ClotGuard FAQ

1. General Overview

- What problem are you solving?
- We are mitigating preventable deaths globally through the use of nanotechnology, microneedles, and clotting factors.

- Why does this problem matter right now?
- Response time is critical; even minutes of delay can determine survival.
- Current solutions create dangerous gaps in care.
- Bleeding remains one of the leading causes of preventable death, especially in trauma and emergencies.

- Who is this for?
- Hospitals, emergency medical services (EMS), and the military, as well as first responders.
- Market reach is huge; there are many different sectors to expand into.

- What is your vision for the company?
- We want to redefine how bleeding is managed by shifting from reactive treatment to instant, autonomous treatment.
- ClotGuard is the first step towards autonomous, responsive systems that can detect and treat critical conditions, saving lives.

- What does success look like in 5 years?
- Success for us looks like having strong foundational research done and having developed strong, clear data showing that our device could genuinely help save millions of lives.

- Why are you and Isavella building this?
- We want to solve real, high-impact problems in healthcare.
- We felt that by combining technologies, there was a huge opportunity to rethink how this is handled.
- There's a delay between injury and intervention; that gap costs millions of lives.

2. Problem & Market

- How big is the problem?

- Bleeding is the leading cause of preventable death worldwide, including trauma, surgery, and emergency care.
- In Canada alone, preventable bleeding contributes to thousands of avoidable deaths per year.
- Globally, millions of patients each year could benefit from faster intervention.

- Who is most affected by this issue?
- Military personnel in combat or training scenarios (high-risk injuries)
- Trauma patients in emergency or accident situations
- Individuals with chronic bleeding disorders

- What is your target market (TAM, SAM, SOM)?
- TAM: Global emergency and trauma care (~$50B+)
- SAM: Military medical systems + EMS systems in North America (~$5-10B)
- SOM: Initial military contacts in Canada and allied countries (~$500M-1B)

- What trends make this problem more urgent now?
- Rising focus on rapid-response healthcare (demand for real-time intervention)
- Wearable and remote healthcare tech adoption is increasing
- Overburdened emergency systems
- Advances in biomaterials and nanotechnology make real-time bleeding control feasible.

- What happens if this problem is not solved?
- Preventable deaths continue in trauma and emergencies
- Hospital and EMS costs increase due to complications
- Delays in intervention can result in permanent disability or higher mortality
- Healthcare systems remain reactive instead of proactive

- Where will you enter the market first?
- Military sector: high urgency, large funding, and strong need for rapid intervention
- Validates technology in extreme conditions
- Provides credibility for future expansion into EMS, hospitals, and civilian applications
- https://globalnews.ca/news/11670421/carney-defence-industrial-strategy/
- Prime Minister Carney launches Canada's first Defence Industrial Strategy to strengthen security, create prosperity, and reinforce strategic autonomy.

3. Solution & Technology

- What stage are you currently at? (idea, prototype, etc.)
- Early prototype stage, with basic concept validated through external research and preliminary design
- Working on a functional proof-of-concept for a nanobot platelet delivery system
- Preparing for pre-clinical testing and safety studies

- What key components make up the system?
- Wearable patch: continuous monitoring of bleeding biomarkers
- Sensors: detect biomarkers such as thrombin, oxygen levels, and blood loss
- Nanobots: carry platelets directly to the bleeding site
- Delivery mechanisms: microneedles for fast, targeted intervention
- Storage cartridge: holds lyophilized platelets safely until activation

- What are the biggest technical challenges?
- Safe navigation of nanobots in the bloodstream without causing blockage
- Real-time detection of bleeding with sensitivity and accuracy
- Biocompatibility of all materials in contact with blood
- Controlled release of platelets to avoid overdosing or clotting issues

- How do you ensure safety and reliability?
- Using biocompatible, biodegradable materials like PLGA encapsulated platelets
- Controlled, measured doses of platelets to prevent overcorrection
- Pre-clinical testing in lab models to validate performance and safety

- How is this different from existing medical devices?
- Unlike traditional treatments, ClotGuard acts immediately and autonomously
- Provides targeted, on-site intervention rather than systemic or reactive treatment
- Designed for both military and civilian applications, bridging a gap that current devices aren't even close to covering

4. Traction & Validation

- What progress have you made so far?
- Developed a clear concept and system architecture for ClotGuard
- Conducted extensive research on bleeding, platelet function, and targeted delivery systems
- Begun early-stage prototyping of the external patch system
- Initiated collaboration support with Microsoft in Vancouver

- Have you built or tested a prototype?
- Currently building an early external prototype of the wearable patch
- In the process of sourcing and integrating key components
- Functional biological testing has not begun yet (finding a research team, lab, etc.)

