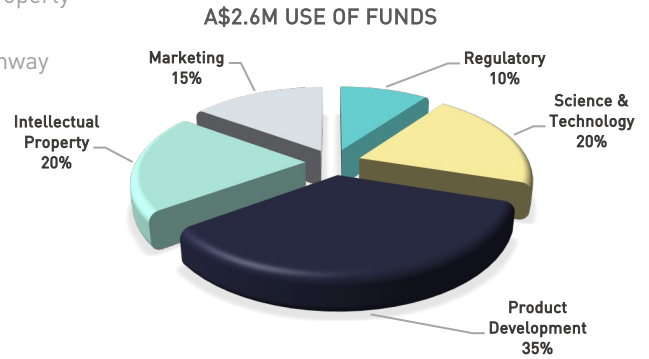


Global Multi-Billion Dollar Opportunity

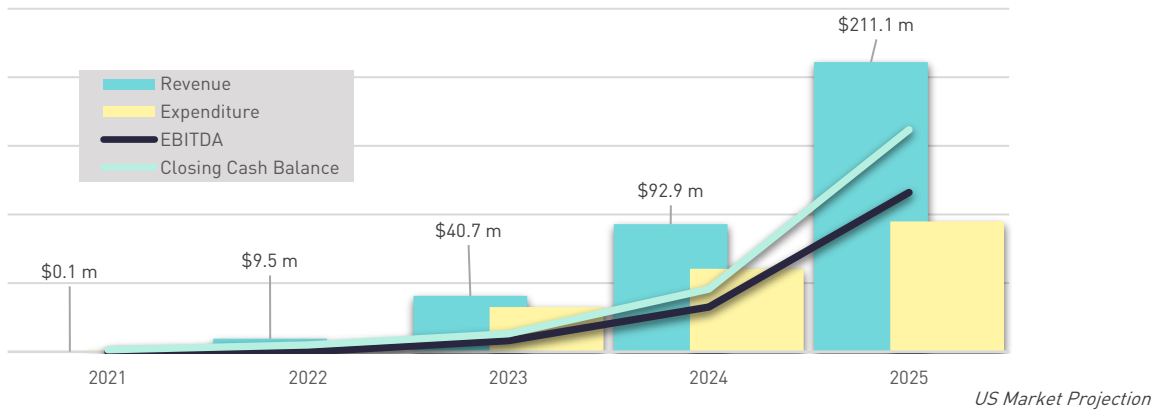
Protected Core Intellectual Property

De-Risked Development Pathway

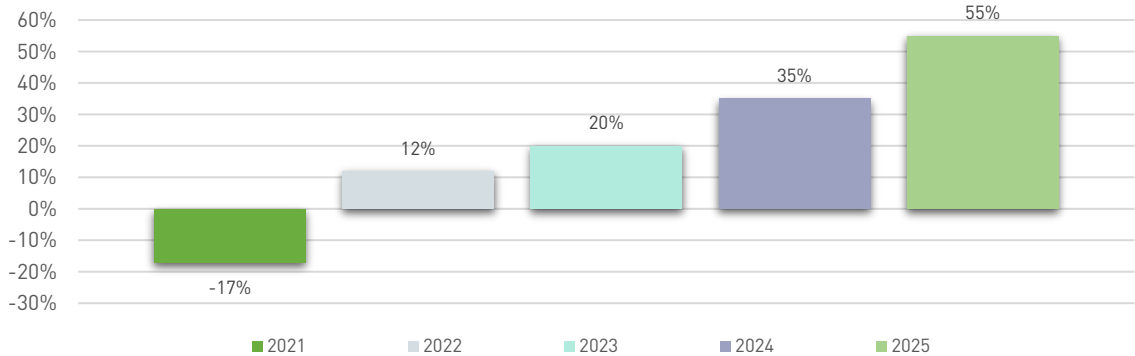
2 to 3 Years ROI



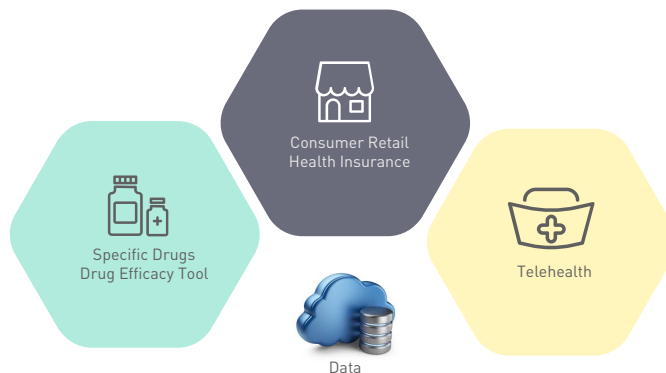
Key Financial Indicators - Years 1 to 5



EBITDA Margin % - Years 1 to 5

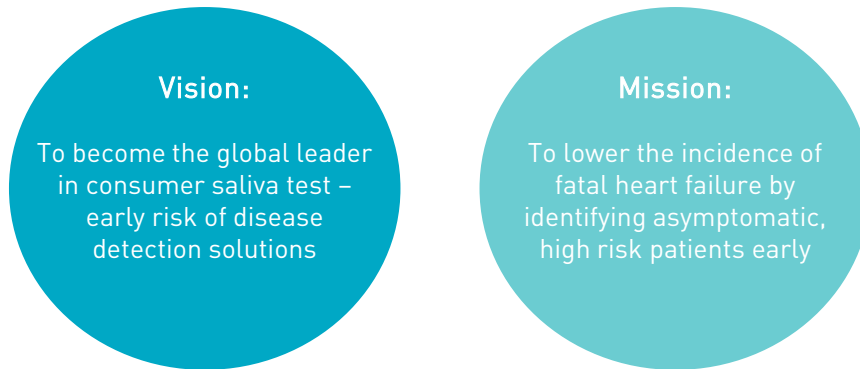


UPLIFT OPPORTUNITIES



1. ESN Cleer Overview

1.1 Vision and Mission



1.2 Detecting Early Risk of Heart Failure

ESN Cleer is an innovative medical device company established in 2017 pioneering a novel approach to one of the most significant health problems affecting the world. ESN Cleer incorporates the latest science and technology developments to develop the *EHF-Test Kit* and *EHF-ESwab* CDx solutions, producing highly accurate preventative solutions accessible to the mass population. The application of nanotechnology, synthetic protein synthesis and sophisticated analytical software coupled with clinical evidence has produced a highly accurate and rapid assay that until now was impossible to create.

The ESN Cleer solutions removes time and cost barriers from the detection of asymptomatic early risk of developing heart failure. Heart failure risk identification will enable effective prevention and thereby significantly reduce the economic, emotional and social burden of the disease and deliver a major impact to the mass population.

The *EHF-Test Kit* deployment by strategic licensing partnership is expected within the next 12 months, providing sustainable revenue, while we anticipate additional Companion Diagnostics Device (CDx) approval with an approved early heart failure drug. The digital *EHF-ESwab* with enhanced features is anticipated for launch by 2022.

The solutions features:

- **First of its kind:** Saliva test platform using three proprietary novel biomarkers that can detect the early risk of heart failure.
- **Affordable cost**
- **Ongoing monitoring solution**
- **Fast results:**
 - EHF-Test Kit* results available in days
 - EHF-ESwab* results available in minutes
- **High accuracy:** Testing to date from an initial control group demonstrated an area under curve (AUC) or C statistic of 95.54%, and 97% sensitivity with 91% specificity.



1.2.1 Solution Overview

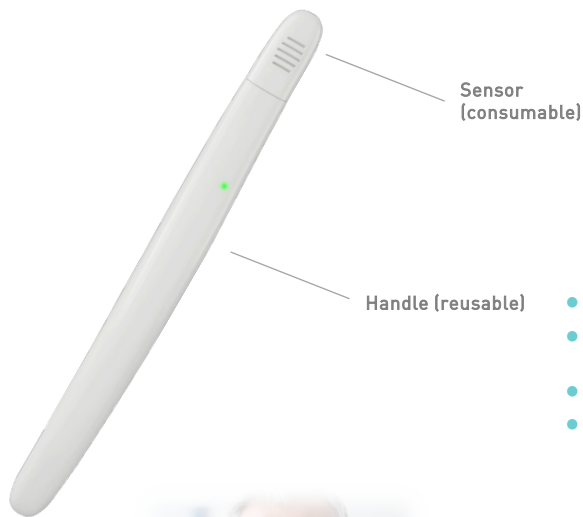
The ESN solutions are designed to be safe and easy-to-use, hygienic, in small form factor and provide rapid results. These benefits make the *EHF-Test Kit* and *EHF-ESwab* suitable solutions for primary care practitioners. The solutions are supported by ESN Cleer's software and data integration, coupled with ESN Cleer's machine learning algorithm. The system provides the ability to monitor progression/regression in a timely manner, supporting physician treatment decisions.

EHF-Test Kit Overview:



1.2.1 Solution Overview

EHF-ESwab Overview:

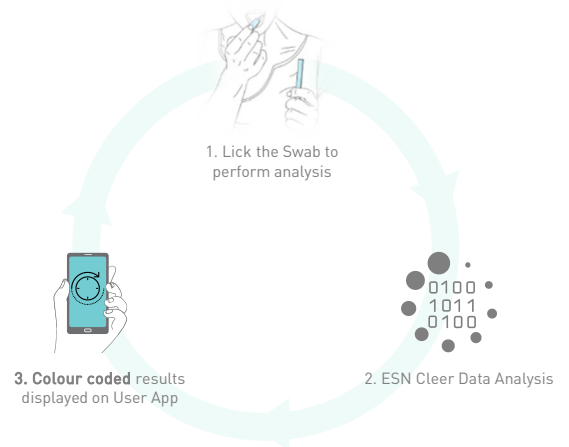


- At the end of the device is a removable, nanoparticle sensor refill cartridge.
- The cartridge houses the Company's three biomarker antibodies embedded on the nanoparticle novel sensor to deliver a shelf-life product (over 12 months) that is highly sensitive and accurate.

- Reusable electronic device
- Houses the battery, electrical componentry, Bluetooth capability and other mechanisms to power the solution.
- Comparable size to an electric toothbrush.
- LED lights on the device to direct the user in its operation.



