# CHECK4 INTRODUCTION

CAPITAL GLOBAL NETWORK (CGN)

OCTOBER 17, 2024

IdentifySensors® Biologics

# THE PROBLEM

## Nucleic Acid Testing is Complex

PCR and LAMP molecular methods require highly complex laboratories, skilled laboratory technologists, invasive sample collection and many liquids and temperature-sensitive reagents.

## Molecular Testing Takes Time & Money

Sample transport, extensive overhead, labor-intensive processes, and application steps all affect cost and timeliness.

## Current Point-of-Care Testing is Antiquated

Lateral-flow Antigen (LFA) testing is legacy technology that performs poorly and lacks data management capabilities.

## Patient Outcomes & Satisfaction Suffers

The cumulative effect can result in delayed diagnosis, treatment and recovery from illness or disease.

# CHECK4® BY IDENTIFYSENSORS

## Rapid Digital Diagnostics

Molecular diagnostic platform for direct digital detection in ~ 5 minutes through secure cloud portal accessed by smartphone app.

## Simplified Molecular Testing

Highly sensitive test not requiring skilled labor, PCR machines or temperature-sensitive reagents, with a preliminary limit of detection of 300 copies/mL.

## Versatile & Accessible

Multiplexed detection of similar symptom pathogens using multiple sample types (blood and saliva); ideal for physician offices, clinics, home use and low-resource areas.

## Clinical Value at Low Cost

Cartridge-based production model is highly scalable, leveraging semiconductor manufacturing base, for an extremely low cost of goods sold (COGS) at <$5.

# AI TO FUEL RISE GENOMIC MEDICINE

## USING A PATIENT'S ENTIRE GENOME FOR PERSONALIZE TREATMENT & GENETIC MONITORING

### GENOMIC MEDICINE

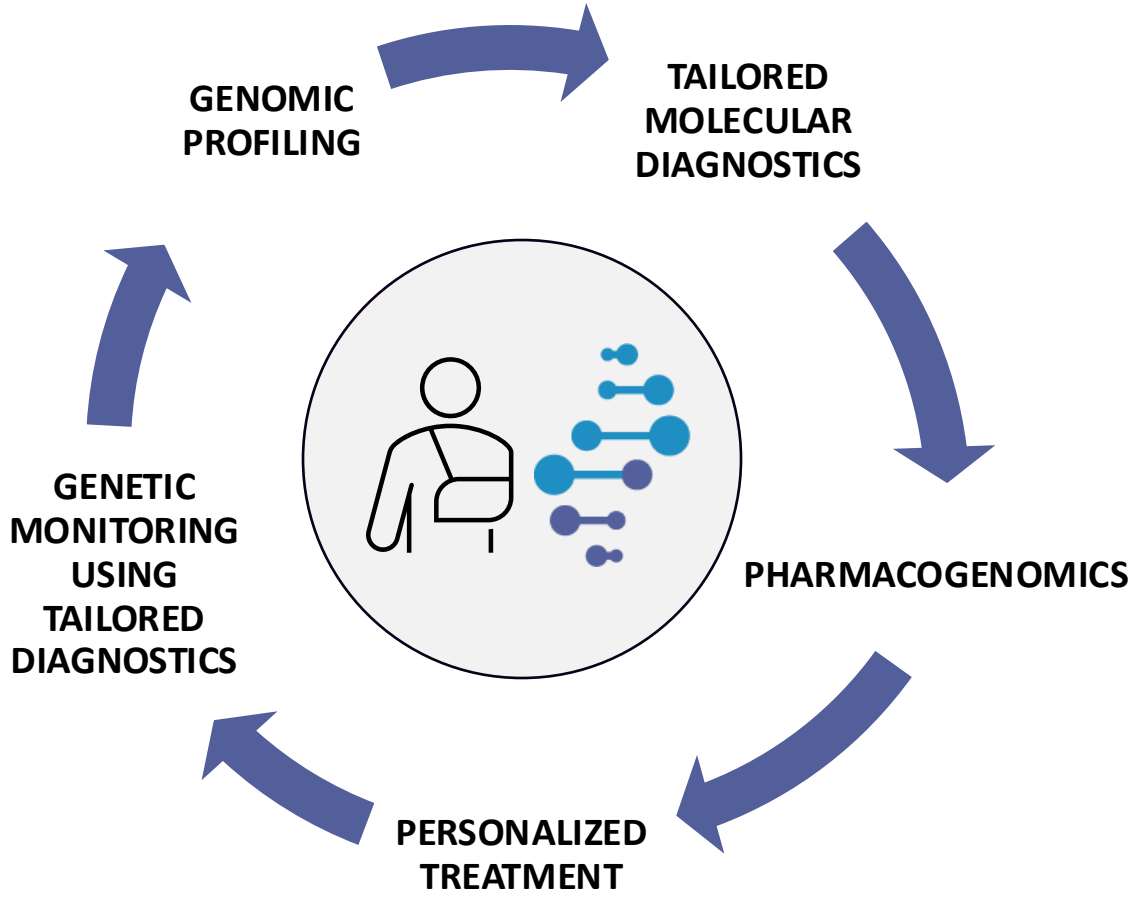
**GENOMIC PROFILING**
Mapping the complete genomic sequence of an individual

