

AureumDX

INFORMATION MEMORANDUM

.....

DECEMBER 2023



AUREUM
DIAGNOSTICS

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EXECUTIVE SUMMARY

AureumDX is focused on the development of high-performance, low-cost electrochemical biosensing platforms for key target partners in the high value decentralised point of care medical diagnostics and biosafety markets.

Led by CEO Oliver Davies, CSO Prof Damion Corrigan and COO Tessa Ogle, the company has built a strong and commercially viable business since launch in late 2021 following a £3.5 million seed funding round.

The leadership team is supported by an exceptional advisory board consisting of leading industry experts in the areas of commercialisation, marketing, business strategy, advanced reagents development, process engineering, quality, regulatory and product development.

With experience of developing and manufacturing multiple high value medical diagnostic products (sales > \$10 billion, including LifeScan's One Touch Ultra Blood Glucose monitoring platform) the AureumDX team has from the outset designed their product platforms using robust regulatory approved materials that are fully compatible with low-cost high volume test strip manufacturing processes.

AREAS OF FOCUS

The company is focused on the development of high-performance and low-cost electrochemical biosensing platforms for the \$50 billion point of care (POC) medical diagnostics and \$4.9 billion biosafety endotoxin testing markets. Its products consist of a measurement platform comprising a low-cost hand-held connected instrument and very low-cost single-use disposable test strips.

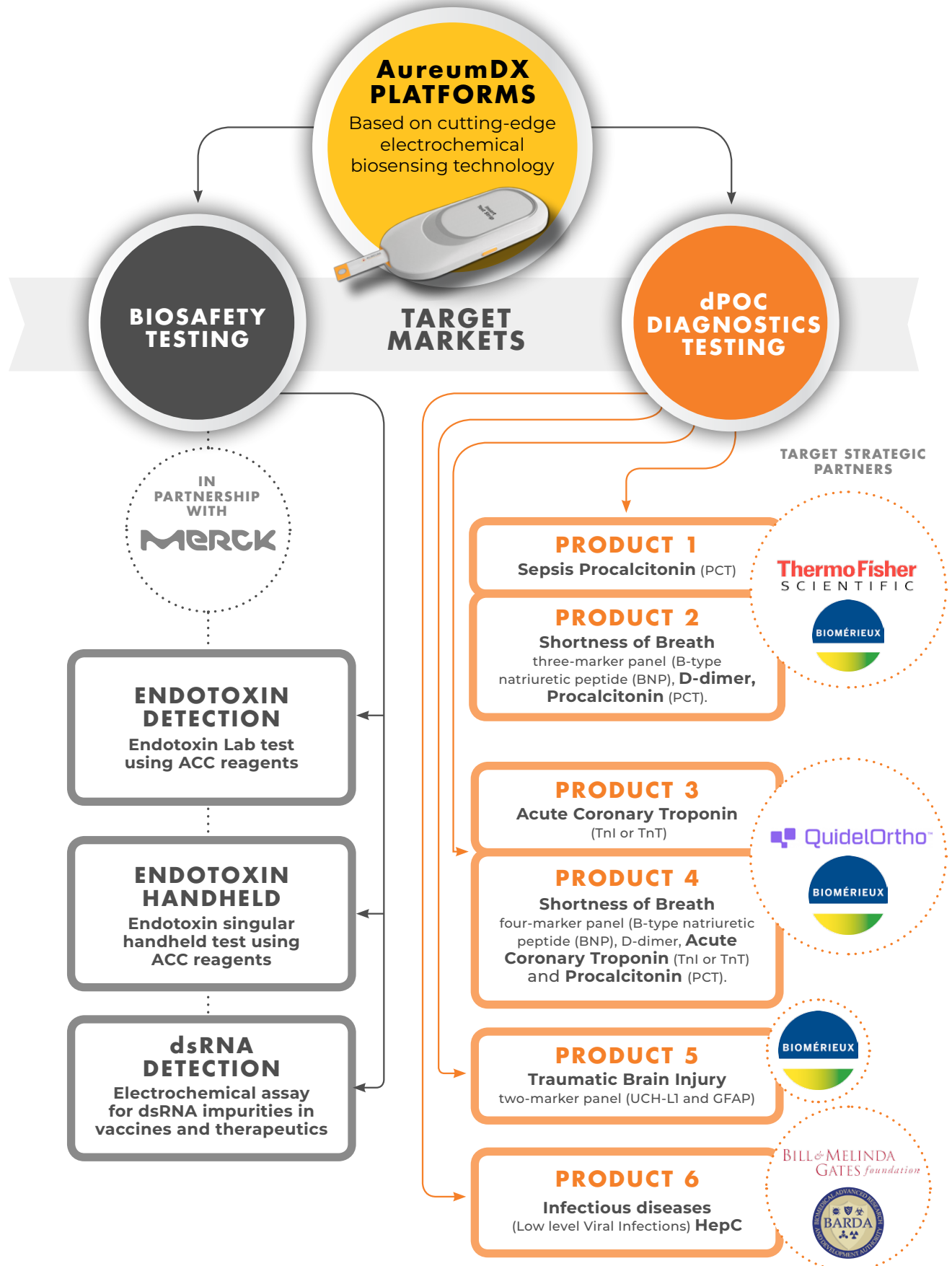
The electrochemical assay platforms deliver the following important competitive advantages:

- Simple, accurate, one-step testing in any environment
- Rapid test time, suitable for in-process testing or a doctor-patient consultation
- Ability to measure multiple substances at high sensitivity in different sample types
- Affordable high-margin products (very low-cost instrumentation and test strips)
- Low environmental footprint of products and manufacturing processes



PRODUCT & TECHNOLOGY OVERVIEW

Two patent-protected electrochemical biosensing assay platforms are under development, each meeting clearly defined unmet needs in the biosafety and point of care diagnostics markets.



MARKETS

BIOSAFETY

All pharmaceutical products have to be tested for freedom from endotoxin which can cause fever and septic shock in patients. Merck KGaA (Merck) has chosen AureumDX as its exclusive partner to achieve a strategic goal of significantly growing its market share in the global endotoxin testing market. This is a high margin market with annual global revenues of \$2.5 billion.

Working in partnership with Merck our first biosafety testing product allows for rapid and highly sensitive detection of endotoxins in raw materials and at each stage of the manufacturing process.

Under the terms of the agreement, Merck is funding a phased R&D program to develop a highly innovative endotoxin test and AureumDX will retain the platform intellectual property and exclusive manufacturing rights. Minimum order quantities have been agreed (minimum value £1.5 million pa).

Merck have a stated goal achieving revenues of \$230 million from its AureumDX enabled endotoxin detection business within 5 years. This equates to \$84 million in revenues to AureumDX.

Within 9 months AureumDX has successfully demonstrated a novel electrochemical endotoxin assay with cost and performance advantages over existing commercial assays. Crucially, the AureumDX endotoxin assay is fully compatible with newly developed recombinant endotoxin reagents thus overcoming the serious ethical concerns of using of horseshoe crab blood extracts, as used in many existing competitor endotoxin assay systems.

This important technical achievement aligns strongly with our core value of delivering fully sustainable, low environmental impact product solutions and has strengthened Merck's commitment to their partnership with AureumDX.

In response to AureumDX's rapid technical progress Merck has agreed in principle to fund the £4.1 million development, validation and regulatory approval activities required to bring AureumDX's endotoxin sensing product to market in Q3 2025.

Whilst AureumDX was originally founded with a primary focus on the point of care in-vitro diagnostics market, the scale and technical synergies of the Merck partnering opportunity were immediately apparent. Recognising the commercial, operational and reputational value that an early and well-funded partnership with Merck brings, AureumDX made the proactive decision to recruit additional technical staff to resource the Merck endotoxin detection project.

DECENTRALISED POINT OF CARE DIAGNOSTICS (dPOC)

In reacting to the Merck commercial opportunity AureumDX has not been distracted from its mission to develop game changing product platforms for the point of care diagnostics market.

AureumDX consider this \$50 billion market ripe for significant disruption through the introduction of next generation, high performance biomarker detection products.

Currently tests taken at POC have to be referred to central laboratories with attendant cost and delay. Speed and accuracy are important in treating time sensitive conditions like heart attack and sepsis. In the case of sepsis one hour delay in diagnosis results in a 10% increase in mortality. The availability of cheap rapid POC tests will have a major impact on democratising health care.

However, to date few point of care biomarker detection platforms have been developed that can quickly, accurately and reliably measure these biomarkers. Those platforms that do exist require complex and very expensive instrumentation, which has substantially limited product adoption.

Accordingly, the widely accepted need to enable earlier disease diagnosis through low cost and decentralised point of care disease biomarker testing has not been realised.

In recognition of this significant market gap AureumDX was founded to develop and commercialise a radically differentiated low-cost high-performance point of care medical diagnostics platform for the rapid, simple and reliable detection of blood-based disease biomarkers.

From the outset AureumDX's unique electrochemical POC biosensor platform has been designed to deliver market leading biomarker measurement sensitivity whilst ensuring unrivalled product simplicity and affordability.

The one step "sample to result" POC biosensing platform ("Hydra") is designed to quantitatively measure low concentration disease biomarkers from a small capillary finger stick blood sample.

The Hydra platform will enable the rapid diagnosis of conditions including sepsis, heart attacks and heart failure with a simplicity and affordability that will transform how and where POC tests can be used.

AureumDX's first product will enable the rapid point of care measurement of procalcitonin (PCT), a major biomarker for the indication of sepsis.

The centralised PCT market is valued at over \$500 million globally and the availability of a decentralised point of care PCT assay is expected to drive significant additional market growth opportunities.

The company plans to launch its PCT test by Q3 2026 in partnership with an existing market leading company.

The ultra low-cost Hydra handheld instrument will have a manufactured cost-of-goods (COGS) of between \$15 and \$30 compared to the \$1000 – \$5000 COGS of competitor instruments.

The unique Hydra electrochemical test strip design can be manufactured in high volumes for less than \$0.50 each in comparison to >\$5, which is the estimated minimum COGS for the competitors' test cartridges.

AureumDX's innovative Hydra platform represents a generational leap in product performance, simplicity, manufacturability, and market acquisition cost.

AureumDX will bring diagnostics closer to the doctor-patient consultation and remove the inefficient workflow associated with central laboratory testing.

Estimated total revenues to be \$84 million in 5 years.

With a fully working "sample to result" prototype AureumDX are now ready to accelerate our product development activities and engage with strategic commercial partners.

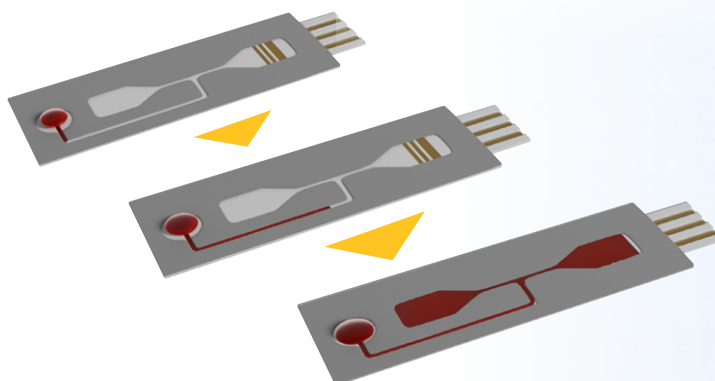
NEXT STEPS

Revenues from launch of the endotoxin platform will begin in late 2025 and are expected to grow considerably during 2026 and 2027.

Having substantially de-risked many important technical and commercial aspects of the business AureumDX now intends to bring in additional equity investment to accelerate its product development, manufacturing and commercialisation activities.

The company intend to raise up to £7.5 million to enable the business to achieve a series of high value milestones over the over the next 2.5 years. The investment will be allocated towards accelerated product development of the first Hydra products, building manufacturing capabilities, the purchase of necessary capital equipment, expanding headcount and funding the drive towards achieving regulatory approval for the first POC products.

The funding will enable AureumDX to quickly and efficiently achieve key milestones and valuation inflection points.



2024-26 KEY TECHNICAL, COMMERCIAL & BUSINESS MILESTONES



In-house fast test **prototyping** facility

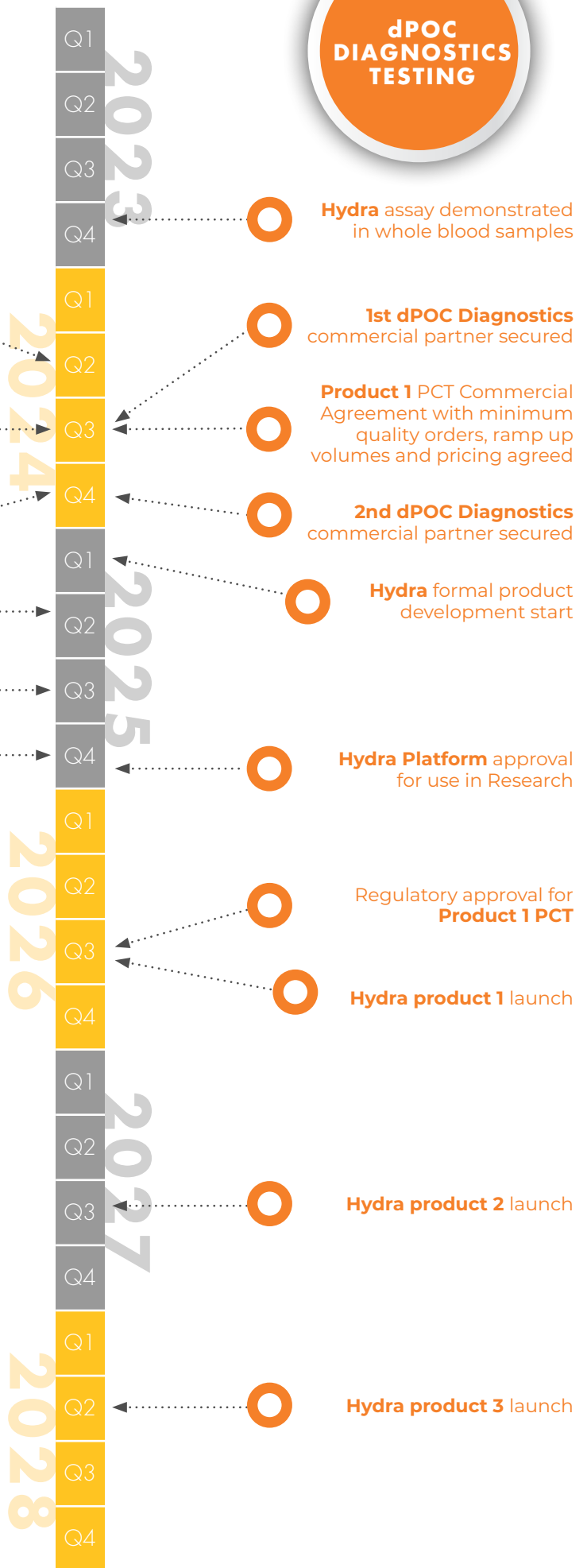
Merck Commercial Agreement with minimum quality orders, ramp up volumes and pricing agreed

Merck Endotoxin detection product design complete

Endotoxin Detection Regulatory approval

Merck Endotoxin Detection system lab product launch

Merck Endotoxin Detection system infield product launch



INVESTMENT SUMMARY

EQUITY OFFERED

23%

MAXIMUM FUNDS TO BE
RAISED UNDER OFFER

**£7.5
MILLION**

TYPE OF SHARE
BEING OFFERED

**A1
ORDINARY SHARES**

PRE-MONEY VALUATION

**£25
MILLION**

1. AureumDX OVERVIEW

AureumDX brings together the skills, facilities, technology, IP and industry network necessary for delivering disruptive medical diagnostics and biosafety product solutions.

