

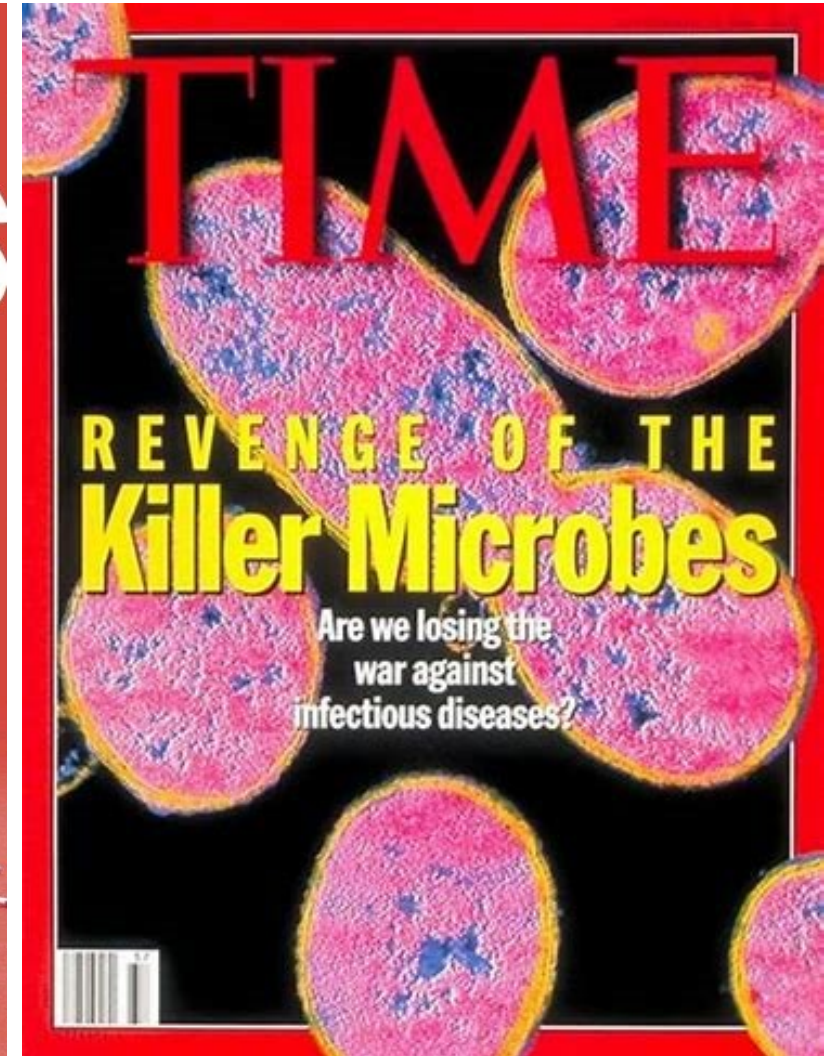
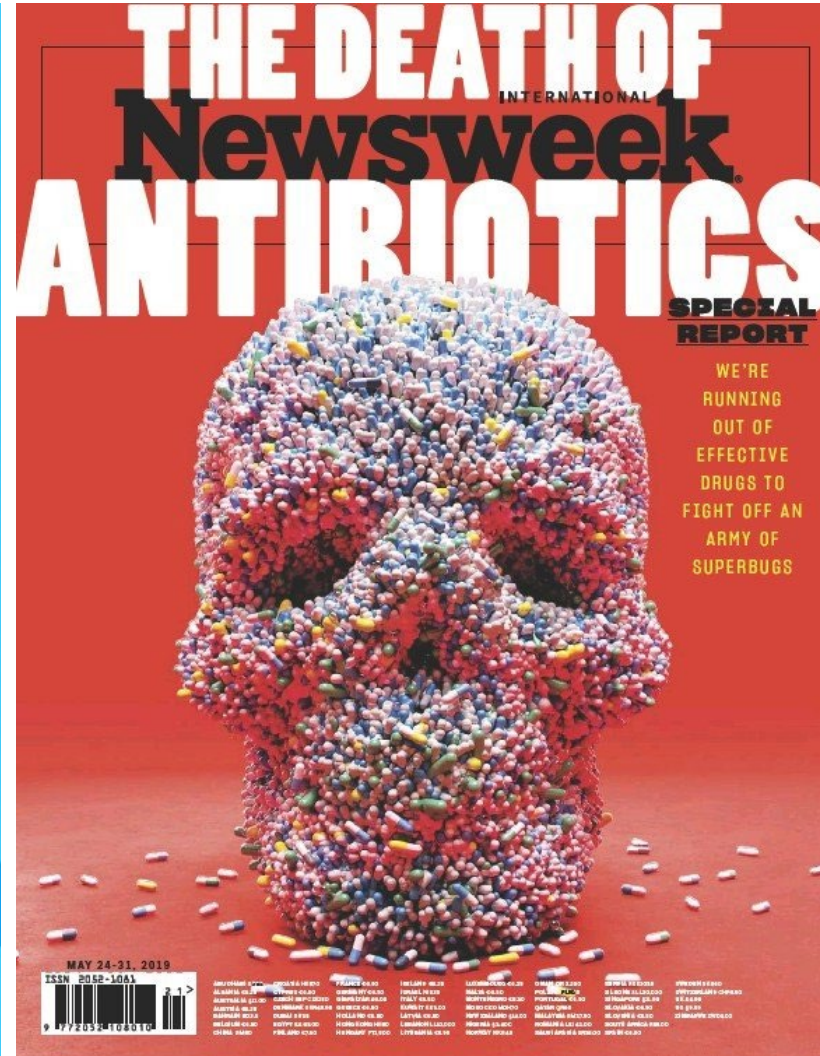
