



## GEMMUS Pharma Inc

### About Gemmus

Gemmus is a founder-owned and operated company focused on the treatment of infectious diseases using an immunomodulatory approach. Currently, we are working with NIH-NIAID on the development of our lead candidate for the treatment of influenza with a focus on H1N1 and H5N1 subtypes.

### Technology Overview – Target Influenza

Unlike traditional antiviral therapies which focus on the virus, Gemmus has taken an alternative approach to the treatment of influenza by focusing on modifying our body's response to the virus rather than on the virus. This therapeutic approach is based on the idea that tissue damage and mortality are due to the overproduction of pro-inflammatory cytokines rather than the virus itself. Therefore, an effective treatment would be to modulate, but not to eliminate, the pro-inflammatory response by using an immunomodulator. Reducing tissue damage allows for the development of an adaptive immune response to eliminate the virus.

A second aspect of our approach is to retarget existing drugs to rapidly meet the challenge of a possible influenza pandemic. We have identified immunomodulators which were developed for other indications and applied them to the treatment of viral infections. Our current lead candidates have the following profile:

- > Orally available, non-peptidic eicosanoid analogs
- > Efficacious in Animal Models
- > Clinically established Safety Profile
- > Intellectual property protection
- > Realistic CMC

### Licensing Opportunities – Small Molecule Therapeutic

Due to the distinctly different targets of antiviral and immunomodulatory therapies, the two approaches can complement each other. Using an animal model of lethal avian influenza, we have demonstrated this synergy which increased the survival rate at lower antiviral dose. The benefit of synergy could be a delay in the development of resistant viruses and, thereby, extend the useful life of current antiviral drugs. We intend to pursue the co-therapy approach alone or through the formation of a strategic partnership.

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## Market Opportunities

Influenza has the potential to become a worldwide disease due to the emergence of mutant strains which can spread easily person-to-person, can cause serious illness, and can sweep around the world in very short time. To counteract this threat, public health agencies have invested in the development of vaccines and have stockpiled antiviral drugs as oseltamivir, Tamiflu®, which had over 1 billion dollars in sales for this purpose in 2006. The demand for oseltamivir has increased, but the development of resistant strains in several parts of the world and the narrow treatment window, 48h, is driving the search for co-therapies and alternative treatments. Due to the substantial investment made by public health organizations in antiviral therapies, we envision a significant market for an effective therapy which could synergize with existing treatments.

The market for antiviral and immunomodulatory therapy would be impacted by significant advancements in the production of effective vaccines. However, the need will continue to exist in community and hospital settings for effective therapeutic agents before a vaccine becomes available and in cases where the vaccine is not effective.

In summary the key drivers are:

1. The difficulty in predicting the scope of the current H1N1 influenza pandemic
2. Emergence of drug-resistant strains (already reported in some areas)
3. Stable formulation and distribution permitting rapid deployment prior to vaccines
4. Prophylactic treatment of emergency response personal