Founded in 2021 with seed funding of £3.5 million AureumDX is led by a diverse executive team whose skills are complemented by a highly experienced team of industry expert advisors.

The company has a 3000 sq ft facility at Maxim Park, Eurocentral near Glasgow in Scotland, which includes office space, laboratories and small-scale test strip prototyping space.

AureumDX is engaged in the design, development and manufacture of high performance low-cost electrochemical sensing products. The company's evolving portfolio of innovative sensing technologies has high value application across a range of industries.

Significant technical, resource and manufacturing synergies exist across internal product development projects and have allowed the business to maximize value creation whilst keeping the organisation lean.

The company's close links with the University of Strathclyde are also of great value and several important AureumDX funded research projects are underway at the University under Prof. Damion Corrigan's guidance, and staffed by AureumDX employees.

The company employs 17 full-time staff and retains a number of industry experts in a consulting capacity.

AureumDX has a growing IP portfolio which protects its core innovations, retains the services of Marks and Clark IP attorneys and is represented in commercial matters by WJM.

Building on 2 years of focused product and platform development work, AureumDX is now preparing to expand its workforce, accelerate its product development activities and take on larger fully contained facilities. This phased expansion will enable the implementation of important fast-turnaround product prototyping and the creation of in-house manufacturing facilities.

2. BIOSAFETY TESTING

The biosafety testing market provides products and services to ensure that biological materials, such as drugs, vaccines, medical devices, and biotechnology products, are safe and effective for human or animal use.

Biosafety testing involves checking for the presence of any harmful contaminants, such as bacteria, viruses, fungi, toxins, or endotoxins, that could affect the quality, safety, or efficacy of the biological materials.

Biosafety testing also helps to generate certificates of analysis, which are documents that certify that the biological materials meet the required standards and specifications set by the regulatory authorities, such as the FDA, EMA, or WHO.

Biosafety testing is important for the development, manufacturing, and distribution of biological materials, as it ensures their quality, safety, and efficacy, and protects the health of the consumers and the environment.

Market Size and Growth: As of 2022, the global biosafety testing market is valued at approximately \$4.9 billion. The market has a CAGR of 12.2%. By 2032, the market is projected to reach a value of \$11.6 billion.

Merck Partnership

In early 2022 AureumDX entered into a partnership with Merck to develop novel high-performance electrochemical testing product solutions for their biosafety testing division, BioReliance.

About Merck

Merck KGaA is a global pharmaceutical and life sciences company headquartered in Germany with a market capitalisation of approximately \$63.30 billion.

AureumDX has two Merck funded projects with BioReliance, Merck's biosafety division.

Market Segments: AureumDX partner funded projects focussed on meeting Merck's needs in two key market segments:

1. Endotoxin Testing:

Market Value (2022): The endotoxin testing market is valued at approximately \$2.46 billion in 2022.

CAGR (2022-2032): This segment is expected to show a CAGR of 6.98% over the decade.

Importance: Endotoxin testing is critical in industries such as Pharmaceutical and Biopharmaceutical manufacturing, Medical Device Manufacturing and Raw Materials Production with over 70 million tests carried out per year.

2. mRNA Vaccines and Therapeutics Batch QC Release Testing:

Market Value (2022): The mRNA vaccines and therapeutics testing market is valued at approximately \$732 million in 2022.

CAGR (2022-2032): This segment is poised for strong growth with a CAGR of 8.8%.

Importance: mRNA-based vaccines and therapeutics have gained widespread recognition for their effectiveness in combatting infectious diseases and certain cancers. These vaccines are produced in bioreactors and batch contamination with double stranded RNA (dsRNA) is a well-recognised quality concern. An accurate, simple and rapid means of detecting this contamination is of critical importance for vaccine batch release testing. To date no test has been developed that delivers the desired sensitivity and specificity.

The contractual partnership with Merck is characterised by:

Broad multi-project relationship: Merck has indicated a desire to partner with AureumDX across a range of novel sensing platform development projects in the areas of biosafety testing.

Exclusive Rights: Under the existing endotoxin detection agreement, AureumDX retains the platform intellectual property and exclusive manufacturing rights for the products. In return AureumDX will grant Merck application specific patent rights and will exclusively manufacture the products for Merck.

Minimum Order Quantities: Both parties have agreed upon minimum order quantities for the endotoxin detection product. This delivers a minimum revenue to AureumDX of £1.5 million per year. MOQs currently relate to “in-lab” endotoxin testing and is set at 10,000 tests per year at a transfer price of \$150 per test. A similar agreement exists for the dsRNA project.

2.1 PROBLEM

Endotoxin Testing

Merck currently use an existing off the shelf endotoxin assay with reagents supplied by Lonza. Merck stated that this assay has several significant drawbacks:

- The assay requires high levels of trained technical resource to run and is very time consuming.
- The reagents supplied by Lonza do not meet Merck’s sustainability requirements since they are derived from Horseshoe crab blood, a species that is now considered endangered.
- Due to the complex assay logic Merck’s endotoxin testing service loses money.
- The assay is not suitable for high throughput testing, limiting the level of market share that Merck can capture.
- The assay cannot be configured for more decentralised “in field” endotoxin testing.

The above challenges mean that Merck is unable to scale its endotoxin testing service, and since this service is carried out as part of a suite of other tests, they are consequently unable to grow this significant part of their biosafety testing market share without a more streamlined lab test. In addition to this, Merck don’t have an endotoxin test kit product to sell to the wider market to compete in the products space with their competitors.

Merck recognise the significant business opportunity for the provision of a decentralised “in field” endotoxin testing product. This requires the type of low-cost handheld product format that AureumDX are expert in developing.

Merck intends to significantly grow its market share of the global endotoxin testing market. They require a strategic partnership with a company capable of both developing and manufacturing a cutting-edge endotoxin testing product that fully meets the existing and emerging market needs.

mRNA Vaccines and Therapeutics Batch QC Release Testing

mRNA vaccines are rapidly capturing significant market share due to their high levels of efficacy and rapid development time. In 2022, Pfizer and Moderna, two leading pharmaceutical vaccine manufacturers, projected nearly doubling their vaccine sales for the same year, as reported by ft.com. But it isn’t just vaccines that are driving these market increases; the mRNA-based cancer therapeutics are expected to triple in the next 5 years.

In all mRNA therapeutic products double stranded RNA is a known potential contaminant that needs to be identified and dealt with in the production process. dsRNA has the potential to provoke undesired immune responses and, in turn, diminish the potency of the therapeutic product.

To date, no effective test exists that delivers the required sensitivity and specificity.

Merck offers biosafety batch testing for mRNA vaccines and recognise the competitive value of having access to a higher performance dsRNA testing solution.

2.2 SOLUTION

Endotoxin Testing

AureumDX have developed a cost-effective test strip, utilising fully sustainable recombinant reagents. The AureumDX developed electrochemical endotoxin assay has been shown to deliver equivalent performance to existing assays but is more cost effective, better suited to high throughput testing, does not require high resource allocation and is suitable for both lab and “in field” endotoxin testing.

This project has now entered Merck’s formal stage-gated product development testing phase and further funding of £4.1 million has been agreed in principle.

mRNA Vaccines and Therapeutics Batch QC Release Testing

A \$150k funded 6-month research project has been initiated between Merck and AureumDX to explore the feasibility of developing a reliable high throughput electrochemical test to detect dsRNA contamination.

Several approaches are under investigation. If the project goals are met the project will move into a fully funded feasibility phase, under the same model used for the endotoxin detection project.

2.3 MARKET OPPORTUNITIES

The endotoxin testing market is valued at \$2.5 billion and there is an estimated 70 million tests carried out each year across a wide variety of industries and in a range of testing environments.

The market trend is towards high performance handheld testing devices used in combination with single use dry reagent test strips, as evidenced by Charles River's recent Endosafe® nexgen-PTST™ product launch.

Whilst the initial engagement with Merck was for a lab-based product solution both parties now recognise the significant commercial potential to enter the high value decentralised hand-held instrument market. AureumDX's endotoxin test platform is ideally suited for this.

Merck have a stated goal achieving revenues of \$230 million from its AureumDX enabled endotoxin detection business within 5 years. This equates to \$84million in revenues to AureumDX in both lab and handheld.

Large-Scale Testing: The shift to a handheld QC detection device enables us to address the needs of key businesses that require high-volume testing in raw materials manufacturing, pharmaceutical and biopharmaceutical sectors.

Accessibility and Efficiency: Handheld devices offer a level of accessibility and efficiency that lab-based products cannot match. QC technicians, laboratories technicians, and field personnel can quickly and accurately perform endotoxin tests at the point of need, reducing turnaround times and enhancing productivity.

Cost Savings: Handheld QC detection devices offer cost savings in terms of equipment and personnel, making endotoxin testing more affordable and accessible to a broader range of customers.

Environmental Responsibility: By developing the AureumDX platform for use with sustainable recombinant reagents the product will be consistent with customer, partner and supplier sustainability goals.

2.4 AureumDX COMPARISON TO MARKET LEADING PRODUCTS

In the competitive landscape of endotoxin detection products, Merck is gearing up to face formidable rivals, Charles River and Lonza, who currently hold the largest market share. Merck's entry into this highly specialised field is particularly challenging as they have traditionally relied on the Lonza assay for their annual 10,000 tests in the pharmaceutical market. Having a test of their own will allow Merck to expand their current offering to customers and sell in the products space competing with the market leader Charles River.

	AureumDX/Merck	Charles River	Lonza
SENSITIVITY	0.005 EU/mL	0.005 EU/mL	0.005 EU/mL
TEST TIME	15min	15min	90mins
INSTRUMENT COST (LAB)	\$20000	\$30000+	\$30000+
TEST STRIP COST (LAB)	\$150	\$210.40 ^{*^}	\$298.22 ^{*^}
INSTRUMENT COST (HANDHELD)	\$1000	\$10551 [*]	N/A
TEST STRIP COST (HANDHELD)	\$5	\$41.98 [*]	N/A
USER STEPS	1	2	Multiple
COLD CHAIN	Y	Y	Y
REAGENT	Recombinant	LAL	LAL
DETECTION METHOD	Electrochemical	Optical	Optical

* Prices available from Thermo Fisher Scientific ^ Assumes 2 samples run on each 96-well plate including standard curves and controls

2.5 STATUS

Endotoxin Detection

AureumDX has successfully completed the feasibility phase of the endotoxin project and the project has now been moved in the Merck's formal product development program.

Completed deliverables / technical milestones.

- **Functional Electrochemical Endotoxin Assay:** The AureumDX electrochemical assay has equivalent performance to existing commercial assays and is compatible with sustainable recombinant reagents.
- **Dry Format Compatibility:** A dry reagent assay format has been demonstrated thus indicating suitability for commercialisation within the hand-held decentralised market sector.

Double Stranded RNA Detection

AureumDX have recently initiated the funded dsRNA detection research project with the aim of developing a simple, high performance electrochemical detection platform for double stranded RNA (dsRNA).

The team have identified four possible detection strategies and are currently comparing these approaches in terms of ease of use, robustness and analytical sensitivity.

Following the successful proof-of-concept phase the AureumDX Research team will begin a second phase of product feasibility which will determine the most effective technical route towards productisation.

At this point the dsRNA project is very early stage and no detailed planning is possible beyond this initial proof of concept phase.

2.6 ENDOTOXIN TECHNOLOGY OVERVIEW

The technical goal has been to innovate a highly sensitive but easy to use platform that is intended to replace the existing labour-intensive and slow plate reader assays that currently dominate the market.