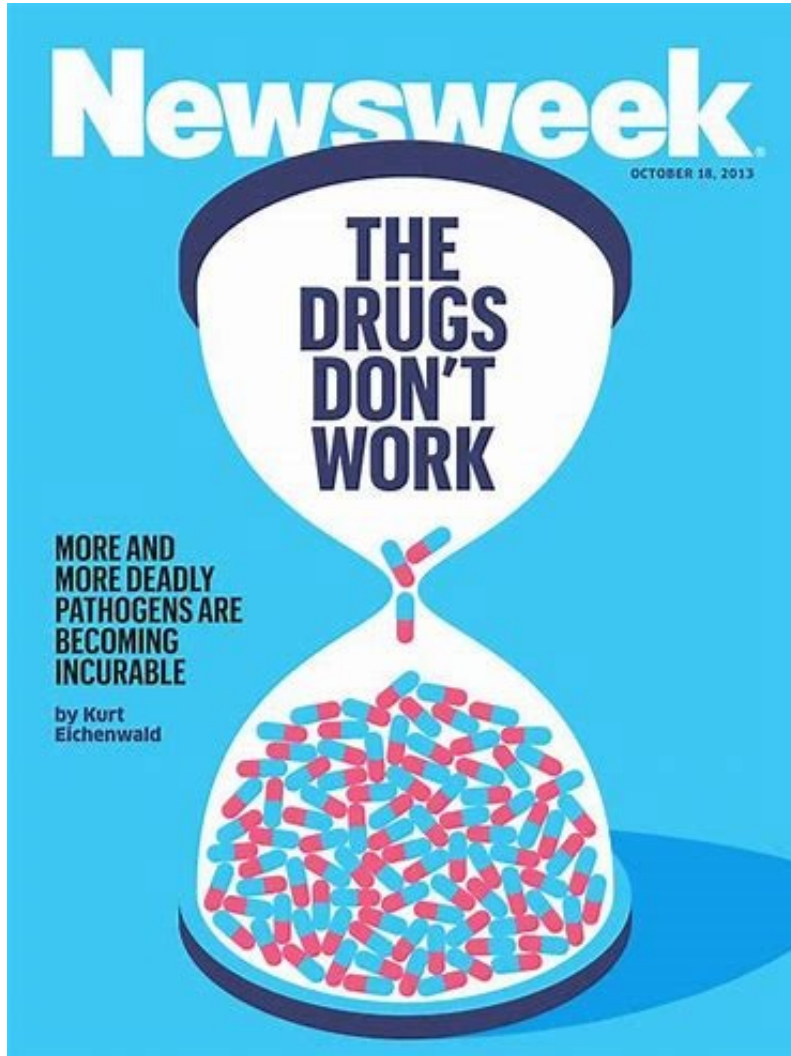


