

IGAN BIOSCIENCES,
INC.

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U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health



National Institutes of Health Commercialization Assistance Program
(NIH-CAP)

Company Profile

Industry Sector: Pharmaceuticals

Company Overview: IGAN Biosciences, Inc. has developed IgA protease as a potential biological therapeutic to treat, and perhaps reverse, IgA nephropathy. This illness begins in adolescence, is the commonest cause of glomerulonephritis in the world, and leads to kidney failure in 30-40% of those affected. The company emerged from academic research conducted at Tufts Medical Center in Boston, MA, and development of the drug is in the late preclinical phase.

Target Market(s): Worldwide. IgA nephropathy is a major public health problem in China, Japan, Singapore, Korea and other Asian countries; lesser but important numbers of patients are in the US and EU countries. A recent review puts worldwide incidence at 25 patients/million/yr. Based on conservative assumptions regarding rate of progression, need for therapy and cost, market opportunity for IgA protease treatment of IgA nephropathy in US, EU and Japan is US\$2.8-4.4B.

Key Value Drivers

Technology: IgA protease, discovered by IGAN scientists, is a naturally occurring microbial proteolytic enzyme that has the unique ability to cleave only one clearly defined substrate: human IgA1 immunoglobulin. IgA1 is the protein that accumulates in the kidney of patients with IgA nephropathy, and eventually causes inflammation and severe kidney damage. IgA protease is intended to be injected intravenously into patients to remove kidney IgA, thus restoring kidney function. The preclinical development is currently funded by a Fast Track SBIR award from the National Institutes of Health, NIDDK, and by individual investors.

Competitive Advantage: Treatment of IgA nephropathy with steroids, immunomodulating drugs, anti-hypertensive drugs and dietary supplements have been disappointing. IgA protease is intended to remove the damaging IgA, with the goal to reverse the disease. Use of IgA protease for this disease has been designated an orphan drug indication by the FDA. Patents have been issued in US, EU, China, and Hong Kong and are pending in Japan.

Plan & Strategy: Seeking a strategic and drug development partner.

Management

Leadership:

Peter Bonis, M.D., CEO

Jiazhou Qiu, M.D., founder and CSO

Andrew Plaut, M.D., founder and CMO

Donald Collins, Ironwood Investment Management, CFO

Scientific Advisory Board:

Product Pipeline

Preclinical: IgA protease produced by the pathogenic bacterium *Haemophilus influenzae*.

The recombinant form of the enzyme is expressed in *E. coli*, and produced in high yield using standard fermentation technology. A crystallographic structure of this protease has been determined.