



# FIGHTING ANTIBIOTIC FAILURE ON TWO FRONTS

[asepmedical.com](http://asepmedical.com)



# A RARE COMBINATION



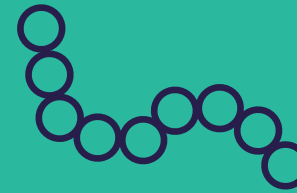
ASEP brings both a novel diagnostic and a therapeutic approach to the urgent, multibillion-dollar problem of antibiotic failure.



## DIAGNOSTIC

Novel assay provides earlier, faster diagnosis and a targeted treatment of sepsis

[Sepset Biosciences Inc.](#)



## THERAPEUTIC

Patented pharmaceutical peptide targets currently untreatable biofilm infections

[ABT Innovations Inc.](#)

**Our purpose is to mitigate the global crisis of antibiotic failure by improving patients' odds of survival and quality of life.**

# THE CRISIS: WIDESPREAD AND DEADLY\*



**49 million/year**  
cases of sepsis

**11 million**  
sepsis deaths per year

**100%**  
incidence of sepsis in COVID deaths

**10 to 1000x**  
more resistant to most antibiotics

**0**  
drugs approved for biofilms

**65%**  
of all infections are biofilms

\*data on file

# MULTIBILLION DOLLAR OPPORTUNITY



**\$41.9B Global Antibiotic Market CAGR: 3%**

Global MRSA  
Market\*  
**\$1.0B**  
CAGR: 4.4%

Global Device  
Infection Market  
**\$2.0B**  
CAGR: 3.6%

Global CRS  
Market  
**\$2.1B**  
CAGR: 7.4%

Global Ear  
Infection Market  
**\$2.8B**  
CAGR: 5%

Global Bacterial  
Vaginosis  
**\$4.5B**  
CAGR: 9%

Global Urinary  
Tract Infections  
**\$9.5B**  
CAGR: 3.6%

Global Wound  
Care Market  
**\$20B**  
CAGR: 4.1%

**\$1.0B Global Sepsis Dx CAGR: 8.5%**

\*data on file

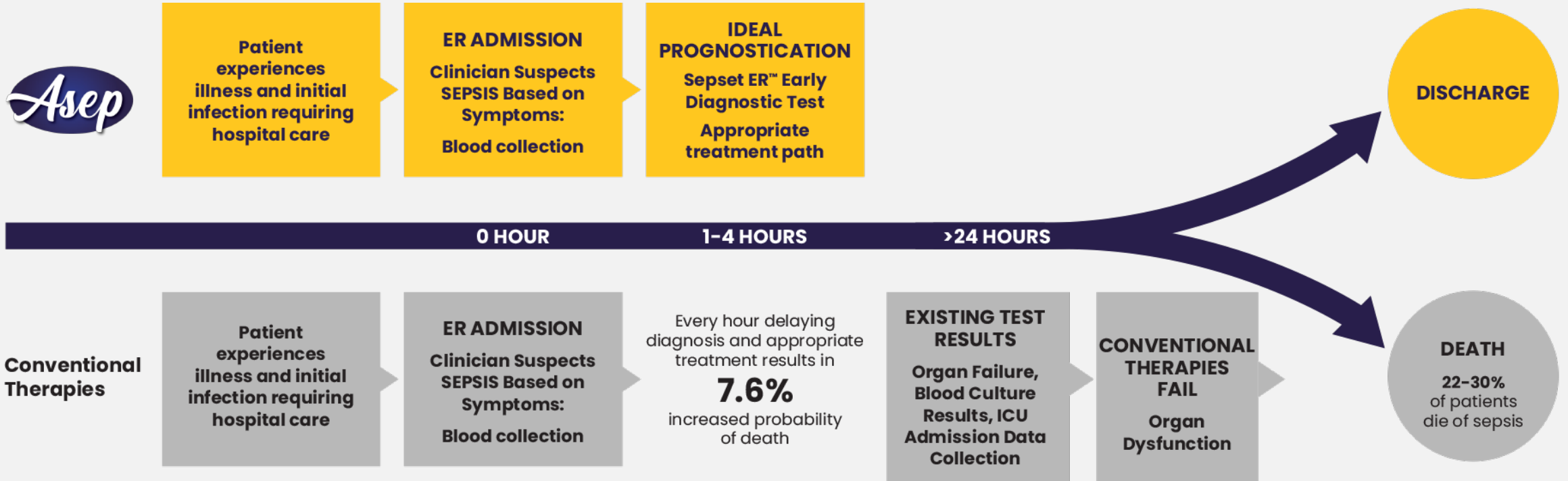


# GROUNDBREAKING DIAGNOSTIC TECHNOLOGY



Rapid diagnostic test delivers results in ~ 1 hour, allowing doctors to make better informed treatment decisions to improve sepsis survival rates.