Top level product requirements include:-

- Compatibility with newly developed fully recombinant reagents
- Multiplexed testing instrument capable of measuring up to 20 test strips simultaneously
- No / minimal sample preparation
- No need for test sample dilution
- Assay tolerant of wide range of test sample types
- Equivalent or faster testing time than existing assays
- Industry leading endotoxin sensitivity and measurement range
- Test strip design able to accommodate control channels if required

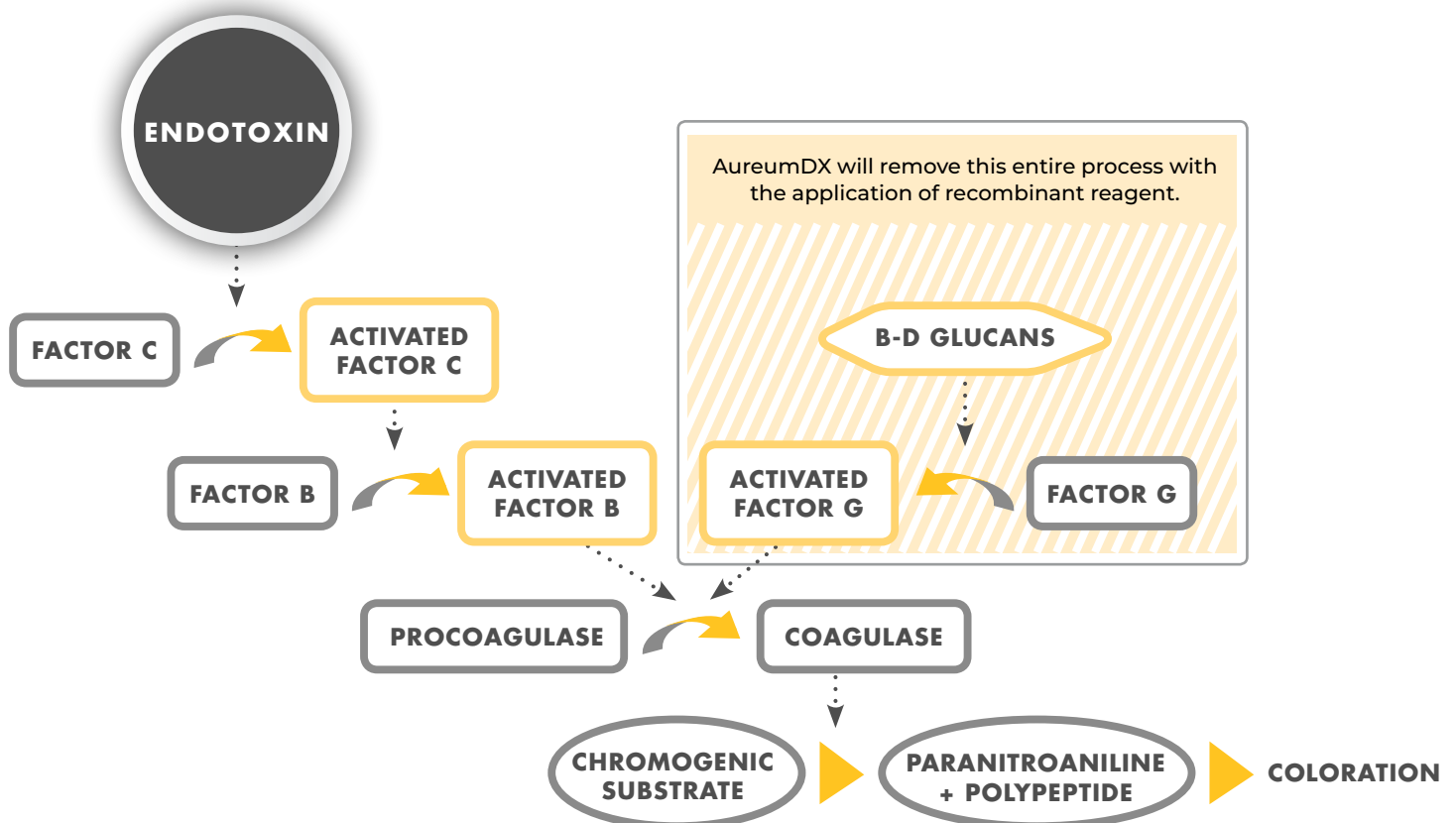
Several reagent design options have been explored by AureumDX, including the assessment of “off the shelf” optical reagents and the development of custom-made reagents designed to maximize electrochemical sensitivity.

AureumDX custom made reagents are considered to have the potential to deliver considerably higher levels of performance and would likely be compatible with the AureumDX Hydra platform.

However, in order to rapidly demonstrate product feasibility, commercially available reagents were screened first and through the use of elegant high sensitivity electrochemical detection methods a functional “on strip” dry reagent assay has now been robustly demonstrated.

Endotoxin detection reagents are based on a biological protease cascade reaction which delivers exceptional signal amplification and yields a measurable product by cleaving a substrate peptide, releasing a coloured compound that can be measured using a spectrophotometer.

Figure 1. The endotoxin detection cascade reaction.



As part of AureumDX's research activities it was demonstrated that this cleaved optical molecule can be sensitively detected using square wave voltammetry.

The AureumDX team have demonstrated that electrochemical detection of this cleaved signaling molecule pNA (paranitroaniline) shows equivalent performance to the optical detection of pNA. This demonstration has been done with both Horseshoe crab derived LAL reagents (Limulus amoebocyte lysate) and recombinant full cascade reagents.

Recombinant full cascade reagents are expected to rapidly dominate the endotoxin detection market in the coming years for two key reasons:-

1. Recombinant reagents provide a fully sustainable alternative to LAL reagents, which are derived from the blood of live Horseshoe crabs. The practice of harvesting the blood of these crabs is increasingly considered unethical.
2. Recombinant endotoxin detection reagents have been engineered for much greater specificity than LAL reagents. A well-known interferent with the LAL cascade assay is the reaction between beta-glucans and the Limulus factor G enzyme present in the Limulus Amoebocyte Lysate mixture. The presence of B-D Glycans therefore causes false positive readings and requires adding additional confirmatory tests to an already lengthy and expensive process. The recombinant reagents have been engineered to remove factor G from the cascade and therefore a major source of interference is removed from the endotoxin testing assay.

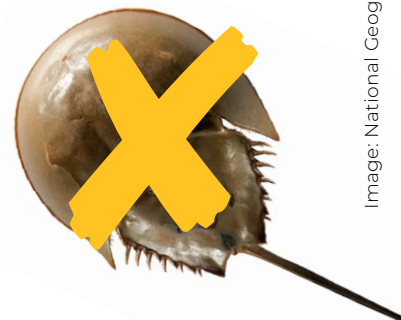
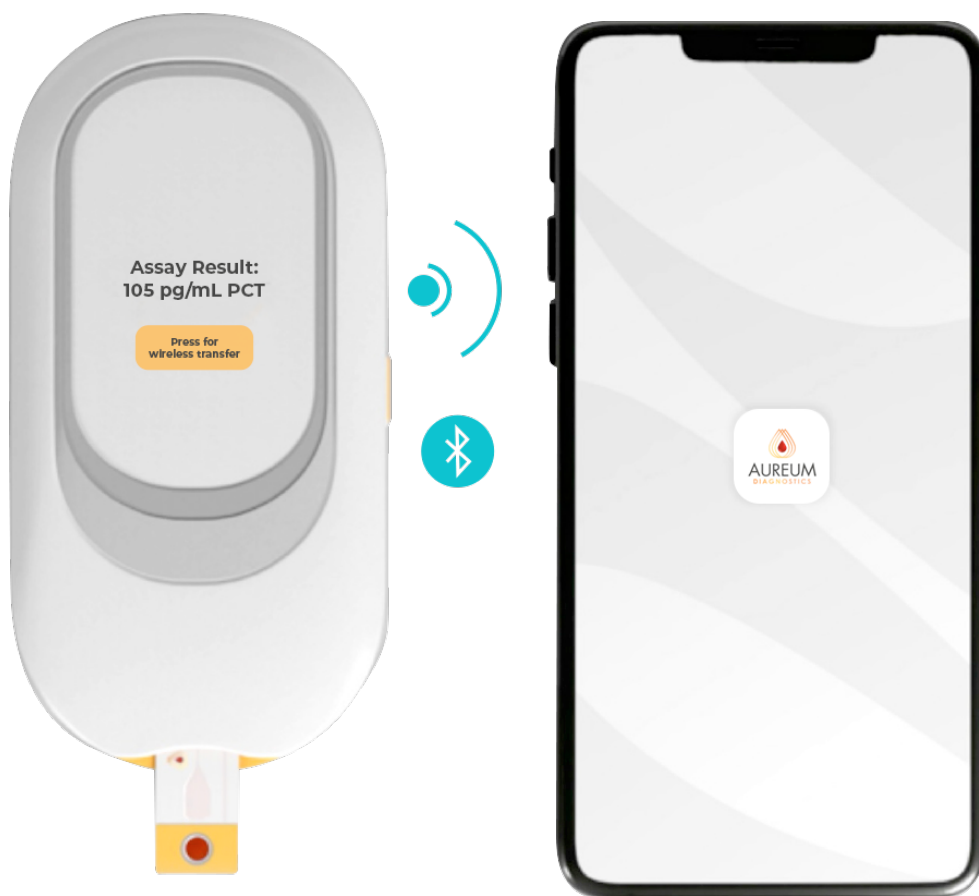


Image: National Geographic



2.7 RESULTS

By algorithmically analysing the square wave voltammetry traces it is possible to derive a reliable pNA calibration curve which in turn is proportional to the endotoxin concentration of the test sample.

AureumDX recombinant endotoxin assay run on AureumDX technology

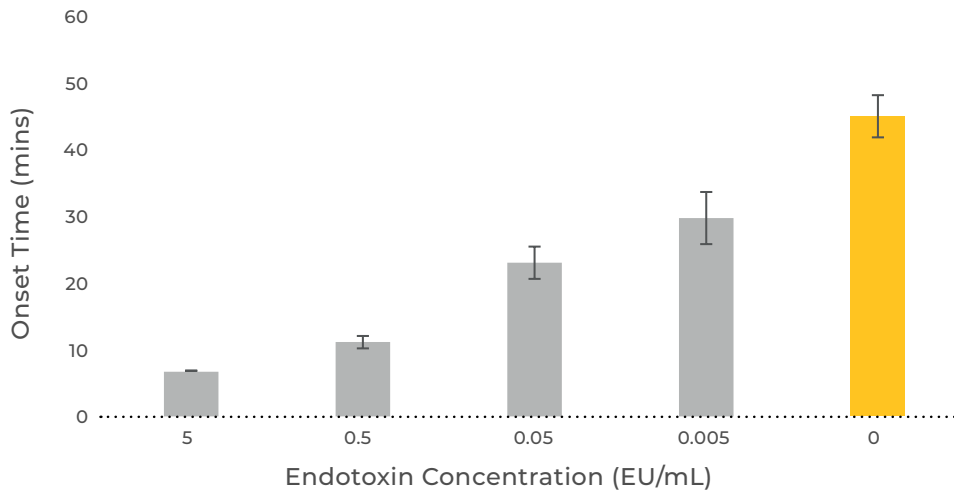


Figure 2. Data showing the response of the pNA released from the enzyme cascade using square wave voltammetry as an electrochemical detection method.

Square wave voltammetry on strip assay after incubation of LAL with 0 to 5 EU/mL (n=10)

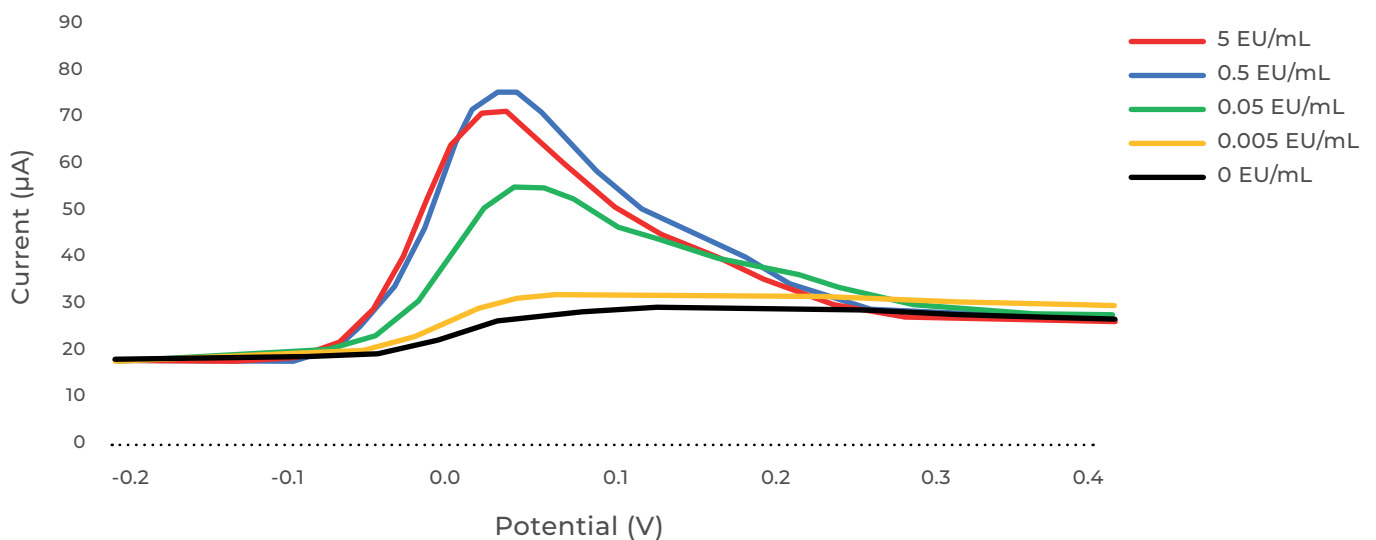
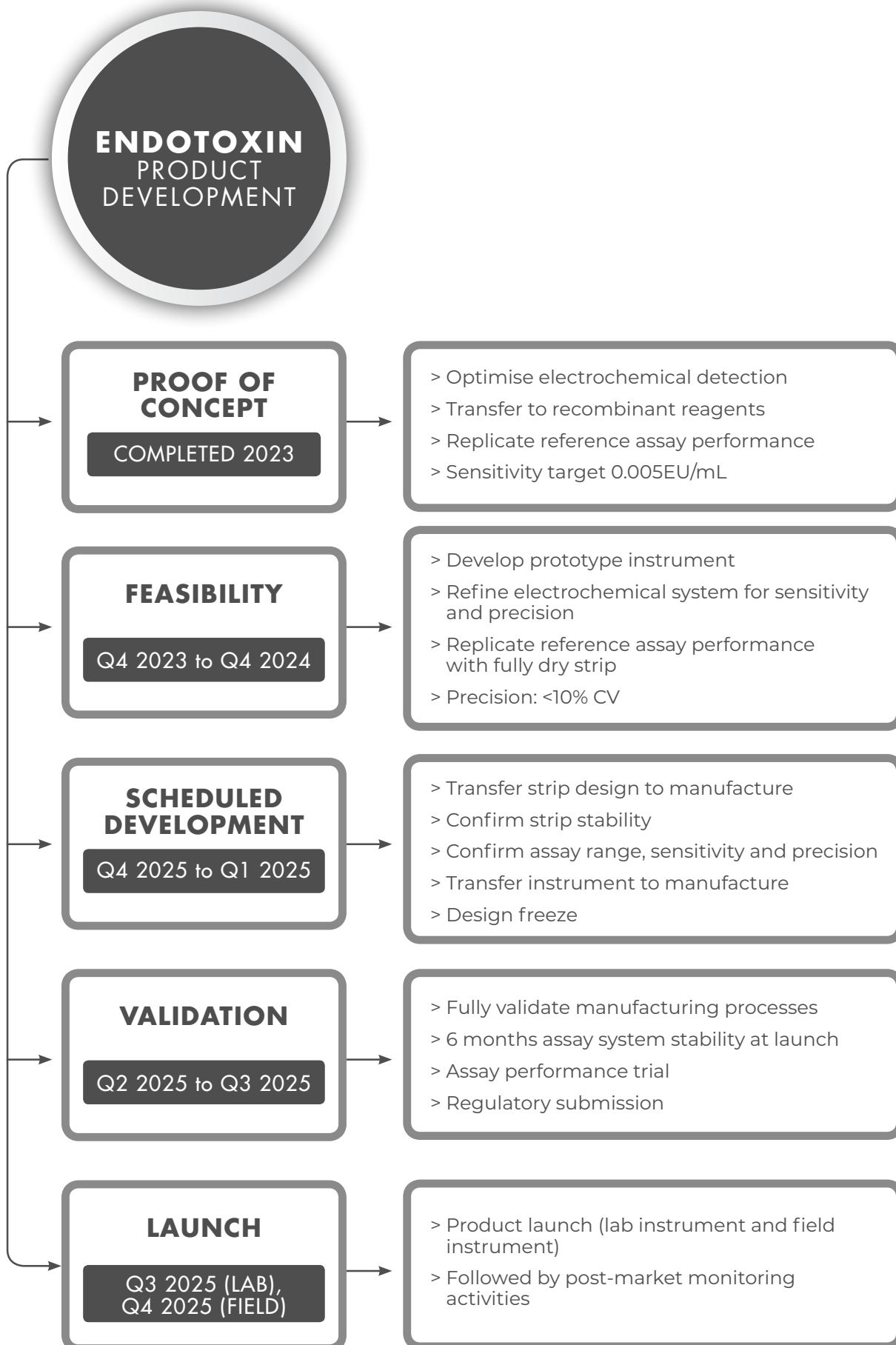


