



### **Point-of-care Blood Clot Analysis Platform**

Revolutionizing Testing With Minimal Blood And Maximum Insights



Levisonics Inc.

www.levisonics.com



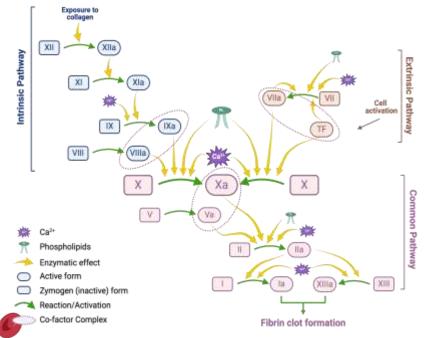
### **1.6 Billion People Worldwide Are Affected By Conditions Impacting Bleeding Or Clotting**





## There Is A Big Need for Easy, Safe, And Comprehensive Blood Coagulation Testing

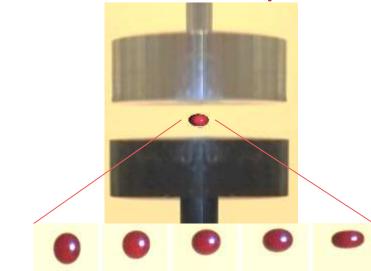




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- Blood coagulation is a complex but important process in the body.
- Clotting involves multiple factors and proteins.
- Diagnosing bleeding or clotting issues is currently <u>very complicated</u>.
- Doctors require a combination of <u>multiple</u> <u>different tests</u> for accurate diagnosis.
- These tests need <u>large amount of blood</u> sample.
- Multiple tests often mean <u>multiple blood draws</u>.
- Existing tests <u>don't serve vulnerable patients</u> like children.

### Our Solution: Minimally Invasive Test With Comprehensive Results

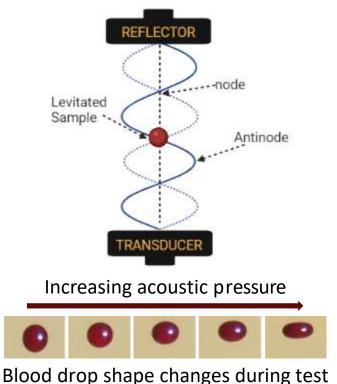


- 6 microliters of blood needed per test
- Noncontact test avoids sample contamination
- Outputs 8 comprehensive clotting parameters



- Fully functional minimal viable prototypes
- Convenient, portable, countertop device
- Easy to use and faster test results

### **Our Innovative Technology**



- Our <u>patented technology</u> uses sound waves to <u>levitate</u> and analyze blood drops.
- Tracks changes in location and shape of the drop during a test.
- Measures <u>mechanical and optical</u> <u>properties</u> of the blood, like current standard tests.
- Need <u>less blood</u> (only 6 microliters per test) easily collected from finger prick.
- Outputs quantitatively and qualitatively superior test results compared to the status quo and provide a more <u>holistic view</u> of the patient's clot profile.