**TAILORED MOLECULAR DIAGNOSTICS**
Customized screening for specific genetic sequences using Check4

**PHARMACOGENOMICS**
Studying how a patient responds to drug treatment

**PERSONALIZED TREATMENT**
Customized treatment based on Pharmacogenomics studies

**GENETIC MONITORING**
Using tailored diagnostic to monitor specific genetic mutations



# CHECK4®: A PLATFORM SYSTEM

## CHECK4® READER

A reusable, Bluetooth-enabled device reader analyzes the cartridge data and transmits to Bluetooth connected devices.

## MULTIPLEX CARTRIDGE

A single-use multiplex test cartridge receives the test sample, provides thermal treatment for cellular lysis and acquires test data for multiple targets.

## CLOUD-BASED HOSTING

An encrypted signal is sent to the Cloud where the result is interpreted, stored, and transmitted to App.

## SMARTPHONE APP

App allows users to assign patient demographics and to view results for actionable medical treatment.

# SUSTAINABLE COMPETITIVE ADVANTAGES

- A sustainable competitive advantage is a unique, long-term edge a company holds over its competitors, allowing it to consistently outperform.

| SUSTAINABLE COMPETITIVE ADVANTAGES | CHECK4 | LABORATORY PCR |
|---|---|---|
| Speed | ~ 5 minutes<br>No skilled labor, temperature-sensitive reagents or expensive equipment | 2-4 hours<br>Requiring skilled technician, temperature-sensitive reagents and complex PCR machine |
| Portability & Accessibility | Point-of-Care, Home Use & Remote Settings | Laboratory |
| Sensitivity | 300 viral copies/mL of sample | 10-1,000 viral copies/mL of sample |
| Selectivity | Highly selective digital test with no cross reactivity from interfering agents | Highly selective chemical test when RNA is extracted properly |
| Multiplex Detection | No practical constraints on number of targets detected with a single sample | Constrained by primer design, reagent optimization and PCR instrument |
| Sample Types | Blood and saliva | Blood and nasal swab |
| Cost of Goods (COGS) | <$5/single-use test cartridge<br><$42/many-use test cartridge reader | >$60/single-use test<br>$15-$50K/qPCR machine that requires annual maintenance ~$8-$12K/year |

