Next-Generation
Exosome Liquid Biopsy Diagnostics

Co-Founders

Gianluca Roma, MS, MBA
CEO

20+ years clinical diagnostics experiences
Marketing, commercialization & BD expertise
Gen-Probe - AutoGenomics - Illumina - Ion Torrent
Co-founder InKaryo - Sold to Esperite N.V.

Yuchao Chen, Ph.D.
CTO

Penn State University- Engineering Science and Mechanics, Ph.D.
System integration, microfluidics and diagnostics expertise
30 publications - e.g. Nature Biotechnology

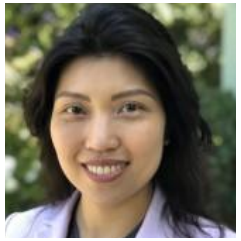
Fei Liu, Ph.D.
CSO

KAIST Chemical and Biomolecular Engineering, Ph.D.
UC Berkeley and Stanford University
Exosome biology & diagnostics expertise
21 publications - e.g. Nature Biomedical Engineering

Advisory Board

Prof. Luke P. Lee, Ph.D.
UC Berkeley and Harvard
350 peer-reviewed publications
> 40 issued international patents

Dr. Robert Cole, M.D.
UC Irvine
Practicing physician > 30 yrs
Clinical and regulatory expertise
Former CMO at AutoGenomics



Jeep Kline, MBA
UC Berkeley
General Partner at Translational Partners
Business & strategy advisor

Problem: Liquid Biopsy Testing Has Limitations

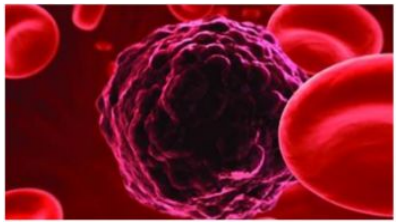
non-invasive sample collection

Urine

Plasma

Saliva

What is analyzed?

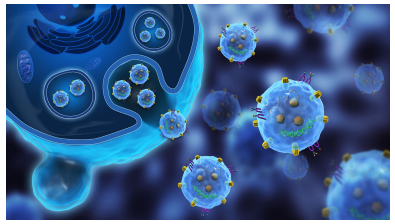


Circulating Tumor Cells

Comprehensive biomarkers <u>but</u> very rare

Circulating Tumor DNA

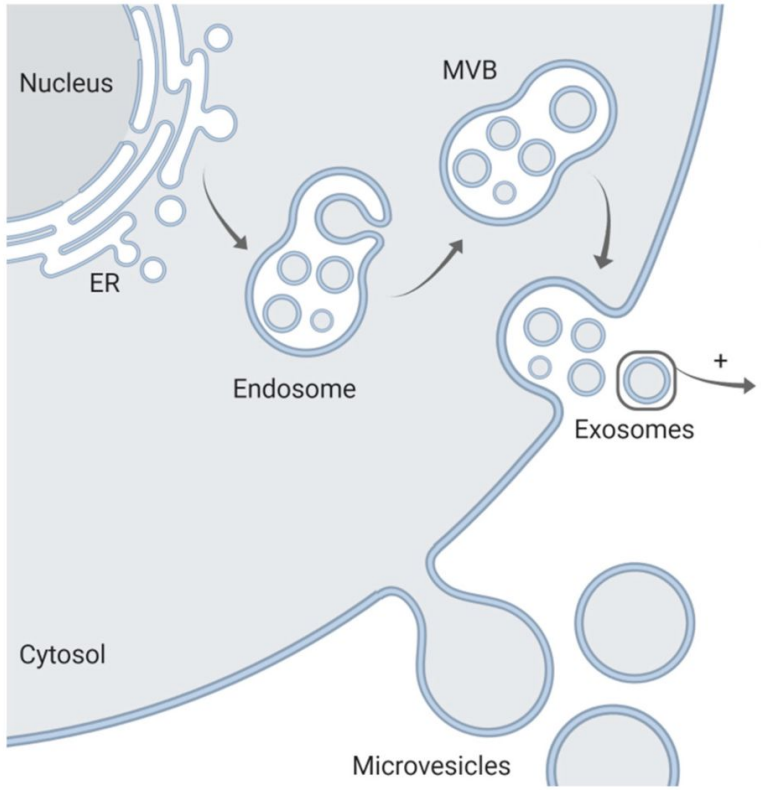
Easy to isolate <u>but</u> DNA not stable, limited biomarker