# EVERY HOUR COUNTS



# DIAGNOSTIC ADVANTAGES



Greater sensitivity and specificity than the SIRS (Systemic Inflammatory Response Syndrome) criteria used today

Earlier recognition of sepsis, at a time when patients are admitted to the emergency room

Reliable diagnosis for determining the most appropriate treatment to improve survival

Next-generation molecular diagnostic focusing on patient-specific immune response



# POTENT THERAPEUTIC TECHNOLOGY

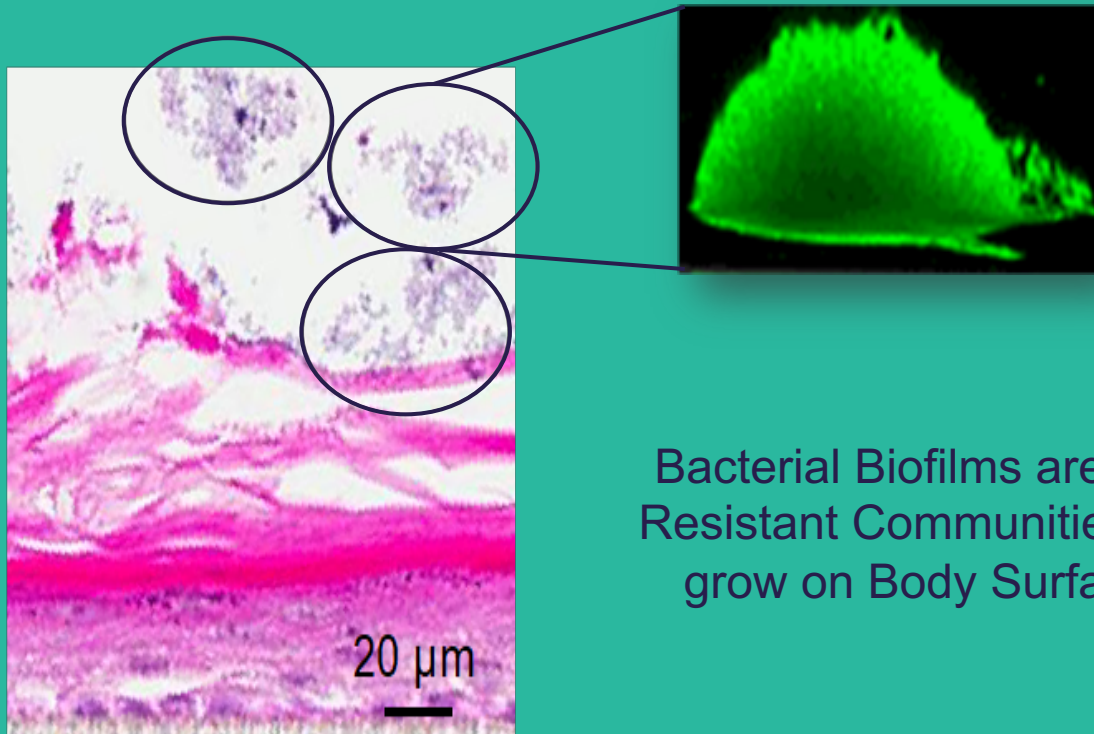


Proprietary peptide technology directly addresses the ineffectiveness of current treatment options by suppressing biofilm growth and reducing inflammation.

# ATTACKING THE BIOFILM



## MRSA Biofilm on Human Skin



Bacterial Biofilms are very Resistant Communities that grow on Body Surfaces

## Our Peptide Destroys Biofilm



# URGENT UNMET NEEDS



- 0 approved treatments for biofilms
- >2.8M antibiotic-resistant infections in US annually
- The most dangerous ESKAPE pathogens include untreatable variants

Methicillin-resistant Staphylococcus Aureus (MRSA) contributes to more deaths in the US per year than homicide, Parkinson's, emphysema and HIV AIDS combined

# PEPTIDE TECHNOLOGY HIGHLIGHTS



## Antibiofilm Activity

Potent activity against all major clinically relevant bacteria growing as antibiotic-resistant biofilms.