# BEHIND THE SCIENCE

## GRAPHENE-BASED ELECTRONIC BIOSENSORS

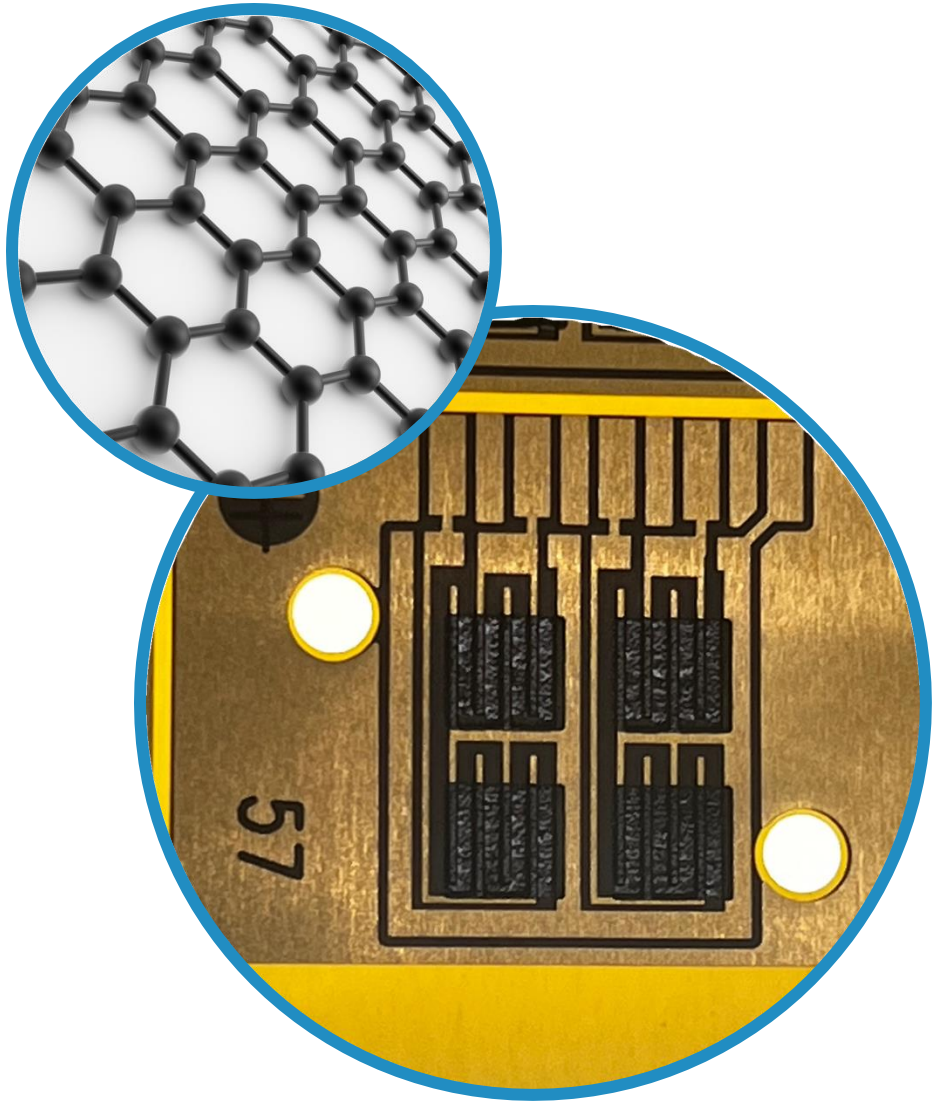
### DIRECT DIGITAL DETECTION

#### PRINTED CIRCUITS

Silk screen printed solid-state electronic circuits that act as semi-conductors with a specially formulated graphene ink.

#### CONDUCTIVE MATERIAL

Graphene is a single atom configuration of carbon atoms. It is among the strongest, most conductive material in the world.



# BEHIND THE SCIENCE

## GRAPHENE-BASED ELECTRONIC BIOSENSORS

## MOLECULAR CAPTURE

### TARGETED DNA DETECTION

The printed sensors are coated with a DNA sequence specifically engineered to detect a target pathogen.

### TEST PERFORMANCE

These electrical circuits become highly sensitive and selective biosensors used in our Bluetooth, Cloud processing devices.

# PRELIMINARY LIMIT OF DETECTION DATA

- Preliminary LoD of Check4 is 300 copies/mL, which is comparable to most lab-based PCR that have an LoD range between 1 and 1,000 copies/mL.

| TEST TARGET | LIMIT OF DETECTION | RESULTS |
|---|---|---|
| Marburg Musoke | 300 copies/mL | Range Finding: 100% - 3/3<br>Confirmation: 95% - 19/20 |
| Marburg Ravn | 300 copies/mL | Range Finding: 100% - 3/3<br>Confirmation: 95% - 19/20 |
| Zaire ebolavirus | 300 copies/mL | Range Finding: 100% - 3/3<br>Confirmation: 95% - 19/20 |
| Sudan ebolavirus | 300 copies/mL | Range Finding: 100% - 3/3<br>Confirmation: 100% - 20/20 |
| Bundibugyo ebolavirus | 300 copies/mL | Range Finding: 100% - 3/3<br>Confirmation: 95% - 19/20 |

**Note:** Range finding for the listed test targets was evaluated on a development version of the Check4 graphene-based biosensor using relevant concentrations in artificial saliva: 700 copies/mL, 300 copies/mL, 150 copies/mL, 75 copies/mL, 50 copies/mL, 40 copies/mL, 30 copies/mL, and 00 copies/mL (as a negative control), respectively.

