

Discovery of Veterinary Spectrum Specific Antibacterial Agents: The Need for Innovation in Animal Health

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27

MANUFACTURING SITES

8

CORE ANIMAL SPECIES



\$5.3 BILLION ANNUAL REVENUE

APPROXIMATE R&D COLLEAGUES

1,000

300

APPROXIMATE NUMBER OF PRODUCT LINES

WE PROVIDE
MEDICINES
VACCINES
DIAGNOSTICS
GENETIC TESTS
BIODEVICES
SERVICES

60+ YEARS OF EXPERIENCE

6 MAJOR PRODUCT CATEGORIES

MARKET PRESENCE IN

100+ COUNTRIES

APPROXIMATE COLLEAGUES WORLDWIDE

9,000

OUR FOCUS

42%¹

COMPANION ANIMAL HEALTH

57%¹

LIVESTOCK HEALTH

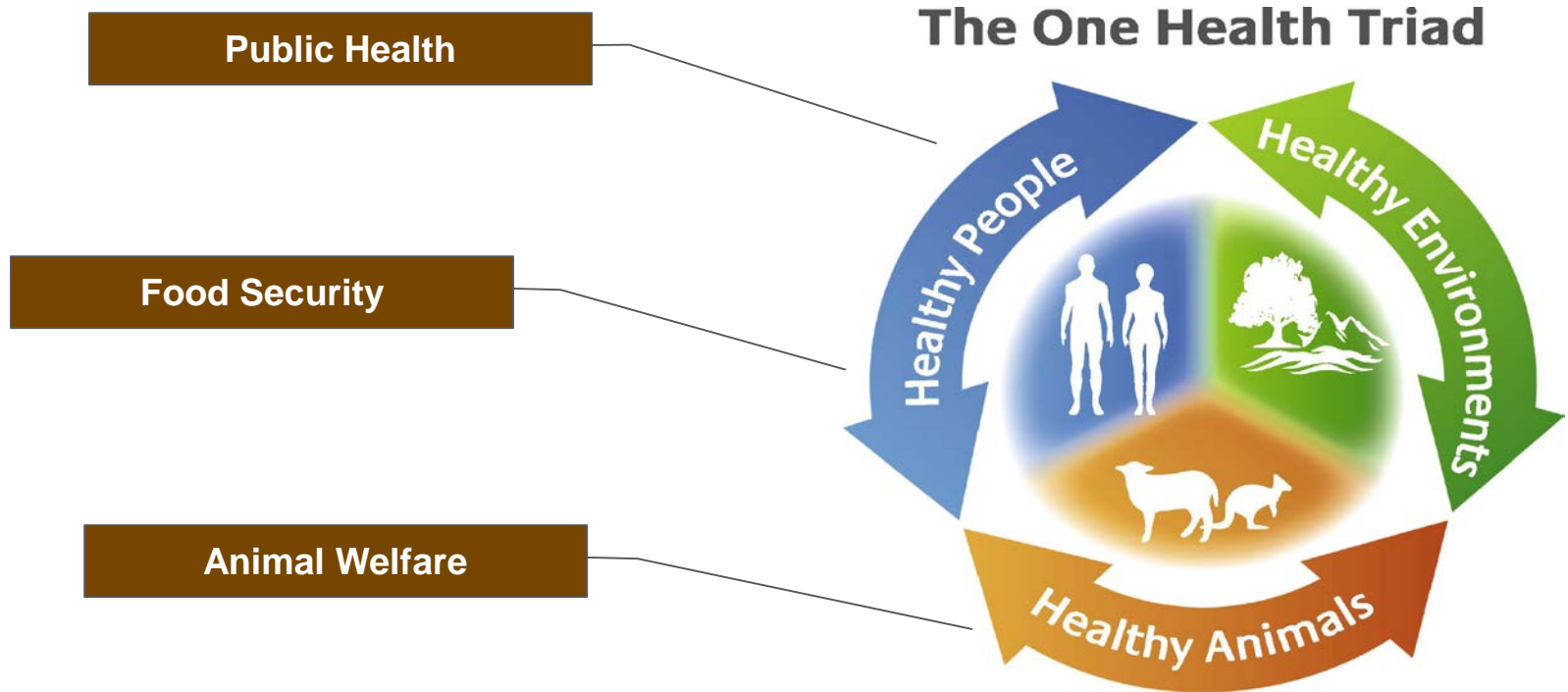
2,900

APPROXIMATE FIELD FORCE MEMBERS

Note: Most facts and figures shown are as of Dec. 31, 2017 | ¹Excludes revenue associated with Client Supply Services, which represented 1% of total 2017 revenue.