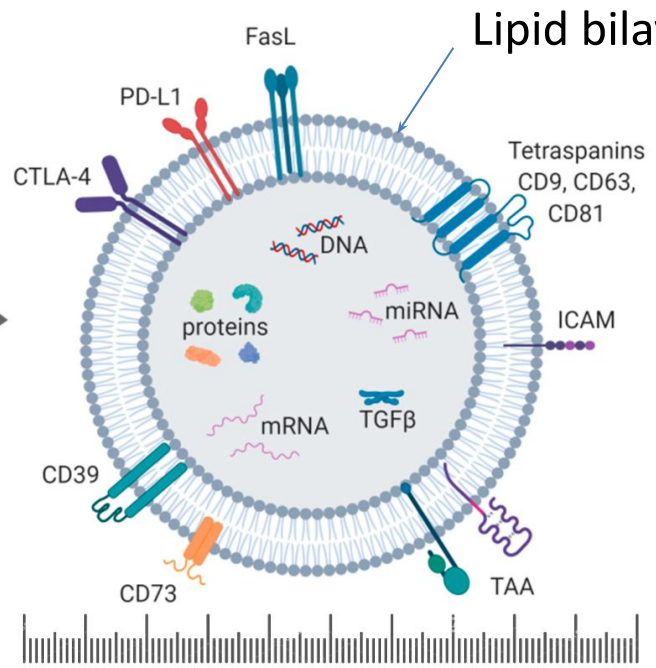


Exosomes

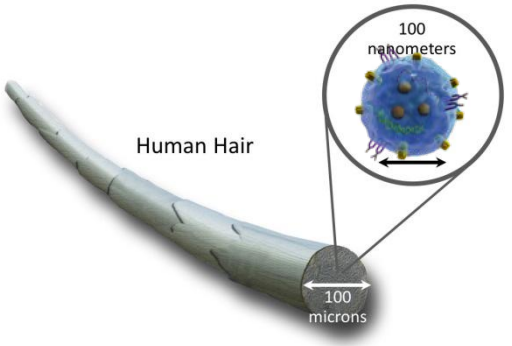
Abundant and released early <u>but</u> difficult to isolate

What are Exosomes?





35 nm – 200 nm diameter



~ 1,000X smaller than a hair

Exosomes are released early, abundant, stable, and diverse biomolecules for analysis

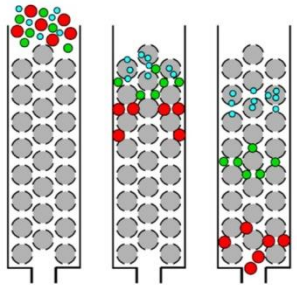
sources: https://www.mdpi.com/ Doyle 2018 liquid biopsy market report/ decibio

Challenges: Exosome Enrichment & Isolation

Ultracentrifugation

Low integrity

Size Exclusion Chromatography

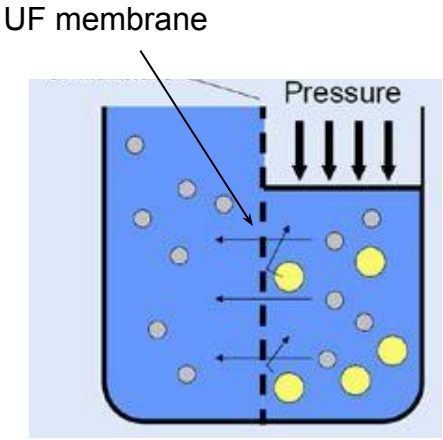


Low yields

Polymer Precipitation (PEG)

Low purity

Ultra-Filtration (UF)



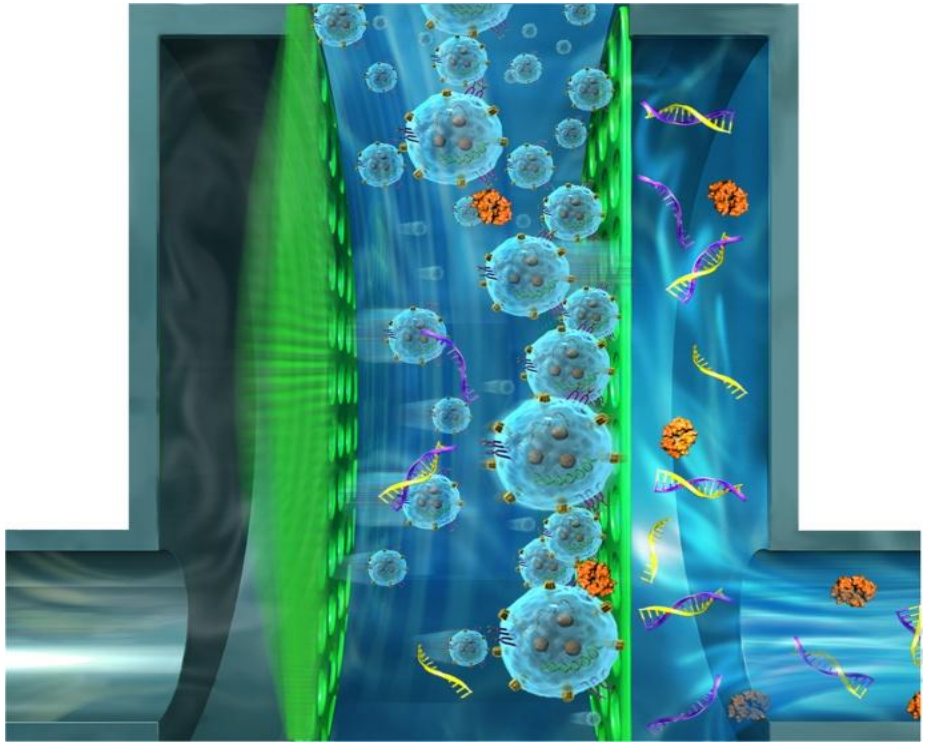
- Small membrane pores clogs easily
- Limited to small volumes processing
- Slow processing
- Difficult to retrieve exosomes