# OUR PATENTS

## Clinical Diagnostics

**Check4®**

**19**

**Granted Patents**

| PATENT NUMBER | CLAIM TYPES | PRIORITY DATE | EXPIRATION DATE |
|---|---|---|---|
| 9,922,525 | Device/System/Method | 08/12/2016 | 08/12/2036 |
| 10,395,503 | Device/System/Method | 02/08/2018 | 08/12/2036 |
| 11,172,339 | Device/System/Method | 07/11/2020 | 07/11/2040 |
| 11,179,061 | Method | 07/11/2020 | 07/11/2040 |
| 11,340,210 | Device | 05/18/2018 | 07/11/2040 |
| 11,527,141 | System/Method | 07/17/2019 | 08/12/2036 |
| 11,614,439 | Device | 04/09/2022 | 07/11/2040 |
| 11,819,323 | Device | 08/12/2016 | 08/12/2036 |
| 11,832,152 | Device/System/Method | 10/11/2021 | 07/11/2040 |
| 11,869,329 | Device/System/Method | 08/12/2016 | 08/12/2036 |
| 11,892,425 | Device/System | 05/18/2021 | 05/18/2041 |
| 11,896,372 | System | 05/18/2021 | 05/18/2041 |
| 12,000,823 | Method | 06/04/2022 | 07/11/2040 |
| 20,220,252,573 | Device/Method | 04/29/2022 | 07/11/2040 |
| 20,220,365,066 | Device/Method | 06/04/2022 | 07/11/2040 |
| 20,230,093,999 | Device/System/Method | 08/12/2016 | 08/12/2036 |
| 20,230,123,845 | Device/System/Method | 12/11/2022 | |
| 20,230,324,364 | Device | 07/11/2020 | 07/11/2040 |
| 20,230,417,732 | Device/Method | 07/11/2020 | 07/11/2040 |
| 20,240,185,700 | System | 08/12/2016 | NOA |
| 20,240,081,677 | Device/System | 11/19/2023 | |
| 20,240,185,700 | System | 08/12/2016 | |

# GLOBAL MARKET SIZE

**TOTAL AVAILABLE MARKET**

**$22B**

**GLOBAL MOLECULAR INFECTIOUS DISEASE**

**SERVICEABLE AVAILABLE MARKET**

**$16.8B**

**MARKET SIZE WHERE WE OFFER A SOLUTION**

Source(s)/ Notes:
ID Dx, p 76
WW POC, p 161

# GO-TO-MARKET WITH DISTRIBUTORS

## WHY DISTRIBUTORS

### COVERAGE

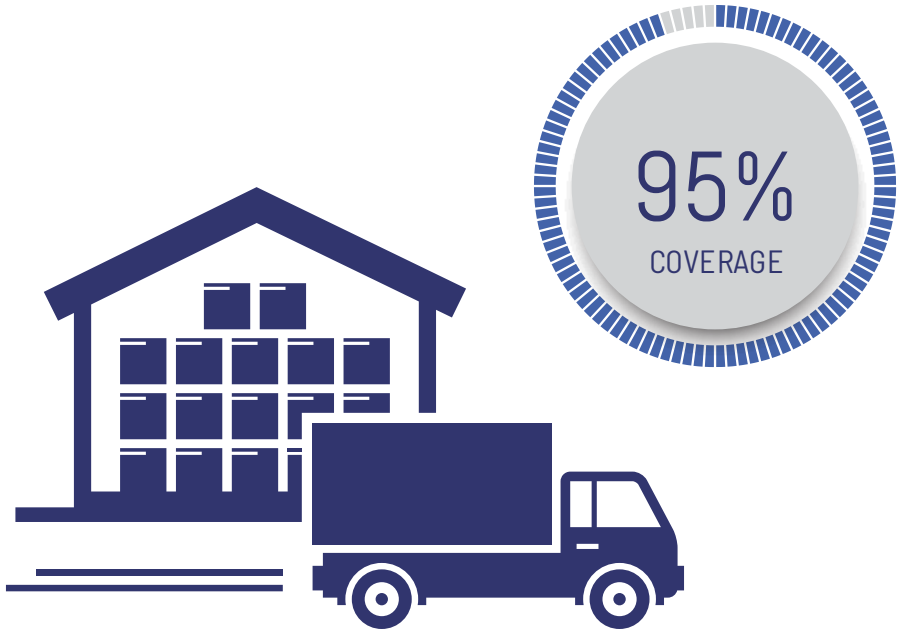
>1,000 distributor reps in nearly all geographies and market segments provide for >95% customer coverage within the market