## Antibiotic Synergy

Work in combination with conventional antibiotics to overcome antibiotic resistance.



## Safe and Effective in Animal Infection Models

Work in *in vivo* models of biofilm infections such as sinusitis and abscesses.



## Anti-inflammatory Activity *in vivo*

As strong as the nonsteroidal anti-inflammatory drug indomethacin.



## Immune modulating activity

Suppress harmful inflammation while boosting protective innate immunity.



## Combined Activities

Optimized peptides with combined activity profiles for clinical applications.



# Initial Clinical Opportunity: **CHRONIC RHINOSINUSITIS (CRS)**



CRS is a lifelong condition causing painful inflammation due to bacterial biofilm infection:

- 242,000 emergency room visits annually
- Antibiotics do NOT work — do NOT target the Biofilm — only treat symptoms NOT the cause
- \$30,000/year: cost of Dupilumab, first treatment approved for inadequately controlled CRS — with poor adoption due to pricing limitations



# GRANT FUNDING



## Molecular Diagnostics

## Peptide Therapeutics

All funding prior to current financing was non-dilutive, largely research grants:

 <p>CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada</p> <p>\$3,387,000 CND</p>	 <p>BILL &amp; MELINDA GATES foundation</p> <p>\$2,736,000 US</p>	 <p>GenomeCanada</p> <p>\$6,978,000 CND</p>
 <p>THE UNIVERSITY OF BRITISH COLUMBIA</p> <p>\$3,600,000 CND</p>	 <p>Michael Smith Health Research BC</p> <p>\$450,000 CND</p>	 <p>NANOMEDICINES INNOVATION NETWORK</p> <p>\$250,000 CND</p>
 <p>NATIONAL INSTITUTES OF HEALTH</p> <p>\$1,256,000 US</p>	 <p>vetoquinol ACHIEVE MORE TOGETHER</p> <p>\$194,176 CND</p>	 <p>DEPARTMENT OF DEFENSE iFyber®</p> <p>\$527,000 US</p>

# INTELLECTUAL PROPERTY



## Diagnostics

**1 PATENT FAMILY  
+ 1 UNDERWAY  
3 PATENTS AWARDED**

Patent protection has been filed for the discovery of a predictive gene expression signature at first clinical presentation of endotoxin tolerance/cellular reprogramming (CR) associated with an inability to respond to bacteria (immune amnesia) present.

Patent for the biomarkers has been filed and already awarded in Europe, China, and Hong Kong. In the national phase entry process for:

**Canada • USA • Australia • Japan • Europe**

## Therapeutics

**3 PATENT FAMILIES  
SEVERAL UNDERWAY  
12 PATENTS AWARDED**

### **Small Cationic Antimicrobial Peptides**

8 Patents in US, Europe, Canada, and Australia

### **Cationic Peptides with Immunomodulatory, and/or Anti-biofilm Activity**

3 Patents in US, Europe, and Canada

### **Small Cationic Anti-biofilm and IDR Peptides**

1 Patent in Canada

# THE SHARE STRUCTURE

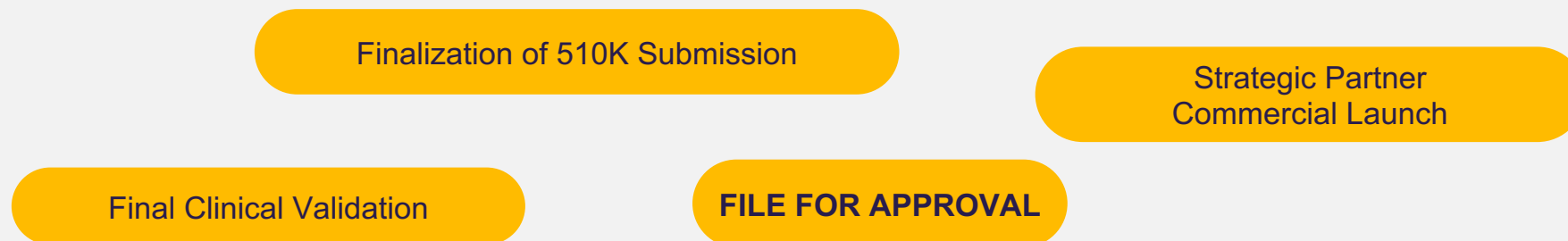


Category	# of Shares
Issued & Outstanding	56,140,344
Warrants & Options	4,540,000 @ \$0.50
<b>Total Fully Diluted Shares</b>	<b>60,680,344</b>

