LEUKO LABS INC.

Noninvasive white blood cell monitoring to improve cancer chemotherapy outcomes

Carlos Castro-Gonzalez, Co-founder & CEO | carlos@leuko.com | www.leuko.com

Company Overview

850k cancer patients start chemotherapy every year in the US and 140k need to be hospitalized because of febrile neutropenia (FN), an infection while their white blood cells (WBC) are critically low as a consequence of their chemotherapy. FN hospitalizations bring negative clinical outcomes (7% mortality) and a total cost of $4.2B ($30k/case) in the US alone. To solve this unmet need, Leuko -an MIT spinout- has developed PointCheck™, the first medical device that enables non-invasive, at-home and frequent WBC monitoring, triggering timely interventions by the care team (e.g. prophylactic antibiotics or growth colony stimulating factors) that can reduce FN hospital readmissions by 50%. Beyond chemotherapy, Leuko aspires to continue growing to serve the 10 million immunocompromised US patients that could benefit from increased monitoring of their weakened immune system.

Market and Commercialization Strategy

By saving 50% of FN-related hospitalizations, the total addressable market (TAM) is $2.1B/year in the US (140k hospitalizations x $30k/case x 50%). Our commercialization strategy -informed by our customer interviews- focuses on Integrated Delivery Networks (IDNs) and Accountable Care Organizations (ACOs) as a starting point in the US. These organizations are an ideal beachhead because of their incentives to generate healthcare savings. We project initial revenue from a value-based leasing model with these customers that will be implemented following FDA approval. Expansion to fee-for-service providers will follow through reimbursement as a Durable Medical Equipment (DME) supplemented by remote patient monitoring (RPM) CPT codes. Future applications include geographic expansion to Europe and globally, and to other therapeutic markets beyond chemotherapy.

Technical & Competitive Advantage

PointCheck™ is the first noninvasive, portable self-test to monitor WBC levels at home. All existing technologies require visits to the clinic, blood draws, healthcare staff, reagents, and biohazard disposal, and thus cannot be easily performed at home and daily. Our technology is protected by 6 patents (3 issued, 2 applications, 1 provisional).

Regulatory Strategy & Intellectual Property

We have worked with regulatory consultants (Hogan Lovells) and submitted a 513g request for classification to the FDA which confirmed a Class II De Novo regulatory pathway. After this, we conducted an in-person pre-submission meeting with the FDA in which we agreed on the intent for use (IFU) and design of the pivotal trial required for clearance, including sample size and performance targets. The company is setting up a quality management system to comply with 21 CFR part 820. Our IP portfolio includes 6 patents: 3 issued, 2 applications and 1 provisional with both US and PCT filings. Our first 3 patents were developed at MIT with whom we have an exclusive licensing agreement.

Key Milestones To Date

Description	Date/Year
Usability study: Guided modifications for final device design (self-operated). Usability, safety & efficacy in >80 cancer patients.	2021
Pre-marketing & partnerships: Unmet need validation, >100 customer interviews, LOIs from 5 hospitals, 1 insurer, 2 medical device distributors and 2 pharma companies.	2020
FDA pre-submission: Class II De Novo classification, finalized pivotal trial design and intent for use.	2019
Early feasibility study: Clinical proof of concept of prototype device (nurse-operated) in >40 cancer patients.	2018

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2020	Grant	NIH SBIR Phase II	$2M
2019	Funding Round	Seed round led by Good Growth Capital, Pegasus Tech Ventures and Nina Capital	$2M
2018	Grant	NIH SBIR Phase I	$225k
2018	Awards	MassChallenge HealthTech, MIT 100k, Rice Business Plan Competition, etc.	$200k

Use of Proceeds (How much are you looking to raise and how will you spend those funds?)

We are looking to raise a $6M Series A to support the following value-inflection milestones: Complete pivotal trial (Q4 2022), FDA clearance (Q2 2023) and US commercial launch (Q2 2023).

Key Team Members

Carlos Castro-Gonzalez, PhD (Co-founder & Chief Executive Officer)

>10-year experience in biomedical engineering. Innovation & entrepreneurship training at MIT. Prior med device startup experience.

Ian Butterworth, MSc (Co-founder & Chief Technology Officer)

>10-year experience in hardware prototyping, electronics and coding. MIT research engineer. Prior med device startup experience.

Aurelien Bourquard, PhD (Co-founder & Chief Data Scientist)

>10-year experience developing AI and computer vision algorithms. EPFL and MIT trained scientist.

Alvaro Sanchez-Ferro, MD, PhD (Co-founder & Chief Medical Officer)

>15-year experience in medical practice, clinical studies and biostatistics. MIT training. Prior med device startup experience.

Partha Paul, MBA (VP Business Development)

>20-year experience in medical device commercialization at Philips and GE.