### SOLUTION SELLING

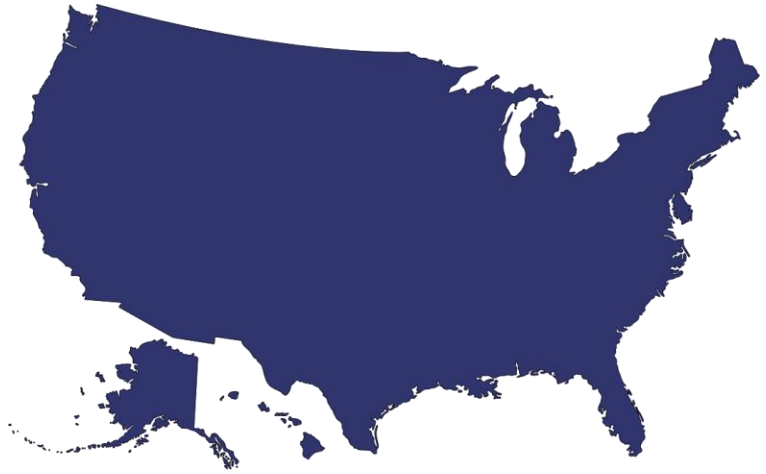
Increased buyer-preference of dealing with fewer vendors, establishing sole-source or preferred agreements, and buying from a catalogue supplier

### ECONOMICS

Considerably lower SG&A expense, benefits of having warehousing, third-party logistics, and streamlined accounts receivable



# SEGMENTATION & STRATEGY



**101,241**

**LICENSED CLIA LABORATORIES IN US**

1 Close Per Day + Average 3 Cartridges Per Day = YR2 Revenue Target

Source(s):
CDC 2023 COVID Report
CLIA 2023 License Data
Commercial Assumptions

## DECENTRALIZE

Decentralize molecular (PCR & LAMP) testing with differentiated user-friendliness & turnaround time

