

## Inherent Biosciences, Inc.

**One-Sentence Summary of What You Do:** Inherent Biosciences is a molecular diagnostics company at the intersection of epigenetics and artificial intelligence tackling clinical problems where epigenetics appears to be involved, namely: infertility, autoimmune disease, autism, and now COVID-19 disease severity and treatment response.

Affiliated Institution: University of Utah

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Angel Funding (including Self or Friends/Family)

Please describe your company and the problem you are trying to solve: Inherent Biosciences is a molecular diagnostics company at the intersection of Epigenetics and Artificial Intelligence. We're tackling clinical problems where epigenetics appears to be involved, namely: Infertility, Autoimmune Disease, Autism, and now COVID-19 disease severity and treatment response. Our IP portfolio focuses on the use of epigenetic biomarkers for precision medicine and includes: exclusive licenses from the University of Utah, Washington State Univ. and assignment of the Skinner 8,586,307 Patent. Our first product "PATH" (PathFertility.com) is for couples trying to get pregnant. Infertility and highrisk pregnancy are increasing as people have children at later ages. Historically the focus has been on the female partner, yet 50% of infertility is due to male factors. Ignoring the male partner leads to a longer time to pregnancy (1.5 yrs), unnecessary treatments (\$60K), and significant emotional toll (3x more divorces). Unlike current semen analysis, we analyze the sperm epigenetics and successfully translated the epigenetic discovery for PATH from the research discovery platform (microarray) to a scalable targeted Next-Gen Sequencing assay. This mitigated our technical risk for future applications like COVID-19 for which we received an NSF grant. The FDA confirmed PATH as a General Wellness test appropriate for direct-to-consumer marketing. We soft launched PATH online and generated \$4.2K (+\$8K pending) of revenue with very little marketing. We partnered with a National Men's Healthcare Provider (Vault Health) and launched a marketing pilot Oct. 10, 2020. Our next step is to validate a clinical epigenetic diagnostic for fertility clinics with a clinical claim that guides treatment.

What is/was your go-to-market strategy? 1 in 8 couples experience infertility (70 million worldwide) and there is an increasing trend as couples wait longer to have children. The U.S. market is about 10% of the worldwide market (7 million) and approximately 23% of couples seek fertility care (1.6 million). Our market research shows that couples trying to conceive are highly motivated for solutions and willing to pay hundreds of dollars out-of-pocket for testing that provides unique insights and treatment guidance. We're marketing a low cost Direct-to-Consumer general wellness

## DESTINATION STARTUP

test for sperm health (sperm count and biological age of the sperm). We've partnered with channel partners (Vault Health) that have established brands and market access. Because PATH is a general wellness test, it potentially extends our market reach to all men between the ages of 25-50 years old (54 million), and not just those men experiencing infertility. We will also launch a Clinical Diagnostic (in development) to fertility clinics with a clinical claim to guide treatment at a higher price. We've asked fertility doctors what would be a reasonable price and they said it needs to be between \$500 and \$1000. Twenty fertility groups control 40% of the market and we are initially targeting these groups. Unlike current semen analysis (looking at sperm with a microscope), we analyze the DNA of the sperm. If you have 20 men (all with infertility) and you only look at their sperm with a microscope you find 3/20 on average. Analyzing the DNA with our technology finds 17/20 (6x improvement).

How will/do you generate revenue? We sell our PATH sperm health Direct-to-Consumer test online for \$199. You can think of PATH like 23andMe for Men and their sperm. Customers order a specimen collection kit. We ship the kit to their home. They collect the specimen in the privacy of their own home and send it to our laboratory (partner) for analysis. Current COGS is approximately \$135 with line-of-sight to \$85 with economies of scale. We will sell our Clinical Diagnostic for \$849 to fertility clinics. Initially patients will pay out-of-pocket for the testing (often the case for fertility treatment). We will also seek benefit coverage from payers for our test as traction increases and the test becomes more of the standard of care. Estimated COGS for the Clinical Diagnostic is \$430 with a path to \$195 with economies of scale. Unlike standard DNA tests, a unique aspect of epigenetics is that epigenetics are modifiable with lifestyle, diet, and also various therapeutics. This introduces the possibility of multiple tests and a subscription model for testing periodically as customers make changes to improve their health and track personal health trends. These first two products for infertility are a blueprint for our pipeline of epigenetic biomarkers and we expect similar revenue and financial models as we commercialize those discoveries. We also have sub-licensing opportunities for the technologies we've licensed and we're actively pursuing opportunities for additional revenue generation. For example, we have discoveries in Autoimmune disease (Rheumatoid Arthritis, Psoriatic Arthritis), Autism, and other infertility assets.

How will this showcase benefit your company or technology? We currently have an open round of Series Seed Preferred Stock with \$150,000 available and unsubscribed. We plan to raise a \$2-\$3M Series A round in 2021 from sophisticated life science investors or corporate and strategic partners. Also, we are looking for some additional team members.

Who are the members of your team and why is this the right team to get the job done?

Two co-founders (MBA, PhD) with prior startup experience and a talented team of technologists, clinicians, former operators in the industry and pioneering scientists.

Andy Olson, MBA: Co-founder & CEO. Led commercialization in 5 biotech startups (4 exits).
 Also commercial experience in large life science companies including Roche Diagnostics.



- Kristin Brogaard, PhD: Co-founder & COO. Training in Epigenetics and Program Manager at a
  wellness startup (Arivale). Proficient in writing SBIR grants and was recently awarded an NSF
  Phase I grant for a COVID-19 project to identify and commercialize an epigenetic biomarker
  predictive of disease severity and treatment response.
- Bryce Daines, PhD: CTO (part-time). Training in Bioinformatics and Genetics. Experience assembling and leading teams of product professionals, software engineers, and bioinformaticians to develop software-as-a-service (SaaS) solutions enabling CLIA/CAP next-generation sequencing laboratories.
- Beth Lingenfelter, MS: Regulatory Consultant. Established the regulatory and clinical affairs department for BioFire Diagnostics and was foundational in the early development of Myriad Genetics regulatory practices. Ms. Lingenfelter has 25 years of experience in regulatory requirements for molecular diagnostics.
- Lewis Rumpler: Executive Chairman. 30+ year entrepreneurial career, a track record of success in founding, building, scaling, and improving enterprise value. Domain expertise includes life sciences, scientific instrumentation and tech based economic development and entrepreneurship.
- Doug Carrell PhD, HCLD: Andrology Advisor. Clinical laboratory director of the In Vitro Fertilization (IVF) and Andrology laboratories at the University of Utah. 250+ research papers. Paul Turek, MD: Clinical Advisor. Men's reproductive health specialist. Experienced medical academician with 175 publications and several dozen grants.

