

ALLORA DIAGNOSTICS



Company Presentation

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At a Glance

Developing a Simple Breath Test:

ALLORA DIAGNOSTICS, is a developer as well as a manufacturer of Urea breath test technology and is managed by Gulf Coast Scientific, Inc.. Allora acquired Avisa's intellectual property and know-how through licensing agreements.

GCS is a leading, revenue producing breath test company specializing in the manufacturing and marketing of its c13 breath test for H pylori disease, one of only 2 companies approved for sale in the U.S. by the FDA.

Allora's rapid c13 breath test detects bacterial infections in respiratory indications and plans a FDA approved clinical trial in ventilator associated pneumonia in 2023.



When treating **pulmonary infection, every minute is critical.**

The AV BreathTest™

A Thermometer for the Lungs

- Detects and Measures the Bacterial Load (BL) in the Lungs in less than 10 minutes
- Monitors Bacterial Load (BL) of patients on ventilators to prevent pneumonia and reduce VAP mortality
- Monitors drug therapy which mitigates antibiotic overuse
- Reduces patient total time in hospital



When treating **pulmonary infection, every minute is critical.**

Investment Highlights

Allora is a clinical stage company that has developed a rapid breath biomarker breath test platform for pulmonary bacterial infections.

A thermometer for the lungs

\$1.7B U.S. VAP Market Opportunity

- **Pre and Post Covid 19 respiratory infections add significant market expansion**
- **Business model enables accelerated commercial adoption**
- Employing a razor/razor blade commercialization strategy

Validated clinical stage technology with rapid path to FDA approval

- VAP-first pivotal clinical trial for FDA approval
- Addition Pulmonary Indications, COPD, CF, Bronchiectasis, Pneumonia in the ED

Products Promise Better Health Outcomes and Value Based Economics for Patients, Providers and Payors

BreathTest (ABT) Quickly Detects Dangerous Bacterial Infection – as Easily as 1-2-3

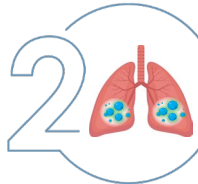
Urease is Expressed by the Most Dangerous Bacterial Pneumonia Pathogens¹

e.g., prevalence in ventilator-associated pneumonia is 40-60%



Patient inhales nebulized urea labeled with ^{13}C -urea (AV-U13)

Bacterial load detected based on inhalation of drug substrate: a stable, non-radioactive isotopically labeled compound (^{13}C -urea)



Conversion of AV-U13 to labeled CO_2 ($^{13}\text{CO}_2$)

If present, virulent pathogens producing urease rapidly convert drug substrate into $^{13}\text{CO}_2$ and ammonia that are exhaled.



Portable AVISAR™ laser spectrometer measures $^{13}\text{CO}_2$

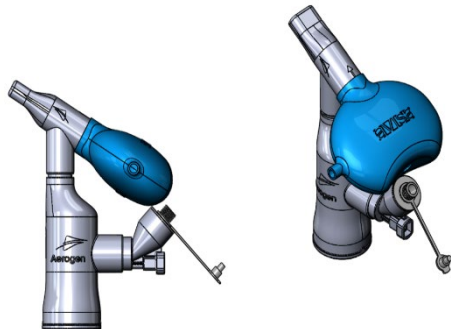
Avisa's proprietary technology measures $^{13}\text{CO}_2$ in exhaled breath: change in ratio between non-radioactive $^{13}\text{CO}_2$ to naturally occurring $^{12}\text{CO}_2$ indicates infection with urease pathogen.

¹ Journal of Breath Research (June 2019) "[Potential for breath test diagnosis of urease positive pathogens in lung infections](#)", Bishai W. R. & Timmins G. S.

Allora Products: The ABT KIT and Spectrometers

ABT KIT

- Vial of 50mg c13 Drug
- A single use ABT Link Nebulizer
- Breath Collection Accessories
- Kit price= \$300



AVISAR: POC Spectrometer



PyloPlus Inpatient Spectrometer











Superior Sensitivity and Test Turnaround over Sputum Culture-Based Tests

	Allora BreathTest	Culture	PCR
Specimen	Exhaled Breath	Sputum (no-BL)	Sputum (no-BL)
Detects live organisms	Yes	No	No
Measures whole lung	Yes	No	No
Monitors treatment	Yes	No	No
Turnaround time	<10 min	24 hours to 3 days	4 to 24 hours
Sensitivity	High	Low	Moderate
Specificity	High Urease	High	High
Point of care, portable	Yes	No	No
Test complexity	Low	High	High
Complementary to ABT	---	Yes	Yes