**RESPIRATORY DIAGNOSTICS | MANAGEMENT PRESENTATION**

**Addressing the Worldwide  
Epidemic of Antibiotic Overuse**

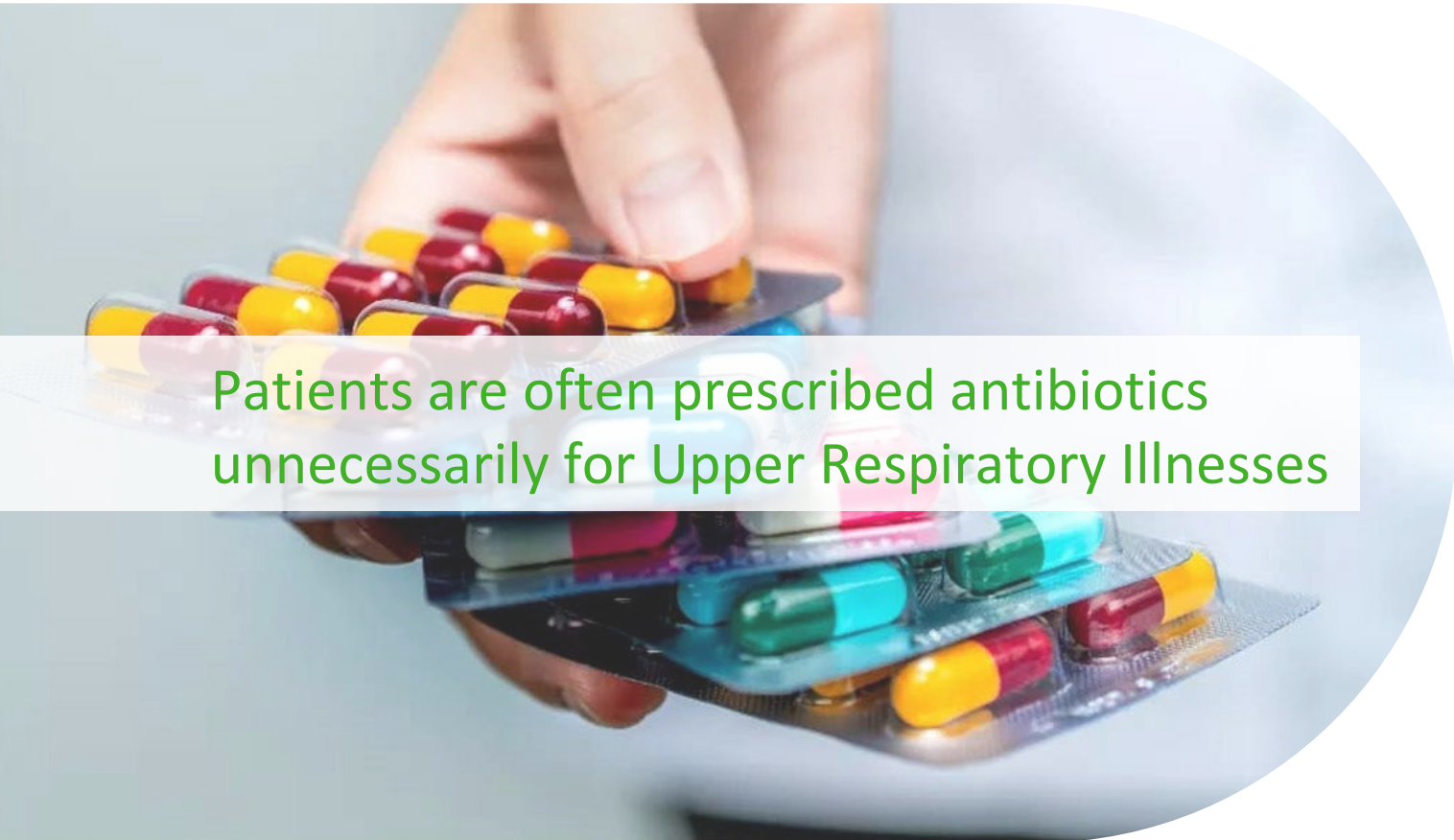


# Antibiotic Resistance: The Next Pandemic





# Problem – The Overuse of Antibiotics



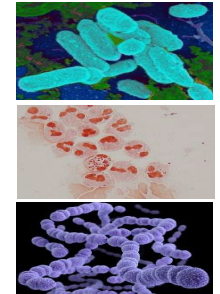
Patients are often prescribed antibiotics unnecessarily for Upper Respiratory Illnesses

## 73 million office visits in U.S.

- Acute Sinusitis-11MM
- Acute Bronchitis-15MM
- Acute Otitis Media-27MM
- Acute Pharyngitis & Tonsillitis-19MM

## Bacterial form of illness is caused by three pathogens

- *M. catarrhalis*
- *H. influenzae*
- *S. pneumoniae*



## Currently Physician makes a diagnosis based on symptoms and history without a test

- Significant number of patients receive unnecessary antibiotics





# First Indication: Sinusitis Opportunity

Largest reason for antibiotic Rx's in clinics



**Affects 73 million in U.S. & EU annually**

- 29 Million in U.S.
- 44 Million in EU

**Physician makes a Dx based on symptoms and history without a test**

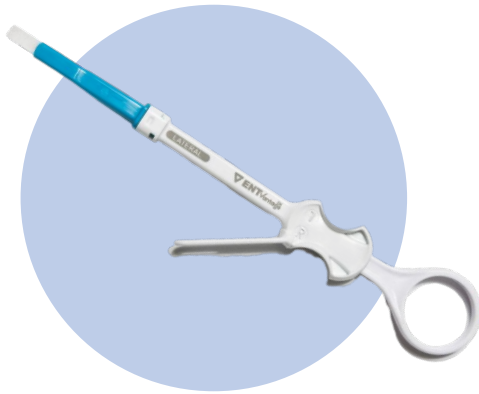
- 80% of patients receive antibiotics
- Only 10% need them



