

STRATEGIC EVALUATION AND TECHNOLOGY ASSESSMENT FOR CORPORATE INVESTMENT: A Case Study

CLIENT: Consortium of board member investors financing an early-stage biotechnology company developing a cell-based therapy for tissue regeneration applications.

OPPORTUNITY: To determine whether to continue financing company operations, the board required an independent review of the company structure, the overall technology, the market opportunity, the product development strategy and the route to commercialization. Areas of particular focus included:

- preparedness for a planned Phase I clinical trial including potential FDA and IRB hurdles and recommendations for their avoidance,
- areas of focus and likely resources required for further process development and product characterization, and
- primary hurdles to commercialization including the regulatory path to approval.

SOLUTION: PCT staff adopted a multi-disciplinary approach to evaluate all aspects of the company's current operations along with future strategic and operational plans, including:

- Corporate structure and financing
- Intellectual property portfolio
- Research pipeline
- Process development & validation
- Assay test method development & validation
- Product shipping and delivery
- Manufacturing facilities, processes and controls
- Quality systems
- Regulatory plan
- Clinical development plan

The above evaluations were compiled into a final report incorporating an assessment of risks and specific recommendations for areas of focus/improvement.

RESULT: PCT's independent assessment and final report enabled the investors to make an informed board level decision regarding the company's future and strategic plans for developing and commercializing the product including future fundraising schedules.



Progenitor Cell Therapy is a client-based cell therapy services company that supports the development of cellular therapies by providing cGMP-compliant cell manufacturing and consulting services that address regulatory, financial, technical, process, and quality system strategies. PCT provides a full spectrum of support including process and product development, consulting, validation, due diligence evaluations, tissue collection, processing, and storage, product manufacturing, distribution and transportation.