Figure 3. Electrochemical data showing the algorithmic time-calling of the AureumDX endotoxin assay based on increasing voltametric signals from enzyme cascades triggered by endotoxin-positive samples.

The endotoxin detection system demonstrated above uses no animal-derived reagents and meets the target specifications for sensitivity from Merck. The lower limit of detection of 0.005EU/mL corresponds to a w/v measure of 500fg/mL. The handheld product will provide a simple, visual read-out of the results.

2.8 ENDOTOXIN PRODUCT DEVELOPMENT PLAN

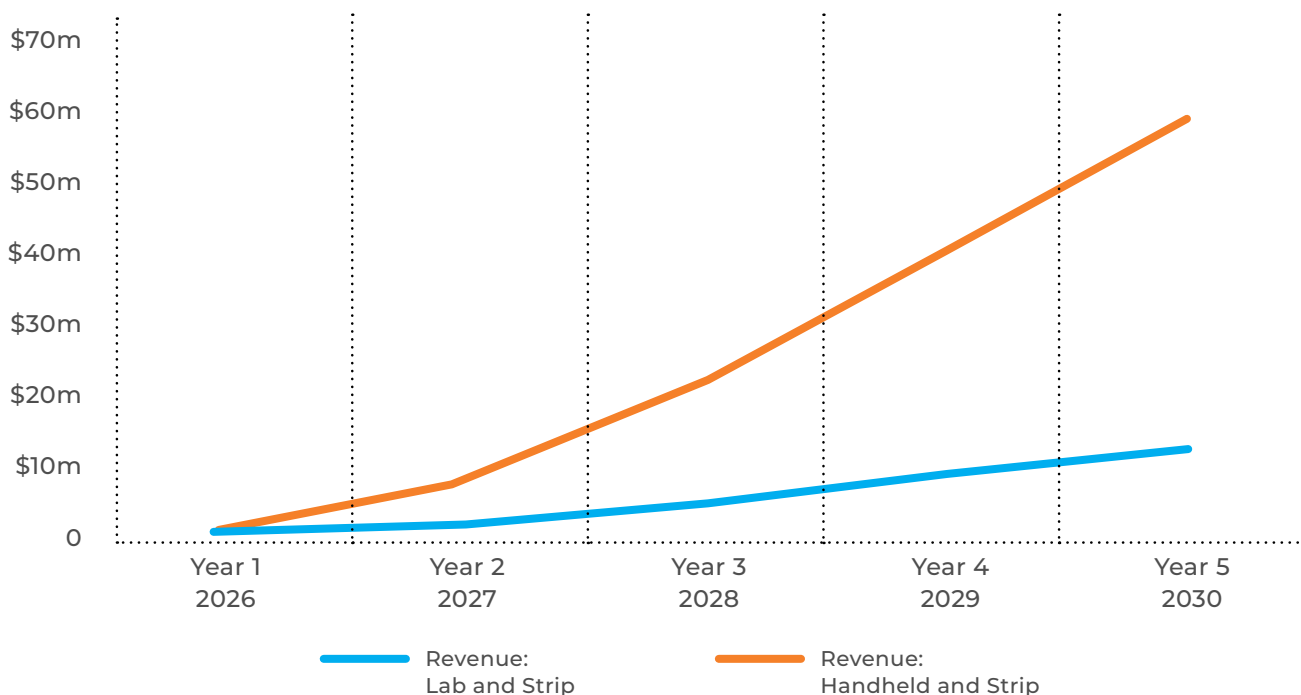


2.9 ENDOTOXIN FINANCIALS

Merck have stated their goal to achieve revenues of \$230 million from its AureumDX enabled endotoxin detection business within 5 years. **This equates to \$84 million in revenues to AureumDX in year 5 and total net profit over 5 years of \$202 million.**

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue lab and strips	\$2.2m	\$3.8m	\$4.6m	\$6.1m	\$7.6m
Revenue handheld and strips	\$23.5m	\$35.3m	\$47.1m	\$59m	\$76.6m
Total	\$25.8m	\$39.1m	\$51.8m	\$65m	\$84.2m

Biosafety forecast revenues over a 5-year period



3. DECENTRALISED POINT OF CARE DIAGNOSTICS (dPOC)

AureumDX will deliver high performance dPOC testing solutions for conditions where early detection leads to reduced mortality, better patient outcomes, greater healthcare efficiency and cost savings.

In Vitro Diagnostic (IVD) tests are regulated medical devices used by healthcare providers for the prevention, diagnosis, treatment, and management of health conditions.

According to research published by Fortune Business Insights, the global IVD market size was valued at \$94.67 billion in 2022 and is expected to grow to \$157.02 billion by 2030 (CAGR of 7.1%) mainly because of an increased burden of infectious diseases and chronic disorders worldwide.

Most diagnostic testing today is still performed using centralised hospital laboratory platforms, has high capital cost, high complexity, and a long turnaround time. Overall, this delays the process of clinical decision-making and patient follow up, is inefficient for the health system, and inconvenient for the patient.

Point of care (POC) diagnostics refers to diagnostic testing that is carried out beyond central hospital laboratories across various care settings, from consumers' homes to bedsides in hospital intensive care units. POC testing is intended to be faster, more convenient and lower cost and this provides important benefits to users, patients and health care professional.

The global diagnostics market size was USD 43.93 billion in 2022 and is projected to reach USD 78.11 billion by 2030, exhibiting a CAGR of 7.9%.

3.1 PROBLEM

Problems and Trends in Medical Diagnostics

Demands on healthcare services are predicted to increase dramatically over the next decade as patient numbers rise owing to ageing populations, detrimental lifestyle changes and increased numbers of people with a long-term condition.

There is significant pressure to improve the efficiency of care pathways and patient self-management.

Around 95% of clinical pathways rely on patients having access to efficient, timely and cost-effective centralised hospital-based diagnostics. Biomarker-based diagnostic testing is still delivered in a sub-optimal way by pathology/laboratory services.

POC testing has not yet achieved the required level of decentralisation to deliver its true potential. The technical challenge of delivering truly affordable high performance decentralised POC testing has yet to be fully met.

Without affordable high performance dPOC testing pressures on centralised healthcare services will continue to grow.

The Importance of Diagnostic Testing in Effective Diagnostic Pathways

Diagnostic tests are involved in the majority of all clinical decisions made across healthcare.

There is a need to increase accessibility to affordable and accurate POC testing for the following settings:

- GP practices, out-of-hours primary care, and care homes; to reduce unnecessary treatment (e.g., antibiotics), and unnecessary admissions to hospital or referrals into secondary care.
- Community care and "hospital at home" services. Utilising high quality connected diagnostic testing which can be performed by the patient or their care-giver, to support shared decision making.
- Community diagnostic hubs; support the development of better care pathways, less dependency on centralised laboratory biomarker tests, and more appropriate referral for diagnostic imaging.
- Emergency departments; early and rapid assessment of potential life-threatening conditions when they are first triaged.

dPOC diagnostic testing improves efficiency of care, leads to fewer and shorter stays in hospital, and frees up healthcare professional resource.

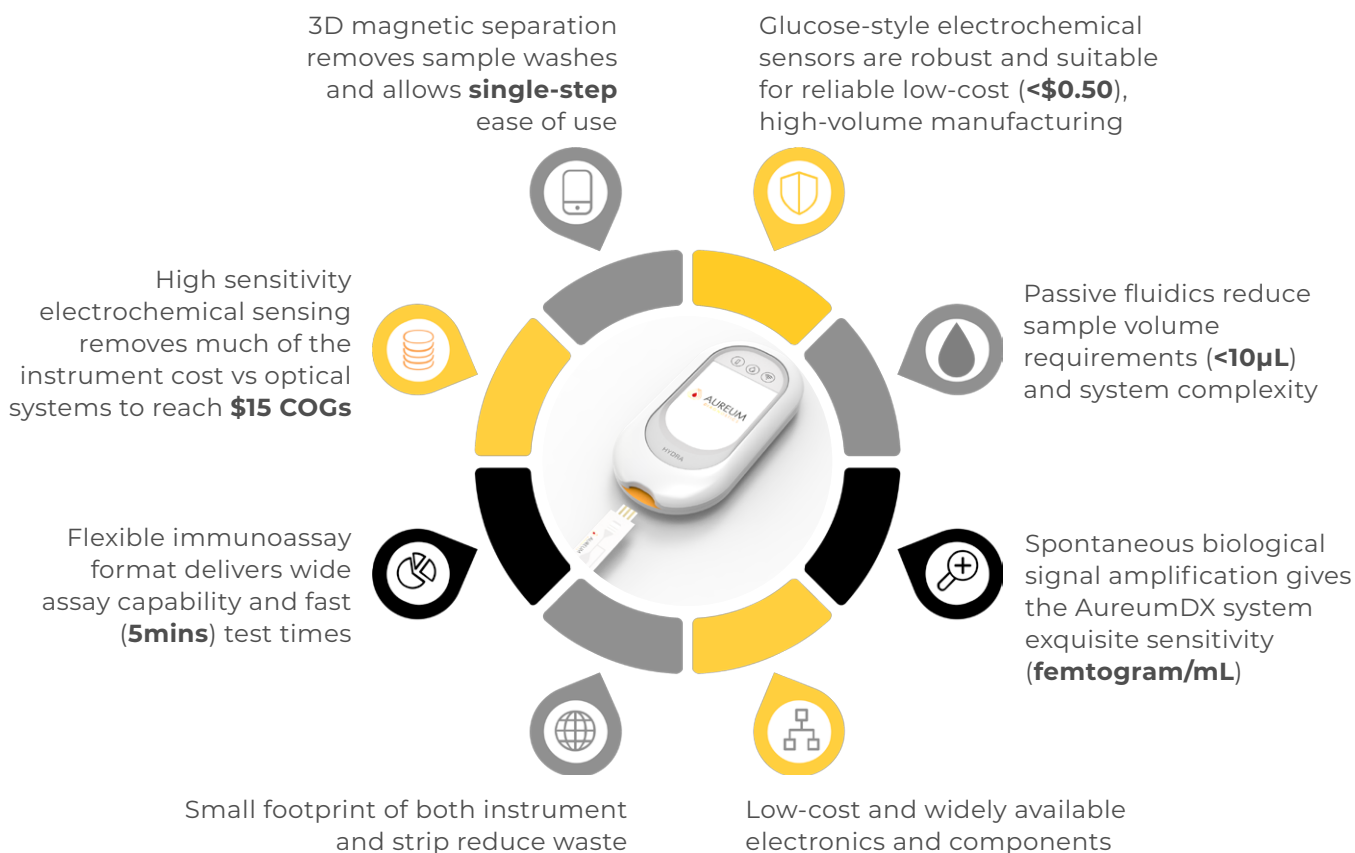
3.2 AureumDX TECHNOLOGY PLATFORM SOLUTION

Hydra decentralised POC platform is fully differentiated from current POC platforms enabling partner IVD companies to participate in new market segments (e.g., community care) and new markets (e.g., developing countries) with a best-in-class platform, as follows:

1. Ease of use. Hydra is a sample-to-result system. No sample preparation or pre-processing is required for patient testing or quality control testing. Once the test strip is placed into the instrument and a sample added to the sample port, the user does not need to monitor the test and can complete other unrelated tasks.

2. Low cost of customer acquisition. Hydra will deliver lab-equivalent performance at a much lower cost than traditional laboratory and POC systems, meaning AureumDX can rapidly scale deployment at a significantly lower cost than competitors. The instrument has a target COGs of <20GBP and the testing strips have a target COGs of <1GBP for a single-marker assay.