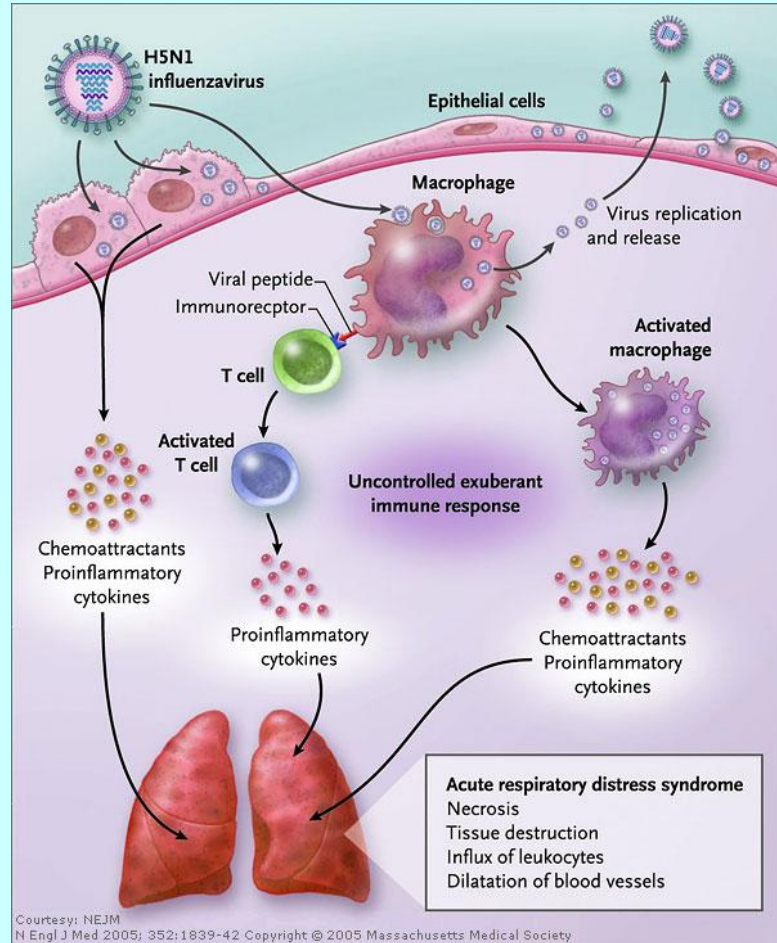
Additional opportunities

The market opportunities for our host-targeted therapies could be expanded to the treatment of other viral diseases. Additional targets include bacterial and fungal infections, as well as, an expanded list of viral infections. There is a clear unmet need for treatments which are not susceptible to the rapid development of resistance and are effective against a wide variety of infections. Support for the expansion of our market opportunities comes from the list of companies who are using immunomodulation therapy to develop novel antibiotics which are not bactericide, but act by modulating the host's immune response.

**Gemmus leases laboratory space in the California Institute for Quantitative Biosciences, QB3 (<http://qb3.org/index.html>), which is affiliated with UCB, UCSF and UCSC and is located in San Francisco, California.**

## Immunomodulation Therapy to treat Avian Flu

The innate immune response to an H5N1 viral infection differs from the response to a typical viral infection in that the response is uncontrolled and more vigorous which results in tissue damage.



Antiviral drugs target virus replication or release.

An immunomodulator reduces the production of Pro-inflammatory cytokines to typical response levels.

Goal: Reduce acute respiratory distress syndrome

## Commercialization Plan

The commercialization of our influenza treatment will follow the path established for antiviral drugs. The key aspects of the plan are:

- > Complete in vivo characterization of lead candidates
- > Profile as stand alone and co-therapy with an anti-viral
- > Identify development partners
- > Submit IND for clinical trial using biomarkers
- > Submit NDA
- > Market lead candidate to government public health departments

In parallel, we will profile our lead candidate against other viral infections, as SARS, and bacterial infections.



## GEMMUS Pharma Inc

### **Executive Management**

#### **CEO: Daryl H. Faulds, Ph.D.**

Daryl Faulds Ph.D. has over 20 years of experience in molecular biology, immunology and pharmaceutical development. Most recently he led the Berlex Biosciences (the US subsidiary of Schering AG) effort for Influenza A therapeutics. He has led projects in respiratory disease (Mycoplasma pneumonia), autoimmune disease (Multiple sclerosis, MS) and basic research. In addition he has served on international project teams for HPV vaccines and bioinformatics. This background has given him extensive experience in pre-clinical project management and management of the transition from research to the clinic. Dr. Faulds has a BA in biology and a Ph.D. in Molecular Biology. He was an NIH postdoctoral fellow at UC Berkeley.

#### **President: William J. Guilford, Ph.D.**

William Guilford Ph.D has 20+ years of experience in biotechnology and pharmaceutical research and development. Dr. Guilford leads the medicinal chemistry effort and manages research collaborations. In previous positions at Berlex Biosciences, ImmuLogic and Sogetal, he gained extensive experience in medicinal chemistry in both the cardiovascular and immunology therapeutic areas. Three of his four drug candidates have entered into clinical trial. Dr. Guilford is an author on over 34 peer-reviewed journal articles and is an inventor on over 30 issued patents and patent applications. Dr. Guilford has a BS and Ph.D. in chemistry. He was an NIH postdoctoral fellow at the ETH in Zurich and a postdoctoral fellow at Harvard University.

### **Advisors**

#### **Dale L. Barnard Ph.D.**

Dr. Barnard's principle research at Utah State University has been in antiviral chemotherapy and toxicology, both in antiviral screening and in secondary in vivo antiviral studies supported by National Institutes of Health, the U.S. Army Medical Institute, and various pharmaceutical companies. Current research focuses on developing treatments for SARS-CoV, influenza H5N1, and viruses of biodefense importance.

Honors and Awards:

- President, Intermountain Branch Amer Soc for Microbiology, 1995-1996, 2001-2002
- Mortar Board Top Professor for 1999-2000
- Top Professor and Internat Student Council Prof of the Year, Utah State University, 2000
- Joe E. Whitesides Scholar-Athlete Recognition Award for the year 2001
- Invited speaker, 2nd International conference on Community Acquired Pneumonia, 2005

#### **John Parkinson Ph.D.**

John F. Parkinson Ph.D. has 17+ years biotechnology / pharma R&D experience in Cardiovascular and Immunology Research at Berlex Laboratories / Schering AG and at Bayer Schering Pharmaceuticals. He led successful drug optimization programs in selective inducible nitric oxide synthase inhibitors (licensed to Pfizer in 2003), lipoxin analogs (currently in phase I human studies) and LTA<sub>4</sub>-h inhibitors. Dr. Parkinson is internationally recognized with over 60 research publications and is an inventor on over 20 patents. Dr. Parkinson did postgraduate training in Biochemistry at the University of Bristol (UK) and fellowships in hematology at Indiana University (Indianapolis, USA) and thrombosis research at Lilly Laboratories (Indianapolis, USA).