### **Our Solution Offers Value To All Stakeholders**









#### Patients

- Reduce Adverse
  Events
- Less discomfort

#### Physicians

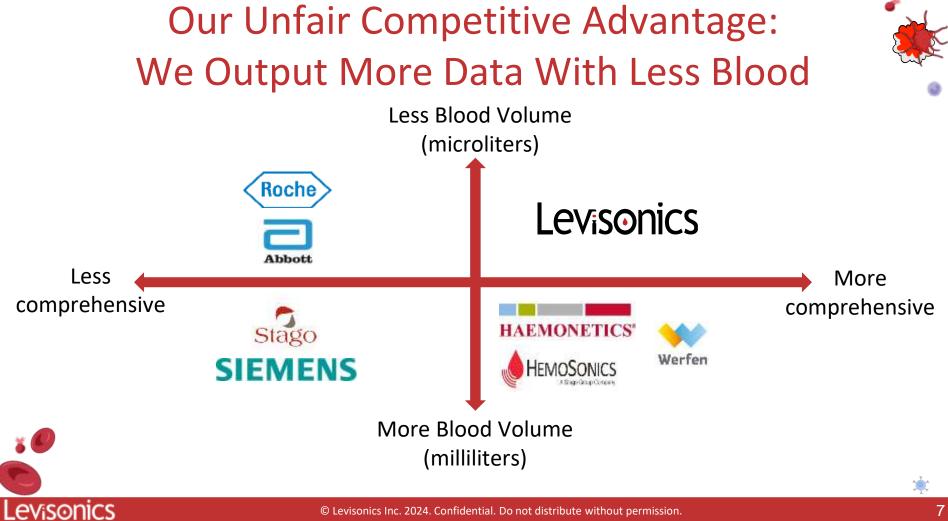
- Empowered with 2x actionable data
- Better diagnosis
- Point of care convenience

#### Payers

- Avoid multiple tests
- Reduce repeat visits
- Reduce care costs







### **Our Business Model**







#### Devices

• Sale or Lease

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- Price: \$30k \$45k
- Profit Margin: 60%

#### Consumables

- Recurring sales
- Price: \$100
  - Profit Margin: 80%

Maintenance Contracts

- Labor and parts
- Profit Margin: 60%



### **Regulatory Strategy**

<u>Description:</u> Drop-of-blood device for comprehensive coagulation analysis via acoustic tweezing	USA Regulatory Classification	
	Medical Device	Yes
	FDA Center	Center for Devices & Radiological Health
	US Classification	Class II
Intended Use:		
Monitoring of blood coagulation	Submission Type	510k – Introduction of new technology May need De Novo Classification for Home Use
Patient Population:		May need be Novo classification for Home ose
Pediatric and adult patients with	FDA Review Panel	Hematology
hematological disorders	Code of Federal Regulation	Non-Significant Risk Device
<u>Care Setting:</u>	Description	
Professional Point of Care – Exam	FDA Product Code	JPA or QFR
Room/Doctor's office, Hospital Lab, Special Coagulation Lab, Research Lab, Operating Room	FDA Product Code Description	JPA: System, Multipurpose For In Vitro Coagulation Control QFR: Coagulation system for the measurement of whole blood viscoelastic properties
	Pre-Market Clinical Study Required	No

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### **United States Market Analysis**

> 244 M Tests Per Year

> 65 M Patients

> 4 M Children

\$1.6B

\$125M

\$530M

Available Market Lab (\$1.1B; Hospital \$420M; Home \$50M); CAGR 7.5%

Addressable Market Outpatient, Home and 33% Inpatient

Initial Target Market
 Pediatric Segment
 11.9 M tests @ \$10.50/test



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Gaps in current market: Pediatrics & Outpatient Clinics

### Go To Market Strategy

#### 1. Pediatrics

- Children's Hospitals (324)
- Hemophilia Treatment Centers (147)
- Pediatric Wards in Hospitals (1,418)
- PICUs (349)

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- Hospitals (~5,100)
- Clinics (~34,800)
- Infusion Centers (~3,600)
- Military Use

# 3. Biomedical Research

- Drug discovery
- Veterinary
- Biofluid Analysis



#### 4. Near Patient

- At Home Therapy Monitoring
- Retail Clinics (~2,700)
- Mobile care units

Direct Sales

#### Sales via Strategic Partnerships

### Traction

10+ years

**Research And Development** 

### 6 MVPs

6 TRL

With Phase I Product

For Pilot Clinical Studies

### \$6.3 Million

Non-dilutive Grant Funding

4 Patents

Peer Reviewed

Publications

Exclusive License + In House

3 Predicates Identified

510k pathway



# 6+

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120+

**Customer Discovery Interviews** 



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Damir Khismatullin, Ph.D. Co-founder Board of Director



Glynn Holt, Ph.D.