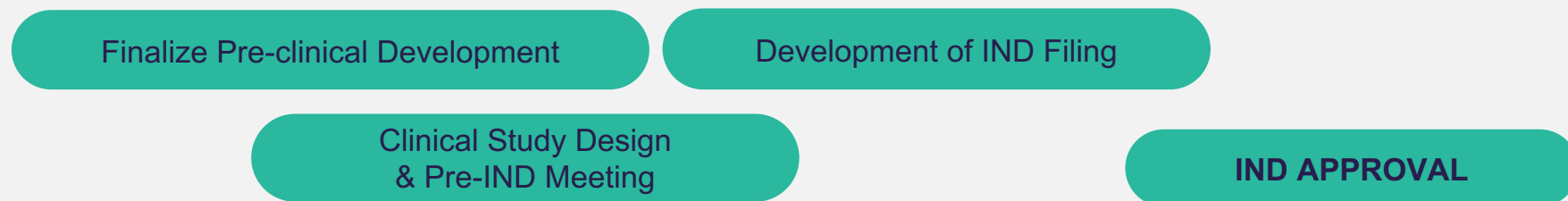
# TIMELINE



## DIAGNOSTICS



## THERAPEUTICS



# INVESTMENT HIGHLIGHTS



## Large Addressable Global Markets

With NO efficient clinical solutions (unmet medical needs)



## Novel Technologies

In the early diagnosis of sepsis and treatment of biofilm Infections



## Extensive Intellectual Property

Portfolio of both Diagnostics and Therapeutics



## Near-term Revenue Models

With multiple corporate partnership targets



## Publicly-Listed

For enhanced shareholder liquidity



## Experienced Management Team

With proven track records in med-tech and biopharma



## ANCILLARY SLIDES



# MANAGEMENT TEAM



## Rudy A. Mazzocchi

### Chairman / CEO

- Over 30 years senior executive management, technology and intellectual property development experience
- Med-tech, bio-tech and biopharma industries
- Founder of over a dozen healthcare companies
- Developed and commercialized multiple technologies
- Deep experience with clinical validation and regulatory reviews

## Dr. Fadia Saad

### Chief Bus. Dev. Officer

- Extensive track record in strategic planning and project implementation for global companies
- Former Head of Business Development, Aspreva Pharmaceuticals
- Produced licensing strategies and led teams in licensing opportunity analysis
- Managed operations of teams in R&D, intellectual property, finance and product commercialization
- Led more than 15 on-site due diligences
- Ph.D., Microbiology, McGill University
- MBA, HEC, University of Montreal

## Dr. Robert Hancock

### Chief Operating Officer

- Nearly 40 years research and teaching at University of British Columbia
- Published over 800 papers and reviews, over 118,000 citations
- 72 patents, h-index of 172
- Prix Galien (highest award for Canadian pharmaceutical research and innovation)
- Killam Prize (Canada Council's prize for health research)
- Michael Smith CIHR Researcher of the Year
- ICAAC Aventis Antimicrobial Research Award
- Inducted as an Officer of the Order of Canada in 2001

## Jennifer Gretchen

### Chief Financial Officer

- Strong managerial experience in financial planning, analysis and reporting
- Assisted multiple companies through IPO and M&A transactions
- Experienced in technology and telecommunications sectors
- CA, Canadian Institute of Chartered Accountants

## Dr. Evan Haney

### Chief Scientific Officer

- Inventor on ASEP peptide patents
- In-depth experience in academic and translational research
- More than 40 papers related to peptide optimization as therapeutics published in scientific journals
- Ph.D., Biochemistry, University of Calgary

# BOARD OF DIRECTORS



## Rudy A. Mazzocchi

### Chairman / CEO

- Over 30 years senior executive management, technology and intellectual property development experience
- Med-tech, bio-tech and biopharma industries
- Founder of over a dozen healthcare companies
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- Prix Galien (highest award for Canadian pharmaceutical research and innovation)
- Michael Smith CIHR Researcher of the Year
- ICAAC Aventis Antimicrobial Research Award
- Founder of 5 companies.
- Inducted as an Officer of the Order of Canada in 2001