Clinical Strategy

- 2023 FDA Investigational Device Exemption (IDE) Approval Comparing the AVBT to Sputum Culture Microbiology for Detection and Monitoring Patients on Mechanical Ventilation and Monitoring Antibiotic Therapy of Ventilator Associated Pneumonia
- Supplemental IDE and investigator sponsored studie for Pulmonary Practices with access to the following indications Bronchiectasis including Covid-19 Long Hauler syndrome, COPD, Cystic Fibrosis and Pneumonia in the Emgergency Department

Pipeline: Multiple Opportunities in Major Disease Areas

ABT Portfolio	Protocol Development	Clinical Studies	IDE/Pivotal
Ventilator Associated Pneumonia			2023
Post-Covid 19 Bronchiectasis			Investigator Sponsored
Chronic Obstructive Pulmonary Disease (COPD)			Investigator Sponsored
Community-Acquired Pneumonia (CAP)			Investigator Sponsored
Cystic Fibrosis			Investigator Sponsored
Tuberculosis			Investigator Sponsored
Aspergillus/Coccii Fungus			Investigator Sponsored
Clostridium Difficile (<i>C. diff</i>)			Developmental

Pilot Studies Validate Clinical Utility & Safety, Paving the Way for Pivotal Trials

Cystic fibrosis (CF) patients with known *P. aeruginosa* infections

Pediatric Allergy, Immunology, and Pulmonary, 29:68-73, 2016.

- Investigator-initiated POC study
- 6 subjects (3 CF, 3 healthy control)
- Clearly elevated signal in infected patients vs control when administered nebulized ¹³C-urea
- Proof of safety and efficacy

Patients with active tuberculosis (TB)

Durban, South Africa

- TB previously confirmed by sputum culture microbiology and PCR
- 49 subjects (29 TB, 20 control)
- Clearly elevated signal in infected patients vs control when administered nebulized ¹³C-urea
- Proof of safety and efficacy

Patients with pneumonia diagnosis in emergency dept.

University of New Mexico & Henry Ford Hospital (Detroit)

- Positive efficacy results: 90% specificity and 75% sensitivity vs sputum culture (93%, 11 had positive signals over baseline without sputum would have resulted in 93% sensitivity)
- 42 subjects unable to produce a valid sputum sample (poor quality or sputum unavailable)
- Proof of safety and efficacy



ABT–

Major Market
Opportunity,
Easy-to-Implement
Commercial Strategy

Ventilator-Associated Pneumonia (VAP)



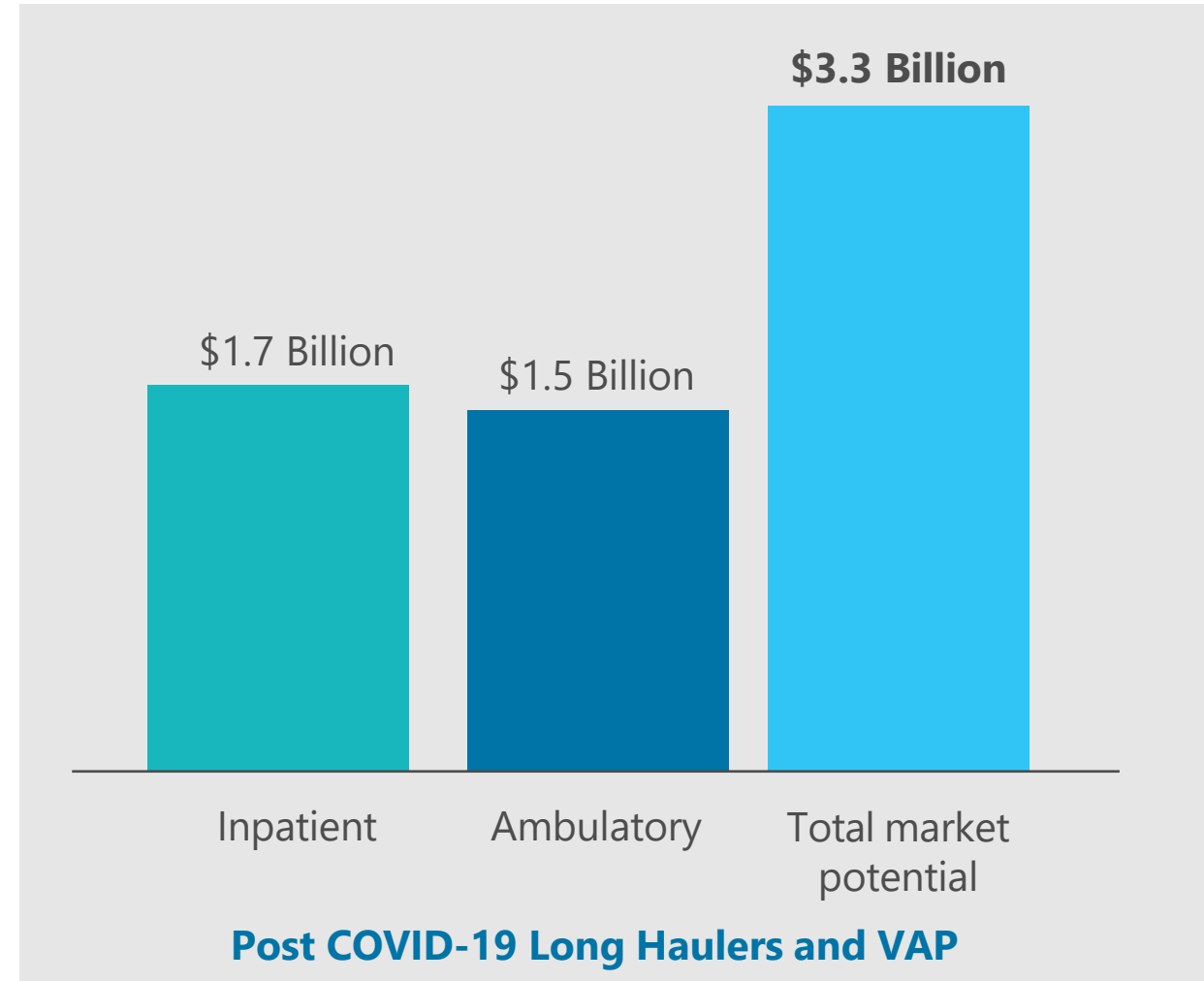
Large Market With Rapid Penetration Strategy