3. Suitable for environmentally challenging settings. Hydra will be designed to perform to specification in any health care delivery setting. The company will design Hydra to operate in settings without a fully equipped laboratory, with limited climate control, only mobile connectivity, and with interruptions or surges in electricity/power.



3.3 MARKET OPPORTUNITIES

PRODUCT	APPLICATION	PROBLEM	MARKET SIZE
Product 1 PCT	Differentiation of bacterial from viral respiratory infections	<p>Clinicians need a decentralised POC diagnostic tool to determine respiratory infection severity.</p> <ul style="list-style-type: none"> Procalcitonin (PCT) is the accepted biomarker for the presence of severe bacterial infection but can currently only be measured using hospital lab analysers. The lack of a rapid, cost effective and decentralised POC PCT test contributes to poor and late diagnosis as well as unnecessary antibiotic prescriptions. 	\$750m USD; A dPOC PCT test will grow the total market and move tests to POC.
Product 1 PCT	Detection and management of sepsis	<p>People with possible sepsis need urgent evaluation and rapid access to antibiotic treatment.</p> <ul style="list-style-type: none"> No decentralised procalcitonin (PCT) test exists so the risk of undiagnosed sepsis remains high, as does sepsis mortality. Early detection is directly linked to improved patient survival. 	\$576m USD (Lab); A dPOC PCT test will grow the total market and move tests to POC
Product 2: BNP, D-Dimer, PCT	Screening for and management of heart failure	<p>The causes of shortness of breath are difficult to determine, especially in an elderly population.</p> <ul style="list-style-type: none"> Possible causes include heart failure, chronic obstructive pulmonary disease (COPD), ischemic heart disease, infection, and asthma. In the absence of the necessary dPOC biomarker testing solutions, reliable diagnosis and appropriate treatments are difficult to provide. 	<p>\$4.4bn USD, of which \$755m is decentralised POC testing.</p> <p>A dPOC PCT test will grow the total market and move more tests to POC</p>
Product 2: BNP, D-Dimer, PCT	Rule-out of venous thromboembolism	<ul style="list-style-type: none"> Elevated troponin levels support a diagnosis of myocardial (heart) injury and a need for urgent investigation. New generation "high sensitivity" assays for troponin enable myocardial injury to be detected early. 	
Product 3: Troponin	Assessment of chest pain		
Product 4: BNP, D-Dimer, PCT: Troponin	Differentiation of causes of shortness of breath (COPD, infection, oedema, heart failure)		
Product 5: UCH-LI and GFA:	Detection of brain injury from trauma	<ul style="list-style-type: none"> TBI is currently diagnosed by computerised tomography (CT) imaging, but this technique is expensive, often the results are negative, and it is insensitive to mild injury which can still be dangerous. 	\$230m USD emerging market opportunity
Product 6: Low level viral infection	Viral elimination programs (specifically Hepatitis C)	<ul style="list-style-type: none"> The WHO has set an elimination target for HCV by 2030: 90% reduction in incidence; 65% reduction in mortality. 80% of patients receiving a highly effective 12-week treatment. Currently, screening for Hepatitis C infection needs a high capital cost laboratory analyser (Abbott Architect Hepatitis C core antigen assay) and this is not suitable to meet the WHO's goals. Lateral flow technology lacks the sensitivity to detect the very low viral antigen levels. A high sensitivity, low cost and simple diagnostic solution is needed in order to enable the WHO targets to be achieved. 	\$950m USD (Lab); A dPOC PCT test will grow the total market and move tests to POC and emerging markets

3.4 AureumDX COMPETITORS

In the table below potential AureumDX competitor technologies are assessed for their suitability for use in a decentralised low-cost point of care setting.

	AureumDX	OSLER	LUMIRA DX	Siemens Atellica VTLI	Roche Cobas h232	Abbott I-STAT Alinity
SENSITIVITY	pg/m	pg/ml	pg/ml	pg/ml	pg/mL	pg/mL
TEST TIME	< 10 mins	Unknown	12 mins	8 mins	12 mins	15 mins
INSTRUMENT COGS	< \$15	est > \$7500	c \$3000	c \$3000	Est \$1000	Est \$5000
TEST STRIP COGS	<\$1	Est \$10	c \$1.50	c \$10	Est \$10	Est \$30
INSTRUMENT SIZE (CM)	12 x 6.5 x 3	Est 40 x 20 x 20	21 x 11 x 7.5	15x10x17	24x11x5	27x14x8
INSTRUMENT WEIGHT	250g	Est 3 kg	1.1kg	780g	526g	840g
MULTIPLEXED	Yes	Yes (claimed)	Yes	No	No	Yes
USE SETTING	Home, Pharmacy, Surgery, Hospital, Community	Pharmacy, Hospital	Pharmacy, Surgery, Community	Pharmacy, Surgery, Community	Pharmacy, Surgery, Community	Pharmacy, Surgery, Community
MULTI-OMIC	Gen 2	Yes (Claimed)	Instrument - Yes	No	No	No
TOTAL INVESTMENT TO DATE	£3.5m	£200m	£900m	£millions	£millions	£millions
PRODUCT LAUNCH	2026	unknown	2020	Launched (CE only)	Launched	(not US and not for POC)

3.5 PRODUCT AND PARTNER OPPORTUNITIES

AureumDX has identified the following target strategic partners who are market leaders in specific fields within the clinical diagnostics market.



AureumDX's affordable, simple, fast, and high-performance multiplex technology will be of high interest to these target partners.

AureumDX's affordable technology is transformational in terms of the cost of customer acquisition (instrument) and retained Partner/Manufacturer margins (consumable). The low-cost instrument (e.g., \$30 price to Partner) is 100x lower cost to access the customer than for the competition (e.g., \$3,000 Triage MeterPro). The low-cost consumable (e.g., \$0.50 COGs) is 10x lower than for the competition (e.g., \$5 COGs Triage cartridge [estimated]).

3.6 POC DIAGNOSTICS TECHNOLOGY OVERVIEW – HYDRA PLATFORM

AureumDX's Hydra test strip and instrument platform have been developed to achieve several key design outputs:

- Wash free “sample to result” assay format
- Ultra-low-cost instrumentation
- Industry leading assay sensitivity
- Whole blood measurement capability to remove the need for red cell separation
- Ability to carry out simultaneous multiplexed biomarker measurements

All of the above requirements have been achieved through the innovative development and integration of the following component assay technologies:

- 3d magnetic reagent positioning to remove the need for wash steps. Instead of washing away any unused reagents the platform precisely and automatically relocates any reagents that have reacted with the target protein antigen. This technology replaces the traditional wash step.
- Spontaneous signal amplification. By precisely repositioning immunocomplexed reagents to a separate location on the test strip, the immunocomplexed enzyme molecules can be brought in to contact with the enzyme substrate and high-performance electrochemical mediators to trigger spontaneous and continuous signal amplification.
- The use of electrochemical detection methods instead of expensive optical methods removes the need to separate red cells from the sample whilst requiring only very low cost yet highly sensitive electronics to measure the assay signal.

Multiplexed biomarker measurement is achieved by adding additional fluidic channels to the Hydra test strip. Each separate channel contains its own biomarker specific antibody reagents. This technique allows multiple biomarkers to be measured at the same time from the same test sample.

HYDRA TEST STRIP

The Hydra test strip has been developed specifically to be compatible with high-volume, low-cost manufacturing techniques.

Test strip COGS have been calculated using existing well known material costs in addition to previously demonstrated assumptions on volume material purchase discounts and typical manufacturing yields.

Final COGS estimates for single biomarker test strips range from \$0.25 - \$0.45 depending on production volumes, production yields and the biomarker specific antibody selection.

Multiplexed test strips COGS increase in line with the level of desired multiplexing since material and reagent usage scales proportionately. A three level multiplexed tests strip has a COGS estimate of between \$0.75 and \$1.35.

Test strip construction materials – base plastic layer, fluidic lamination later and top hydrophilic layer – are all available at low cost from established and trusted ISO accredited suppliers. These materials are commonly used in the POC diagnostics industry and are available in large volumes at low cost.

Test strip manufacture requires several highly automated and controlled production processes including precision high speed screen printing, fully XY registered lamination, low volume noncontact reagent dosing and digitally controlled material laser cutting.



HYDRA LOW-COST INSTRUMENT

The Hydra low-cost handheld instrument is designed to work in combination with the Hydra test strip to provide single step, rapid and high accuracy point of care biomarker measurements.

The instrument contains all the necessary hardware and software to enable this measurement in addition to allowing wireless data transfer to an app enabled mobile phone.

Since no optical measurement is necessary the instrument dispenses with the costly optical components typically found in competing devices.

The Hydra electrochemical measurement componentry is widely available at low cost and is routinely used in low cost in blood glucose monitoring systems, which can be manufactured for as little as \$5.

The COGS estimates for the Hydra instrument is below \$15, as compared to competing high sensitivity POC instruments which typically cost up to \$5,000.

Instrument costs increase slightly as multiplexing capability is added, since an additional low cost potentiostat chip (c\$0.5) is required for each separate channel.

Hydra instrument prototype design will be managed by the AureumDX instrumentation team but final design and manufacture will be outsourced to an established medical diagnostics device manufacturing partner.

Multiple prototype Hydra instruments are already in use in the AureumDX labs enabling full assay development to be carried out.

Prototype instruments have the same core functionality as the final handheld version but are more widely configurable for maximum flexibility.

Instruments will be designed to have a maintenance free lifetime of over 5,000 tests, as is commonly achieved with blood glucose monitors.



3.7 RESULTS

The Hydra platform core technologies have been sequentially developed and integrated to deliver the current fully working system.

The Hydra assay sensitivity is achieved through engineering a spontaneous and location specific enzyme signal amplification. By bringing an enzyme in to contact with its substrate and a carefully matched electrochemical mediator a high-speed continuous enzyme reaction can be enabled which converts the mediator to a form that can be measured electrochemically.

Careful design of these amplification reagents provides exceptional signal amplification. Proof of principle using polymerized amplification enzyme has been demonstrated with hundreds of active enzyme molecules can be relocated to the test strip detection zone for every target biomarker molecule captured.

AureumDX immunoassay reagent sensitivity

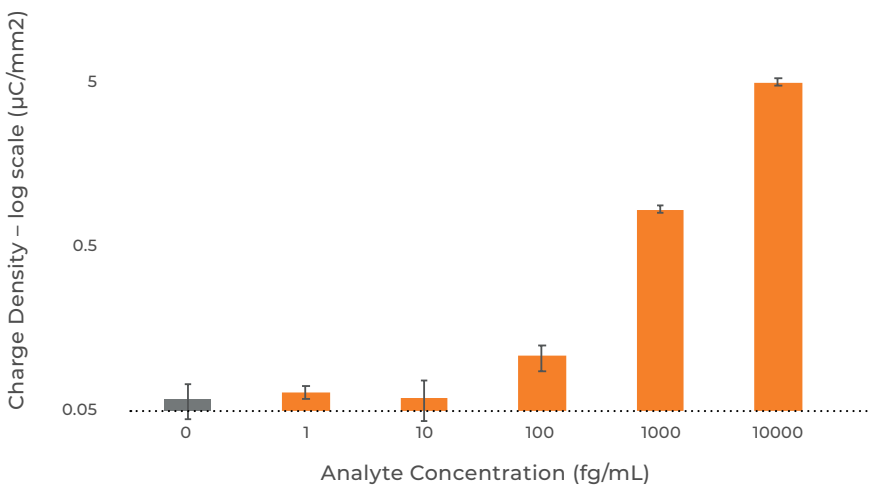


Figure 4.

Sensitivity data from polymerized-HRP showing the detection of femtogram/mL concentrations of enzyme using AureumDX strips and instruments.

Having innovated the core component assay technologies these have been integrated into a full dry reagent assay to demonstrate the Hydra platform performance.

The results below show the reliable detection of C Reactive Protein at its lowest clinically relevant concentration.

The assay was carried out in full “sample to result” format with all reagents dried down on the Hydra test strip with the test sample (in human plasma) added to the sample application port of the test strip. Sample fluidics, antigen capture, 3d magnetic reagent relocation, spontaneous signal amplification and signal measurement were all carried out by the prototype instrument with no necessary user steps.