Opportunity to enable rapid & large volume processing

Solution: Rapid Exosome Enrichment Technology

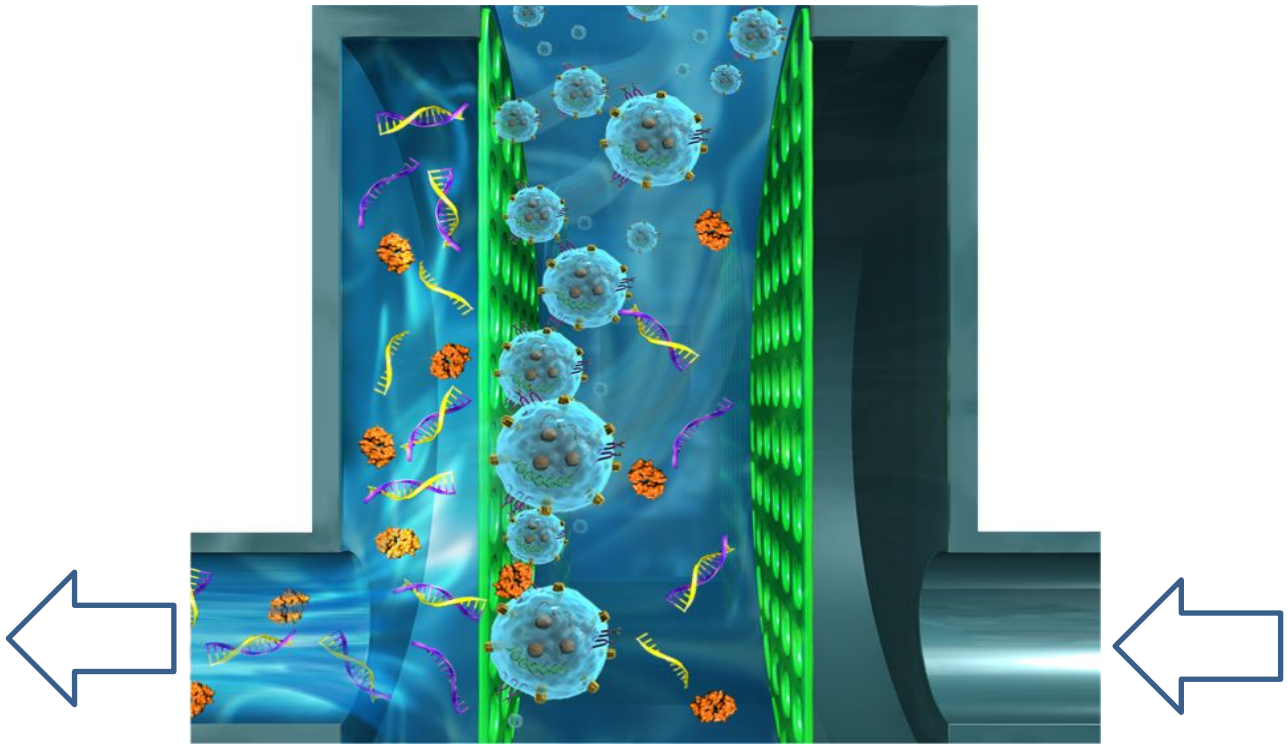
sample in

Microfluidic
LEAP Chip



Negative Pressure Oscillation

Solution: Rapid Exosome Enrichment Technology



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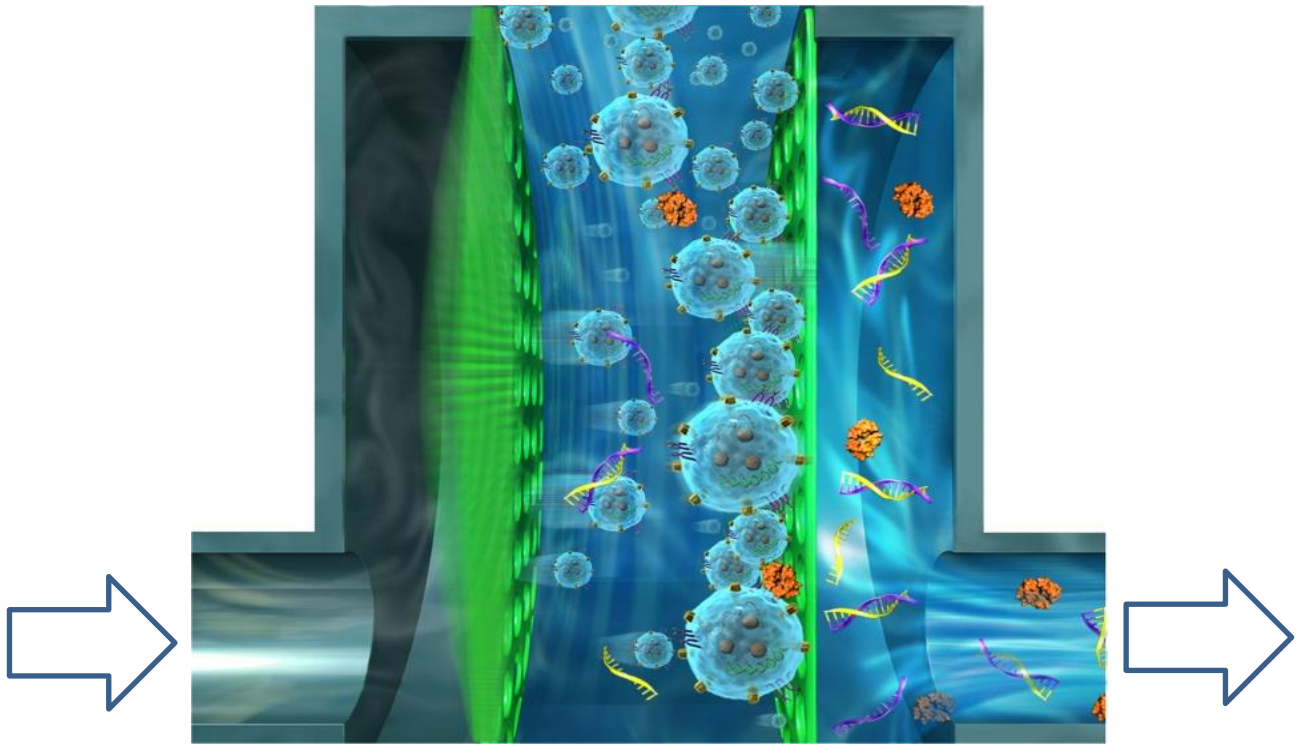


