



Point-of-care Blood Clot Analysis Platform

Revolutionizing Testing With Minimal Blood And Maximum Insights



Levisonics Inc.

www.levisonics.com



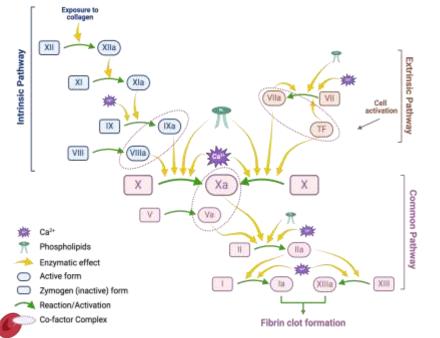
1.6 Billion People Worldwide Are Affected By Conditions Impacting Bleeding Or Clotting





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

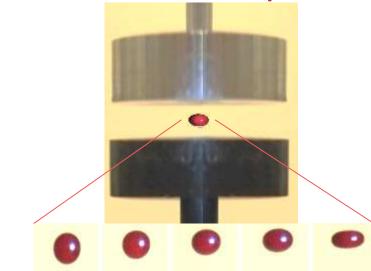




Levisonics

- 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

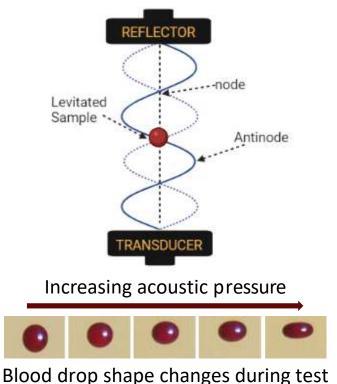


- 6 microliters of blood needed per test
- Noncontact test avoids sample contamination
- Outputs 8 comprehensive clotting parameters



- 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

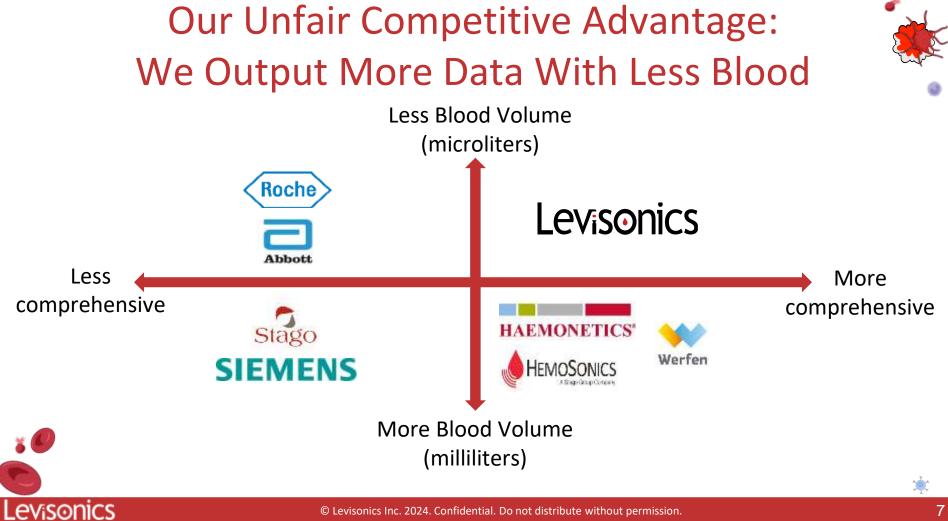
- Empowered with 2x actionable data
- Better diagnosis
- Point of care convenience

Payers

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







Our Business Model







Devices

• Sale or Lease

evisonics

- 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

Levisonics

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



evisonics.

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)

evisonics



- 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+

© Levisonics Inc. 2024. Confidential. Do not distribute without permission.

