



EXECUTIVE SUMMARY

Iris is a histology platform and service for musculoskeletal drug discovery and medical device companies for de-risking their devices, and biologics resulting in faster, safer, and more efficient FDA pre-submissions.

Contact:

David Rowe, Co-founder
263 Farmington Avenue
Farmington, CT 06030
drowe@uchc.edu

Industry: Pharma Services

IrisAdvance, IrisReporter, Iris
Bone histology products and services customized for early-discovery biocompatibility studies; used in FDA submissions by pharma and medical device companies.

Executive Leadership:

David Rowe, MD
Co-founder & CSO,
Director-Regenerative
Medicine, UConn Health

Dong-Guk Shin, PhD,
Co-founder, Director of
Bioinformatics,
Prof. UConn

Advisory Board:

Betty Cosgrove
Business Manager, East - SQI
Diagnostics

Nathaniel Dymont, PhD
Assistant Professor,
McKay Research Labs, UPenn

Pamela Robey, PhD
Branch Chief, NIDCR/NIH
Skeletal stem cells GMP

Fundraising:

Seeking: \$500K, IP, GLP
Certification, Salary

Business Opportunity:

The emergence of innovative medical materials and regenerative cell therapies for the treatment of musculoskeletal disease provides a new market opportunity for advanced skeletal tissue histology methods to evaluate their safety and efficacy. Current bone histology techniques are non-quantitative, time-consuming and labor intensive and does not allow high-throughput screening for lead candidates in the early feasibility stage. They are also highly subjective and lack sensitivity for efficacy and biocompatibility of materials and outcomes for cell-based therapies. This results in an improperly de-risked lead candidate product, causing unexpected failures in large animal and clinical trials. The estimated average loss from a failed large animal testing and regenerative medicine clinical trial is \$250,000¹ and \$120M², respectively.

Solution: Iris is the first pre-clinical histopathology service to provide rapid-turnaround end-point studies predictive of efficacy and biocompatibility and successfully approved FDA pre-submissions. It uses a revolutionary cryohistology method called **IrisAdvance** that is automated for high content and quantitative evaluations of biotherapeutics and medical devices. Iris' platform can deliver testing results that are 6X faster and cost 1/3 of competitor services³. Our value proposition is to de-risk medical product development and facilitate both accelerated and successful FDA approvals.

CRO Market: Musculoskeletal histopathology, a sub-class of the pre-clinical CRO market, has a serviceable available market (SAM) of \$225M annually (USA & Canada). Iris' immediate serviceable obtainable market (SOM) is \$50M⁴. Our competition comes from large, multi-service-provider CRO companies, such as: Charles River, Wuxi Apptec, Covance, and NAMSA; and the small histology service providers, such as: Stagebio, and Histion.

Development Milestones.

IP and Legal: Establish protection of the core technologies

IrisAdvance (high-throughput cryohistology and image analysis method);
Licensing agreements: **Iris' reporter-mice** (CRL & JAX); Company structuring with NDAs – Nov. 2020; \$250K

Regulatory Submission Services:

GLP Certification - Jan. 2022; \$500K; Establish formal QC for cell therapy testing - Jan.2023; \$2M

Company Launch (2 phases)

IrisAdvance (Non-GLP pilot) – Jan. 2021; **IrisClear** (GLP regulatory)– Jul. 2022.

Financials⁵

	2020	2021	2022	2023	2024	2025
Revenue	\$ 10K	\$ 205K	\$ 850K	\$ 3.5M	\$ 4.1M	\$ 7.6M
Gross Profit	\$ 8K	\$ 164K	\$ 595K ⁵	\$ 2.4M	\$ 3.3M	\$ 6.1M
Gross Margin	80%	80%	70% ⁶	70% ⁶	80%	80%

Financial Milestone: \$2M profitability by Dec. 2023

(1) Study director academic pre-clinical center, personal communication; (2) Average from Form 10-K OrthoBio company (3) Case study evaluating 3+ medium and large histopathology services (4) List of 300+ companies, emergent and mid-sized pharma (5) Total Revenue from academic core (2019) = \$225K, e.g. co.'s Novartis, and J&J (5) Break-even point in 2022 (6) ~ 50% increase in marketing costs in 2022 for launch of IrisCell in 2023, Hiring FT histology technician and database - web-development expert.