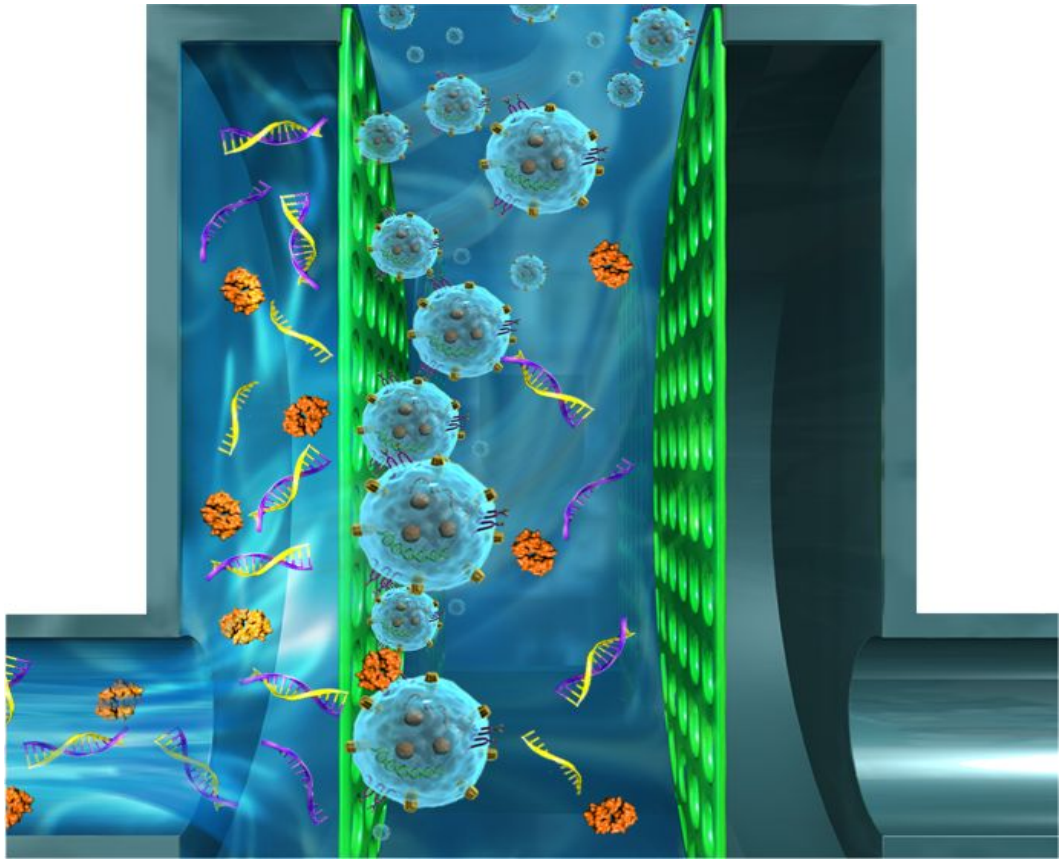
Negative Pressure Oscillation

Solution: Rapid Exosome Enrichment Technology

large samples

fast processing

automated & easy



high concentration

>99% purity

30 nm – 5 µm broad particle size selection

Products: Automated Exosome Isolation

Patented LEAP Systems

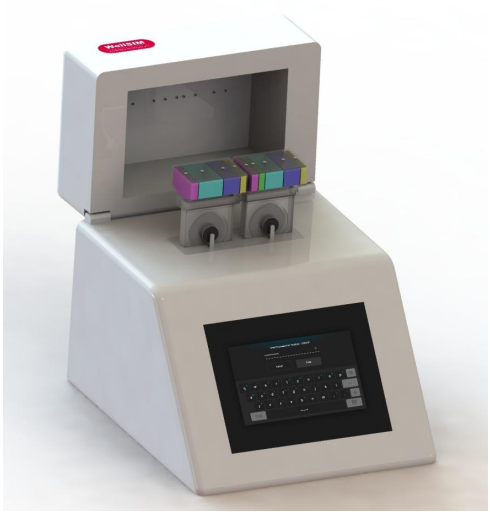
LEAP Chip

LEAP Reagent Kits

LEAP Auto Station

- Bench top sized
- Process very large volumes (50 ml)
- Flexible programming
- Semi-automated
- Versatile applications – biomarker discovery

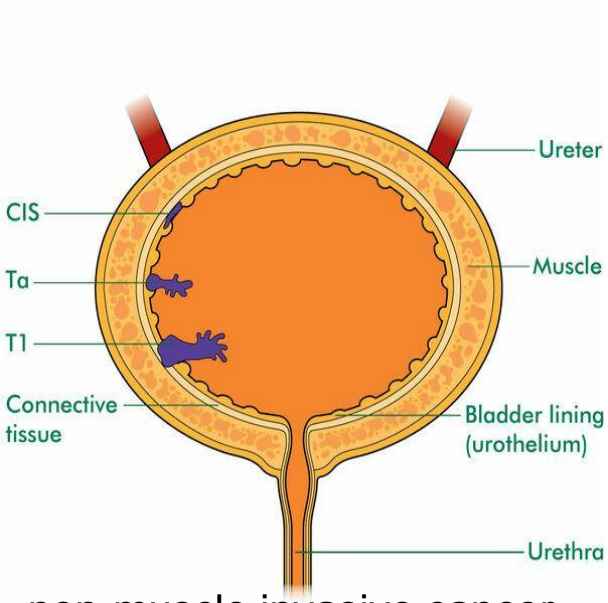
LEAP Regent Cartridge



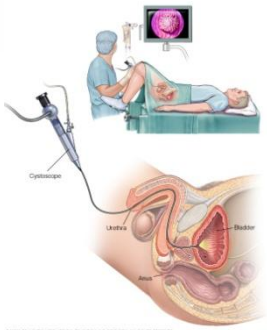
LEAP Auto Mini Station/ LEAP Analyzer

- Point-of-care sized
- Rapid sample-to-answer solution
- Detection module (PoC option)
- Pre-programmed for ease of use
- Specific applications

Unmet Need: Accurate Bladder Cancer Test

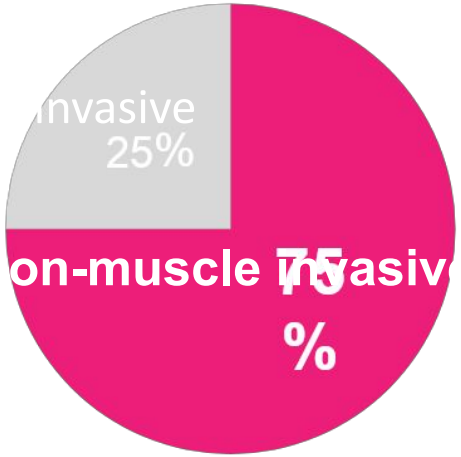


non-muscle invasive cancer



cystoscopy procedure

$4B Bladder Cancer Surveillance



Statistics:

- > 60,750 new cases/year of non-muscle
- Ave. 50% recurrence rate in non-muscle
- > 600,000 living in fear of recurrence in US
- Kills 17,240 people every year

opportunity for an easier, more sensitive & specific, and less expensive monitoring test

Source: American Cancer Society 2018 Report, Data from the National Cancer Institute website/ Mayo clinic

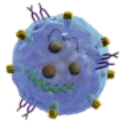
Exosome Bladder Cancer Biomarker Discovery

Pre-analytical

large urine samples
(50 ml)