ONE HEALTH AND THE ROLE OF THE VETERINARIAN



INNOVATING ACROSS THE CONTINUUM OF CARE

PREDICT

PREVENT

DETECT

TREAT



GENETICS



**VACCINES,
ROBOTICS &
AUTOMATION**



**DATA
ANALYTICS &
SENSORS**



DIAGNOSTICS



MEDICINES

INTERNAL CAPABILITIES COMPLEMENTED WITH EXTERNAL PARTNERSHIPS

The emergence of therapy limiting antimicrobial resistance in both human and veterinary pathogens over the past decade is driving the need for novel, non-shared class agents for treatment of animal diseases

Veterinary Spectrum Specific Agents

Tune spectrum for treatment of specific animal diseases

**Reduced activity against
ESKAPE pathogens**

**Bovine Respiratory Disease
Swine Respiratory Disease
Bovine Mastitis
Canine Pyoderma**

**Claim Structures
Prevention
Control
Treatment**

**Routes of Administration
Parenteral
Oral
Topical
Intramammary**

TRADITIONAL SMALL MOLECULES

Capable of effectively treating acute disease as standalone therapies

Novel Analogs

Agents in existing antibacterial classes

Analogs selected for activity against veterinary pathogens

Reduced activity against zoonotic pathogens

Novel Classes

Agents in novel classes

May have activity against human pathogens

Has safety issue that precludes use in humans

Veterinary Specific

Uses genomic comparisons to identify targets specific to veterinary pathogens

No activity against human pathogens

SMALL MOLECULE ANTIBIOTIC REPLACEMENTS (SMARS)

- “Alternatives to Antibiotics” or “Non-Traditional Antibacterials”
- Direct swap out for traditional antibacterials
- Multiple Categories
 - Antimicrobial Peptides
 - Bacteriophages (including Phage Lysin Constructs)
 - Immunomodulators
 - Virulence Modifiers
 - Monoclonal Antibodies
 - Microbiome (including Probiotics and Competitive Exclusion)
- Learning curve to understand appropriate applications and issues associated with specific substrate
- Most likely limited to applications in the Prevention and Control indications
 - Exception may be bacteriophages as ultra-narrow spectrum agents

PROSECUTE INDIVIDUAL ASSETS OR INVEST IN SUBSTRATE-SPECIFIC PROGRAMS?

Individual Asset Prosecution

- Leverage substrate from human health programs
- Single assets from external sources
 - Startups/BioTech
 - Academia
- Majority are single asset opportunities
 - Often declined as “too early stage”
 - *In vitro* data/rodent data
 - No POC efficacy data in target animals
 - POC efficacy study cost often barrier to further asset development
- Sponsors must have sufficient scouting expertise to identify opportunities within a substrate area and have internal capabilities to rapidly evaluate the assets

Substrate Specific Programs

- Analogous to traditional pharma research programs
- Requires sponsor to maintain internal research capabilities in specific substrate areas
 - May leverage external substrate as entry into area
 - May leverage external expertise to create/maintain program candidate stream
 - Candidates reprioritized based on screening program criteria
- AH companies may lack resources to maintain multiple programs within a research area

RECOMMENDATIONS

- Recommendations fit under Goal 4 of National Action Plan
- Section 4.3: Intensify R&D for new therapeutics
 - Add requirement for need for novel animal health agents to address MDR animal pathogens
 - Require all human health programs to include veterinary pathogens in screening programs for identification of agents that may have animal pathogen specific activity
- Section 4.4: Develop non-traditional therapeutics
 - Provide clear research guidance by defining alternatives to antibiotics with separation of SMARS from other agents (i.e., vaccines, disinfectants)
- Sections 4.6 and 4.7: Enhance Public-Private Partnerships
 - Animal health components should be included
 - Enhance public-private partnerships by supporting veterinary startups with additional funding and expertise

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