- What research supports your approach?
- Established research on lyophilized platelet function in clotting and trauma care
- Studies show early intervention significantly reduces mortality in bleeding cases.
- Existing work in nanomedicine and targeted drug delivery systems

- Research into biomarker-based detection

- Have you spoken to experts or potential users?
- Yes, engaged with advisors and professionals in biomaterials and medical technology.
- We have also discussed ClotGuard with end-users
- Discussed material selection, feasibility, and design considerations
- Beginning to explore insight from clinical and emergency care perspectives

- What feedback have you received?
- String validation that the problem is real and high-impact
- Emphasis on the importance of biocompatibility and safety in design
- Advice to prioritize material selection and realistic prototyping pathways
- Reinforcement that this requires a structured research and testing approach

- What are your next key milestones?

5. Business Model & Use of Funds

- How will ClotGuard make money?
- Selling ClotGuard as a medical device system
- Recurring revenue through different single-use components
- Potential long-term contracts with military and healthcare systems

- Who are your paying customers?
- Military organizations (initial market)
- Hospitals and healthcare systems
- Emergency Medical Services (EMS)
- Potentially, government health agencies

- What is your go-to-market strategy?
- Start with military partnerships and pilot programs
- Validate technology in high-risk, high-urgency environments
- Expand into EMS and hospital systems after initial validation
- Build credibility through clinical data and strategic partnerships

- How much funding are you seeking?
- We are seeking early-stage funding to support initial research and prototype development
- This phase requires a dedicated research budget due to the complexity of the system.

- How will you use the funding?

- Access to laboratory facilities and specialized equipment
- Procurement of biomaterials, sensors, and prototype components
- Funding consumables for iterative testing and development
- Outsourcing specialized assays
- Supporting early-stage prototyping and validation efforts

- What milestones will this funding help you achieve?
- Development of a functional prototype
- Initial lab validation of sensing and delivery systems
- Early biocompatibility and safety testing
- POC demonstrating the feasibility of the system
- Positioning for next-stage funding or partnerships

- What does your cost structure look like?
- R&D costs
- Testing and validation
- Prototype development
- Regulatory preparation
- Minimal operational costs at this stage

6. Team

- Who are the founders?
- Sophia Dhami and Isavella Tsoulias, student founders who are passionate about building high-impact healthcare solutions
- Background in research, innovation with emerging tech, and early-stage startup development
- Focused on solving real-world problems at the intersection of healthcare and technology

- Why are you the right team to build this?
- Proven ability to take ideas from concept to research to structured solutions
- Deep interest in biomedical innovation and high-impact problem solving
- Already actively engaging with researchers, mentors, and industry professionals
- Strong willingness to learn fast and seek expert input

7. Risks & Challenges

- What are the biggest risks to your success?
- Ensuring that nanobot delivery works safely in real biological systems
- Medical devices can take years to reach the market, so regulatory approval timelines would definitely be one

- Integrating a novel system into conservative healthcare environments
- Funding and access to lab/testing environments at the early stage

- What technical challenges remain?
- Achieving precise targeting and navigation of nanobots in the bloodstream
- Ensuring accurate, real-time detection of bleeding without false positives
- Developing safe and controlled platelet release mechanisms
- Ensuring full biocompatibility and biodegradability of materials
- Integrating all components into a wearable and reliable system

- What regulatory hurdles do you face?
- Classification as a combination product (device + biologic), increasing complexity
- Need for extensive preclinical and clinical trials to prove safety and efficacy.
- Approval processes through regulatory bodies.
- Strict requirements around biomaterials, nanotechnology, and blood interaction

- What are the biggest barriers to adoption?
- Trust in new technology, especially involving nanotechnology in the body
- Resistance from healthcare systems is slow to adopt novel devices
- Need for integration into existing emergency workflows
- Cost considerations for hospitals, the military, and healthcare providers

- How do you plan to mitigate these risks?
- Start with military applications, where urgency and openness to innovation are much higher.
- Conduct phased testing, beginning with lab validation before clinical trials.
- Work with medical experts, researchers, and regulatory advisors early
- Focus on biocompatible, well-studied materials to reduce any safety concerns
- Secure funding to support R&D, testing, and regulatory navigation

8. Regulatory & Clinical Pathway

- What is your regulatory pathway?
- ClotGuard will likely follow a medical device regulatory pathway, initially scoped as a Class II device, with potential classification as a combination product due to platelet delivery.
- In Canada, our approval would go through Health Canada; for the U.S., it would be the FDA
- We plan to engage with regulatory bodies early to clarify classification and requirements.

- What testing will be required before clinical use?
- In vitro testing to validate sensor accuracy and platelet delivery mechanism
- Preclinical (animal) studies to assess safety, targeting, and effectiveness

- Biocompatibility testing for all materials in contact with blood
- Clinical trials to evaluate safety and performance in humans
- Validation of device reliability and response time

- How will you ensure biocompatibility and safety?
- Use of biocompatible and biodegradable materials
- Designing nanobots to degrade safely after completing their function
- Controlled and localized platelet delivery to avoid systemic clotting risks
- Extensive lab and preclinical testing before human use
- Incorporating fail-safes and controlled dosing mechanisms

- What is your timeline to approval?
- Timeline may vary due to final classification and trial outcomes
- Short term (2-3 years): prototype development + lab validation
- Midterm (4-6 years): Preclinical testing and early clinical trials
- Long term (7-8+ years): Regulatory approval and initial deployment