+

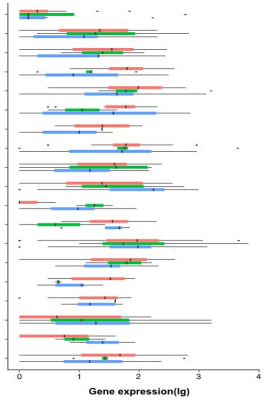
LEAP Auto Station



highly concentrated &
purified exosomes

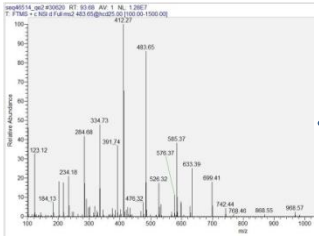
Data

Illumina NGS



exosome
transcriptomics

Thermo-Fisher MS



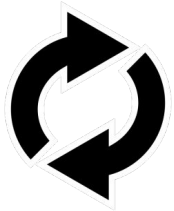
exosome
proteomics profiling

Analysis

AI

Artificial Intelligence

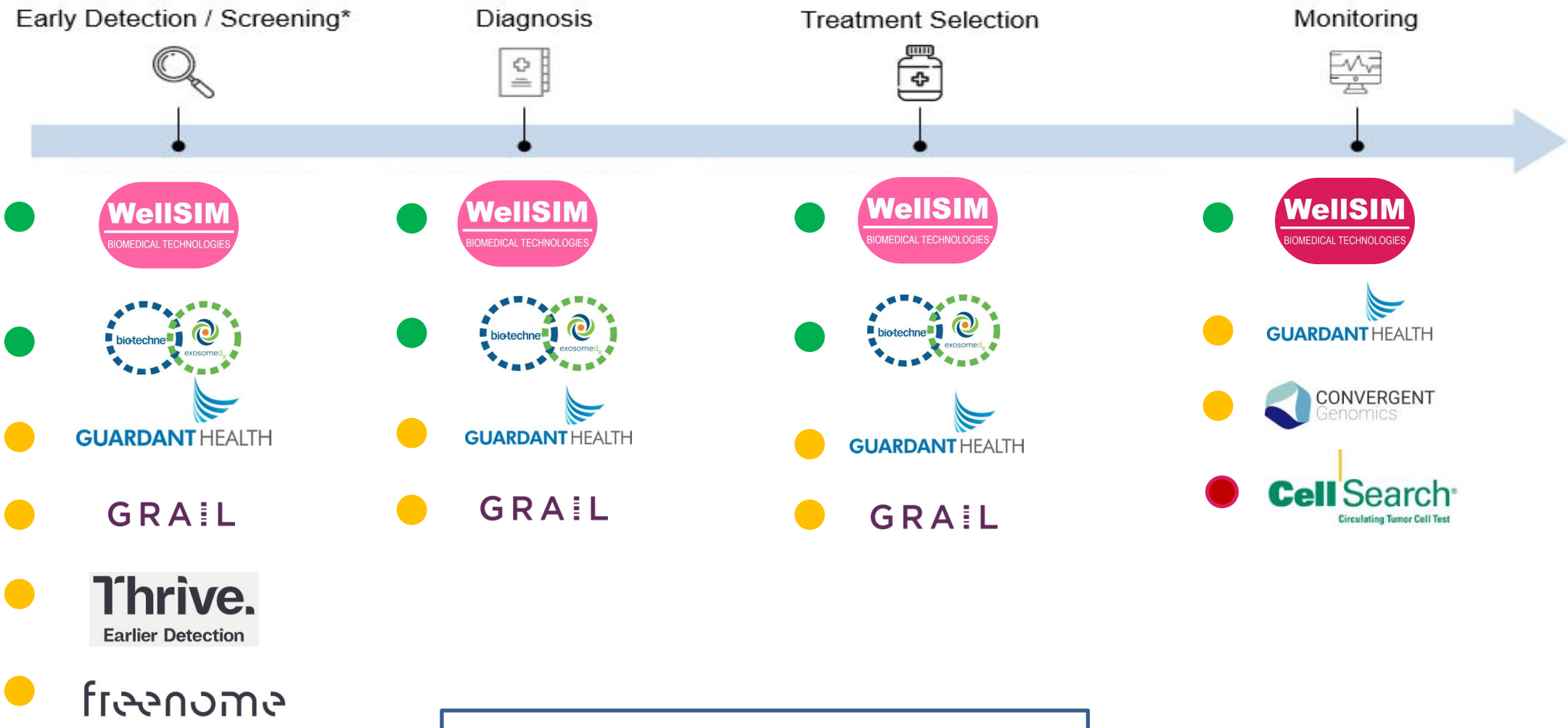
Interpretation



Monitor
cancer patient
to assess
early recurrence

discovered 17 novel biomarkers

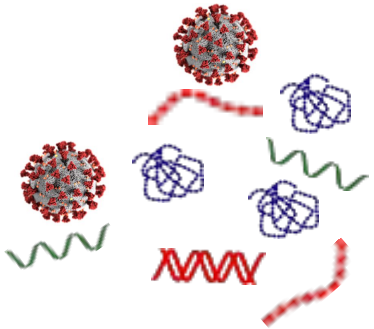
Liquid Biopsy a $35B Market Opportunity



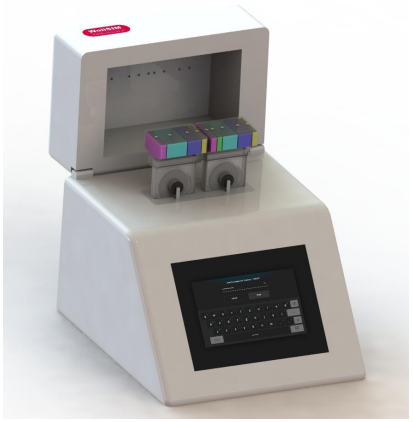
Saliva Coronavirus Rapid Point-of-Care Test