Test with Results
Treatment



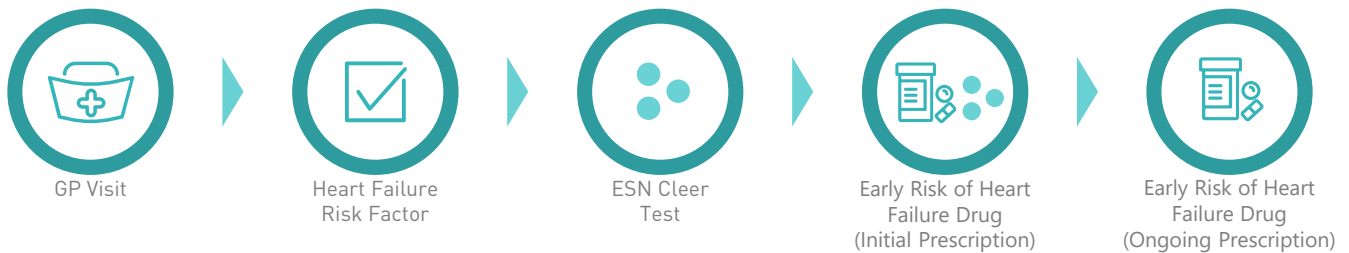
The ESN Cleer *EHF-ESwab* corresponding App will report with sliding scale (low, medium, or high) risk level, while data can also be accessed by the physician.

	Low	Medium	High
Discovery	The user is in a low risk range	The user may be at increased risk of heart failure.	The user has clear indication of heart failure risk and may be suffering from early disease.
Next Steps	Ongoing testing is advised to ensure the user stays within a low risk range in the future.	Consult a doctor to be examined and possibly conduct clinical tests such as ECG, echocardiogram, and an assessment of exercise capacity to provide clarity on the risk of heart failure. The physician can provide a proposed cause of action, such as treatment or lifestyle changes.	Consult a doctor or specialist immediately, to determine if through further clinical testing presence of any health issues leading to the heart failure risk indication.
Expected retesting frequency	6 months	Monthly	Fortnightly

1.2.3 Patient Journey – Primary Care

ESN Cleer’s primary focus is primary care market segment with revenue at leverage points. Patients and strategic partners (stakeholders) will attain benefits throughout the journey.

Statistically, over 230M doctor visits occur per year in the US, of which 47% of the population present with at least 1 risk factor for the development of heart failure. A simple and effective test can be conducted during the visit to identify early risk of heart failure at a level of precision that can be acted upon. In future, after clinical trial validation, we expect a coupled specific preventative drug can be prescribed upon risk detection.



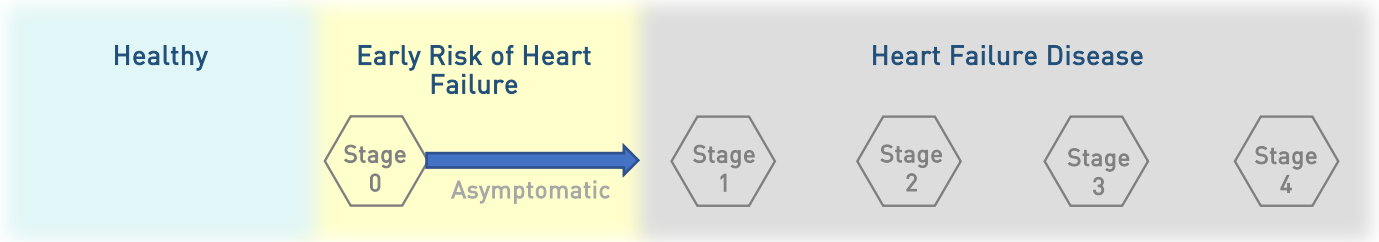
1.2.4 Value Chain

The ESN Cleer solutions provides compelling stakeholders’ value propositions with reimbursement opportunities.

Physicians	<ul style="list-style-type: none"> • Simple screening tool with minimal resources required for use • Coupled with dedicated drug for implementation • Low cost
Consumers	<ul style="list-style-type: none"> • Asymptomatic detection • Non-Invasive and easy to use • Fast results • Preventative action can be taken • Minimize heart failure disease further stages development • Preventing heart disease physical and financial burden
Manufacturing and Distribution Partner	<ul style="list-style-type: none"> • Manufacturing capability • Low cost of production • Vast distribution opportunity
Pharmaceutical Partner	<ul style="list-style-type: none"> • Identifies new patient population to supply coupled drug, CDx • Supports ongoing drug prescriptions, CDx • Provides drug efficacy monitoring, Personalised Medicine
Health System and Insurance Companies	<ul style="list-style-type: none"> • Prevent significant costs associated with medical care and hospitalisation • Reduce current traditional symptomatic heart failure detection resources • Reduce enormous heart failure economic and social impact

1.3 Future Value - Pharmaceutical

One of the most valuable elements is that the ESN Cleer solutions will support the most recent established drug class for heart failure, the SGLT2i, for treating an early risk of heart failure. The solutions will dramatically increase SGLT2i drug candidates as there are currently limited drug recipients with inadequate screening applications available. ESN Cleer is making substantial progress with a major Pharmaceutical company, towards collaboration on CDx heart failure disease prevention treatment solutions. The collaboration will radically enable people with early risk to take control and minimise further disease development.



Companion Diagnostic Device
CDx

ESN Cleer has developed bespoke technology to miniaturise a multi-marker panel. This can bring detection and hence the chance to prevent direct to many people otherwise not effectively reachable by conventional heart failure prevention programs which depend on over-run and expensive clinical referral patterns.

It is a strange and not widely appreciated fact that established heart failure treatments such as ACE inhibitors, ARB's, beta blockers, aldosterone antagonists and the most recent Sacubitril/Valsartan are indicated only to treat established heart failure (or other cardiovascular disorders) and not to prevent heart failure in a person detected to be at risk.

The widespread use of ESN Cleer's technology could identify a very large new population with commercial partner pharmaceutical companies, linking the potential ability of their drug to reduce the development of heart failure coupled with ESN Cleer's patented detection technology. Such advanced products in this field are currently unavailable; conventional competitors use single marker technologies, either in research biochemistry laboratory settings or using limited near-patient testing, but none is designed to detect early or pre-heart failure syndromes so comprehensively. Conventional echocardiography or exercise testing is used to diagnose heart failure in those thought to be at risk (such as those with a family history of an inherited cardiomyopathy), but both are impractically expensive and cumbersome to use as widely as ESN Cleer's technology.

1.4 Technology Results to Date

Queensland University of Technology and ESN Cleer collaboratively developed a novel multi-protein panel for detection of high-risk developing Heart Failure disease. This protein panel exists in saliva and is detectable with the aid of nano-particle sensors.

Heart failure patients and healthy controls were identified through screening of saliva from participants. Saliva samples were collected from healthy controls (n=88) and from heart failure patients (n=100).

The testing data and peer-reviewed science demonstrated an initial overall detection accuracy of 78% (sensitivity of 83.3% and specificity of 62.5%) when distinguishing heart failure patients from healthy individuals. Consequent follow up on participants history since samples were taken and combined with the protein panel analysis. Combining these datasets yielded an improved ESN algorithm and generated an area under curve (AUC) or C statistic of 95.54%. The detailed performance obtained was 97% sensitivity and 91% specificity which confirms positive correlation between the protein panel and additional context such as medical history.

These results demonstrate the ability to measure the salivary concentrations of three proteins combined as a panel to accurately predict future heart failure patients from healthy controls. While this requires confirmation in larger cohorts, the findings suggest that this three-protein panel has the potential to be used as biomarkers to early detect heart failure. These results provide the basis to complete a clinical study and commercialize this technology into a production ready medical device.

1.5 Commercial Milestones

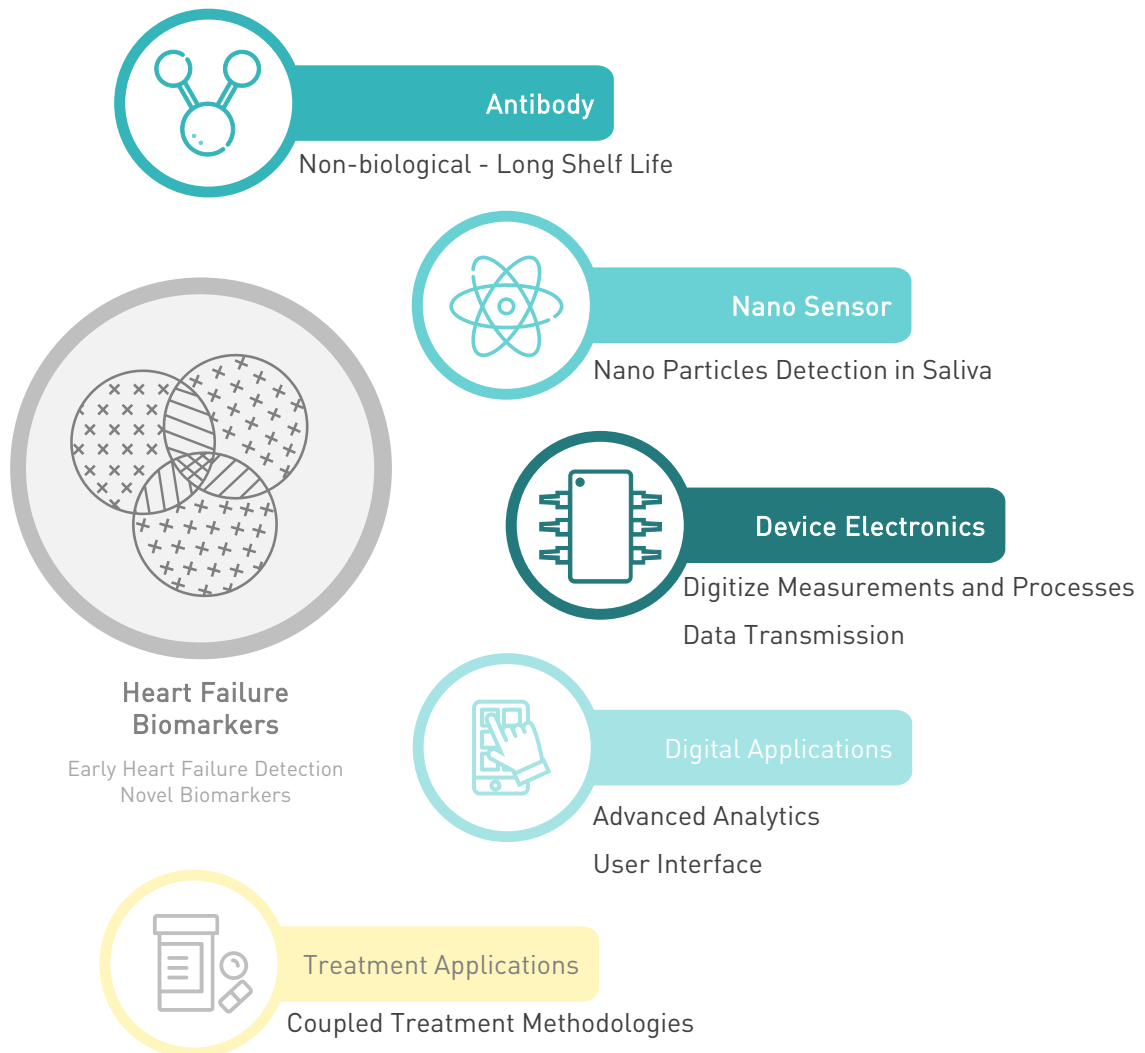
ESN Cleer has made valuable commercial, scientific and product development progress. Milestones to date and traction achieved include:

- Peer reviewed research from a sample of 188 people demonstrating overall detection generated an area under curve (AUC) or C statistic of 95.54%³, and 97% sensitivity with 91% specificity.
- Completed engineering samples through a medical device design partner
- Designed the Clinical Trial Protocol
- Market study, engineered product operations and production feasibility, regulatory strategy
- Shortlisted partner/s:
 - Science development
 - Sensor development and manufacturing (incl. science)
 - Sensing circuitry development compatible with the sensor
 - Medical device (with an integrated sensor) and user interface integration
 - Regulatory specialist
 - Pilot and full scale manufacturing
 - Clinical trial execution
- Functional concept device, mobile App and cloud back-end for data storage and user management
- Exceptional performing Machine learning platform deployed and used for algorithm development and analysis
- Submission of initial patent families and licensing of key pieces of supplementary IP
- Commenced commercial discussions with potential strategic partners; multi-national pharmaceutical companies, primary care providers, manufacturing and distribution company
- Preliminary engagement with cardiology groups
- Assembled a prestigious board and team committed to the success of ESN Cleer
- Third party due diligence assessment confirming ESN Cleer in the top quartile of startups

³ Combining original datasets with ESN algorithm results.

1.6 Intellectual Property and Technology Strategy

ESN Cleer continuously generate and managing its intellectual property portfolio. The Company has also secured several license agreements integral to the operation of the technology and activation of the business model.



1.7 Regulatory Pathway

ESN Cleer's EHF-Test Kit and laboratory analysis is expected to require a relatively swift regulatory process. Laboratory analysis will be reviewed by a recognised body to approve the testing method for diagnostic use. The saliva proteomic collection kit will consist of pre-approved FDA Class I component.

Meanwhile, the *EHF-ESwab* is expected to be FDA Class II with the De Novo pathway. This is achievable with the *EHF-ESwab* being a "Device 'type(s)' that have never been marketed in the U.S., but whose safety profile and technology are now reasonably well understood." (Source: FDA) The De Novo process provides a pathway to classify the novel *EHF-ESwab* for which general controls alone, or general and special controls (Class II), providing reasonable assurance of safety and effectiveness for the intended use, but for which there is no marketed predicate device.

One of FDA's principles is to ensure new products entering the US market are unique, novel, provide distinctive application improvements with clear product purposes – population benefits. ESN Cleer's *EHF-ESwab* is methodically aligned to FDA's principle.

ESN Cleer's regulatory strategy was developed with industry regulatory specialists with continuous engagement, ensuring preparations and implementations are completed effectively with high efficiency.

1.8 Risk Analysis

ESN Cleer recognises many challenges in multiple areas of the business. We continuously identify and mitigate the strategic and operations risks, with continuous monitoring at operational, management and board levels.

	Risk	Mitigation
Regulatory	The ESN Cleer medical devices are not fully commercialised. The device will require the FDA regulatory authorisations and registrations for sale and distribution in the US.	ESN Cleer is on track to complete a clinical study supporting its early findings. ESN Cleer has engaged experts with experience in medical devices and regulatory submissions.
Product Performance	Any product performance failure during clinical studies or a failure of a product to meet a customer's needs when in market could affect ESN Cleer's reputation and result in loss of sales.	Combination of original datasets and the ESN algorithm generated an area under curve (AUC) or C statistic of 95.54%, and 97% sensitivity with 91% specificity. The early introduction of EHF-Test Kit solution will provide additional datasets to enable continuous performance and improvements.
Pharmaceutical, Medical Devices, CDx Partnership	Secure suitable strategic partnership(s).	ESN Cleer has begun engaging with several global pharmaceutical and medical devices companies with heart failure focus. Discussions are at varying stages and collaborative structures. Companies are selected with prior experiences in similar partnership models to minimise barriers to maturity.
Supplier Partnership	ESN Cleer is reliant on arrangements with third parties in relation to the regulatory submission, design, manufacture and in the future for sale and distribution for its devices. There is a risk that the third parties do not comply with their obligations.	ESN Cleer has service level agreement in place with each supplier. Only reputable and experienced suppliers are contracted, while ESN Cleer has access to multiple contingency suppliers if required to further mitigate this risk.
Personnel	Sufficient personnel resources available to sustain progression and growth.	ESN Cleer has budgeted for personnel requirements to sustain continuous growth at future phases. ESN Cleer has also developed a network of industry experts to leverage for talent as required.
Intellectual Property Risk Competition	Sufficient scientific and technological protection, ensuring protected barriers of entry to competition.	ESN Cleer has secured significant intellectual property while continuously securing and developing additional IP to its portfolio, increasing barriers of entry to any potential future competition while increasing its market opportunities.
Market Adoption	Product rollout – market, user adoption level.	Research has been conducted to reflect market suitability, while multiple industry networks have been established for deployment when ready for market launch.
Funding	The Company may not raise sufficient capital to get the product to market.	ESN Cleer's agility has enabled continuous evolution of its solutions development. The <i>EHF-Test Kit</i> will provide early revenue while finalising the EHF-ESwab development. ESN Cleer continuously work towards value inflection milestones, non-dilutive funding, strategic partnerships and M&A opportunities.

2. Corporate Information

2.1 Directors and Executive Team

The ESN Cleer executive team incorporating the Directors and C-Level personnel have extensive commercial and industry experience with proven track record across all facets of the business.



Prof. Andrew Coats
Non-Executive Chairman
Head of Medicine, Pharmaceutical

- Internationally renowned academia and cardiologist leader
- Experienced Entrepreneur
- President of the Heart Failure Association
- Board experience in the Biotechnology, Health and Tertiary Education sectors



Matt McNamara
Non-Executive Director
MedTech Commercialisation

- More than 20 years as Venture Capitalist
- Over 30 years' experience in healthcare and medical sciences sector
- Over a decade in the Pharmaceutical industry at Merck & Co. and Johnson and Johnson Medical



Leopoldt de Bruin
Managing Director
Founder

- CFO of an AHG (ASX: AHG) business
- Lead M&A activities
- Pioneer of growth within SME



Johnny Feng
Executive Director and Co-Founder
Chief Operations Officer

- Seasoned product lifecycle management and delivery for global mass markets
- Novel technology – consumer market commercialization
- Organisational and business development



Gustav de Bruin
Chief Information Officer
Solutions Integration, Regulatory Affairs

- Over 20 years electronic and software engineering development, program management and business development.
- Experienced solutions program director at multi-national corporations.
- Data science and analytics with machine learning applications.

2.2 Advisory Board

ESN Cleer is supported by a multi-skilled advisory board offering expertise in corporate development, cardiovascular diseases, saliva screening technologies, artificial intelligence, Nano-technology research, medical device sales and consumer distribution..



Johan Andries Meyer

- Seasoned CEO executive with international expertise in leadership, strategy, business improvement, commercial activities, project performance and change management.
- Advisory on strategic development, M&A, board relations and governance.



Dr Geoff Strange

- Leads the Pulmonary Hypertension Society of ANZ, creating the world's largest pulmonary hypertension patient's registry.
- Undertaking the largest 'big data' echocardiographic research project globally as the CI of the "National Echo Database of Australia" involving 1,000,000 studies and 50,000,000+ parameters on 700,000+ individuals.