- Over 30,550 Inpatient and Ambulatory Facilities in the U.S.
 - 5,500 Hospitals - Emergency Departments, ICU/CCU's, Nursing Units & Clinics
 - 15,000 Skilled Nursing Facilities
 - 7,500 Urgent Care Center
 - 550 Free Standing Emergency Rooms
 - 2,000 Walk-In Clinics
- Go-to-Market via Razor (AVISAR unit)/Razorblade (ABT) model
 - \$200 price for ABT kit (breakeven: 35 tests or ~1 month)
- Powerful Economics – a large U.S. hospital that admits 1,000 pneumonia patients/year could save up to \$4.8MM/yr
 - ABT: sensitivity = 95%, specificity = 65%
 - 15% prevalence of urease pathogen pneumonia (Negative Predictive Value = 99%)

Strong U.S. Market Potential in Lead Indications Alone

Compelling pharmaco-economic model

- **Inpatient** - reimbursed under the DRG system as an ICU/CCU and nursing floor
 - \$300 ABT disposable kit
 - Lead Indication: Ventilator Associated Pneumonia (VAP). Others includes hospital acquired pneumonia
- **Ambulatory** –
 - **Can save a \$15,000 unnecessary hospital admission** through the emergency department, prevent antibiotic overuse
 - and TB