Received 3 RADx/NIH Awards ($ 500K)

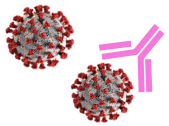
Raw saliva
(2 mL)



SARS-CoV2 with
contaminants



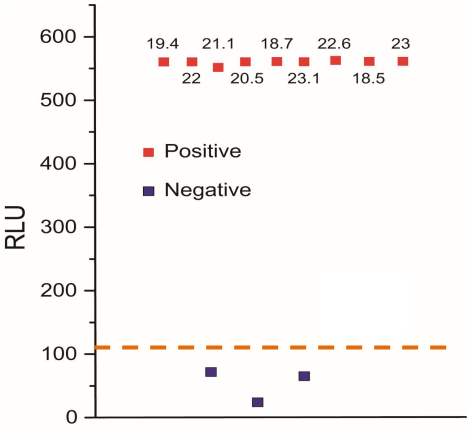
LEAP Mini Analyzer



Anti-SARS-CoV2
antigen antibody

Purified
SARS-CoV2
(50 µL)

SARS-CoV2
Virus Antigen Detection



100% PCR concordance

High detection sensitivity
(0.250 copies/µl)

SARS-CoV2
(70 – 100 nm)

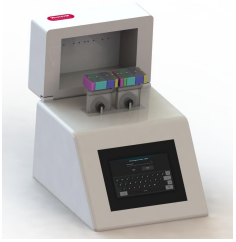
Exosomes
(35 - 200 nm)

40X virus concentration in 3 min.
sample-to-answer in 15 min.
ultra-sensitive detection chemistry

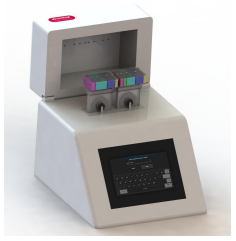
Business Model

LEAP Systems

LEAP Auto Station



LEAP Auto Mini
In dev.



LEAP Mini Analyzer
In dev.