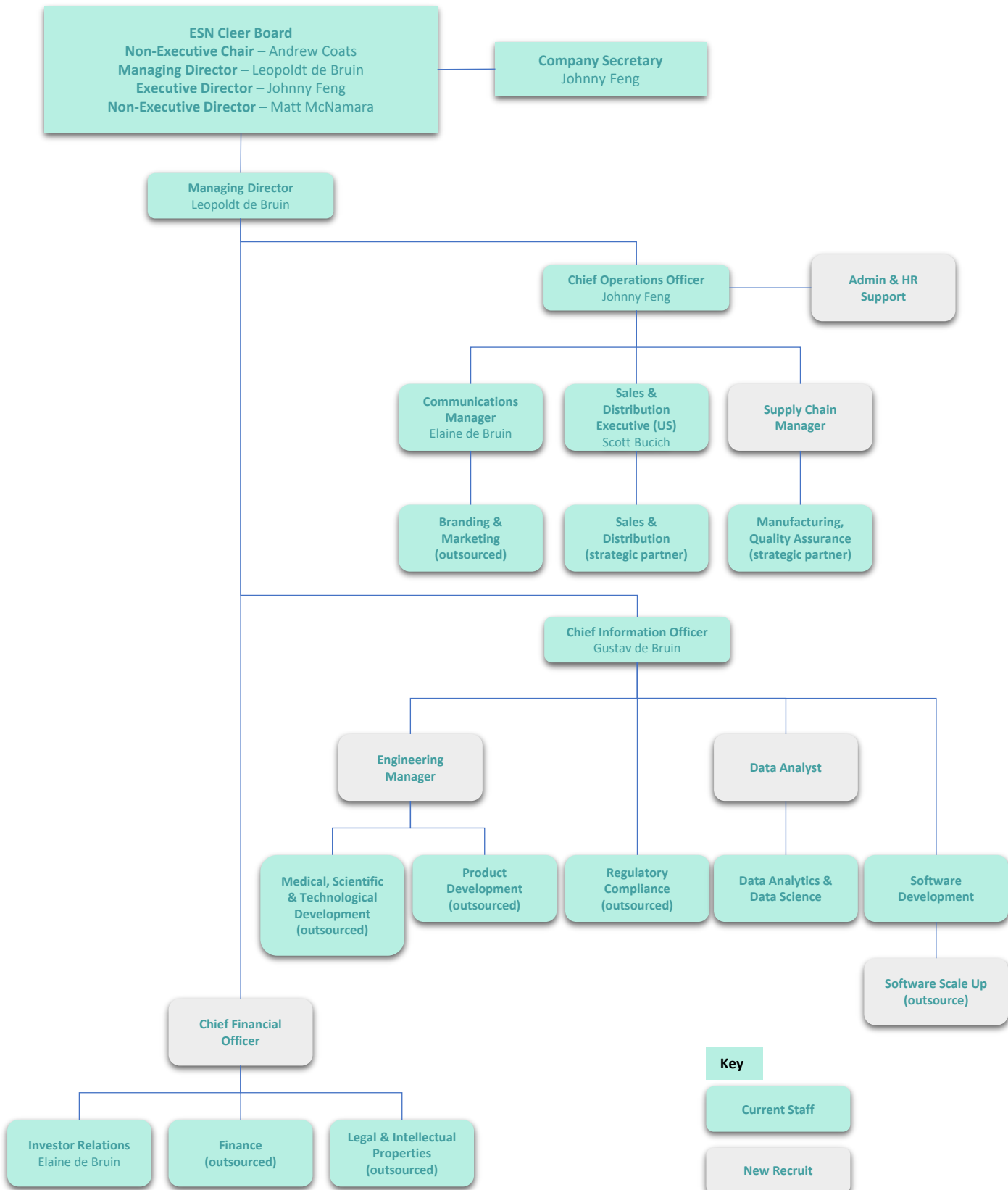


Dr Georg de Bruin

- Pathology specialist with over 40 years of experience as consultant pathologist and as Associate Professor in medical microbiology.
- Elected Member of the American Society for Microbiology, South African Society of Microbiology and Infectious Diseases, and a founding member of the South African Society of Allergy and Immunology.

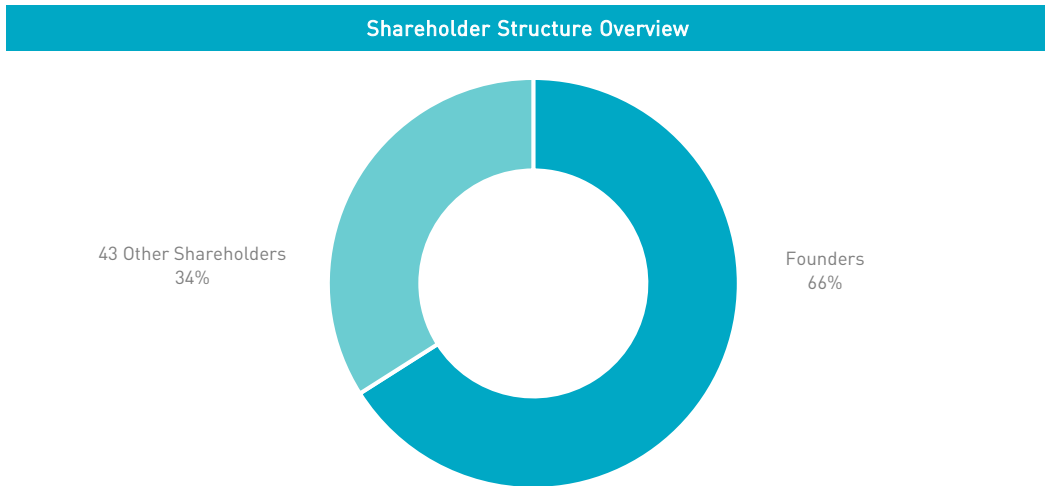
2.3 Organisational Structure

The executive team oversees the organisation that comprises of scientific, technical, clinical and regulatory teams. The company is also supported by external consultants to expedite commercialization. An overview of the structure of the operation is below.



2.4 Corporate Structure

Endothelium Scanning Nanotechnology Pty Ltd is an Australian private company, currently with four directors, Andrew Coats, Matt McNamara, Leopoldt de Bruin and Johnny Feng. The Company is structured to incorporate eligible investors. Incoming investors will receive Ordinary Shares in the Company. There are currently 45 shareholders.



3. Market Opportunity

3.1 Heart Failure Disease

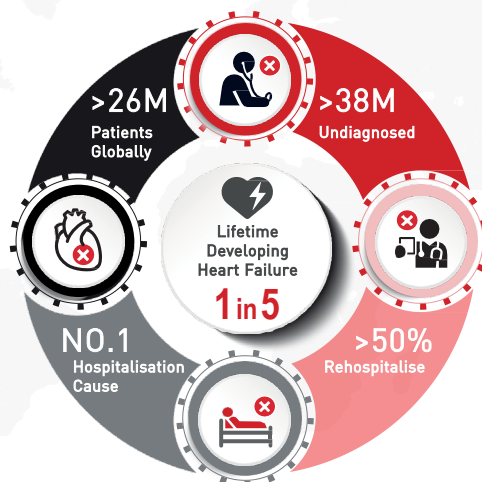
Heart Failure is the scourge of the modern world. As populations age and as we get better at treating other previously fatal conditions, both heart-related and non-heart-related (such as cancer) we are paradoxically seeing much more heart failure.

Heart failure, in its severest form, is when the heart fails to pump properly, causing dizziness, collapse, congestion of the lungs and a risk of sudden death. It now affects over 68 million of the global population. There are many effective therapies for heart failure, delaying death and ameliorating symptoms, yet these are only given when a diagnosis has been made, and this is usually only when an extreme event has occurred and the sufferer has had to be admitted as an emergency to hospital with life-threatening lung congestion and severe shortness of breath.

ESN Cleer provides the solution to detect this condition significantly earlier, when it is almost free of symptoms, or with symptoms so mild they are put down to ageing, obesity or unfitnes, whereas in fact they could be the signal that a serious disease is developing. ESN Cleer's technology can detect such early cardiomyopathy simply and reliably and allow lifestyle and drug treatments that will slow the progression to frank heart failure and improve survival substantially. It allows people to detect this silent killer earlier. An early detection can mean the difference between life and death.

3.1.1 Current Global Impact

The following are some statistics of the insidious heart failure disease's colossal global impact.



Sources:
Centers for Disease Control and Prevention
World Heart Federation

50%

Health care practitioners are not fully aware of the risks for heart failure

50%

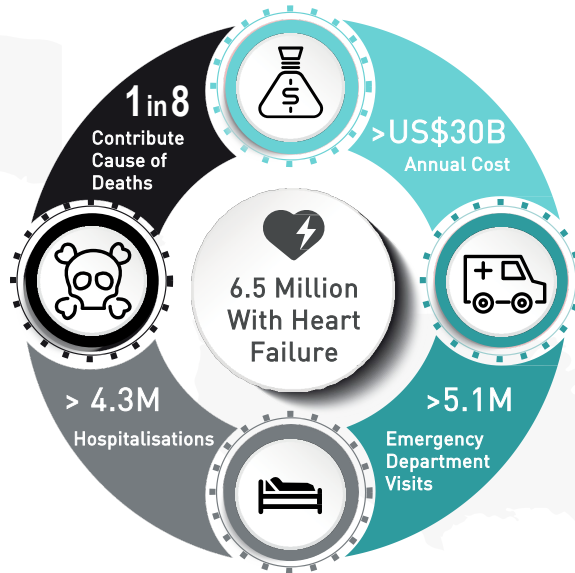
Do not have appropriate and timely access in the cardiology department of a public hospital to diagnostic tests

60%

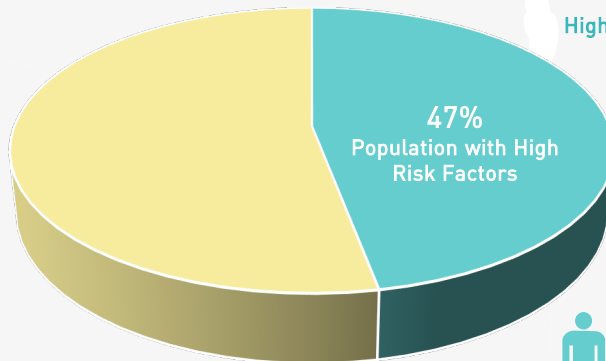
Patients do not have access to follow up treatment programs on adherence and lifestyle management

3.2 Target Market: Primary Care

ESN Cleer’s current primary focus is primary care market segment. While we have a global solution, our first market entry is targeted for the US. Annually over 230 million general and family practice visits take place in the US, excluding specialists. Statistically, 47% of the US population are prone to developing early heart failure disease by having 1 of the 4 major factors. This forms the basis of the market opportunity.



230M General & Family Practice
Physician Visits Per Year



- High Blood Pressure
- High Cholesterol
- Smoking
- Obesity / Pre-diabetes, Diabetes



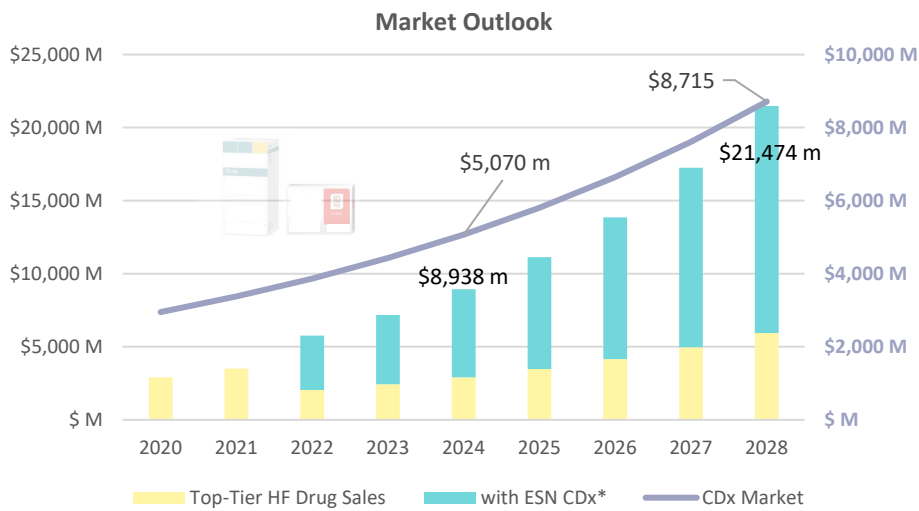
108 million

3.3 Pharmaceutical Market

ESN Cleer’s solutions will support the most recent established SGLT2i drugs in managing an early risk of heart failure. The device can dramatically increase SGLT2i drug utilization as there is currently a limited uptake of this drug class because it is a 6th-line agent for the treatment of established heart failure with inadequate screening or preventative applications available. ESN Cleer is making substantial progress with these Pharmaceutical companies, towards collaboration on a combined risk detection–drug heart failure disease prevention treatment solution. The collaboration may radically enable people with early risk to take control and minimise further disease development.