## Derrold Norgaard

### Director / Chair – Audit Committee

- Fellow of the Chartered Professional Accountants of British Columbia
- Formerly Tax Partner and Office Managing Partner at KPMG
- Expertise in personal tax planning, international tax and corporate taxation
- Instructor in Canadian tax programs
- Frequent speaker and author of several articles on Canadian tax planning

## Tim Murphy

### Director

- Seasoned business executive and international lawyer
- Founding Partner of Murphy & Company, LLP
- Over 15 years of experience advising high-growth companies on mergers and acquisitions, technology and finance matters
- Served as CEO, and on the boards of numerous public and private companies

# BIOFILM ASSOCIATED DISEASES AND AFFECTED ORGANS



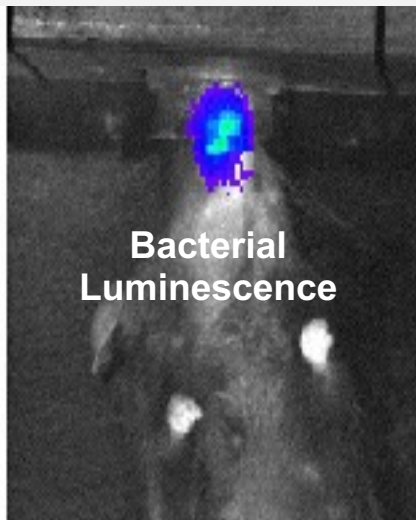
BODY SYSTEM	AFFECTED ORGANS	DISEASES
Respiratory	Upper and Lower Airways	Bronchiectasis; Pneumonia; Tuberculosis
	Upper and Lower Airways	Cystic Fibrosis
Ear, Nose and Throat	Middle Ear	Otitis Media
	Nasal cavity and Paranasal Sinuses	Chronic Rhinosinusitis
	Throat	Pharyngitis and Laryngitis
Device Infections	Local and Systemic	Catheters; Stents; Prostheses; etc.
Integumentary	Skin and Underlying Tissue	Wound and Burn infections; Abscesses; Skin and Soft Tissue Infections; Surgical Site
Oral Infections	Oral Cavity	Dental; Mucositis
Cardiovascular	Cardiac Valves	Infective Endocarditis; Valve Replacements
	Arteries	Atherosclerosis
Digestive	Gastrointestinal Tract	Inflammatory Bowel Disease; Helicobacter; Diarrhea
Reproductive	Vagina	Bacterial Vaginosis
	Uterus and Fallopian Tubes	Chronic Endometritis
	Mammary Glands (breasts)	Mastitis
Urinary	Prostate Gland	Chronic Bacterial Prostatitis
	Urethra, Bladder, Kidneys	Urinary Tract Infections

# VALIDATION STUDIES ASEP Solution to CRS



ASEP Peptides address both Biofilm Infections and associated Inflammation and have demonstrated excellent results in Animal Models

Imaged 5 Days Post-Infection



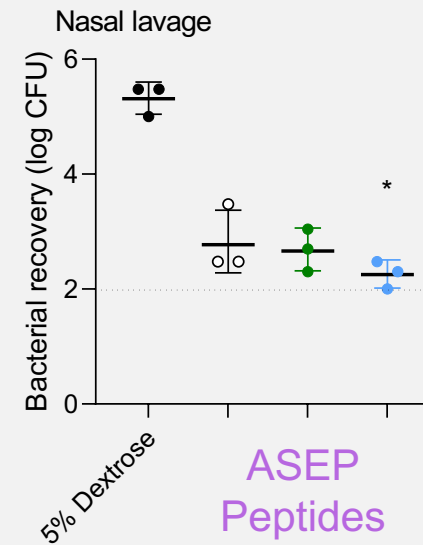
Bacterial Luminescence



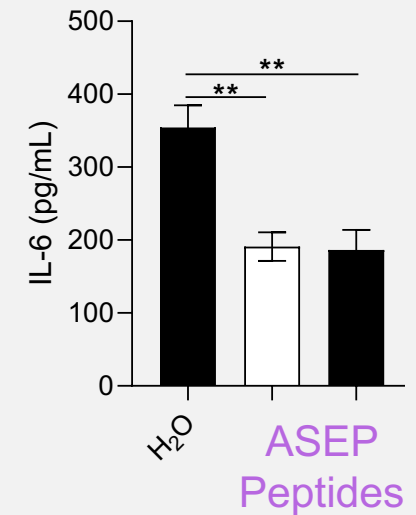
Peptide Treatment Anti-biofilm Effect

Bacteria NO Treatment → Sinus Infection

Strong Anti-Bacterial Response



Strong Anti-Inflammatory Response



Alford, Choi et al. 2021. Frontiers Cell. Infect. Microbiol. 11:75.