# ENTVantage's Sinu-Test® Bacterial Sinusitis Test Kit

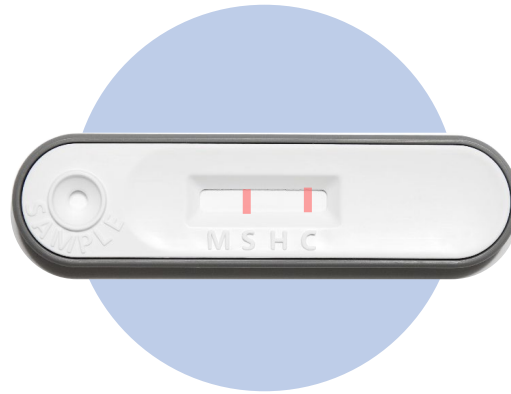


Our diagnostic product enables physicians to provide rapid diagnosis at the point-of-care and avoids patients getting unnecessary antibiotics.



## Sinu-Test® Collection Device

Quick collection of sinus specimen



## Bacterial Assay

Rapid pathogen detection



## Digital Reader

Rapid, accurate results



# Unrivaled Competitive Position



## Entvantage has multiple key issued patents that limit competition

- Collection Device
- Lysis Buffer
- H. influenzae cell markers

**No Office Based Diagnostic Product Available**



**Uses established clinical workflows and procedures**



# Competitive Landscape



	Primary Care	ENT
Acute Sinusitis Patient Visits/Year	<b>10MM</b>	<b>1MM</b>
Point-of-Care Test	<b>No</b>	<b>No</b>
Endoscopic Exam & Culture	<b>No</b>	✓
Imaging (CT or X-ray)	<b>No</b>	✓
Empiric Treatment	✓	<b>No</b>



# Patent Status



- US:
  - 10,921,320
  - 10,620,221



Patents Issued in U.S., EU, China Pending in Japan

- US:
  - 9,606,118



Patents Issued in U.S. and EU

- US:
  - 9,568,472
  - 10,048,261
  - 10,345,300



Patent Licensed From OSU/NCH Issued in U.S., EU, Australia, Canada & Japan





# Preclinical Performance Data



- **Anatomical Studies**
- **Pilot Human Studies**
- **Assay Performance Studies**



**Demonstrated that Product Performance Meets FDA Requirements for Clearance**

**Sinu-Test is a FDA Class II Denovo Product**





# Reimbursement in Place



## Established Reimbursement with Independent Validation

Average reimbursement of **\$55** per test using existing CPT codes

**87804**  
**87899**  
**87899-59**

**H. Influenzae**  
**S. Pneumoniae**  
**M. Catarrhalis**



## Use of ENTV Test Lowers Treatment Costs

- Standard of Care cost = **\$402**
- Sinu-Test Treatment Cost = **\$124**



# Simple Business Model



## ENTVANTAGE



- **\$30 per test**
- **\$6 per test cost**

## PHYSICIAN



- **\$55 clinic revenue**
- **34% increase in office visit revenue**



# Product Pipeline



INDICATION

ANNUAL U.S. OFFICE VISITS

ANNUAL U.S. MARKET SIZE

DEVELOPMENT STATUS

Acute Sinusitis

10.9 MM

\$605<sub>MM</sub>

FDA pivotal trial underway in U.S.