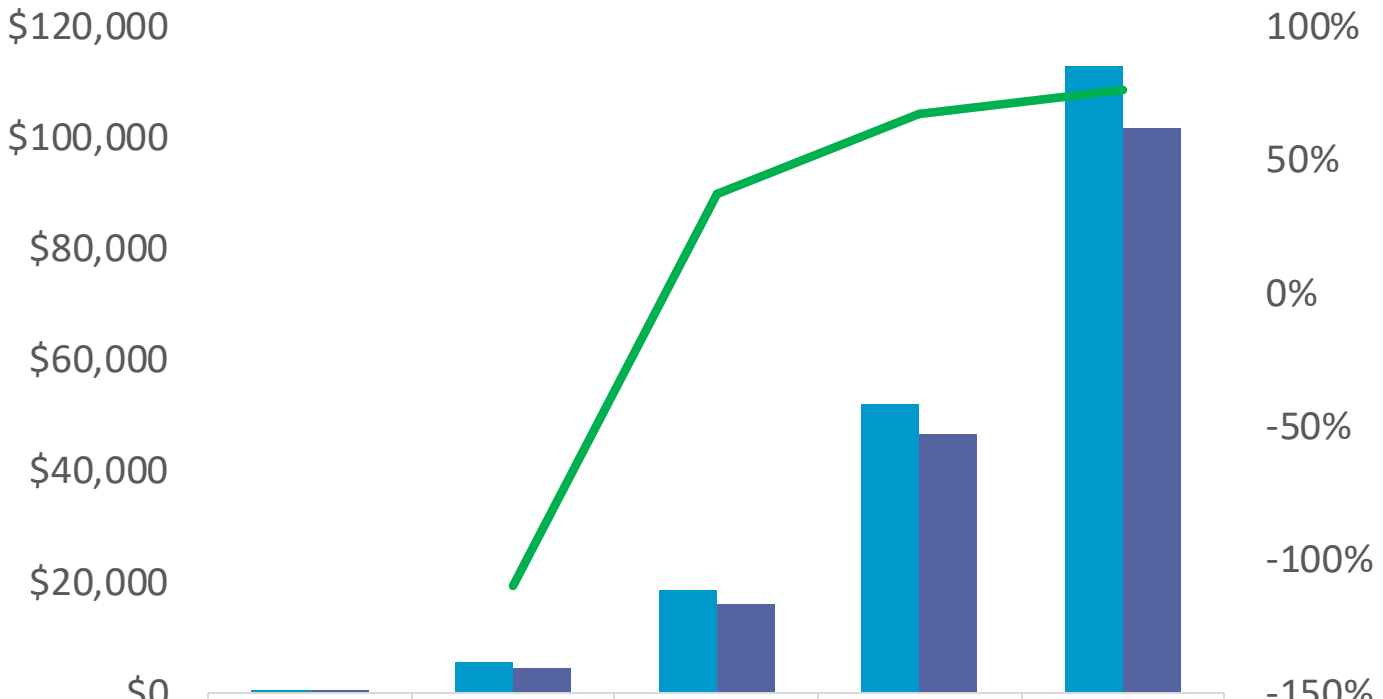
## DISPLACE

Displace antiquated lateral flow antigen (LFA) through technology, performance, and data management

## DISRUPT

Disrupt serology & core lab testing by offering near-patient alternatives that enhances patient care

# 5 YEAR PROJECTIONS (,000)




| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|
| Revenue | $26 | $5,359 | $18,461 | $52,190 | $112,860 |
| Gross Margin | $24 | $4,498 | $16,162 | $46,574 | $101,651 |
| EBITDA | | -109.70% | 37.40% | 67.40% | 76.10% |

# COMMERCIAL BASIS

## FACTS & ASSUMPTIONS

### DETAILED SEGMENTATION & DEFINED CLOSE RATE

>101,000 bricks-and-mortar CLIA licensed facilities. Using distributors sales model, close 1 account/day, with a 3 cartridge/day utilization throughout Year 1.

### CAGR of ~175%

Increased familiarity and technology adoption will accelerate closes to 3 accounts/ day in Year 2. Growth in platform test menu, geographical reach, and professional services will drive continued growth in Year 3-5.

### REMARKABLE EDITA PROFILE ENHANCED AT SCALE

Biosensors are not heavy on raw materials and components and are conducive to notable manufacturing efficiency. Cartridge volume will support marked decreases in manufacturing costs.

# COST OF GOODS SOLD ESTIMATES

| Product | | YEAR 1 | YEAR 2 | YEAR 3 | YEAR 4 | YEAR 5 |
|---|---|---|---|---|---|---|
| CHECK4 READER | Volume | 1,000 | 2,500 | 5,000 | 10,000 | >15,000 |
| | COGS | $42.85 | $48.85 | $42.00 | $35.00 | $35.00 |
| CHECK4 TEST CARTRIDGE | Volume | 150,000 | 550,000 | 1,500,000 | >5,000,000 | >5,000,000 |
| | COGS | $7.50 | $5.00 | $4.00 | $3.50 | $3.00 |

# FINANCIAL PROFILE

| Measure | | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | MIT Benchmark |
|---|---|---|---|---|---|---|---|
| $ | Revenue | $0.026 MM | $5.4 MM | $18.5 MM | $53.2 MM | $112.9 MM | - |
| % of Revenue | **COGS** | **-** | **16.1%** | **12.5%** | **10.8%** | **9.9%** | **49%** |
| | R&D | - | 117.4% | 21.8% | 8.6% | 5.2% | 3.8% |
| | SG&A | - | 76.2% | 28.3% | 13.3% | 8.8% | 12% |
| | **EBITA** | **-** | **(109.7)%** | **37.4%** | **67.4%** | **76.1%** | **24%** |
| | Market Share | - | 0.32% | 1.1% | 3.1% | 6.7% | - |