Electrochemical data showing full CRP drydown assay run on AureumDX strips using human plasma (n=3)

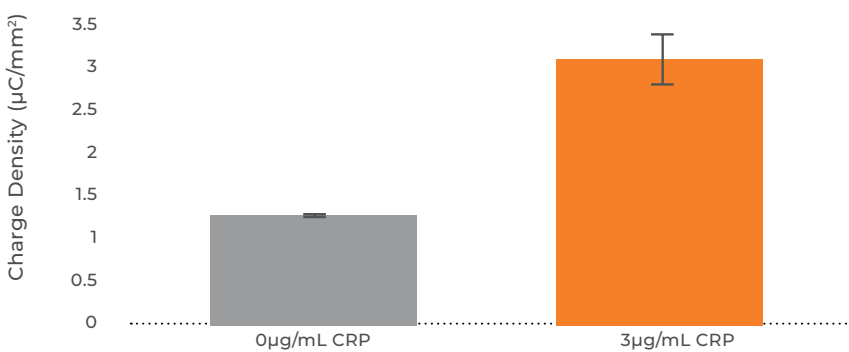
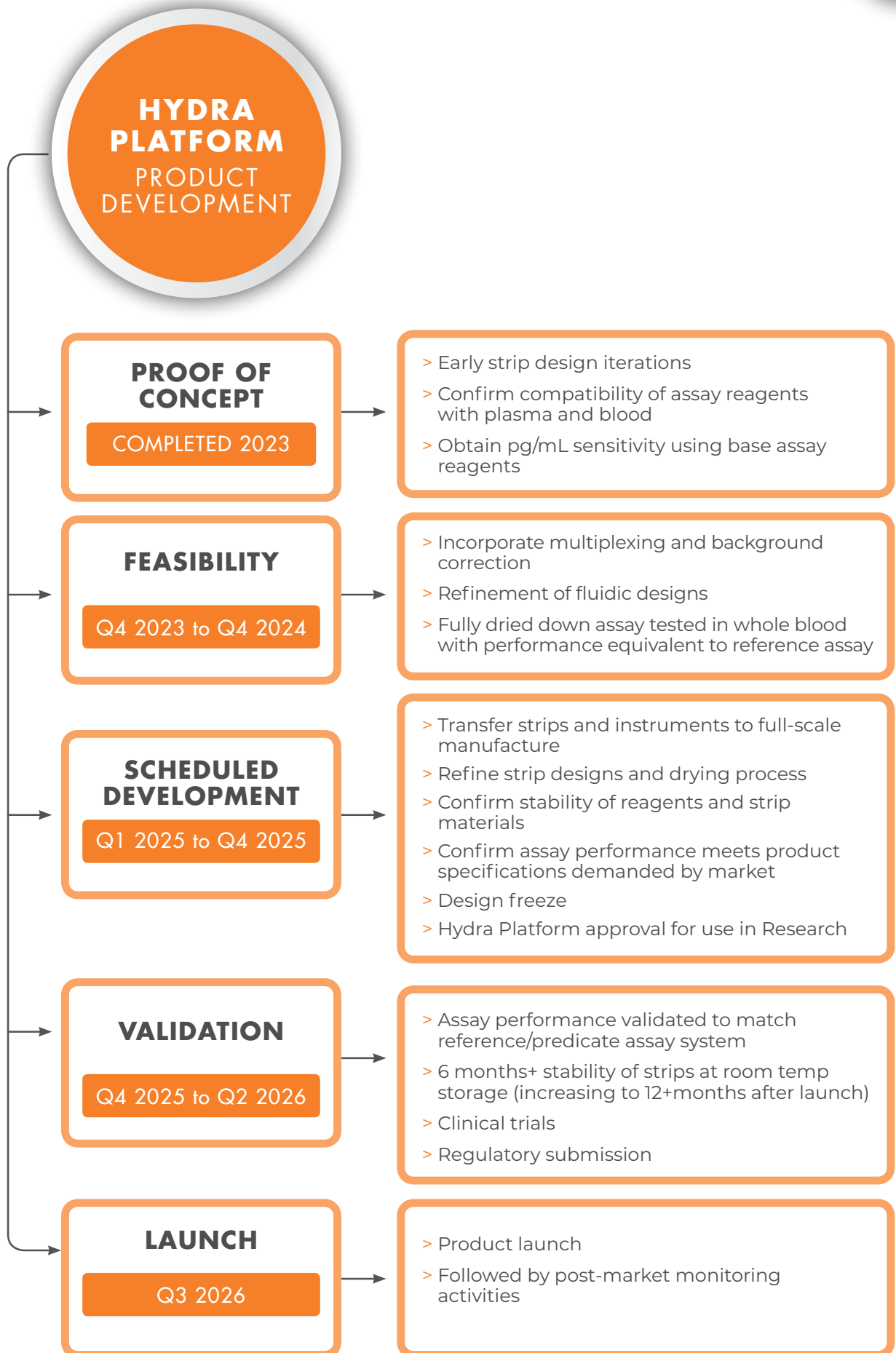


Figure 5.

Full “sample to result” CRP detection in plasma using Hydra platform.

3.8 DEVELOPMENT PLAN HYDRA PLATFORM

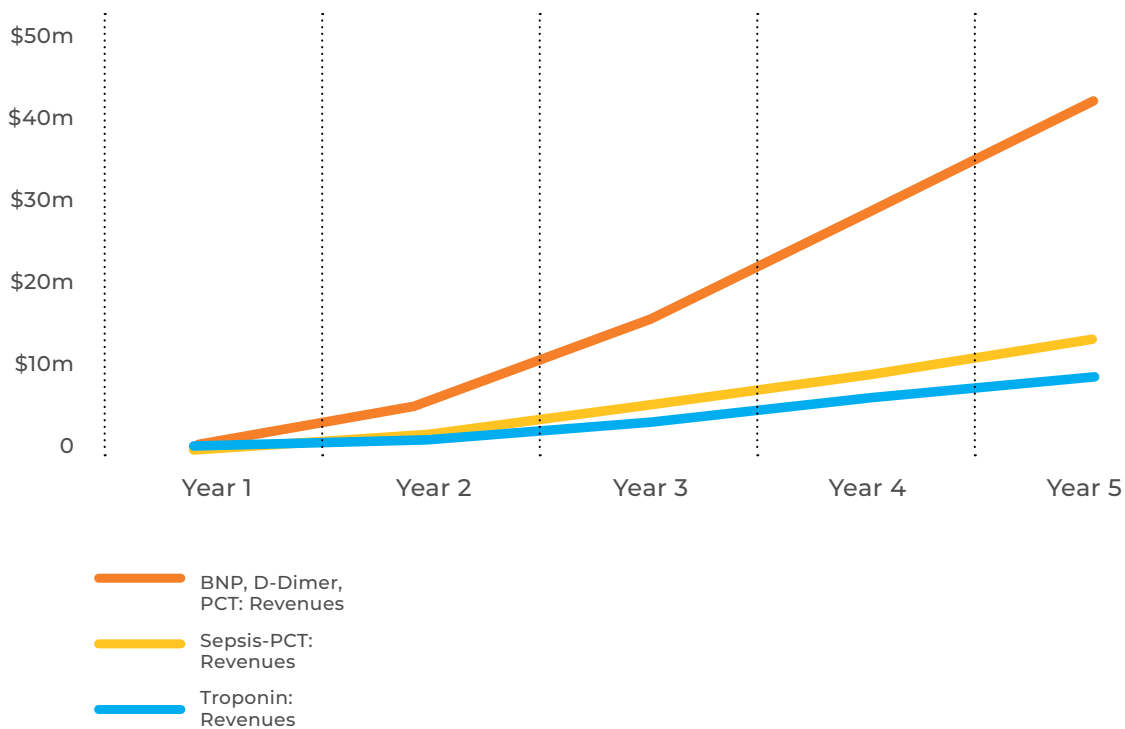


3.9 PRODUCT FINANCIALS

AureumDX plans to bring 3 products to market over a 5-year period with revenues of \$62 million within 5 years of launch and a gross profit of \$51.9 million.

	Year 1 (2026)	Year 2 (2027)	Year 3 (2028)	Year 4 (2029)	Year 5 (2030)
Product 1: Sepsis-PCT	\$186k	\$1.58m	\$4.7m	\$8.7m	\$12.9m
Product 2: BNP, D-Dimer, PCT	\$0	\$919k	\$7.7m	\$22.7m	\$41.6m
Product 3: Troponin	\$0	\$0	\$312k	\$2.6m	\$7.3m
Total	\$186k	\$2.5m	\$12.8m	\$34m	\$62m

dPOC forecast revenues over a 5-year period



4. AureumDX POC RESEARCH ACTIVITIES

Two major research themes exist within the company and are under the direction of Prof. Damion Corrigan.

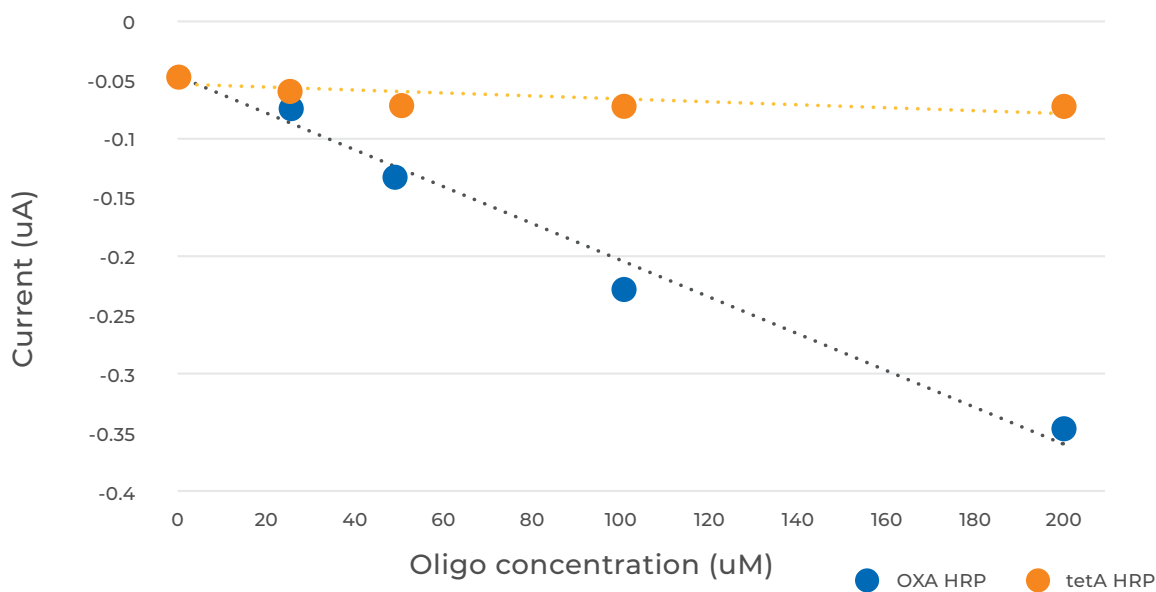
Hydra assay multi-omic capability development

A research program is underway to further expand the Hydra platform capabilities to include the detection of molecular targets. The Hydra assay logic can be adapted for this purpose by the development of target specific, enzyme labelled molecular probes and initial results have been very promising.

Work is also ongoing to explore the most effective technical options to allow target amplification “on strip” using isothermal amplification.

The addition of molecular diagnostic sensing to the Hydra platform is expected to create broader and valuable commercial opportunities in addition to those already identified for the Hydra immunoassay configuration.

Graph showing electrochemical molecular target detection on the Hydra platform. Control used was the non-specific tetA DNA sequence.



Other Hydra research avenues under investigation include the development of enzymatic biofuel cell like biochemistries that have the potential to simplify reagent designs and remove the need for electrochemical mediator compounds.

A parallel research activity is centred around the use of organic electrochemical transistors (OECTs), which have the potential to drive the Hydra assay sensitivity towards ground-breaking single molecule detection capability.

Initial research results have been promising and should OECTs prove capable of delivering this exceptional level of sensitivity they can be seamlessly integrated into the existing Hydra architecture in place of the existing electrochemical measuring electrodes.

5. FACILITIES & MANUFACTURING

Relocation to larger facilities will enable implementation of rapid turnaround in-house product development and manufacturing processes, greatly accelerating time to market. New facility preparation and capex budget is £1.5 million.

Currently, operations are located at the Maxim Park facility, chosen for its suitability and capacity to accommodate initial research and development needs.

MAXIM PARK FACILITY

The Maxim Park facility has the capacity to accommodate up to 25 individuals in the office and laboratory space.

The lease agreement for the Maxim Park facility includes a break clause which comes into force in October 2024

PROTOTYPING FACILITY EXPANSION

As part of their growth plans, AureumDX is currently in the process of selecting a site for a dedicated prototyping facility. This facility will allow the business to establish in-house, fast turnaround test strip prototyping and mid volume manufacturing capabilities. In house prototyping will greatly increase the speed of product development allowing multiple test design iterations to be manufactured and tested rapidly and cost effectively. AureumDX's current external prototyping partner requires 3 months from design to product delivery, but in house capabilities will reduce this to just 10 days.

The installed prototyping equipment will also allow low to mid volume product manufacture before AureumDX's larger facilities are available.

Estimated investment required to achieve these capabilities is £234,000.

FULL FACILITY

The second stage of AureumDX's phased growth plan will see the business take on a 12,000 – 15,000 fully integrated facility, enabling large volume test strip manufacture and ensuring that the entire AureumDX team are located together – which is crucial for seamless interdepartmental communication.

This larger facility will provide expanded laboratory, prototyping, manufacturing, office and warehousing space.

An estimated investment of £1.5 million will be required to bring this facility online during 2025.

Up to 50% grant support for required capital expenditure is anticipated from Scottish Executive.

AureumDX's staged approach to facility expansion ensures that the manufacturing capabilities align with the demand for AureumDX's products while maintaining the highest standards of product quality and innovation. This adaptability allows the company to respond quickly to market dynamics and emerging opportunities.

6. REGULATORY PATHWAY

In Q4 2025, the Hydra platform will be approved for research use.

Product 1 (PCT) will require CE, UKCA and 510k marking to enable distribution within the European Union (EU), Great Britain and the USA. The timeline to approval for Class C system is 18 – 22 months from technical documentation submission.

The endotoxin product does not meet the definition of a medical device or in-vitro diagnostic device per MDR or IVDR definitions. It is also not a test applied to specimens from the human body. AureumDX will develop the endotoxin test under a full quality management system and work to the required standards for this device. Full approval is expected in Q3 2025.

7. INTELLECTUAL PROPERTY

AureumDX have made two new IP filings for the 'Hydra' technology, a novel approach for detecting targets in samples, and the electrochemical method for detecting endotoxin.

AureumDX recognises the importance of a robust Intellectual Property (IP) strategy in supporting its commercial objectives. The company adopts a proactive and diligent approach to develop and manage the IP portfolio, ensuring that it aligns with the business plan and product development direction. Regular meetings between the science team and AureumDX's IP attorneys ensure that AureumDX technology innovations are captured for IP protection.

TITLE	OFFICIAL NUMBERS	PRIORITY DATE	FILING DATE	TERRITORIES	NOTES
Electrochemical Sensor	PCT/GB2021/052781; AU2021371064;	27 October	26 October	Australia Canada, China, EPO, Japan, US	This application is for an electrochemical biosensor comprising a SAM of hydrofluorocarbon or fluorocarbon molecules bonded to an electrode via a sulfur or silicon atom. The biosensor is for detecting a target analyte.
CCL17 Electrochemical Biosensor	PCT/GB2022/051872	20 July 2021	20 July 2022	PCT	This application is for an electrochemical biosensor system comprising a CCL17 capture layer on an electrode or substrate, with the capture layer comprising a ligand binding specifically to CCL17.
Methods and Devices for Detecting Analytes	GB2308560.8	8 June 2023	-	GB	This application relates to the "Hydra" technology, offering a novel method of detecting a target in a sample.
Electrochemical Detection of pNA	PG450652GB	6 August 2023		GB	This application relates to the Merek Project, offering a novel method of detecting an endotoxin in pNA.