Applications

Biomarker Discovery,
Clinical Test Services &
Bio-production/Therapeutic

Life Science Research
& Academics

Point-of-Care
Sample-to-Answer
Exosome Diagnostics

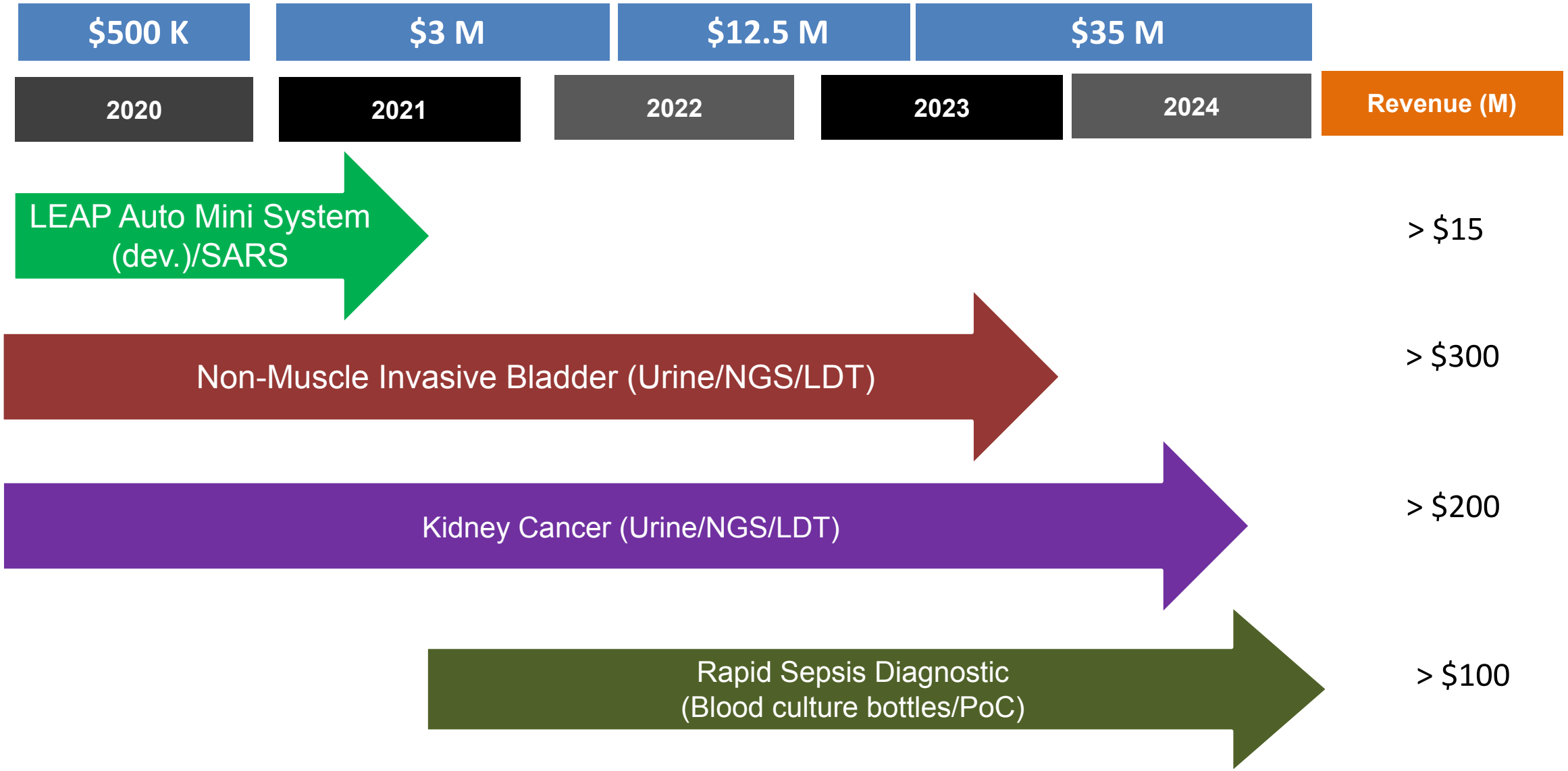
Product & Service Offering

- Sell **LDT Cancer Test Service (CLIA Lab)**
- Sell to pharma for **Bio-Production** of exosomes from cell culture media for therapeutic applications (e.g. drug delivery)

- **Research Use Only Product**
- Sell to virologist, bacteriologist, cell research customers.

- **EUA / FDA-Cleared Product**
- Sell to clinical laboratories.

