

LeptoX Biopharma, Inc.
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[LOGO – TBD]

Industry: Biotech, Animal Health

Management:

Carla Devillers, MBA, Founder, CEO
Seeking to fill additional roles:
Chief Scientific Officer:
VP of Business Development
VP of Product Development

Board: Seeking members

Scientific Advisory Board:

Joseph M. Vinetz, MD, Professor of Medicine
(Infectious Diseases), Yale – Founder

David Kaslow, MD, CSO, PATH

Jerome Kim, MD, Director General,
International Vaccine Institute

Richard Squires, DVM, PhD, Associate
Professor, James Cook Univ.,
Australia; Chair, World Small Animal
Veterinary Assoc.'s Vaccination
Guidelines Committee

Richard Marconi, PhD, Professor of
Microbiology, VCU; inventor of canine
Lyme vaccine

Number of Employees: 2

Finance:

Accounting: internal

Funding to Date:

Founders: \$10,000

Int'l Vaccine Institute grant: \$20,000

Foundation grant: \$80,000

Financing Sought: \$5M

Pre-clinical studies

R&D

IP protection

Operating Costs

IP:

Patent use licensed from Yale University

Legal:

Wiggin and Dana LLP

Business Description / Company Background:

LeptoX Biopharma, Inc. is a start-up R&D company focused on development of vaccines, therapeutics and diagnostics for infectious diseases for both human and animal markets. Product candidates are based on novel technology, leveraging genomics, that comes out of the Vinetz laboratory at Yale School of Medicine. We are addressing enormous unmet needs for several diseases starting with leptospirosis, for which we already have *in vivo* proof of principle.

Market Opportunity / Unmet Need:

- Kills people; affects travelers, military and certain occupations
- Millions affected, up to 20% fatality rate (*source: PubMed*)
- Kills dogs, makes livestock (cattle, pigs) unproductive
- No human vaccine actively marketed
- Animal vaccines on market are sub-optimal
 - short duration, narrow coverage, don't prevent transmission or infection, serious adverse event profile
 - our genomically-driven recombinant protein vaccine approach has clear potential advantages in terms of efficacy and safety

Products / Services – Launched & Pipeline:

Our first product to launch will be a pan-lepto vaccine for dogs. The data from the animal experiments, including dogs, will then be used to develop vaccines for cattle, swine and horses. The same data will be used in a parallel track to develop a pan-lepto vaccine for humans.

Commercial / Technical Milestones:

- Discovery - target candidate (2021)
- Incorporated (2022)
- Animal prototype validation (Year 2)
- Animal IND submission (Year 3)
- International human "Clinical Trial Application" (Year 3)
- International human clinical trials (Years 4-5)
- US FDA human IND submission (Year 6)

Competition / Competitive Advantages / Customer Benefits:

- Our recombinant protein-based animal vaccines are anticipated to have fewer side effects, full spectrum coverage, prevent infection and transmission – characteristics lacking in products currently marketed by all major animal health companies.
- The Imaxio lepto vaccine for humans is a bacterin based on a single serovar, is not pan-lepto, has a significant adverse event profile >> hence a very limited potential market

Financial Projections (Unaudited):

Years 1-5: development, pre-clinical and clinical studies: will require investment of \$25MM (to be funded by LeptoX and its partner International Vaccine Institute ("IVI"), a U.N. affiliate) plus further costs for commercialization of the human vaccine to be covered by IVI.

We are not submitting a financial table at this time due to the early-stage phase of our company.