2025 Market Launch



INDICATION

ANNUAL U.S. OFFICE VISITS

ANNUAL U.S. MARKET SIZE

DEVELOPMENT STATUS

Acute Bronchitis

14.8 MM

\$814<sub>MM</sub>

Proof of Concept Completed

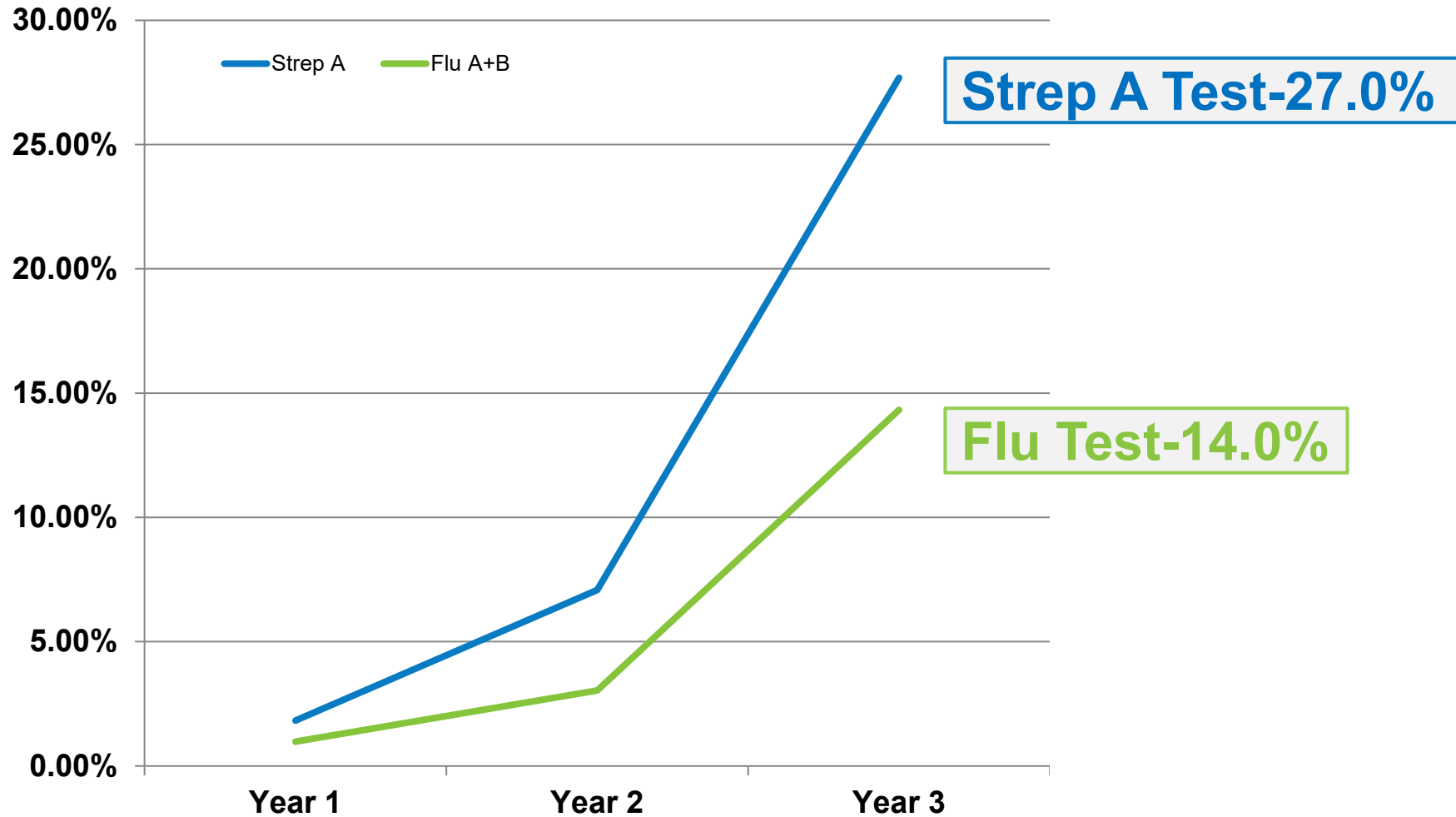
2026 Market Launch







# Market Penetration Comparisons





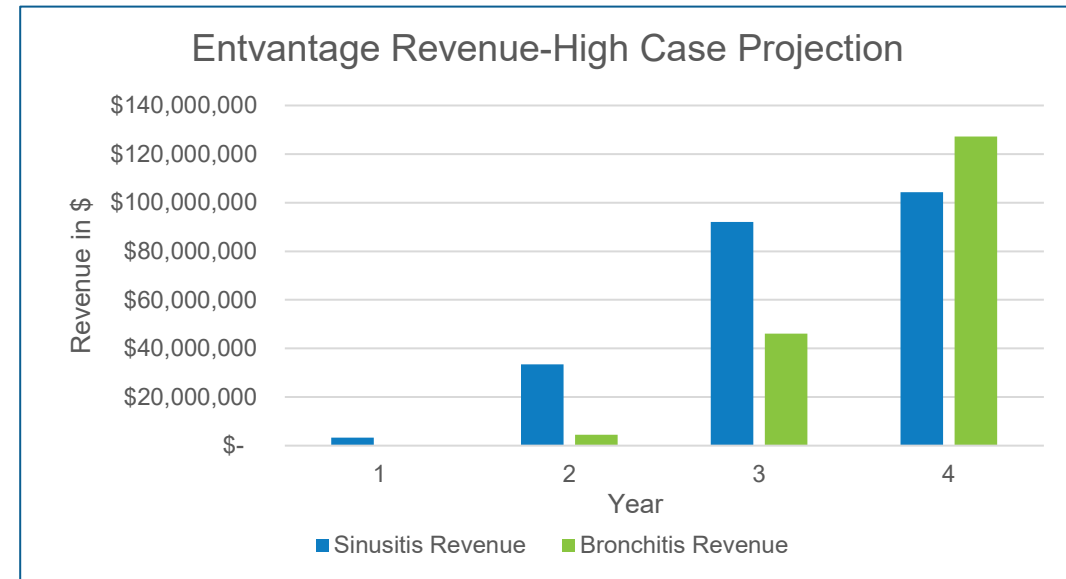
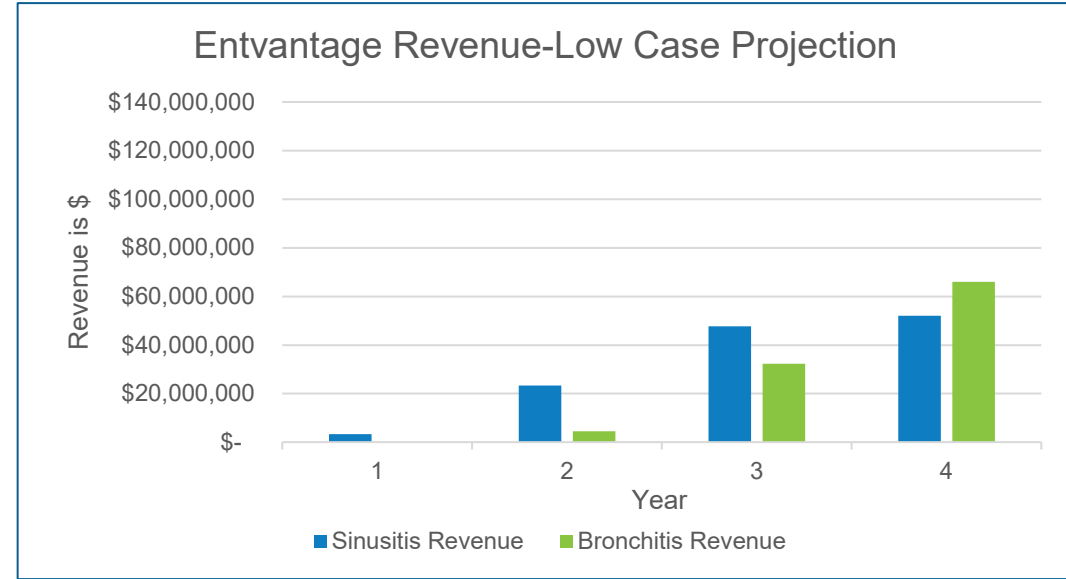
# Revenue Projections

Market Size in Cases-U.S. Only	Year 1	Year 2	Year 3	Year 4
Acute Sinusitis	10,923,520	11,141,990	11,364,830	11,592,126
Acute Bronchitis	14,794,682	15,090,575	15,392,387	15,700,235

Market Size in \$-U.S. Only	Year 1	Year 2	Year 3	Year 4
Acute Sinusitis	\$ 327,705,590	\$ 334,259,702	\$ 340,944,896	\$ 347,763,794
Acute Bronchitis	\$ 443,840,454	\$ 452,717,263	\$ 461,771,608	\$ 471,007,041

Low Projections	Year 1	Year 2	Year 3	Year 4
Market Penetration Rate	1%	7%	14%	15%
Units Sold	109,235	779,939	1,591,076	1,736,501
Sinusitis Revenue	\$ 3,277,056	\$ 23,398,179	\$ 47,732,285	\$ 52,095,016
Market Penetration Rate		1%	7%	14%