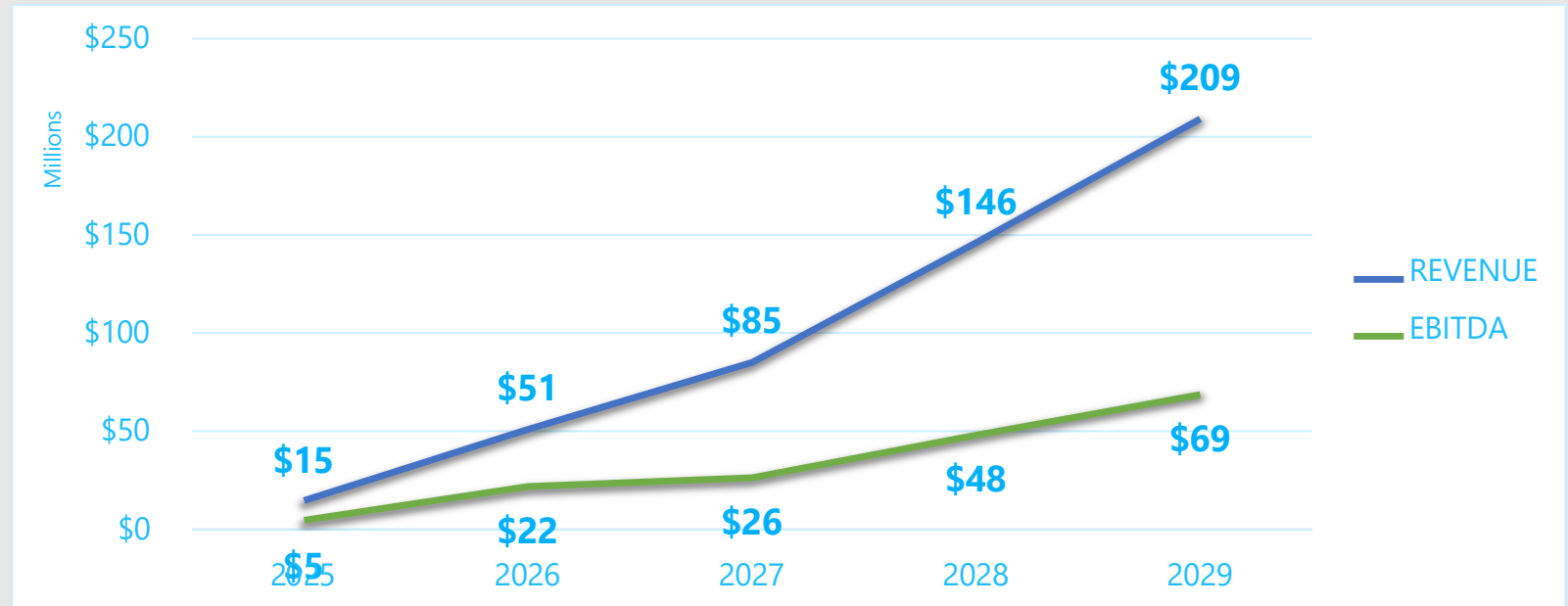


Growth Outlook for Lead Indication - VAP

Conservative Assumptions

- Razor-razorblade business model once commercial in 2024
- Strong 80% projected gross profit margin on ABT Kit sales
- Assumes small, in-house direct sales team
- Only VAP markets in the U.S. modeled
- Conservative 6% 5-year market penetration assumption
- Does not include ambulatory and clinic indications market expansion

Allora Financial Projections



	2025	2026	2027	2028	2029
Device Placements:	30	75	188	263	383
ABT Sold:	48,600	170,100	425,736	729,972	1,467,010

Broad and Deep Intellectual Property Protection

2020 2025 2030 2035 2040

Core Platform Patents

Stable, non-radioactive isotopic ratio of c13-c12



ISSUED 7,717,857: Method for diagnosing *P. aeruginosa* (U.S.) 2033



RE-ISSUED RE 44533 Expanded coverage for other urease bacteria (U.S.) 2033

Method of Diagnosing *Clostridium Difficile*



ISSUED 10,000,787 2040



PENDING Non-US EP13845074.7 TBD

Using Isoniazid for the Diagnosis of Lung Infections



ISSUED 9,453,253 2038

Method: AVISAR laser spectrometer for diagnosing bacterial infections



ISSUED 9,518,972 2038



GRANTED 2038EP13779680.1 (France, Germany, Great Britain, Italy) 2038



GRANTED CN104822841B (China) 2038



PENDING Japan TBD

Method of Breath Fractionation for Detecting Lung Infections



PENDING 62/277/121 2018



Method of Breath Capture from a Mechanical Ventilator

PENDING No. 17/644,150 2021

Experienced Leadership Team

Philip Ross - President/CEO

President & Co-Founder

- Will Serve as President of Allora Diagnostics
- 20 years of development, device manufacturing and distribution of medical devices
- Vast experience working with the FDA for 510K and PMA applications

Graham Timmins, PhD Co-founder

Chief Science Advisor

- Assoc. Professor of Med. Chemistry at UNM
- Co-inventor of Avisa patent portfolio
- Author/co-author of > 50 publications; awarded several federal grants

David S. Joseph Co-founder

President & CEO of Avisa Diagnostics

- 40+ years commercial medtech/pharma
- Co-founder of 4 companies with successful exits (IPO, M&A)
- Multiple past and present board positions
- Will serve as a consultant to Allora

Richard Murray, MD

Chief Medical Officer

- 25+ years industry experience
- Executive at Merck & Co. in business, medical and scientific areas, most recently as VP and Deputy Chief Patient Officer
- Previously practicing physician in cardiovascular-pulmonary medicine and asthma researcher at Hospital of the University of PA

\$10 Million Capital Required for FDA approval

Avisa (Licensor) investment \$16 million in the technology development and clinical studies

- \$5 Million Series A Preferred
 - Phase 3 Pivotal Trial
 - General Working Capital
- \$5 Million Series B Preferred
 - Complete Pivotal trial
 - File NDA
 - General Working Capital

Key Take-aways



Compelling technology: Simple, ultra-rapid breath test to save lives, time and money



Thermometer for the lungs: Measuring bacterial load to enable better diagnoses, monitor therapy and mitigate the overuse of broad-spectrum antibiotics



\$3.3 billion U.S. market opportunity for post-COVID-19 bronchiectasis and VAP alone, opportunity in multiple additional respiratory diseases



Clinical risk mitigated: Novel use of existing technology with clinical point-of-care



FDA IDE Pivotal Trial: within 12 months



ALLORA

**Better Health Outcome
Saves Lives and Money**