

CryoCrate LLC

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Value Proposition

Our technology provides unique feasibility in long-term storage of human corneas for the corneal transplantation market. The product will significantly improve the tissue quality for both domestic and international transplantation, reduce the operational cost for eye banks, provides time for screening additional vital diseases, and potentially increase success rate of surgeries.

Business Description

CryoCrate specializes in development of novel cryopreservation technologies and products. Our first product, C80EZ(R) media, creates a new platform for cell and tissue cryopreservation without involving liquid nitrogen facilities, and generates revenue and partnership with Fisher Scientific for marketing. Our second product, IcyEye(TM) kit uniquely enables long-term storage of human corneas by the combinative use of C80EZ and a disposable mechanical device that further filters tissue damaging ice crystals in normal deep freezers. The IcyEye kit can also be used for cryopreservation of other types of valuable donor tissues, as well as scaffold-based bioengineered tissues. Therefore, it is versatile for a wide range of applications in clinical and surgical practices, bio-industrial R&D and production, and academic research and management. We are also developing an ultra-fast cooling cryopreservation device.

Core Technology / Products

The mechanical part of IcyEye possesses a unique function of preventing the direct contact between tissues and growing ice crystals and filters tissue damaging ice crystals. The liquid media part of the kit prevents ice recrystallization (regrowth) during storage at non-cryogenic temperatures (e.g. at -80 degree C, operating temperatures of regular lab deep freezer) instead of using liquid nitrogen facilities (typically at -196 degree C to -120 degree C, liquid nitrogen storage temperature range), and is bio-compatible polymer based and xeno free. Using IcyEye, human corneas can be stored for an indefinitely long period with tested post-thaw viability of corneal endothelial cells approaching 100%, in sharp contrast to the results from the one to two weeks as storage period using hypothermia media (current standard) or unsuccessful traditional cryopreservation.

Market Opportunities

Clinicians and researchers need a novel approach to cryopreserving tissues. No other commercial technologies exist worldwide that would allow corneal tissues to be frozen and stored for clinical use. While there are protocols by which these tissues can be refrigerated for short periods (typically for one week), they have no value of clinical use after that short window, so eye banks and OPOs operate on a 24/7 basis. Meanwhile, over 90,000 corneal transplants will be performed in US during 2021 growing at a rate of 5% per annum. International transplantation (for potentially 20M patients) is highly challenging. Identifying viruses in tissues will be vital but currently impractical. Approx. 10% of transplanted corneas are rejected in US, which can be potentially improved if better tissue quality is maintained.

Proprietary Rights

The technology is under the protection of a US provisional filing US62/724,959 with the company founder as the leading inventor. The IP belongs to University of Missouri (MU) and CryoCrate has obtained the exclusive license for the technology. PCT filing is pending, and CryoCrate will cover all the patenting costs using fees from ongoing and incoming SBIRs. MU has signed an agreement, stating it will enter a 90 day good faith negotiation when a potential acquisition appears.

Management Team

Tim Wheeler, CEO
Xu Han, CTO and President

Year Founded

2012

Industry

Biotechnology

Funding to Date

\$2,620,000

Current Investors

NIH SBIR phase II incoming award in 2019 (NIH 2R44 OD020163-02A1)
Centennial Investors' Convertible Notes in 2017
NIH SBIR phase I award in 2015 and 2018 (NIH 1R43OD020163-01 and NIH 1R43OD026279-01A1)
NIFA SBIR phase I award in 2018 (NIFA 2018-00489)
Counter Translational Research
Partnership, NIH SBIR subcontract, MU IP
Fast-track awards

Competition / Competitive Advantage

Currently, most of the donated tissues are stored in either Optisol or Dexsol media, i.e. hypothermia media that preserve corneal endothelial cells for only 5-10 days. The tissues are decaying during that short period, too. Attempts for long-term storage of corneal tissues with viable cells have NEVER been successful : traditional cryopreservation methods typically result in 30-50% cell loss, unsuitable for clinical applications. Our technology overcomes all above challenges, and is cost efficient. Optisol and other media have been used to store low quality corneas (20K tissues/yr) for research or training, and using our medium will save more costs for those purposes.