3.4 CDx, Early Heart Failure Drug

In recent years, there has been a significant increase in CDx deployment globally for personalised medicine. Multi-million dollar strategic partnerships continue to rise to provide fully integrated detection-treatment solutions. ESN Cleer is at the forefront of the next wave of CDx applications in cardiology.



Total Heart Failure drug market is at 19.5% CAGR, from \$20B in 2018 to \$118B by 2028, with Generic competing Top-Tier heart failure drugs expected by 2022. ESN Cleer CDx solution can support sustainable Top-Tier drug sales with its added IP protection. Total Companion Diagnostic Devices market is at 14.5% CAGR from 2019 to 2025.

Source: Pharmaceutical Technology, IndustryARC
* Projected ESN Cleer CDx application

The CDx model has been a proven detection-treatment mechanism with successful multiple deployments in oncology¹.

BRCAAnalysis
A test for Hereditary Breast and Ovarian Cancer (HBOC) syndrome

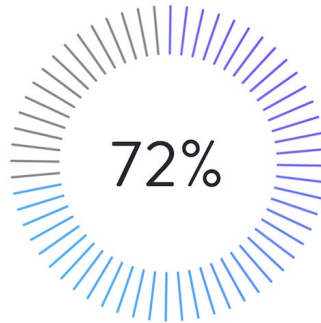
Strategic Pharma Partnership
CDx FDA Approved
US\$4,000 per test with successful Reimbursement

CDx Solution for Cancer Detection

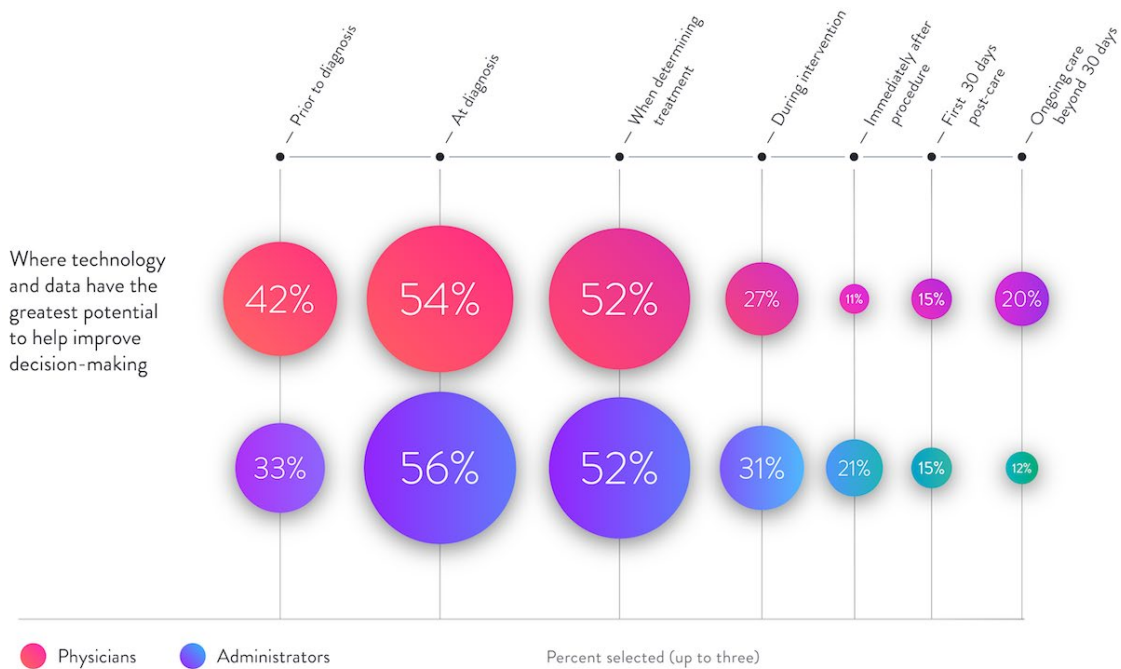
¹ “List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)”, [US FDA](#), August 2020

3.5 Market Demand

The demand for technology innovation continues to grow rapidly. A recent study² has shown strong emphasis for technology and accurate decisions before intervention. The study included a survey of over 1,400 physicians, administrators and patients throughout nine countries between December 2019 and January 2020. The results have further substantiated ESN Cleer’s solutions are well aligned to the market needs.



Patients want doctors with ability to see patients’ problem with tailored actions²



Technology has the potential to help connect the dots across the care continuum - not just at the point of intervention.²

² “Beyond Intervention: Personalized Vascular Care Through Technological Innovation”, [Abbott](#), August 2020

3.6 Competitive Landscape

There is no straightforward way to diagnose heart failure. Patients undergo a physical exam, blood tests, an electrocardiogram, an echocardiogram, and an exercise stress test (Peak VO₂ exam). These occur in a clinic, are expensive and are typically not carried out if a patient is asymptomatic.

There is a significant market opportunity for an effective, low-cost consumer saliva test for the rapid detection of early heart failure risk. Currently there are no comparable products in the market. Consumers typically wait until they are symptomatic to obtain medical attention and the expensive testing outlined above.

There is an internationally recognised clinical need for pre-screening for heart failure risk with an inexpensive, non-invasive test. Compared to other screening and monitoring approaches, ESN Cleer aims to be the only effective, cost effective, rapid, non-invasive, pre-diagnostic screening test for heart failure risk once commercialised. ESN Cleer seeks to position its proposed solutions as the primary screening tool for heart failure risk detection.

3.6.1 Biomarker Research

Over the years, there has been a number of heart failure – biomarker researches taken place. ESN Cleer is clearly outperforming the researches in the market to date. A recent research of significance was completed by a multi-collaboration between several Australian universities and hospitals.

	Early Risk of Heart Failure Detection	Instant Results	Affordable	Non-Invasive	High Accuracy
ESN Cleer	Can detect imminent Risk (<3 months) and medium term risk of Heart Failure (3 months to 2 years)	< 5 Minutes	US\$100	Saliva test	Sensitivity – 97% Specificity – 91%
NT-Pro-BNP	Can detect an increase in risk of Heart Failure developing over long term – 5 years	Not Available, laboratory processes required, days to weeks lead time for results	Estimates at US\$250 minimum	Invasive blood test	Sensitivity – 76% Specificity – 47–69%

3.6.2 Current Market Non-Invasive Applications

The following are some of the more popular generic tests that have emerged with general acceptance as possible tools for pre-diagnosis of health status. ESN Cleer expects to lead the market in terms of focus (specific health issue), cost (substantially cheaper), accuracy (non-generic specific biomarker-antibody based) and speed (results in minutes instead of weeks).

	ESN Cleer EHF-ESwab	23andMe	Genos	Veritas Genetics
Service	Biomarker test	SNO genotype testing	Exome sequencing	Whole genome sequencing
Result wait time	Minutes	4 weeks	9 weeks	7 months
Cost	Projected: US\$100	US\$199	US\$499	US\$999
Opt-in for research	✓	✓	✓	✓
Allows download of raw data	✓	✓	✓	✓ (US\$99 fee)
Early detection of heart failure risk	✓	✗	✗	✗

3.6.3 Recent New Cardiovascular Devices

The common focus of innovative cardiovascular devices in the market are post-diagnosis monitoring equipment. ESN Cleer will have the only device that screens for early risk of heart failure disease, asymptomatic preventative solution.

	ESN Cleer EHF-ESwab	Genetic tests (as above)	Shape Medical Systems	Repirix	Innamed
Status	Startup	Established	Established	Startup	Startup
Purpose	Screening of Heart Failure Risk	General Health Info	Post-diagnosis monitoring	Late stage detection	Post-diagnosis monitoring
Target	Asymptomatic Heart Failure	General DNA gene	Systemic heart failure physiology	Cardiac monitoring	Chronic conditions
Type	Saliva	Saliva	Cardio pulmonary exercise testing	Physiological signals	Blood
Location	Primary Care / Home	Home	Clinic	Critical care / in-patient	Home test / remote monitor
Results	Primary Care / Home	Send away	Onsite	Onsite	Monitored
Timing	Minutes	Several Weeks	Minutes	Minutes	Minutes
Cost	US\$100	US\$199 – US\$999	n/a	n/a	n/a

3.6.4 Market Trends

In recent years, the health industry has seen enormous continuous growths, especially with the latest global COVID-19 pandemic. The most astounding growths seen are the Telehealth and Health & Awareness industries. ESN Cleer’s solution will have multiple industries access opportunities.



“US Telehealth Market to reach **\$266.8 Billion** by 2026”,
Fortune Business Insights 2020



“The Health & Wellness Industry Is Now Worth **\$4.2 trillion**”,
Medium 2019



COVID-19 and CVD

Individuals with pre-existing medical conditions, such as heart disease, are at higher risk

4. Commercialization Pathway

4.1 Go to Market Strategy

ESN Cleer has developed strategic partners development plan designed to minimise capital requirements and accelerate commercialisation. The plan is focused on pharmaceutical company collaboration, manufacturing partnership and industry endorsements (traction).