FREEDOM-TO-OPERATE (FTO)

AureumDX acknowledges the importance of conducting a comprehensive FTO analysis before commercial launch. While many features of the company platform are still under development the company have adopted a staged approach to assess FTO:

Novelty Search: A novelty search has been commissioned for the "Hydra" application, titled "Methods and devices for detecting analytes." Results from this search will be analysed to identify IP of relevance.

Landscaping Searches: As the diagnostic device approaches its final commercial embodiment, the company will conduct landscaping searches to gain a comprehensive understanding of the FTO landscape.

Specific FTO Searches: The company will perform specific FTO searches focusing on any particularly important features of the final diagnostic device and system before the commercial launch.

By implementing this comprehensive IP strategy, AureumDX aims to secure its innovative technologies, protect its competitive edge, and ensure the continued alignment of IP assets with its business goals and product development direction.

8. MANAGEMENT & COMPANY STRUCTURE

The AureumDX team brings a proven track record of innovation, commercialisation, and impactful exits, driving game-changing biosensing solutions with exceptional returns on investment.

Founder: Prof. Damion Corrigan

Early Investors: Norcliffe Capital and Strathclyde University

KEY TEAM MEMBER BIOS

Oliver Davies - Chief Executive Officer (CEO)

Olly has over 30 years' experience working at the cutting edge of the Medical Diagnostics industry. During his career Olly has held multiple leadership positions including CEO, CTO, COO, and VP R&D within early-stage innovative VC funded start-ups and established blue chip companies. He has worked for Abbott, Inverness Medical, Alere and Johnson & Johnson as well as a number of medical VC funded start-ups and university spinouts.

Olly has co-founded two of his own medical diagnostics companies and successfully raised 7 figure venture capital finance for these ventures.



Prof. Damion Corrigan - Founder and Chief Scientific Officer (CSO)

Professor Damion Corrigan FRSC holds the Laboratory of the Government Chemist funded Chair in Measurement Science for Health and is Director of the Centre for Advanced Measurement Science and Health Translation at the University of Strathclyde, Glasgow. As an acknowledged leader in his field Professor Corrigan guides a team of talented researchers who work on a diverse range of diagnostic challenges, including antibiotic resistance detection, liquid biopsies for cancer, sepsis detection, epilepsy measurements and liver health.



Tessa Ogle - Chief Operating Officer (COO)

Tessa Ogle, Chief Operating Officer, drives operational excellence within AureumDX. With a strategic and results-oriented mindset, Tessa oversees various facets of the company's operations, ensuring seamless coordination among departments and effective execution of the initiatives. Her dynamic leadership and proven track record in optimising processes contribute to the overall efficiency. Tessa's adeptness in translating strategy into action makes her an invaluable part of the leadership team.



Dr. John Shillingford - Non-Executive Director (NED)

Dr. John Shillingford brings a wealth of expertise and experience to his role as Director at AureumDX. He holds a BSc in Biochemistry and a PhD in Biochemical Pharmacology from the University of Surrey.

With over 40 years of experience in the pharmaceutical and contract research industry, John has established himself as a prominent figure in clinical trial design and implementation across Europe and beyond. For the past eight years, he has provided valuable consultancy services to global firms, specialising in the development of clinical drug trials and MedTech devices.



Prof. Steve Howell - Non-Executive Chairman

Prof. Steve Howell brings over twenty-five years of invaluable experience in the life sciences and diagnostics industry as he assumes the role of Non-Executive Chairman at AureumDX.



Dr. Alexis Roberts-McIntosh - Non-Executive Director (NED)

Dr. Roberts-McIntosh brings with her a wealth of experience from her time at Abbott in healthcare transformation, innovation, and commercial success, making her a valuable addition to the board.

With a proven track record and deep understanding of the industry, Dr. Roberts-McIntosh's is a valuable addition to the AureumDX board.



Industry Experts:

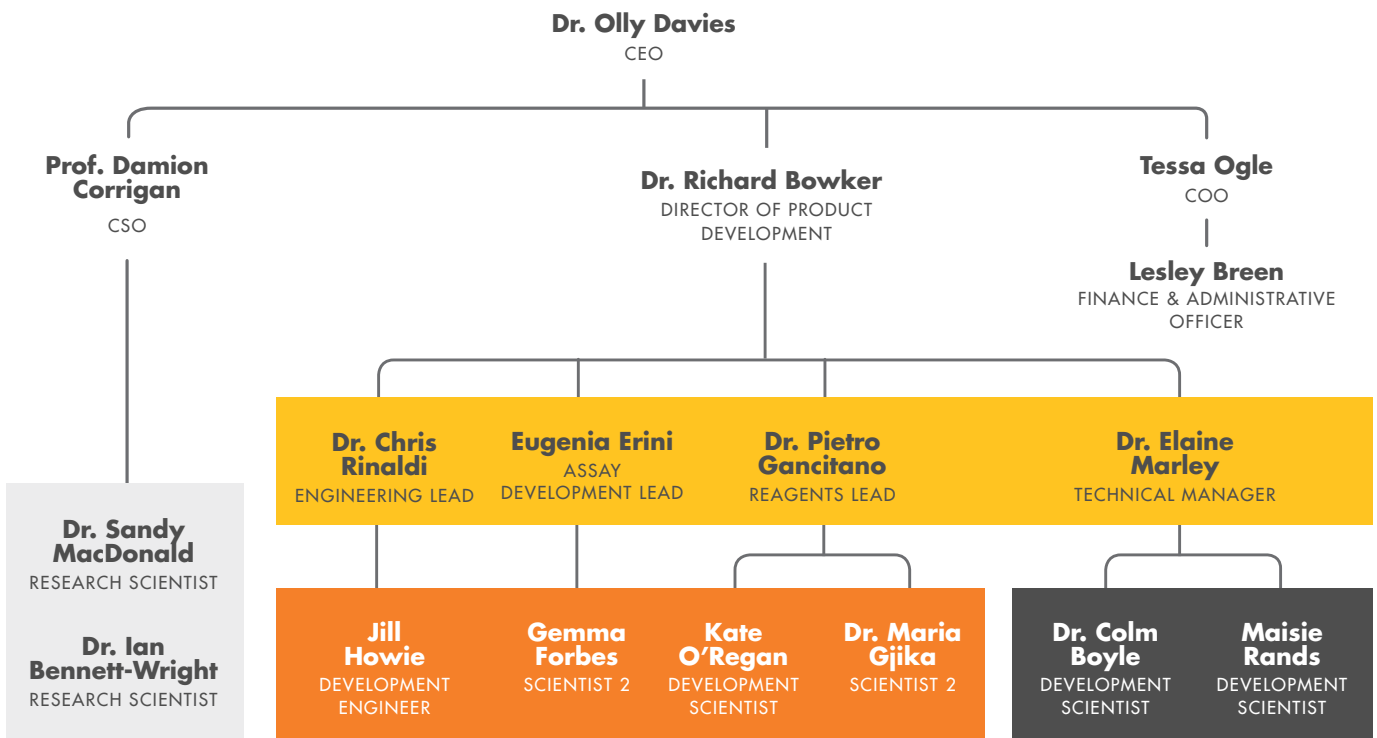
Dr. Geoff Hall has held pivotal roles in several startup companies. As the second employee at Inverness Medical Ltd, he contributed significantly to the company’s growth and continued as a key member of its leadership team, culminating in its \$1.3 billion acquisition by Johnson and Johnson in 2001. Geoff is also co-founder, with Olly Davies, of Suresensors Ltd, and served as CEO until the company was acquired by Lumira Dx in 2019.

Dr Paul Sheard is Managing Director of inspireDx Ltd., a medical device consulting firm providing strategic and tactical business development and market development advice to in-vitro diagnostic (IVD) companies, with clients ranging from start-up companies to major international companies.

Malcolm Yeudall is a seasoned engineering and manufacturing leader with over 25 years of industrial expertise within the medical device and diagnostics industry.

Dr. Nick Gee. Nick is a seasoned industry veteran and entrepreneur who previously founded and successfully sold Innova BioScience, a bioreagents enterprise that achieved notable success with a sale valued at approximately \$13 million.

ORGANISATIONAL STRUCTURE



BOARD

- Prof. Steve Howell**
NON-EXECUTIVE CHAIRMAN
- Oliver Davies**
CHIEF EXECUTIVE OFFICER (CEO)
- Prof. Damion Corrigan**
FOUNDER & CHIEF SCIENTIFIC OFFICER (CSO)
- Tessa Ogle**
CHIEF OPERATING OFFICER (COO)
- Dr. John Shillingford**
NON-EXECUTIVE DIRECTOR (NED)
- Dr. Alexis Roberts-McIntosh**
NON-EXECUTIVE DIRECTOR (NED)

EXPERT ADVISORS / CONSULTANTS

- Dr. Nick Gee**
REAGENTS EXPERT
- Dr. Geoff Hall**
MANUFACTURING & ASSAY DEVELOPMENT EXPERT
- Malcolm Yeudall**
MANUFACTURING EXPERT
- Dr. Paul Sheard**
MARKET & BIOMARKER EXPERT

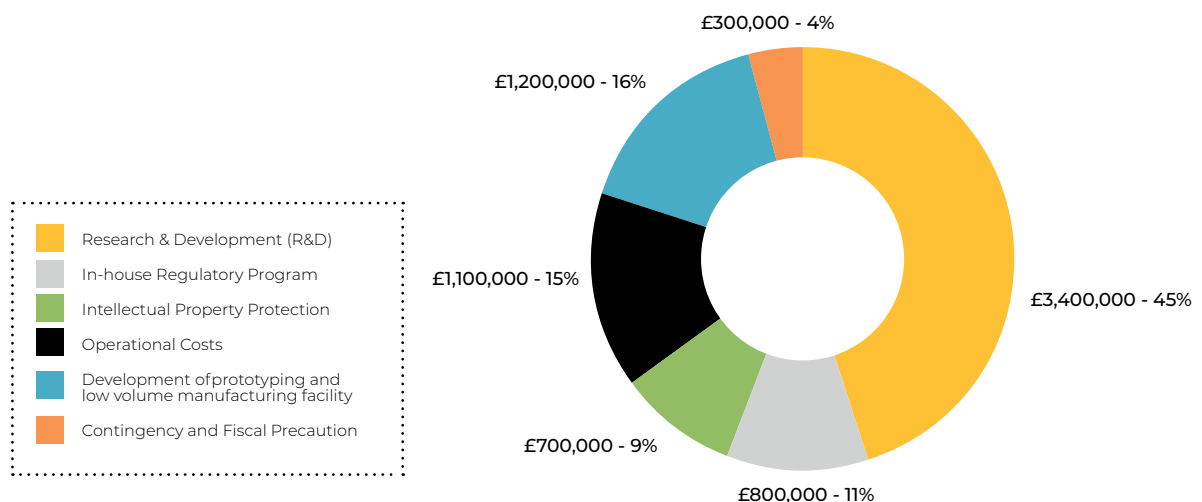
AureumDX'S DEVELOPMENT PARTNERS

- DEVELOPMENT MANAGEMENT TEAM** (Yellow)
- ENDOTOXIN TEAM** (Dark Grey)
- HYDRA TEAM** (Orange)
- RESEARCH TEAM** (Light Grey)

9. FINANCIALS

AureumDX is seeking up to £7.5 million to accelerate the development and commercialisation of the company's biosafety and decentralised point of care diagnostics platforms.

The company secured seed funding of £3.5 million in October 2021, supported by Norcliffe Capital Limited. AureumDX is presently engaged in discussions with a prospective partner regarding the development of the Hydra platform. Should this partnership be successfully secured during the ongoing fundraising effort, it is anticipated that the required fundraising amount may be subject to reduction. Partnerships of this nature can offer valuable financial support, technical expertise, and additional resources, thereby potentially enhancing the overall prospects of the project and its associated fundraising campaign.



USE OF FUNDS

AureumDX is seeking up to £7.5 million, which will be utilised as follows:

Breakdown of Funding Utilisation:

- 1. Research and Development (R&D):** £3.4 million will be allocated to research and development activities, including assay development, optimisation, and validation on both the endotoxin project and the Hydra Platform. The funds will also support collaborations with ISO 13485 partners to expedite the regulatory-compliant development process.
- 2. In-House Regulatory Program:** To ensure compliance with industry standards and regulations, £0.8 million will be used to implement a comprehensive in-house regulatory program.
- 3. Intellectual Property Protection:** AureumDX will allocate £0.7 million to aggressively prosecute its intellectual property strategy. This investment will safeguard the company's novel technologies and provide a competitive edge in the diagnostics market.
- 4. Operational Costs:** An allocation of £1.1 million will cover operational expenses, including office space, equipment, and administrative costs during the initial phase of operation at both the Maxim park facility and the University of Strathclyde.
- 5. Development of prototyping and low volume manufacturing facility:** To facilitate the planned move to an independent location at the end of year 3, £1.2 million will be dedicated to relocation expenses.
- 6. Contingency and Fiscal Precaution:** A contingency fund of £0.3 million has been set aside to account for potential subcontract overrun costs and as a precaution against R&D tax changes.

MARKET VALUATION

AureumDX's market valuation is set at £25 million, reflecting the value of the company's disruptive and highly differentiated technology platforms, its IP assets and its existing valuable commercial agreements with Merck.

Market Conditions and Industry Trends

The valuation considers current market conditions and industry trends within the medical diagnostics and biosafety testing sector. These global markets' size and growth potential, coupled with the increasing demand for decentralised, affordable and high-performance diagnostics create a favourable market environment for AureumDX.

Comparable Analysis

AureumDX's valuation may also be benchmarked against similar companies in the industry such as Osler Diagnostics. Comparable valuation analysis indicates a c£80 million valuation. Although later stage than AureumDX, the Osler platform is very high cost and not well suited to dPOC use. The AureumDX Hydra platform will compare favourably in terms of performance but will have a dramatically lower cost structure. Accordingly, AureumDX's valuation would be expected to track to at least a similar level to Osler as the Hydra platform develops.

Risk Assessment and Discounted Cash Flow (DCF) Analysis

An evaluation of risks associated with AureumDX, including market risks, regulatory challenges, competition, and operational risks, is factored into the valuation. Additionally, a DCF analysis estimates the present value of the company's expected future cash flows, considering the time value of money. This method provides a quantitative basis for assessing AureumDX's intrinsic value.