120+

Customer Discovery Interviews



Levisonics











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

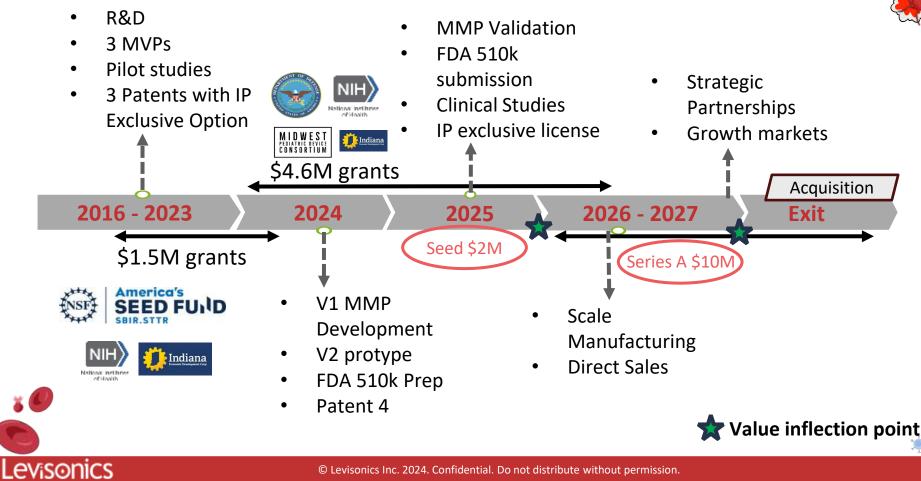


Collaboration and Support

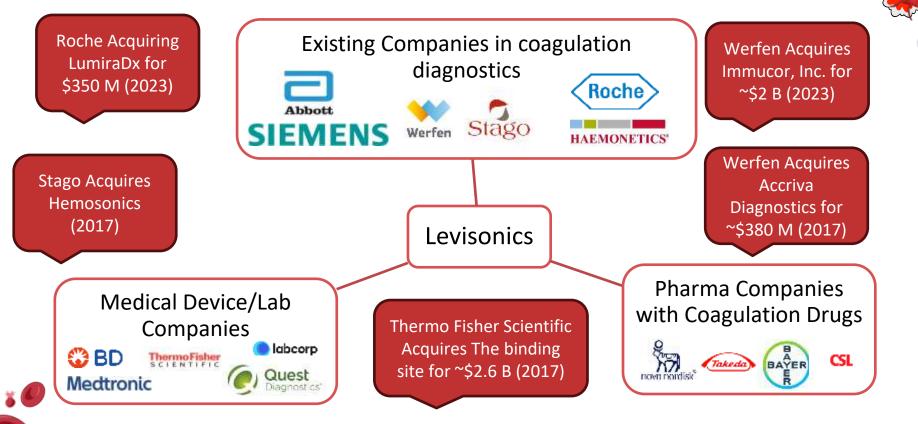


Levisonics

Milestones



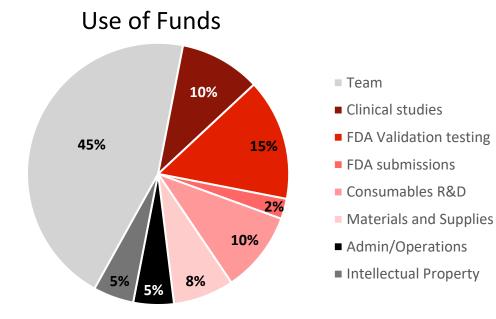
Multiple Options For Acquisition



Levisonics

Our Ask

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





17

Additional Ways To Support Us





Introductions with Hospital Networks



Ť,

R

_evisonics



Introductions to Potential Strategic Partners

Introductions to Industry Experts









Point-of-care Blood Clot Analysis Platform

Revolutionizing Testing With Minimal Blood And Maximum Insights

Contact Us

Nithya Kasireddy CEO, Levisonics Inc. <u>nkasireddy@levisonics.com</u> <u>www.levisonics.com</u>