Pharmaceutical Partnership	<ul style="list-style-type: none"> Materials support with clinical validation (supporting data for FDA) Develop JV collaboration, ESN Cleer solution - SGLT2i drug treatment solution Provide distribution channel access Collaborate prospective study towards reimbursement
Cardiovascular Specialist Alliance, Traction	<ul style="list-style-type: none"> <i>EHF-Test Kit</i> first product launch Cardiovascular specialist's distribution network Establish market confidence Enable early sales and traction
Manufacturing & Distribution Partner	<ul style="list-style-type: none"> <i>EHF-ESwab</i> second product launch Scale up manufacturing Distribution operations
Endorsement, Traction	<ul style="list-style-type: none"> Cardiovascular specialists Influential groups, associations Non-profit organisations
Government, Commercialisation Support	<ul style="list-style-type: none"> Influential government network Regulatory specialist Reimbursement specialist

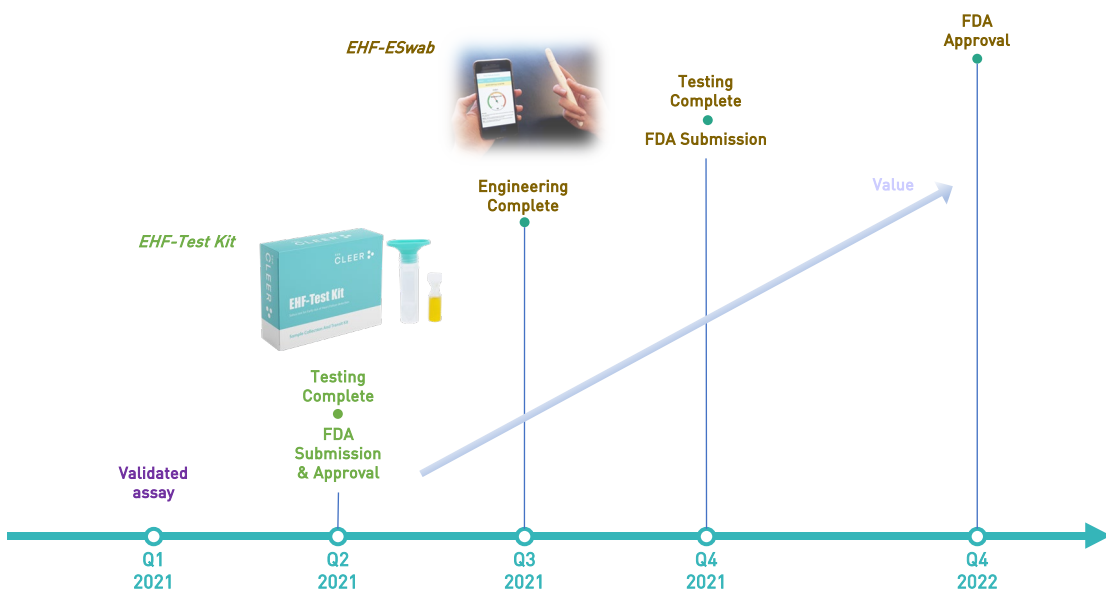
4.2 Achievements, Development & Value Inflection Pathway

Advanced medical, technological engineering and regulatory specialised teams has been assembled. Coupled with artificial intelligence and machine learning developments, will enable ESN Cleer to accelerate towards market entry.

Meticulous product requirements and compliance will ensure the device:

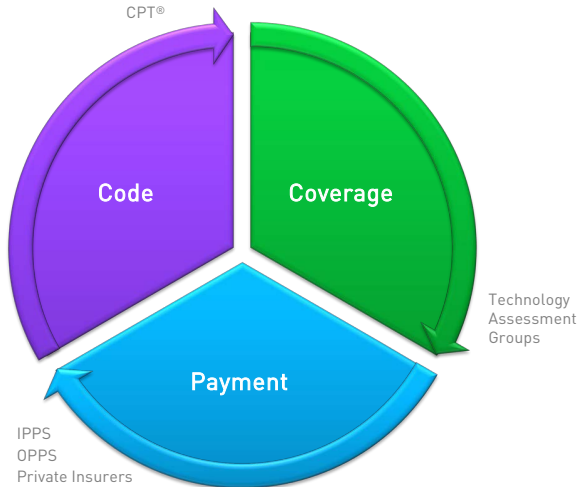
- has been designed and tested in accordance with stringent quality systems;
- complies with all necessary standards and regulations; and
- is safe and fit for its intended use.

ESN Cleer's major product development phases indicative timeline is shown below.

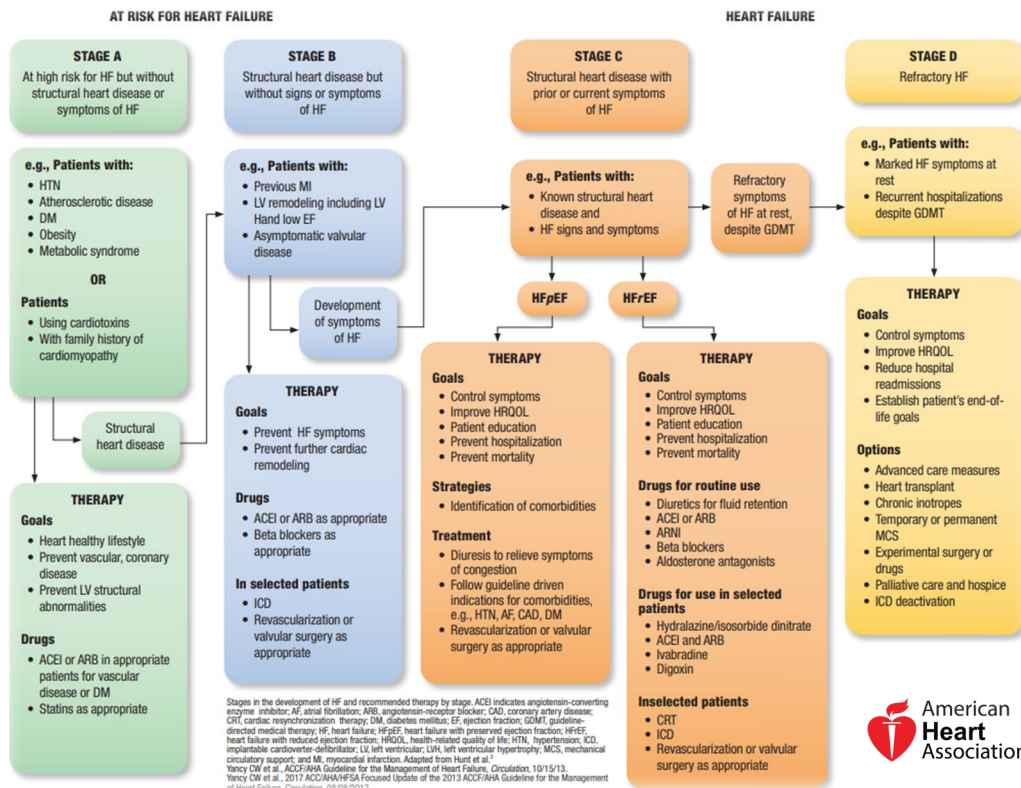


4.3 Reimbursement, Heart Failure Guideline Pathway

ESN Cleer will progress towards reimbursement with its distinctive advantages of reducing emergency heart failure hospitalisations and as a heart failure patient monitoring tool. Initial market inception phase will be supported by ESN Cleer as part of its marketing and regulatory budget. ESN Cleer will subsidise for the devices of the initial tests conducted by physicians for the first year of market rollout. The data gathered will support its reimbursement initiatives.



In parallel, the data will also support the specific coupled SGLT2i drug preferential advancement on the heart failure guideline. This will be achieved by continuous concurrent post-market data and cardiomyopathy cohort development, progressing as the preferential detection-treatment.

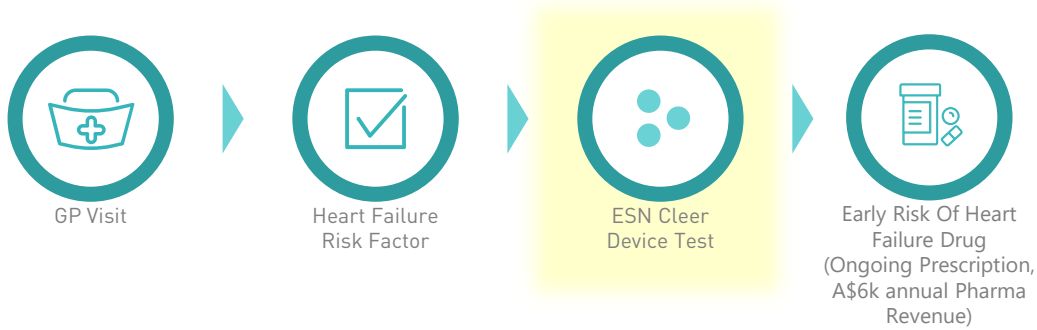


5. Financial Information

5.1 Revenue Model

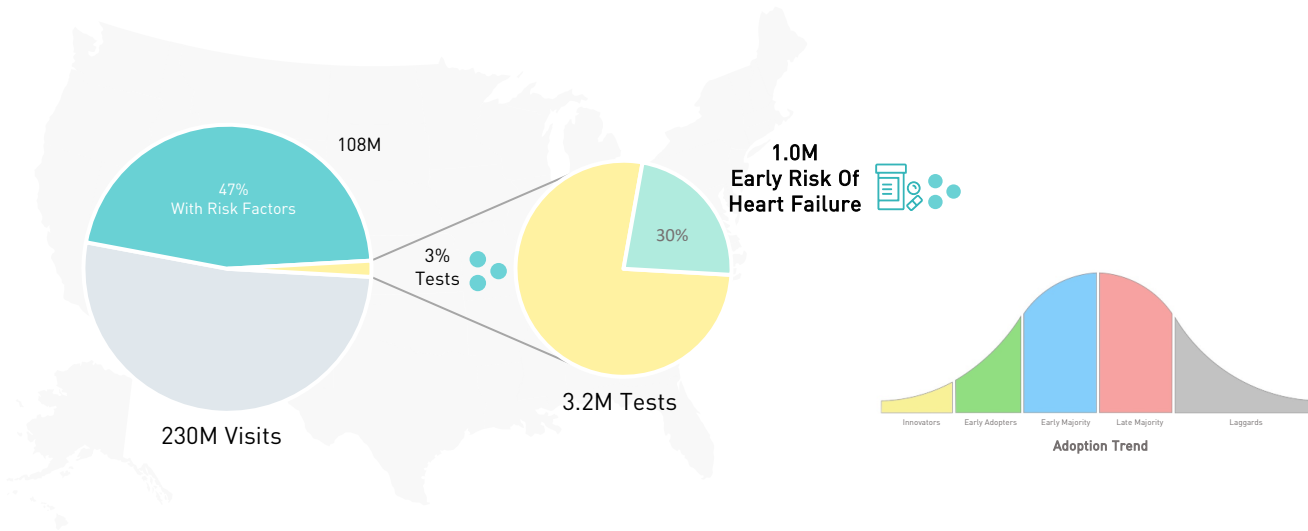
ESN Cleer's primary care revenue model is based on two principal sources throughout the patient journey.