Units Sold	-	150,906	1,077,467	2,198,033
Bronchitis Revenue	\$ -	\$ 4,527,173	\$ 32,324,013	\$ 65,940,986
<b>Total Revenue</b>	<b>\$ 3,277,056</b>	<b>\$ 27,925,352</b>	<b>\$ 80,056,298</b>	<b>\$ 118,036,002</b>

High Projections	Year 1	Year 2	Year 3	Year 4
Market Penetration Rate	1%	10%	27%	30%
Units Sold	109,235	1,114,199	3,068,504	3,477,638
Sinusitis Revenue	\$ 3,277,056	\$ 33,425,970	\$ 92,055,122	\$ 104,329,138
Market Penetration Rate		1%	10%	27%
Units Sold		150,906	1,539,239	4,239,063
Bronchitis Revenue		\$ 4,527,173	\$ 46,177,161	\$ 127,171,901
<b>Total Revenue</b>	<b>\$ 3,277,056</b>	<b>\$ 37,953,143</b>	<b>\$ 138,232,283</b>	<b>\$ 231,501,039</b>





# Management Team



**Joe Skraba,**  
President & CEO

- Medical Device Engineer
- 30 years of experience in medical product commercialization
- MSTC Graduate 2003  
University of Texas at Austin



**Oriana Hawkins,**  
PhD-Assay Development Director

- PhD Microbiology/Immunology-  
Univ. of Oklahoma
- NIH Sponsored Post Doc-Vanderbilt



