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# Welcome

## Haemograph Pty Ltd

**Improving anticoagulant therapy with a novel  
portable, point of care blood coagulation rheometer**

**Harold Lubansky**

# Improving anticoagulant therapy with a novel portable, point of care blood coagulation rheometer

- Presenter – Harold Lubansky – Managing Director – Significant Commercial & Industry Experience
- Team – CTO - Dr Alex Lubansky - World Class Rheologist leads an in house team of engineers / scientists of various disciplines; and extensive external collaborations with Universities and CSIRO.
- Main Expertise – Rheology and Removal of bubbles in small flows.
- Our rheometer:
  - Performs blood viscoelastic testing during coagulation;
  - Provides information such as clotting time and clot strength;
  - Can use up to 6 reagents simultaneously to help diagnose coagulopathies or guide anticoagulation therapies.
- Applications extend to triage and diagnosis for Sepsis and Envenomation.



# Guide Clinicians in Optimising Patient Specific Anticoagulation Therapy

- Anticoagulation therapy is needed to prevent the extremes of patient death by bleeding or from blood clots.
- Known benefits of the use of thromboelastography include:
  - improved prediction of bleeding, reduced risk of thrombosis, improved transfusion protocols;
  - reduced risks of complications and adverse effects and their associated costs;
  - reduced length of stay, time in ICU and time to extubation.
- When removed from the body, blood begins to coagulate:
  - Either need to test within 3 minutes or citrate and then recalcify, adding chemicals that can affect results.
  - Most devices are in centralized labs and/or are complex/cumbersome to operate.
- Blood behaves differently at different shear rates:
  - Current devices operate at a single shear rate, there is a need to inform on arterial, venal and capillary flows
- Patients can react differently to different drugs. Testing blood against different drugs before administration could:
  - Forewarn against intolerances and adverse effects such as HITT.
  - Guide clinicians for patient-specific optimal dosage and drug type.
- Market potential estimated annual cartridge sales in Australia of approx. 5 mill units/pa and USA 330 mill units/pa for anticoagulation therapy, not including potential for diagnosing coagulopathies, sepsis and envenomation.
- Global medical and non-medical sales have a multi-billion dollar potential.

# Portable, point of care, easy use, multi-channel rheometer resolves problems & optimises diagnosis.

- Problem – blood needs to be loaded before coagulation begins:
  - our rheometer is portable, and can be used at the point of care;
  - our rheometer is simple to use, with loading, distribution, and reagent mixing automatically handled;
  - our rheometer technology is implicitly vibration-proof and does not need a leveling process, enabling it to be used in noisy clinical settings and even in moving vehicles.
- Problem – blood behaves differently at different shear-rates, and experiences different shear-rates in the body:
  - our rheometer operates at three different shear-rates;
  - shear-rates are based on arteries, veins and capillaries.
- Problem – incorrect dosing can create adverse impacts:
  - our rheometer enables the clinician to select up to 6 different candidate drugs / dosages;
  - clinicians are able to assay the blood against the candidate drugs before administering;
  - our rheometer performs the pre-mixing automatically, guiding clinicians to the anticoagulants' dose-response
  - reduces the impacts of incorrect / insufficient dosing while reducing the costs and impacts of administering excess dosages
- Problem - intolerances and adverse effects such as HIT:
  - our rheometer enables loading of reversal agents and reporting on intolerances.

# Differentiation to existing coagulation testing

- Direct competitors are variants on viscoelastic testing (VETs) such as TEG, ROTEM and Sonoclot.
- Indirect competitors performing common coagulation tests (CCTs) which are variants on coagulation time such as INR or APTT-type tests.
- A summary of the advantages of VETs over CCTs is: “CCTs offer only a snapshot of hemostatic competence and do not provide a clear insight into the patient’s real-time hemostatic condition. VETs offer a holistic and concurrent picture of the coagulation process.” ( J. Clin. Med. 2022, 11(4), 1119)
- Existing VETs:
  - are often in central locations, we are point of care and able to be mobile;
  - offer limited preselected reagents, we enable clinicians’ choices with easy mixing;
  - offer a single shear rate, we offer multiple based on arteries, veins and capillaries;
  - have a significant potential for operator based loading error, we eliminate that;
  - are susceptible to noise and vibration, we overcome that;
  - use indexing and arbitrary units, not true rheology measurements preventing quantitative analysis from the rheology, we provide true rheology measurements enabling quantitative microstructural analysis.

# Critical Factors

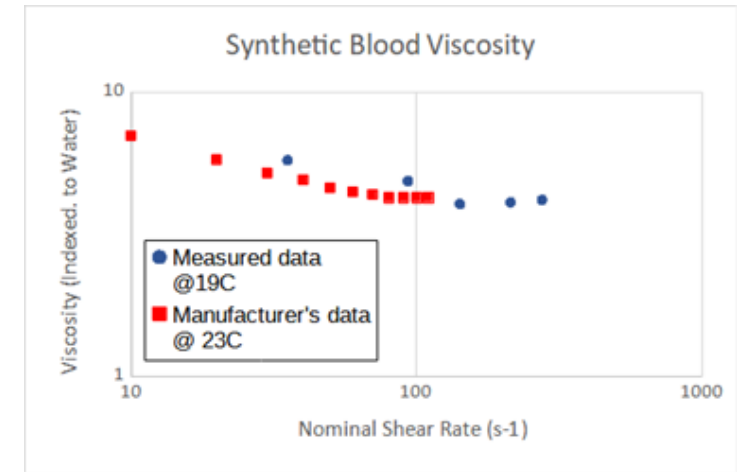
- We own all IP and Patents associated with our rheometer and other licensable products, including:
  - Rheometer and method for the use thereof – granted AU2017361981B2 & extensive international
  - Fluid check valve and fluidic systems for gas venting – grant AU2020335029B2 & international under examination
  - Reagent pre-loading system and measuring device AU2021902880A under examination
  - Vented piston AU2022900290A0 under examination
- Assisted by CSIRO Kickstart, we developed a method of mass manufacturing the cylindrical micro-channels needed for measurement. CSIRO performed micro-CT imaging to enable us to validate the precision and accuracy within the tolerance necessary for rheological testing.



- Regulatory approval for stage 1 reporting is anticipated to be granted using TEG as the predicate device. Clinical testing will be required for greater diagnostics for coagulopathies, sepsis and envenomation.
- We understand competitor devices to be about \$30 – 60k and consumables \$10 – 50 we anticipate being competitive, profitable and cost conscious to maximise market penetration.

# Development plan & investment proposal

- 12 months significantly funded from current share tranche. A small balance is available for sophisticated investors.
- Significant investment proposal: a 15% equity for \$2 million.
- We're currently approaching MVP for both rheometer and cartridge, we have significant data testing of the elements of our device, our first set of data against synthetic blood is very promising.
- 12 months – MMP of rheometer and cartridge.
- 3 years – Regulatory approval commensurate with predicate device
  - significant testing and development for advanced diagnostics toward regulatory approval
  - sales into non-medical markets
- Note: benefits veterinary applications and does not require regulatory approval;
  - applications in mining to eliminate tailings dams, we have university endorsements, anticipate funding to achieve this without dissipating efforts or distracting from medical.
  - we have developed an air evacuation / bubble free syringe, interest from major manufacturers.
- Investment funding to complement potential grants to cover: an experienced senior executive, QA, admin & logistics staff; development of commercial molds; ongoing R&D and patent costs; and clinical trials.





Thank you – I welcome any questions.

# Haemograph Pty Ltd

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