Development Timeline

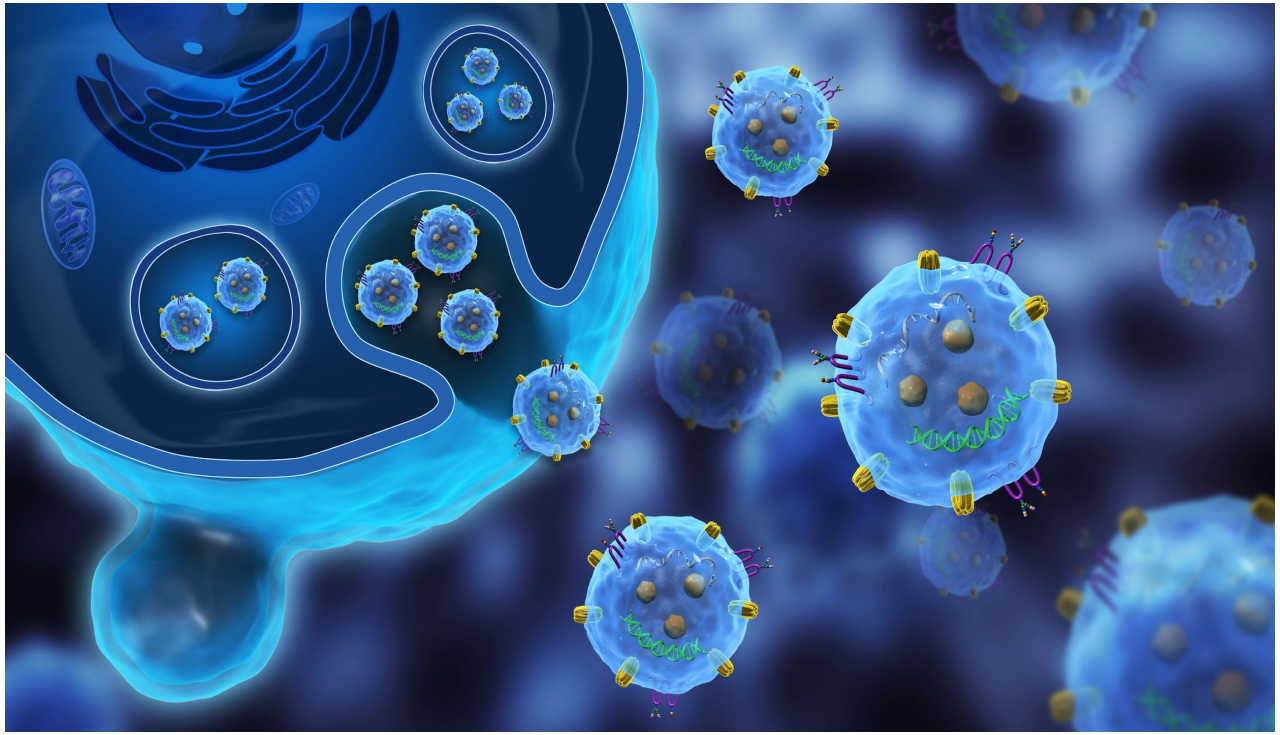


Key Take Away

- Experienced and innovative team
- Cutting-edge exosome technology
  - Urine-focused diagnostics

Seeking to raise $3.0M

- Complete urine biomarker discovery
- New application development
- Product launch/commercialization
- Support early access customers



WellSIM BIOMEDICAL TECHNOLOGIES

Next-Generation
Exosome Liquid Biopsy Diagnostics

RAD
x

NIH National Institutes of Health

qb3

CLSA California Life Sciences Association

Illumina ACCELERATOR

WiNG

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