**Elisa Maldonado-Holmertz,**  
Director of Regulatory & Quality

- Significant experience in life science industry
- Expertise in medical device quality and regulatory
- Bachelor degree in Biology  
University of Texas at Austin



# Board of Directors



**Rick Hawkins,**  
Chairman Of The Board

- Serial Life Science Entrepreneur
- Founder of Pharmaco, Sensus Pharma & LabNow
- Current Founder/CEO Lumos Pharma



**Friedhelm Blobel, PhD,**  
Series B Director

- Former CEO SciClone Pharma, sold in 2017
- Former CEO of Gryphon Therapeutics
- Former Senior Executive Hoechst Group & Boehringer Mannheim Group



**John Paulos, PhD,**  
Director & Series A Lead

- Ex-semiconductor executive
- Former Director of Central TX Angel Network
- Active Angel investor & Board Member



# Medical Advisory Board



## Amber Luong M.D., Ph.D.

- Professor in Otolaryngology & Immunology
- Vice Chair of Research

THE UNIVERSITY OF TEXAS  
Medical School at HOUSTON



## Brent Senior, M.D.

- Vice Chair of Academics and Outreach
- Chief: Division of Rhinology, Allergy and Endoscopic Skull Based Surgery



## Ayesha Khalid, M.D., MBA

- Assistant Professor Otolaryngology-Harvard Medical School Staff
- MIT Sloan MBA



## Samer Fakhri, M.D.

- ENT at Kelsey-Seybold Clinic-Houston
- Former Professor and Chair in Otolaryngology

THE UNIVERSITY OF TEXAS  
Medical School at HOUSTON



## Karen Stierman, M.D.

- ENT Surgeon
- Affiliate Faculty of the Department of Surgery and Preoperative Care

 The University of Texas at Austin  
Dell Medical School

# Multicentered Clinical Trial Status



**FDA Pre-Submission Meeting Held**

**Commenced Multicentered Trial in October 2021**

**Single visit trial**

- 6 U.S. sites expanding to 15 sites

**Compare endoscopic collection vs Sinu-Test assay**

- Composite endpoint using bacterial culture and PCR

**200 patients enrolled in pivotal study**

**Initial results show 95.7% Overall Percent Agreement**



# What We Need?



Lead investor for **\$7 million**  
equity round

- Complete **multicentered clinical trial for 510(k) and CLIA Waiver**
- Submit for **FDA Clearance**
- Commence clinical testing for **Bacterial Bronchitis**
- Commence early **commercial scale-up** activities
- Seek **U.S. distribution partner**
- Seek ex-U.S. **distribution and licensing partners**



## Testing for Sinusitis and Bronchitis a \$1.4 Billion U.S. Market Opportunity

No rapid diagnostic tests available

## Established & Lucrative Reimbursement

Average reimbursement at ~\$55 per test

## Strong and Growing IP portfolio

Issued and pending applications in multiple territories



## Favorable Regulatory Environment

Clear 510(k) regulatory path

## Reduces Treatment Cost

Reduce standard treatment cost from \$400 to \$125 with use of test

## Experienced Management Team and Advisors





# Everybody Wins



## Patient

- Individualized, Personalized care
- Defend against antibiotic resistance.