# DESIGNATION BENEFITS









**Orphan Drug Designation Awardees** are granted the following benefits from the FDA:

- Lower hurdles to approval, longer exclusivity, lower market costs, faster uptake, premium pricing, favorable reimbursement,
- Tax credits of 50% off the clinical drug testing cost awarded upon approval,
- Eligibility for market exclusivity for 7 years post-approval, and
- Waiver of new drug application (NDA) fee (~ \$2.2M value)
- Acceleration of the development process, and advantages post-marketing.

# COMPARABLES – MOLECULAR DIAGNOSTICS



COMPANY	STOCK SYMBOL	CLINICAL INDICATIONS	PHASE OF DEVELOPMENT	2020 REVENUES (\$MM USD)	MARKET CAP (\$MM USD)
 Immunexpress	-	Distinguish between sepsis and non-infectious systemic inflammation	Approved (SeptiCyte)	-	-
 Molzym	-	Detection and identification of a broad range of Gram-positive bacteria, Gram-negative bacteria and fungi within a working day	Approved in EU (SeptiTest)	-	-
 Abbott	ABT	Identify infection-causing pathogens directly from a patient's sample, without the need for culture	Approved (IRIDICA)	\$34,600	\$210,380
 Roche Diagnostics	RO	Detection of 25 common blood pathogens considerably faster than conventional blood culture	Approved (SeptiFast)	\$15,370	\$279,890 (RO)
 Seegene	-	Detection and identification of more than 90 sepsis causing pathogens	Approved in EU (MagicPlex Sepsis)	\$1,007	\$3,268
 BIOMÉRIEUX	BMXMF	Tests for a variety of pathogens that cause viral respiratory, pneumonia, bloodstream, gastrointestinal infections and meningitis-encephalitis as well antimicrobial resistance genes	Approved	\$3,780	\$19,140



# COMPARABLES – THERAPEUTICS



COMPANY	STOCK SYMBOL	CLINICAL INDICATIONS	PHASE OF DEVELOPMENT	2020 REVENUES (\$MM USD)	MARKET CAP (\$MM USD)
Omnix Medical	-	Hospital-acquired or Ventilator-acquired bacterial pneumoniae	Pre-clinical	Pre-revenue	-
Peptilogics	-	Prosthetic Joint infections	Phase II	Pre-revenue	-
POLYPHOR	POLN SW	Pseudomonas aeruginosa infections in CF	Pre-clinical	\$14.39	\$89
VENUS <i>Crystalline Innovations</i>	VENUSREM	Skin infections, Bloodstream infections, Endocarditis	Pre-clinical	\$78	\$54
ContraFect MOLECULAR TREATMENTS FOR INFECTIOUS DISEASE	CFRX	Bacteremia, including endocarditis Prosthetic joint infections MRSA bacteremia in COVID patients	Phase III Phase I Phase I	(\$28.2)	\$146.32
		Hospital-acquired or Ventilator-acquired bacterial pneumoniae, Cystic fibrosis associated infections, Complicated urinary tract infections, Bloodstream infections	Lead optimization		



# CRS REGULATORY STRATEGY



- **Pursue Orphan Drug status** for CRS in cystic fibrosis patients—a high unmet medical need, with no approved drugs.
- **Pursue “fast track” status** for drugs addressing antimicrobial resistance—(equivalent of orphan classification, used for drugs treating serious conditions and unmet needs)



PROJECTED REVENUE FOR  
ORPHAN DRUGS IN 2026

255bn USD



GLOBAL GROWTH  
FOR PRESCRIPTION  
ORPHAN DRUGS IN 2018

11.1%



AVERAGE ANNUAL COST  
OF ORPHAN DRUGS  
PER PATIENT IN 2018

150,854 USD