- Device is procured for the initial test: Manufacturing distribution partner royalty
- The SGLT2i drug initial prescription: Pharmaceutical partner charge



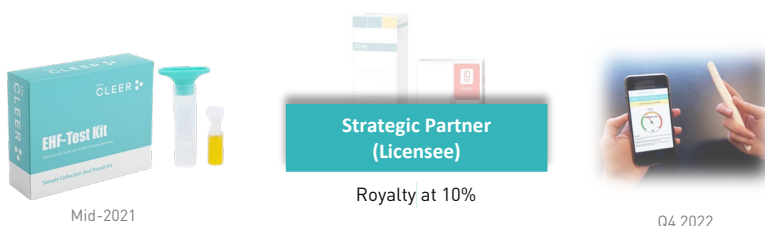
5.1.1 Principle Forecast

The conservative revenue forecast is based on US healthcare statistical data and novel technology market adoption trend normal distribution estimates.



5.1.2 Revenue Streams

ESN Cleer is anticipating the EHF-Test Kit will be launched into the market by mid-2021, generating early revenue. While EHF-ESwab will begin market deployment during Q4 2022. Strategic partnership with pharmaceutical or medical devices organisations will be formed to collaborate on licensing business model basis.

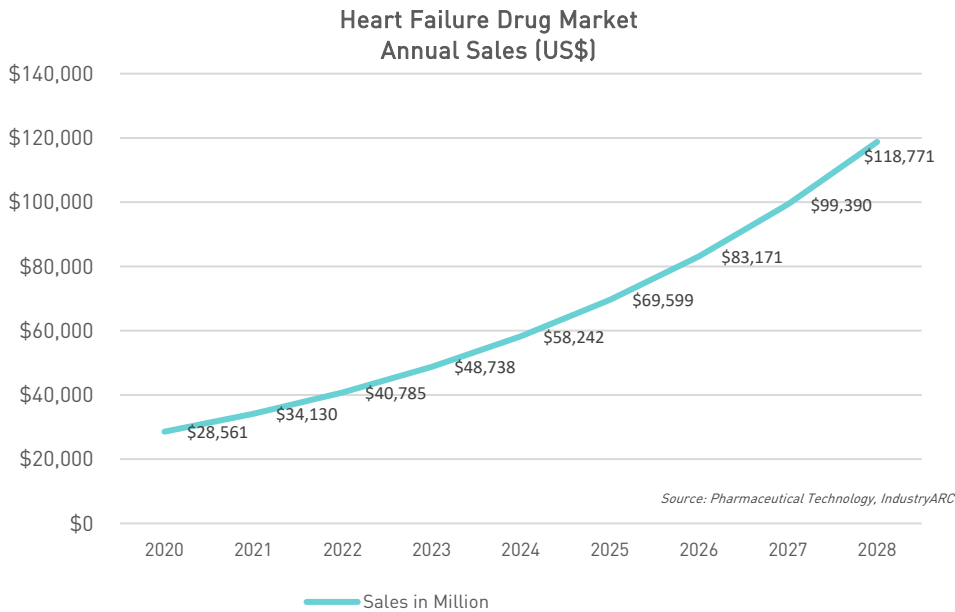


5.2 Stakeholder (Strategic Partners) Value

ESN Cleer’s vision is to provide substantial financial growth to its stakeholders, in particular – the pharmaceutical and manufacturing distribution partners, while ESN Cleer maintains focus on its core innovation and technological solutions development.

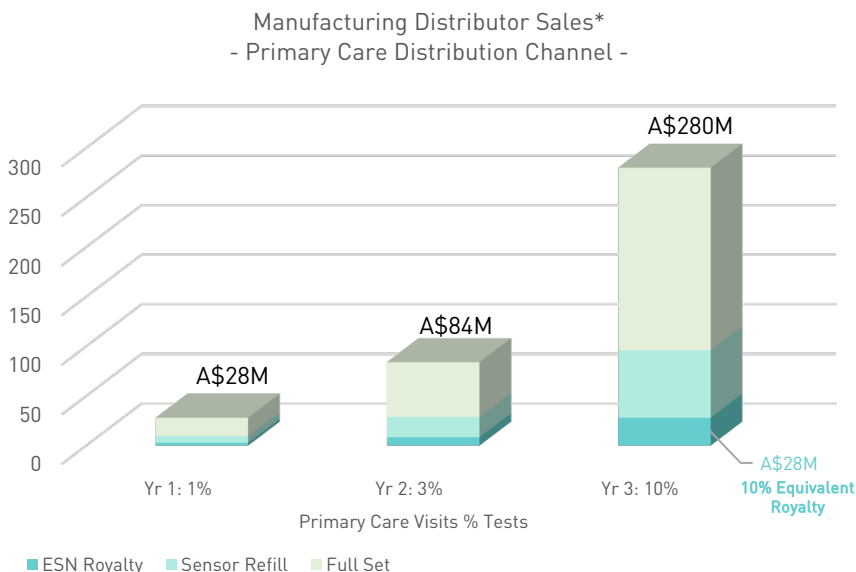
5.2.1 Pharmaceutical Partner

Total Heart Failure drug market is growing at 19.5% CAGR, from US\$20B in 2018 to an expected US\$118B by 2028. Fierce competition is expected with generic drugs entering the market. The ESN Cleer solutions will provide pharmaceutical partner/s with an exceptional competitive advantage and protection.



5.2.2 Manufacturing Distribution Partner

The ESN Cleer *EHF-ESwab* will enable substantial growth to its manufacturing distribution partner, leveraging its expertise in manufacturing and distribution channels. While primary care being the initial focus, other market sector distribution channels will become accessible as ESN Cleer’s solutions continue to evolve, with opportunities for home-use.



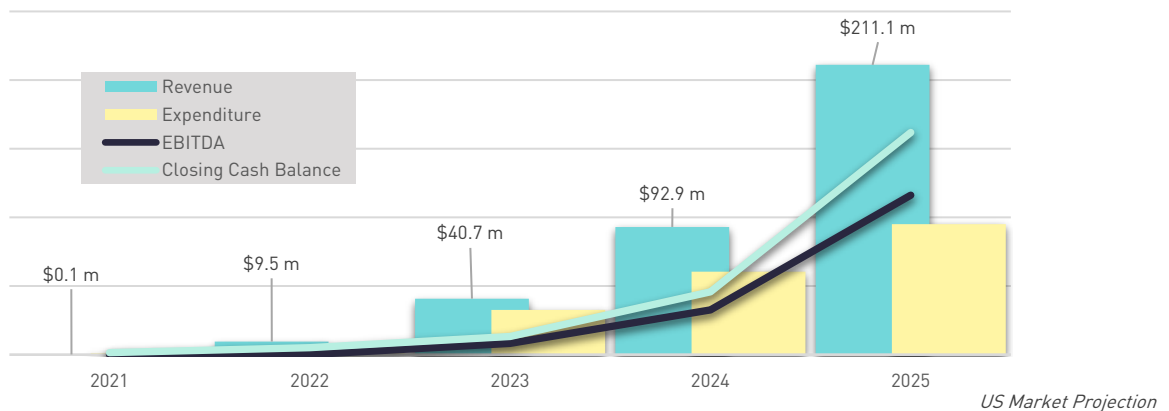
* Based on 30% Full Set, 70% Sensor Refill

5.3 Financial Indicators

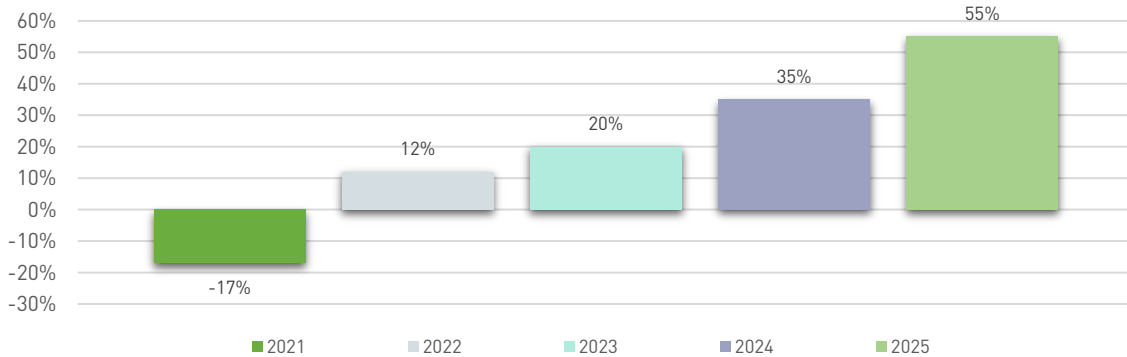
ESN Cleer’s financials are based on the following principle assumptions:

- Revenue and Operational Expenses accounts solely for primary care market sector as per Revenue Model outlined, excludes any other revenue opportunities.
- Capital Expenses (e.g. regulatory, development) does not include additional new product development.
- Gradual annual market adoption growth expected, while substantial adoption is expected by 4th year in market with reimbursement becoming available.

Key Financial Indicators - Years 1 to 5 (A\$)



EBITDA Margin % - Years 1 to 5



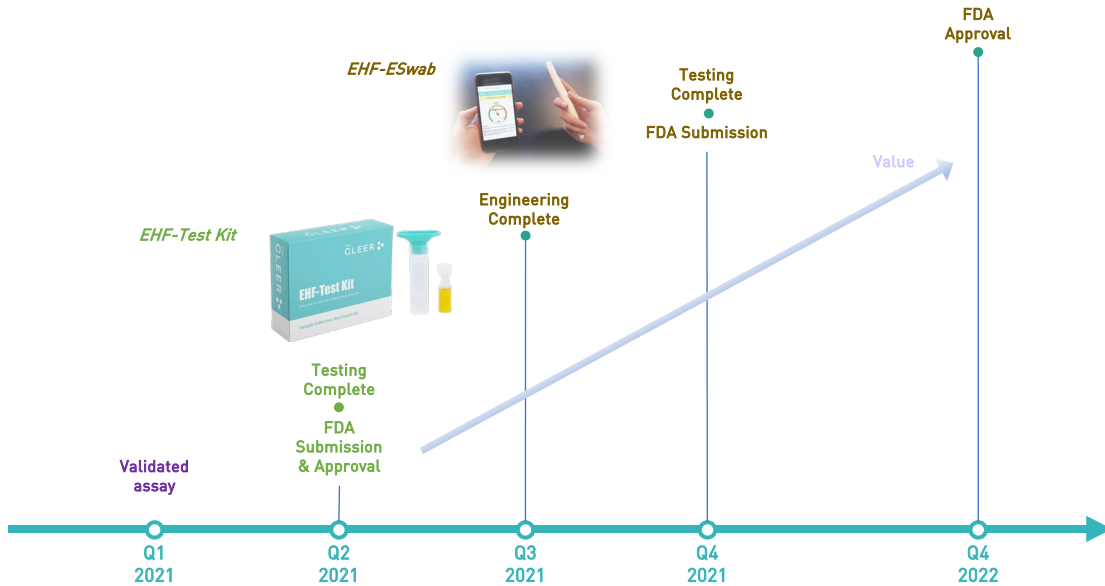
5.4 Additional Opportunities

There are several opportunities that can outperform the current forecasts providing substantial uplifts for ESN Cleer and its stakeholders.