Exit Strategy Considerations

The valuation accounts for potential exit strategies, including acquisition opportunities and the potential sale of the endotoxin business to Merck.

INDUSTRY COMPARATORS

Siemens'/Minicare from Philips (\$332 million) 2016

Siemens' acquisition of Minicare from Philips can be seen as a relevant comparison to AureumDX's business strategy in the context of advancing POC testing technology. The MInicare platform seeks to deliver similar benefits to the AureumDX Hydra platform and this is reflected in the acquisition price.

Sense BioDetection

Acquired by Sherlock Biosciences in Q1 2023: Sense BioDetection is a dPOC molecular diagnostics company founded in 2014. Whilst the terms of the acquisition have not been disclosed Sense BioDetection raised \$65 million in Q2 2021 at an estimated pre-money valuation of \$250 million.

Alere acquired Axis-Shield in 2011, for £235 million (£293 million at today's value)

Axis-Shield's main revenue was from tests for rheumatoid arthritis and chronic damage associated with diabetes. Alere acquired Axis-Shield primarily for its point of care technology, which provides immediate, portable and convenient diagnostics.

EXIT POTENTIAL

AureumDX anticipates that a trade sale to an existing market incumbent as the most probable exit strategy. The company's unique technology platform positions it as an attractive acquisition target for leading diagnostic firms, with potential trade sale opportunities, including the endotoxin business to Merck.

AureumDX's versatile platforms have the potential to both complement and replace existing technologies, making it highly appealing to companies seeking dPOC diagnostic solutions. Prominent industry leaders, such as Thermo Fisher, bioMérieux, Roche, Abbott, Siemens Healthcare, Beckman Coulter, and Quidel, are potential acquirers.

COMPANY OWNERSHIP AND CAPITAL STRUCTURE

AureumDX is owned by a well informed and supportive group of shareholders including venture capital firms and private individual investors. No single shareholder has a controlling share, and all hold ordinary shares. The shareholders have collectively invested £3.51 million.

The Company operates an Enterprise Investment Scheme (EIS) from HMRC so welcomes investment from EIS approved investors.

The capitalisation table is shown here:

Investor	Amount Subscribed	Number of Shares	What was paid	Share Class	Nominal Value
Norcliffe Nominees Limited	£3,507,120	3,507,120	£3,507,120	Ordinary A1	1.000
Patricia Reynolds	£12.00	12,000	£120.00	Ordinary A2	0.001
David Onions	£12.00	12,000	£120.00	Ordinary A2	0.001
University Of Strathclyde	£60.00	60,000	£600.00	Ordinary A2	0.001
John Shillingford	£60.00	60,000	£60.00	Ordinary B	0.001
Damion Corrigan	£600.00	600,000	£600.00	Ordinary B	0.001
Oliver Davies	£120.00	120,000	£120.00	Ordinary B	0.001
Steve Howell	£60.00	60,000	£60.00	Ordinary B	0.001
Patricia Reynolds	£60.00	60,000	£600.00	Ordinary C	0.001
David Onions	£60.00	60,000	£600.00	Ordinary C	0.001

Norcliffe Nominees Limited serve as the nominee company representing investors through Norcliffe Capital and is under the ownership of Tricor Woodside and its parent companies. Unlike some other nominee entities, Norcliffe Nominees does not hold voting rights or decision-making authority on behalf of the underlying beneficiaries. Instead, its role primarily involves the administration of investments.

Within this framework, Norcliffe Nominees acts as a facilitator for the 82 individual high net worth/sophisticated/professional investors who are the underlying beneficiaries. These investors retain their voting rights and maintain control over their investments. While Norcliffe Nominees administers votes or resolutions as needed, it does not make investment decisions on behalf of the investors.

EMI OPTIONS SCHEME

Following the successful conclusion of the second fundraising round, AureumDX is proposing to implement a 10% Employee Management Incentive (EMI) Options Scheme. The envisaged structure of this scheme entails a vesting period spanning four years, with an incremental vesting rate of 25% per annum. This initiative underscores AureumDX's commitment to fostering long-term employee engagement and aligning the interests of the team with the company's growth objectives.

FINANCIAL PROJECTIONS

Please note that the company is not intending to make or pay dividends or distributions to holders of ordinary shares for at least the first 3 years from the issue of the last of the shares allotted in this round and any dividends declared will be subject to the company's performance.

Financial projections have been set out below based on anticipated valuation of the company once full product development is complete and upon exit. The table below sets out what the Investor might receive on an exit at the values set out in the table and is included for illustration purposes only. The examples demonstrate the returns for a £7.5 million investment.

Potential investors should note that the Investor Returns outlined in the table below do not take into account any tax that might be payable by the company on an exit by an investor nor does it take into account other fees or costs of such exit which might be payable by the company or individual investors which would reduce the proceeds available for Investors. The company has no fixed target date for an exit.

£7.5 million investment for 23% equity

	Low	Mid	High
Total Gross Sale Price	£150,000,000	£250,000,000	£350,000,000
Series A Total Return	£31,153,846	£51,923,077	£72,692,308
Gross ROI	4.15	6.92	9.69
Net ROI	5.93	9.89	13.85

*Net ROI represents investor returns net of 30% EIS income tax relief.

The above financial projections are for illustrative purposes only and do not imply any representation or warranty by the company, its directors or professional advisers, as to whether such projections would be achieved. The exit sale price used for the purpose of the illustration is based on anticipated low, mid and high valuations of the company once the technology is fully developed and in the marketplace. The company will not be updating these financial projections, nor will it provide any business or share valuation to any shareholders on any regular basis.

10. SUMMARY

Since incorporation AureumDX has worked hard to create £25 million value for early shareholders.

With an experienced and responsible leadership team, focus has been on rapid yet robust technology development for key high value markets, strategic partner development with Merck and the generation of highly protective intellectual property.

AureumDX's two technology platforms both represent very significant advancements over the current market leading alternatives.

The AureumDX endotoxin detection platform is already factored into Merck's planned drive for substantial market share growth, with Merck projecting up to \$230 million revenues from sales within 5 years.

We believe that the AureumDX endotoxin detection products will drive the company rapidly in to significant profitability and reduce or remove the need for additional equity investment.

For the decentralised point of care diagnostics market the Hydra platform represents a truly generational shift in performance, affordability and ease of use. Revenues and margins are projected to be strong, and AureumDX will begin partner discussions in early to mid 2024.

Whilst the Merck segment of the business will drive early revenues and profits, AureumDX consider the Hydra platform likely to drive significant acquisition interest from existing market incumbents. The POC market has a strong history of high value acquisitions for companies that deliver genuinely differentiated product offerings.

Having carefully developed the business, established a strong commercial partnership and demonstrated their technology offerings, AureumDX is now ready to accelerate its activities, recruit additional skilled staff and invest in high volume manufacturing capabilities.

Accordingly, AureumDX are seeking an equity investment of up to £7.5 million with a pre-money valuation of £25 million to fund these value adding activities, either from a single investor or through a syndicated investment.

We are targeting completion by the end of Q2 2024.

11. RISK FACTORS

The opportunity described in this Information Memorandum may not be suitable for all recipients of this Information Memorandum. Before making an investment decision, prospective Investors are strongly recommended to consult their professional adviser, who should be authorised under the Financial Services and Markets Act 2000 and who specialises in investments in unlisted shares.

Past performance and success of the Company or its management team is not a guide or reliable indicator to future performance of an investment in the Company.

There is no guarantee that the Company will succeed in its objectives, as outlined in this Information Memorandum. **There is a risk that by investing in the Company, investors may lose some or all of the capital invested.** In particular, if the development of the Device is not successful and/or the Company is unable to obtain the required regulatory approvals for the Device then the Company does not anticipate that its business will have any meaningful value.

Before deciding to invest in the Company, a prospective Investor should consider carefully whether an investment in the Company is suitable considering their personal circumstances and their available financial resources. Investment in the Company will only be suitable for investors who have capacity to absorb the potential loss of all capital invested.

Investment in the Company will generally be illiquid. The Company does not anticipate that a public market in its shares will develop. Investors may not be able to sell their shares in the Company at a reasonable price, or at all. Transfer of its shares will be subject to the consent of the Company, which it will not unreasonably withhold. In addition, it may be difficult for an investor to obtain reliable information about the value of the Company's shares or the extent of the risks to which its shares are exposed.

The principal risk factors in the Company considered as relevant are:

- The Company has received confirmation from HMRC that the E shares to be issued under the offer will be qualifying investments for the purposes of EIS tax relief.
- Advance assurance would not, in any event, guarantee formal EIS status, as that will depend upon continued compliance with the EIS legislation throughout the three years from share issue. Whilst the Directors intend that Shareholders should be able to obtain the EIS tax benefits, understandably no guarantee is given, or warranty implied.
- It is intended that shareholder capital will be applied to the business from the first drawdown of Investor funds.
- Whilst the Directors have taken professional advice and consider it likely that EIS status will be granted, the Directors believe that Investors should be focused on the potentially large investment merits of the business and not what are in monetary terms, relatively small levels of tax reliefs in proportion to the potential returns.
- The Company has a small management team and the loss of a key individual could adversely affect the Company's business.
- The aims, strategies, targets, plans, intentions and projections referred to in this Information Memorandum do not imply a forecast of future profitability or successful commercialisation.
- Whilst due diligence has been carried out with an independent valuation firm, such due diligence does not constitute a representation or warranty that the valuation will be achieved. The adviser shall only be liable to Investors in respect of the due diligence carried out by such adviser and then only if such due diligence was carried out in a fraudulent manner.
- Third parties may claim ownership of or an interest in the Patent or that such patent rights infringe other patent rights owned by such third parties. Such claims may prevent the further development of the Device. The Company is not aware of any such ownership, interest or infringement.
- Third parties may claim that the patent rights in the Patent are invalid, or, in relation to the patent applications, third parties could choose to raise objections with the relevant authorities. The Company is not aware of any such claim or objection. However, and notwithstanding such due diligence process, there can be no guarantee that third parties will not raise any such claims in the future.

- Intellectual property challenges either in respect of ownership of Patents or validity of Patents are a regular feature of the technology sector as such challenges can enable a competitor to delay or even prevent the entry into the market of a competing product. This is a commercial risk of investing into a technology company. Should the Company receive any challenge to its intellectual property it may incur costs in defending its rights but does not intend to delay or cease developing the Device, raising funds under the Offer and/or ultimately commercially exploiting it merely because the Company has received a claim or challenge to the Patent.
- The due diligence carried out is provided for information purposes only and does not constitute any form of representation or warranty that the development of the Device will be successful and/or can be commercially exploited.
- The Company will be operating in a competitive industry where the commercial risks are high. Accordingly, an investment in the Company is speculative; Shareholders may not get back the amount of their original investment and returns on investment are not guaranteed. If the project is not commercially successful, a loss of the entire sum invested is highly likely.
- Investment in the Company should be considered a high risk/potential high return investment: if the development work is successful and appropriate regulatory clearances obtained there is a realistic chance of high returns but if not, then investors should anticipate little or no return as all funds will have been expended on human capital, professional services and intellectual property.
- Changes in government regulation or practices relating to the technology and/or MedTech industry could have a negative impact on the Device by increasing the cost of, and/or requiring more extensive, testing and/or development before regulatory approvals may be granted for the Device. Government agencies throughout the world strictly regulate the development, testing and use of technology products such as the Device. Any such changes may make the development of the Device more expensive or more time consuming before regulatory approvals are granted and/or may result in the Company being less profitable than forecasted.
- The granting of all regulatory clearances and approvals that the Company applies for may take longer than anticipated and may be refused.
- Even if all necessary regulatory clearances and approvals in key countries are granted there is a possibility that the Company is unable commercially to exploit the Device due to changes in technology or due to competing products. This is a commercial risk that the Investors are taking and therefore is a key commercial risk that any potential Investor should consider.
- Neither the Company, the Directors, nor the Company's advisers give any warranties or undertakings that EIS Relief, capital gains deferral relief or any other relief described in this Information Memorandum will be available or that, if given, such relief will not be withdrawn.
- Shareholders wishing to obtain EIS Relief must retain their Shares for three years from the date of issue. If the Shares are not held for such three-year period, income tax relief obtained initially will be lost, and must be repaid with interest. Accordingly, for Shareholders wishing to obtain EIS Relief, investment in the Company is not suitable as a short-term investment. In addition, there are various conditions attached to EIS Relief which individuals must satisfy for a relevant period, so it is vital that potential Shareholders take advice from their own professional adviser on the likelihood of their qualifying for EIS Relief.
- Shareholders wishing to obtain the benefits available from the EIS income tax relief and the EIS loss relief will need sufficient taxable income or gains (as appropriate) against which these reliefs can be off set.
- The Company has not been structured to generate immediate gains and Shareholders will need to be prepared to take a medium-term view of an investment. Accordingly, no secondary market for the Shares exists or is likely to develop and Investors should consider their investment to be illiquid. Investment in unquoted shares carries higher risks than investments in quoted shares and may be difficult to realise and proper information for determining their current value may not be available.

- It may be necessary for the Directors to place the Company into administration or insolvency. There is a risk that Subscribers may face a total or partial loss of investment in this event.
- Information in this Information Memorandum regarding taxation is based upon current UK taxation legislation and HM Revenue & Customs practices. Tax law and practice is subject to change. Any changes in the level and basis of taxation, in tax reliefs or in HM Revenue & Customs practices may affect the value of an investment and returns to Shareholders.
- This information memorandum includes statements that are (or may be deemed to be) “forward-looking statements”. These forward-looking statements can be identified by the use of forward-looking terminology including the words “believes”, “continues”, “expects”, “intends”, “may”, “would” or “should” or, in each case their negative or other variations or comparable terminology.

These forward-looking statements include all matters that are not historical facts. Forward-looking statements involve risk and uncertainty because they relate to future events and circumstances. Forward-looking statements contained in this information memorandum based on past trends or activities should not be taken as a representation that such trends or activities will continue in the future.

- The Company has made an Enterprise Risk Management Statement, and it is the responsibility of the CEO to ensure compliance with this.

