ZUYRIC

Complex Human Therapeutics Manufacturing

Executive Summary

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- Several large therapeutic markets are still dependent on human donations, a high-overhead, limited, and unstable supply source.
- Lyric Bio is leveraging proprietary tissue engineering technology to develop high-density, tissue-mimicking bioreactors for production of therapeutics currently derived from human donation, starting with immunoglobulin (Ig) therapies (IvIg, ScIg).
- Ig is an ~\$15 B market completely dependent on human plasma and blood donations.
- Lyric's process will alleviate dependence on donors, increasing supply, reducing costs, and improving quality of lg therapeutics.
- Lyric's bioreactors mimic lymph node tissue to solve a critical hurdle to Ig manufacturing, high density B cell culture.
 - Lyric is raising \$7 M to validate manufacturing processes.





The Biotech Revolution Was Driven by Manufacturing Advances, But Several Large Markets Were Missed



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Lyric is Reversing the Donor to Recipient Paradigm for Ig

Lyric Bio has an exclusive license to Prellis Biologics' bioprinting technology to produce high-density bioreactors for the industrialization of therapeutic immunoglobulin (Ig) manufacturing



Est. 7-10 donors per lvlg dose



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Est. 1000 lvlg doses per donor

Our process will produce the same IvIg product with a 10,000+ fold reduction in donations required.

What are Immunoglobulin (Ig) Therapies?





Ig is a mixture of polyclonal antibodies purified and concentrated from donor serum.

- Ig can be administered in two formulations intravenous (IvIg) and subcutaneous (ScIg)
- Ivig has been used therapeutically since the 1950s
- Human B cells produce it, but it is highly cost prohibitive to manufacture with existing technology
- Two known mechanisms of action are immune system replacement and reduction of inflammation.



Ig therapies are FDA-approved for use in 7 diseases:

- Immune thrombocytopenic purpura (ITP)
- Primary immunodeficiency, secondary immunodeficiency
- Pediatric HIV infection
- Kawasaki disease

- Graft versus host disease (GVHD) prevention
- Infection in bone marrow transplant recipients
- Chronic inflammatory demyelinating polyneuropathy (CIPD)



Most Ig use is off-label (>100 diseases):

Including: Lupus, Myasthenia Gravis, Multiple Sclerosis, Multifocal motor neuropathy (MMN), CLL, Alzheimer's Disease (in Clinical Trials), Chronic fatigue syndrome, and Long-COVID (in Clinical Trials).

Ig: Current \$15B Market with Significant Limitations



High-Overhead

- 1000s of donation centers
- Donors paid ~ \$2.6-4.8 B / yr. (in US)
- Millions of liters of plasma shipped and processed annually



Unstable & Limited Supply

- 7-10 donations per standard dose
- Paid donation only legal in 5 countries

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• Unstable supply revealed by COVID-19

High Cost	Infection Risk	Market Shortages	Demand Increase
~\$56,327- \$277,119 per year per patient	Donor derived materials can spread bloodborne pathogens	Physicians would use lg more often without supply constraints	Currently in clinical trials for diseases impacting >25M Americans

Ig: Growing Market with Room for Disruption

HARMA







Opportunity to expand current 7% annual market growth by increasing supply, allowing physicians to prescribe more freely



Trend toward at home, subcutaneous administration requires 30-50% higher doses of immunoglobulin exacerbating cost and supply concerns



Industry operating model has significant overhead that can be eliminated by industrialized manufacturing with raw materials and CapEx accounting for 85% of costs

Alternative Technologies in Development Have Limitations



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Our Process: Leverages Natural Ig Producing Cells



B cells naturally produce Ig and are primarily found in your lymph nodes B cells are not efficient with suspension bioreactors and manufacturing technologies Lyric uses 3D bioprinting to make lymph node mimicking bioreactors for B cell culture

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Our Process: One Donor, One Bioreactor, Thousands of Doses



Est. 10X - 100X lower cost

Estimated industry costs for plasma collection vs lg production excluding purification costs

Est. >90% gross margin

At current reimbursement rates and protein purification on par with efficient mAb processes

Ig Manufacturing Limited by Surface Area to Volume Ratios

At ~\$1,000/liter, media costs require high-density 3D culture systems for cost efficient lvlg production

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2D cell culture is not sufficient: Standard B cell culture (2D) does not allow high enough densities to enable cost effective production, 3D culture improves IgG production by B cells.

Existing 3D cell culture technologies are not sufficient: Lyric has an exclusive license to use world's fastest and highest resolution bio printer providing a 10x advantage in surface area-to-volume relative to other 3D cell culture technologies

Lyric Biosciences can produce bioreactors capable of cost efficient lvlg production



Key science derisked at Prellis Biologics to tackle a decades old therapeutic market



IgG comparable polyclonal antibodies can be produced *in vitro* (2D culture)



Prellis LNO organoids are routinely within range of highdensity bioreactor numbers



Ig is a long-standing therapeutic, first used in the early 1950's



Market Size

\$15B market growing at 7% annually and potential to accelerate that growth

Unmet Need

Inefficient supply source leads to high cost and shortages

Product Fit

We address existing issues will supplant existing products and expand market

Derisked Science

Most scientific aspects already demonstrated in literature or at Prellis

Major Impact

IvIg is a life saving therapeutics used by millions

pedsRN68

My son received multiple IVIG infusions when he was diagnosed with Kawaski's disease at age 3. His cardiologist believed it saved his life by preventing an aortic aneurysm.

6-28 Reply

user641055865288

Used it for MECFS. It helped a lot. Like ALOT. But had to pay cash and I ran out of money.... So I suffer

7-1 Reply



Tammy

My life depends on IVIG. I get infused for 3 days every 4 weeks. I have Myasthenia Gravis. It is extremely affective for me, until it wears off. Ins.hates paying but it's cheaper than icu

6-29 Reply

\$7 M Fundraise: 18 Month Runway





- \$7M provides 18 months of runway for 7-10 FTE, including 5-7 lab staff
- Base Case: Demonstrate POC for lvlg production in a 1cm³ bioreactor
- Bull Case: Initial test of production size (150 mL) MVP bioreactors
- Series A will focus on industrialization of manufacturing capability and FDA regulatory approval

Founding Team





Kayj Shannon Co-Founder & CEO 10 years at large Pharma and start-up companies







Melanie Matheu, PhD Co-Founder & CSO Prellis Biologics, Inc. Founder and CTO

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University of California San Francisco



Erin Stephens, PhD Scientific Director Prellis Biologics, Inc. VP of Tissue Engineering





Cornell University

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