## Physician

- Provide improved patient care
- Increased clinic revenue

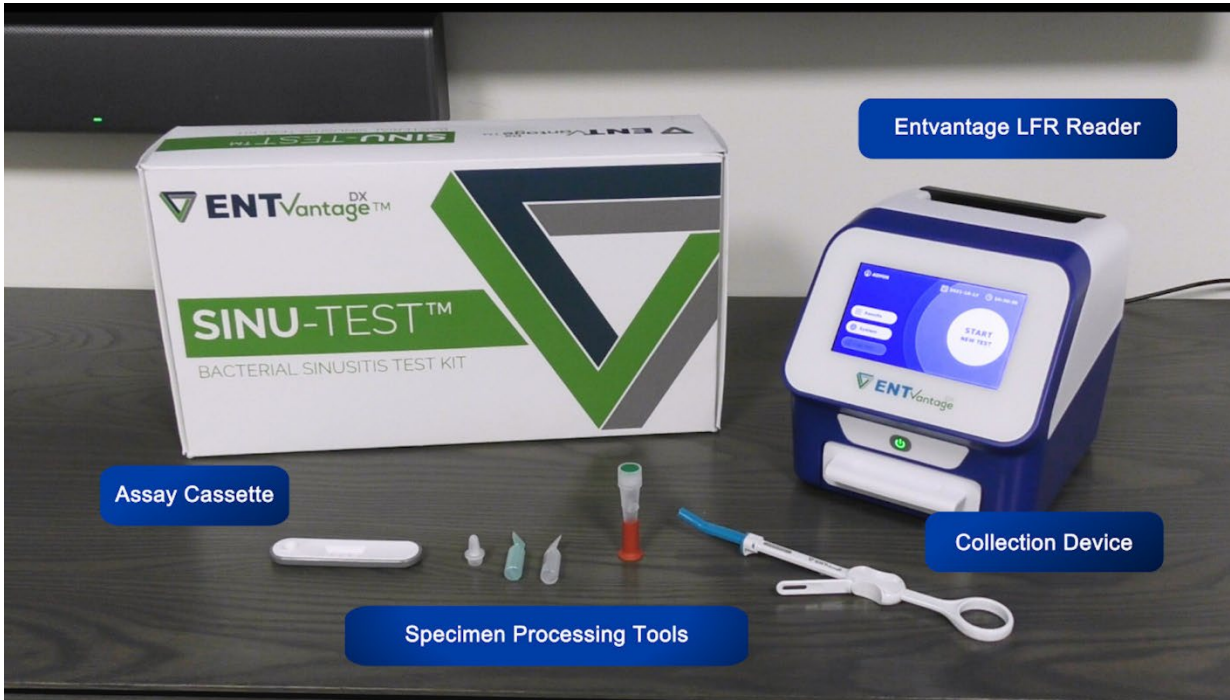


## Insurance Payer

- Improved patient care
- Reduced treatment cost



# Thank you!



**Joe Skraba**

 [\*\*jskraba@entv-dx.com\*\*](mailto:jskraba@entv-dx.com)

 **512-431-6071**



# Market Model Assumptions-Sinusitis:

Case 1-Sinusitis			Case 2-Sinusitis		
Condition		Total by Illness	Condition		Total by Illness
Acute Sinusitis		10,709,333	Acute Sinusitis		10,709,333
Acute bronchitis		14,504,590	Acute bronchitis		14,504,590
Year 1 Market Share		1.0%	Year 1 Market Share		1.0%
Year 2 Market Share		7.0%	Year 2 Market Share		10.0%
Year 3 Marketshare		14.0%	Year 3 Marketshare		28.0%
Increase in Marketshare post Year 3		7.0%	Increase in Marketshare post Year 3		7.0%
Market Growth for Years 2-7		2.0%	Market Growth for Years 2-7		2.0%
Market Growth for Years 8-10		2.0%	Market Growth for Years 8-10		2.0%
Growth Rate for Terminal Value		2.0%	Growth Rate for Terminal Value		2.0%
Sales Price per Procedure		\$ 30.00	Sales Price per Procedure		\$ 30.00
COGS per Procedure		\$ 6.00	COGS per Procedure		\$ 6.00
SGA as a % of Sales		25%	SGA as a % of Sales		25%
Effective Tax Rate		23%	Effective Tax Rate		23%
Discount Rate		15%	Discount Rate		15%
<b>Sinusitis Totals</b>			<b>Sinusitis Totals</b>		
Market Share-Year 10		21.0%	Market Share-Year 10		40.5%
Present Value without Terminal Value		\$ 85,077,149	Present Value without Terminal Value		\$ 168,197,393
Present Value with Terminal Value		\$ 176,231,095	Present Value with Terminal Value		\$ 251,720,863



# Market Model Assumptions-Bronchitis:

Case 1-Bronchitis			Case 2-Bronchitis		
Condition		Total by Illness	Condition		Total by Illness
Acute Sinusitis		10,709,333	Acute Sinusitis		10,709,333
Acute bronchitis		14,504,590	Acute bronchitis		14,504,590
Year 1 Market Share		1.0%	Year 1 Market Share		1.0%
Year 2 Market Share		7.0%	Year 2 Market Share		14.0%
Year 3 Marketshare		14.0%	Year 3 Marketshare		28.0%
Increase in Marketshare post Year 3		7.0%	Increase in Marketshare post Year 3		7.0%
Market Growth for Years 2-7		2.0%	Market Growth for Years 2-7		2.0%
Market Growth for Years 8-10		2.0%	Market Growth for Years 8-10		2.0%
Growth Rate for Terminal Value		2.0%	Growth Rate for Terminal Value		2.0%
Sales Price per Procedure	\$	30.00	Sales Price per Procedure	\$	30.00
COGS per Procedure	\$	4.00	COGS per Procedure	\$	4.00
SGA as a % of Sales		25%	SGA as a % of Sales		25%
Effective Tax Rate		23%	Effective Tax Rate		23%
Discount Rate		15%	Discount Rate		15%
<b>Bronchitis Totals</b>			<b>Bronchitis Totals</b>		
Market Share-Year 10		19.6%	Market Share-Year 10		37.9%
Present Value without Terminal Value	\$	90,007,256	Present Value without Terminal Value	\$	175,117,235
Present Value with Terminal Value	\$	171,919,681	Present Value with Terminal Value	\$	339,580,861