Source(s):
Benchmark source: Kelkha, S., "Benchmarking Medical Device Product Development", Massachusetts Institution of Technology, May 2012

# R&D PIPELINE

| MULTIPLEX CARTIRDGE | PATHWAY | TARGET DATE |
|---|---|---|
| Filovirus | RUO | Q1 2025 |
| HPAI (H5N1) | RUO | Q1 2025 |
| Filovirus | EUA | Q3 2025 |
| HCV | 510(k)/ De Novo | Q4 2025 |
| Respiratory | 510(k)/ De Novo | Q2 2026 |
| Strep A | 510(k) | Q4 2026 |

# USE OF FUNDS (IN MM)

## Regulatory

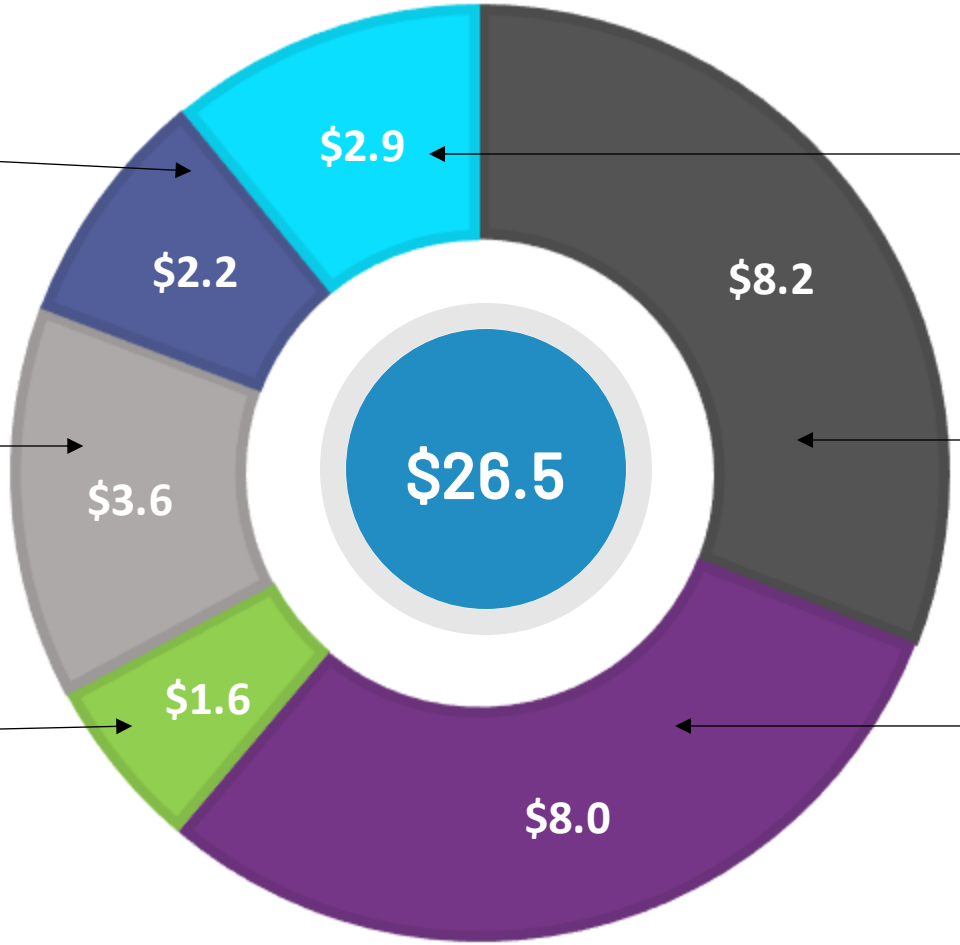
Supports critical regulatory staff and filing fees for current, and futures cartridge submissions.

## CAPEX Support

Expenditure to support increased investment for volume production as demand increases.