Strategic Partners / Alliances

We will ally with Saving Sights, the major eye bank in Missouri, as early adopter and marketing partner. We will collaborate UMKC Vision Research Center, our NIH SBIR subcontract, for all the associated tests requested by FDA for a class II device. We will hire Cardinal Health for regulatory and cGMP manufacturing consulting, and we have obtained their quotation for pre-IDE meeting documentation and preparations. We found three potential injection molding companies for the device production.

Management

Tim Wheeler, CEO

Dr. Wheeler joined CryoCrate in 2017 as CEO, bringing distinguished experience spanning nearly 30 years with senior roles in sales and marketing for major internal corporations. He holds undergraduate degrees in biology/chemistry, master in chemistry, and advanced degree in business administration. He previously worked for Fish, GE, Sigma, and Biomerieux

Xu Han, CTO and President

Dr. Han, founder of CryoCrate, inventor of CryoCrate technologies, is a nationally recognized cryobiologist, a recipient of NIH SBIR, Coulter Foundation, University of Missouri Fast-track and Faculty Innovation awards, Top Reviewer for the Journal of Cryobiology and is NIH SBIR reviewer. Dr. Han holds a B.S. and a PhD in mechanical engr.

Financial

Based on discussion with partners and manufacturers, each IcyEye kit can be priced at least as \$200 per cornea (less than 7% of the reimbursement value of a transplantable cornea, i.e. \$3,200-\$4,000 for eye banks), and COGS for each is less than \$25 for mass production. The \$200 price is highly competitive, because the current short-term hypothermia storage kit (e.g. Optisol) is higher than \$200. For corneas used for research and training (priced as \$300-\$800 for researchers or biotech. companies), our media product alone is sufficient, and will be priced as \$50 per cornea. That pricing is even more competitive, comparing to current \$200+ short-term storage kit for all corneas. We assume we can achieve 70% market capture in YR5 (similar to that for current hypothermia solutions). We will need 6-12 months for 510K clearance for a Class II device and establish cGMP production line for clinical use corneas. For research use corneas, our medium product is ready for manufacturing by ourselves. In the meanwhile, our research media products (C80EZ[®]) for cell lines have generated sales after our working with a local distributor for a year. Based on our feedback from users for storing commercially available cell lines in freezers, Fisher Scientific has provided us a vendor number and will partner with us for heavily used cell lines (e.g. cancer, cardiovascular, kidney, and insect cell lines) and primary cell lines (e.g. primary neurons and white blood cells, for which traditional cryopreservation media don't work). With a new sales specialist and biologist, the sales of the media products will be significantly promoted through new e-commerce platform with Fisher and new testimonials of additional cell lines. Our incoming SBIR award (\$1.5M in total) will cover salaries for CTO and CEO, facility rental, cGMP consulting, pre-IDE meeting documentation, patent costs, etc, for two years. We are submitting additional NIH proposals for other cell types, tissues and even organ cryopreservation. From the new round of investment, we will need \$1M-\$1.5M to cover operation, manufacturing and management for three markets, corneal cryopreservation, research use cell line cryopreservation, and cell banking. We WON'T need any additional third or more round of investment to achieve our exit. The combined sales for all related products are project to be more than \$20M in YR5, which predicts a potential exit for \$100M. In the meanwhile, Bausch Lomb, who spent \$300M+ to acquire the Optisol hyperthermia technology, or its competitors, may acquire earlier. Our current investor, Centennial Investors, can potentially provide \$300K-\$500K to match a second round investment, and convert their notes. The financial project provided in the package is for the combination of all CryoCrate products, which is different from our initial file for the IcyEye kit for surgical use corneas alone. The total revenue is defined as the summation of investment, SBIR grant (excluding potential awards from additional proposals to be submitted in the soon future), and sales of three different products, including cGMP grade IcyEye kits for corneas for surgical use, research grade C80EZ medium for corneas and cell lines for research use, and GMP grade C80EZ for cell and tissue banking or industrial use.

Financial Projections

Item	2019	2020	2021	2022	2023
Revenue	\$1,560,000	\$900,000	\$2,000,000	\$8,000,000	\$22,000,000
Expenses	\$740,000	\$840,000	\$1,500,000	\$1,000,000	\$3,200,000
Net Income	\$820,000	\$60,000	\$500,000	\$7,000,000	\$18,800,000