Co-founder

**Board of Director** 



Manik Dautta, Ph.D. Lead Engineer



- Decades of experience in acoustics and biomedical research
- Strong scientific and technical expertise.
  - Multiple collaborations with potential customers
  - Supporting team of consultants and advisors

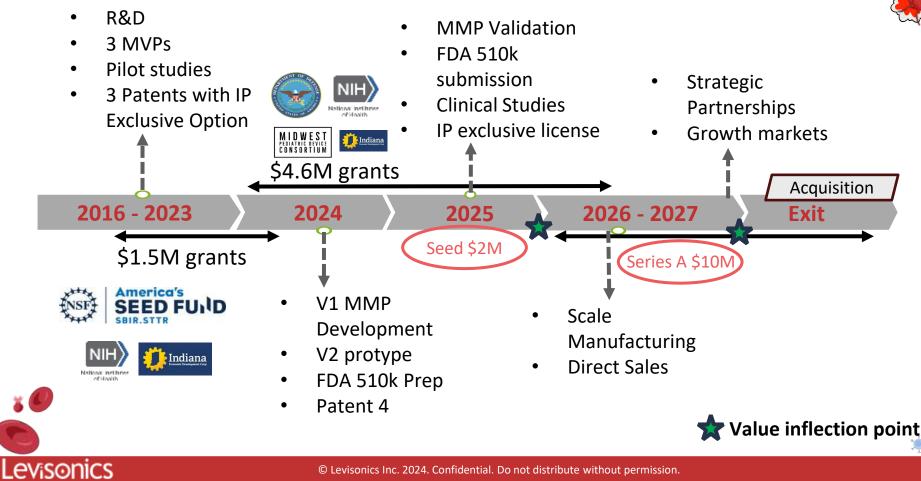


### **Collaboration and Support**

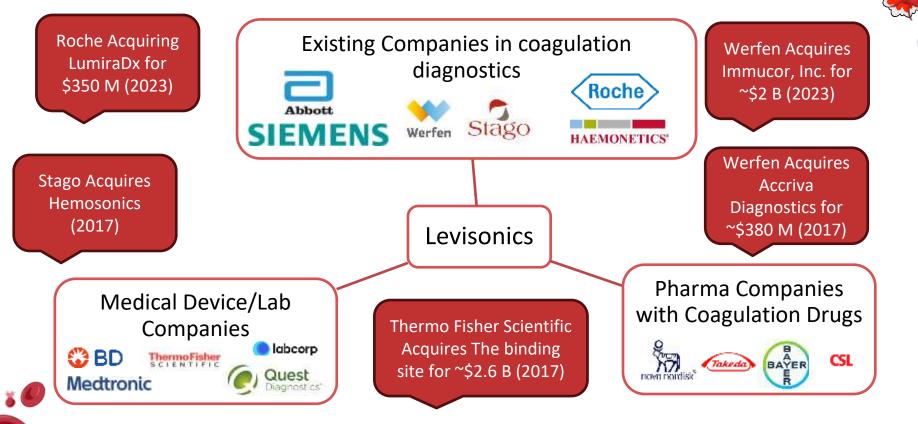


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### Milestones



### **Multiple Options For Acquisition**

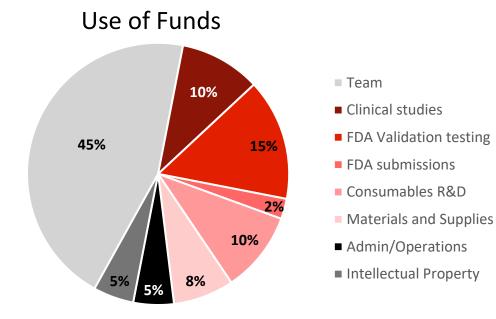


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#### Our Ask

#### Seeking \$2 Million Seed Round To Complete MMP Validation Testing And FDA Submission





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### Additional Ways To Support Us





Introductions with Hospital Networks



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Introductions to Potential Strategic Partners

Introductions to Industry Experts









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#### Contact Us

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