- Pharmacy retail (additionally supported by in-store clinics)
 - Top 8 US pharmacy retail chains with over 33,000 stores
 - National Association of Chain Drug Stores with over 40,000 stores
- Telehealth sector
 - US Telehealth market to reach over US\$226 billion by 2026
- US Health Insurance sector
 - Top 5 largest US health insurance companies with over 140 million members
- Global opportunities
 - The ESN Cleer solutions are global
- Data
 - Regulated data monetarization in support for future disease, treatments developments and personalised medicine

5.5 Value Inflections & Exit Opportunities

The market positioning of ESN Cleer’s novel solution with its strong potential revenue and opportunities provides the Company’s substantial strong valuation growth potential. The valuation of ESN Cleer will also increase pre-revenue as value gates are passed with its progression. Each of these validation gates provides exist opportunities with JV or M&A activities. Substantial value inflections are expected as major milestones are reached. It is ESN Cleer’s endeavour to expedite with highest efficiency to achieve continuous progression.



Typically, major pharmaceutical companies evaluate investment, partnership or acquisition opportunities when clinical validation or regulatory approval is achieved. ESN Cleer has begun early collaboration with a global pharmaceutical company with a recently launched SGLT2i early stage heart failure drug. The medical device industry is highly acquisitive globally, especially in diagnostics and cardiovascular devices, with many recent exits. Recent examples of major exits include:



Genetics Test, 2018,
\$375m Acquisition



Remote Heart Failure
Patients Monitoring,
2014, \$455m
Acquisition
(St Jude Medical – Abbott)

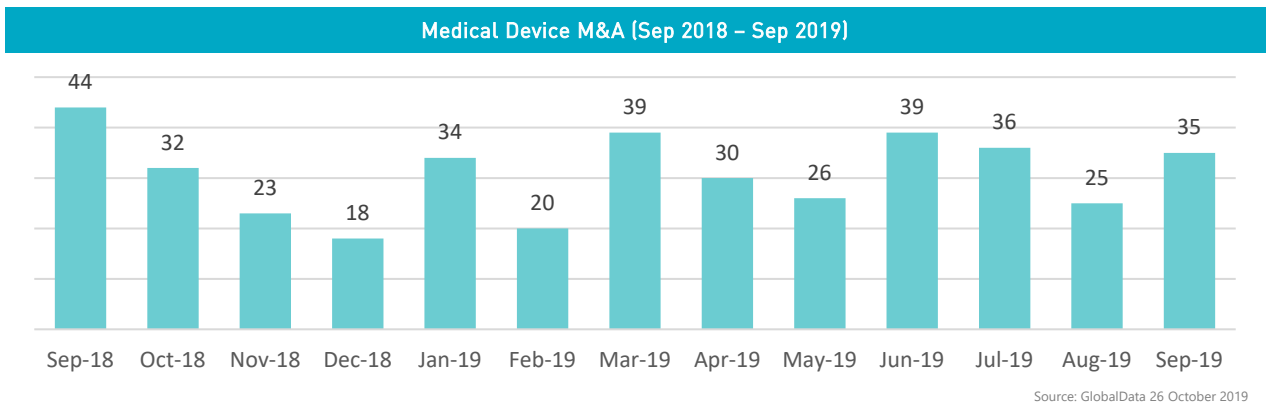


Genomic Profiling,
2015, \$2.4b
Acquisition

Company	Acquirer	Category	Valuation	Date
Corinder Vascular Robotics	Siemens Health	Cardiovascular	US\$1.1B	Aug 2019
Mobius Imaging	Stryker	Diagnostics	US\$500m	Sep 2019
Blue Earth Diagnostics	Bracco Imaging	Diagnostics	US\$475m	Jun 2019
Endospan	CryoLife	Cardiovascular	US\$450m	Sep 2019
SentreHEART	AtriCure	Diagnostics	US\$300m	Aug 2019
Cheetah Medical	Baxter International	Cardiovascular	US\$230m	Sep 2019

“These devices are not expected to replace the drug; rather, they may amplify the effectiveness of certain treatments as they sit alongside existing therapies.”, GSK

In the period from September 2018 to September 2019, 401 medical device acquisitions have taken place.



ESN Cleer continuously attracts global enterprises for collaborations. It is in its endeavour to capture the opportunities while maintaining agile and vigilant for potential exit opportunities.

6. Funding Program

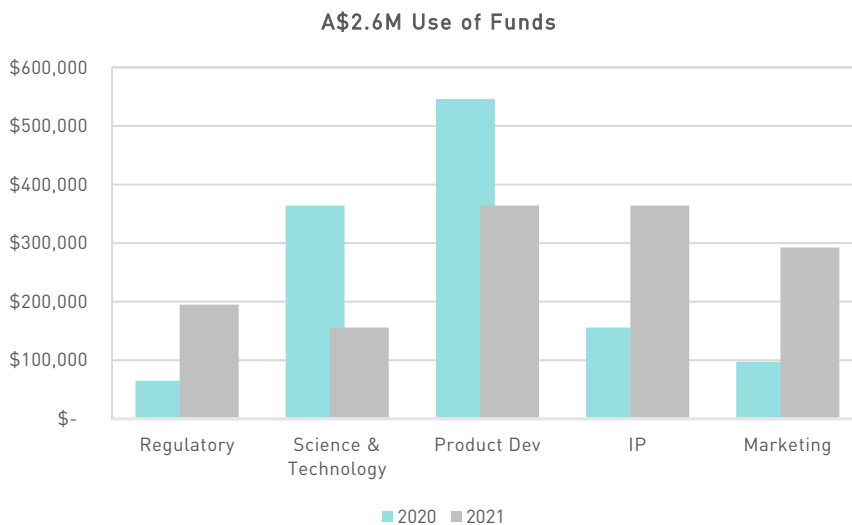
6.1 The Investment Offer

ESN Cleer presents a ground-breaking technology that will save lives. The ESN Cleer solutions has global potential once commercialised and in the market. ESN Cleer has reached the following substantial milestones:

- Peer-reviewed data from a sample of 188 people demonstrating overall detection at above 90% accuracy
- Completed engineering samples in collaboration its medical device design partner
- Clinical validation protocol designed, ready for implementation
- Established database and developed algorithms with proprietary machine learning platform to power the app's capabilities
- Submission of initial patent families and licensing of key pieces of intellectual property
- Begun multiple strategic partnership engagement
- Committed distinguished board and team
- A\$2.5M capital raised to date
- A\$3.5M Australian government IMCRC grant
- Named Amongst Top Tier Start-ups



ESN Cleer is raising up to A\$2.6 million capital. The funds together provide the runway for the Company to fund the following:



ESN Cleer is also eligible for a number of Australian grants such as Accelerating Commercialisation grant and R&D tax incentive rebates. There are also potential overseas government and industry grants the Company may be eligible for. Each of these can provide sources of non-dilutive funding to the Company.

6.2 Investment Attributes

The present shareholders have invested into ESN Cleer, which has helped to de-risk the business. For this contribution, they will retain a significant portion of the shareholding following the offer. Investors will benefit from the following:

- **Financial and time investment to date:** The ESN Cleer management team, investors, and partners have invested A\$2.5 million and considerable resources into design, intellectual property, technology development and partnerships to date.
- **Key intellectual property assets:** ESN Cleer has patent applications across several patent families that are at the core of its solution creating barriers to competition.
- **Ongoing management and development of the business:** The founders, board and executive teams have a deep affinity with the ESN Cleer business. This is a multi-year business plan and there is a commitment to ensure the business is successful.
- **Secured a world class go-to-market team with deep industry knowledge:** ESN Cleer has an experienced executive, clinical and science team, and is supported by leading heart failure specialists. The broader team is experienced in all aspects of the business necessary to successfully bring ESN Cleer solutions to market.
- **Value of the business model:** ESN Cleer has adopted a business model to maximise the full commercial potential of the Company.

6.3 Proposed Share Capital Structure

The proposed share capital structure at the completion of the Offer is as follows:

Share Capital Structure	
Proceeds under the offer	A\$2.6 million
Issue price	A\$1.40
Total number of shares available under the offer	1,857,143 15.6%
Total number of exiting shares	9,997,230
Total number of shares at the completion of the offer	11,854,373
Valuation at completion of the offer	A\$16.6 million

The company reserves the right to alter the share capital structure, or the share capital structure may alter if the Offer is not fully subscribed. The Company reserves the right to complete the capital raising if a lower amount than the target is achieved. The minimum amount to proceed is A\$300,000.

ESN Cleer is positioned to capitalise on its success to date and accelerate its go-to-market strategy.

“Heart failure affects approximately 64 million people worldwide, and about half will die within five years of diagnosis. It is also the leading cause of hospitalization for those over the age of 65 and represents a significant clinical and economic burden. Digital solutions such as the one being developed by ESN Cleer have the potential to help healthcare systems fighting heart failure and its associated burden by providing affordable and scalable early diagnostic tools.”

Olivier Delannoy
 Senior Director - CVRM Engagement
 Global Commercial Digital
 AstraZeneca



Global Multi-Billion Dollar Opportunity

Protected Core Intellectual Property

De-Risked Development Pathway

2 to 3 Years ROI



The Offer opens on the date of this document with ESN Cleer able to receive Expressions of Interest. Investors wishing to participate can contact:

Leo De Bruin
 Managing Director

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 E: ldebruin@cleer.com.au