

http://lumen.bio

Biologic drugs at small-molecule costs

- 1. The idea of addressing therapeutic targets in the G.I. tract with biologics has been widely ignored by researchers.
- 2. This is largely due to the high cost of traditional biologics production (in part because of the larger doses required, particularly for chronic treatments).
- 3. It is a blind spot for researchers and industry alike, rarely appearing in the research literature, which focuses exclusively on small molecule drug development for enteric diseases, and infusion/injection for biologics.
- 4. Lumen is the first to make orally delivered biologics commercially viable.
- 5. The G.I. tract is full of enormous unmet medical needs, with several low-risk near-term product opportunities in ID, and enormous long-term opportunities in oncology and auto-immune diseases.



Lumen turned spirulina into a new biotechnology platform

Unique biology

- Spirulina is the **only** microbe grown at commercial scales for food
- Lumen holds **broad**, **exclusive IP** on all spirulina genetic engineering
- FDA approved for oral consumption.
- No cold-chain requirements
- **cGMP production** already built
- Collaboration with the Google Accelerated Science Team using AI to enhance productivity

Advanced protein design

- Oligomeric frameworks displaying therapeutic antibodies (VHHs)
- Multivalent presentation/increased avidity
- Proteolytic and pH stabilization



Examples of *in silico*-designed nanoparticle frameworks



Ultra simple manufacturing enables patient safety at *de minimis* cost



All cGMP/CMC aspects have been formally pre-cleared with FDA staff, in writing, through the formal PDUFA pre-IND meeting process



Patent pending

Lumen's initial products are edible antibody therapeutics



Game-changing cost structure enables a new treatment modality

Projected cost per gram of orally-delivered biologics



New oral biologics treatment paradigm:

- Flexible dosing at much lower cost creates a viable path to new targets and new drugs
- Applications where COGS are the key driver for widespread adoption
- Simplified application means simplified health care infrastructure (no cold chain, no needles)



Lumen's antibody therapeutics target intestinal pathogens



Advantages of VHHs :

- Technology validated by \$3.9bn acquisition of VHH pioneer Ablynx in 2018
- Successful oral VHH delivery demonstrated in humans and animals
- Simple regulatory path
- High amounts expressed in spirulina
- Biologically active when expressed in spirulina
- Highly temperature stable and protease resistant
- Readily engineered to further enhance potency and stability



Oral spirulina-VHH provides complete protection against campylobacter

Lumen's spirulina-VHH therapy of campylobacter infected mice – model #1

Daily gavage with 200 μl of PBS + 10% spirulina biomass (20.0 mg) x 5 days. 500 micrograms of VHH per dose. Inoculum = 10⁷ Campylobacter jejuni Collaboration with Drs. Richard Guerrant and David Bolick, University of Virginia School of Medicine



State of platform development

Consistent positive results across:

- multiple animal models, large and small
- multiple diseases, and therapeutic modalities
- multiple classes of biologic molecule



Expedited pre-clinical and clinical pathway have been formally pre-cleared with FDA staff, in writing, through the formal PDUFA pre-IND meeting process



Lumen's path

Before Lumen's innovation it had been impossible to deliver cost-effective cuttingedge biotech drugs to developing nations.

The G.I. tract is full of enormous unmet medical needs, with several low-risk nearterm product opportunities in ID, and enormous long-term opportunities in oncology and auto-immune diseases.

Lumen has developed a unique spirulina drug platform which can help millions of children at a fraction of the cost. It would substantially reduce the use of antibiotics as prophylactics, and by decreasing disease prevalence, would reduce empiric antibiotic use.

The Bill & Melinda Gates Foundation has supported Lumen's early development because these diseases are a major cause of infant mortality/morbidity, and a major driver of antimicrobial resistance.



Our collaborators





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