## Manufacturing

Supports the pre-commercialization production of R&D kits and first lots-to-stock.




## Incremental Staff

Addition of key staff members in finance, HR and senior leadership to support business growth.

## Clinical Studies

Conduct clinical studies for Respiratory, Step A, HCV, and assay in development occurring in Y3/Y4.

## Product Development

Comprehensive budgets for scientific headcount, laboratory supplies, software revisions, and prototype development.

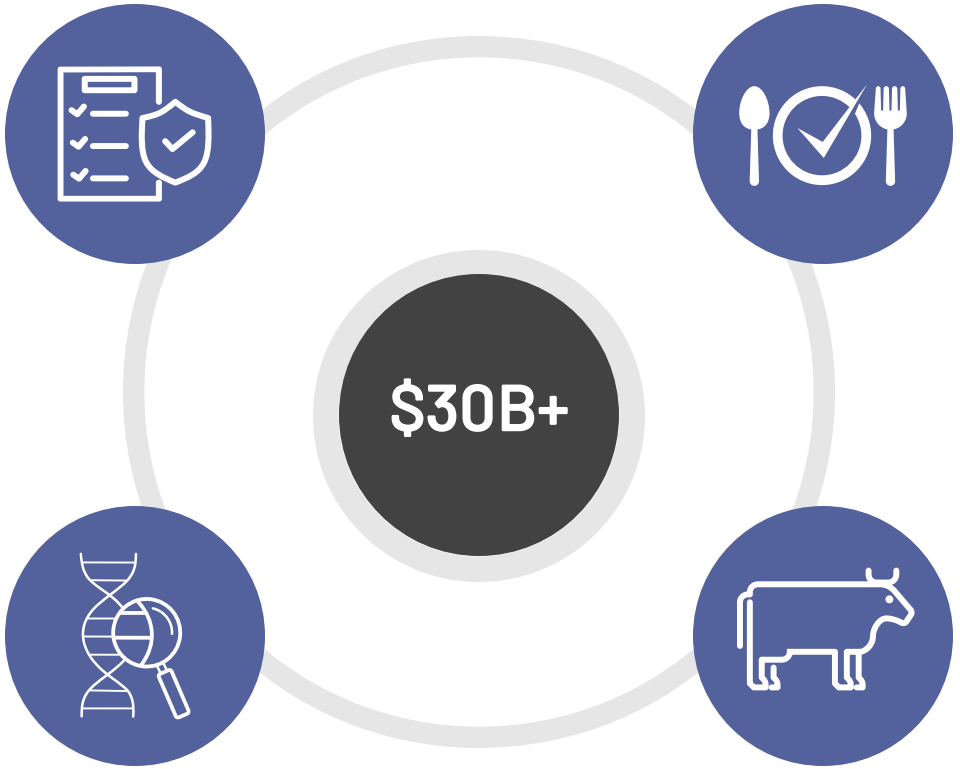
# ADJACENT SECTOR OPPORTUNITIES

## Environmental Testing

Monitoring microbial contamination in water, soil as well as antibiotic resistant pathogens transmitted in healthcare settings

## Genetic Monitoring

Support life science firms develop new life-saving products in the Pharmaceutical and Biotechnology industries




## Food Safety

Enhance supply-chain surveillance of foodborne pathogens with food growers, packagers and retailers

## Veterinary

Adaptive use for pathogen testing of domesticated and farm animals.

Source(s):
Kalorama Molecular Dx Datastream 2022
Market.Us Food Safety Pathogen Markets

# CURRENT COMPANY STATUS

$18MM

## Money Raised

Over $18MM raised from a combination of SEC-qualified (Reg A+ and Reg CF) and private placement (Reg D 506C).

## Manufacturing

Readers have been manufactured and package. Cartridge production currently transitioning into manufacturing. Building cartridges for trials.

$26.5MM

## Equity Opportunity

A variety of investment options including REG A, REG CF, REG D and Preferred Series A and upcoming Series B. Company is SEC Qualified for Reg A+, Reg CF and PCAOB audited.

## Use of Funds

Supports manufacturing of pilot production, trial studies, FDA submissions, and commercialization scale.

IdentifySensors®
Biologics