

The Brand New Center for Cell Therapy and Regenerative Medicine

A Proposal to Change the Current Business Model

Background

The Brand New Center for Cell Therapy and Regenerative Medicine (BNCCTRM) evolved from the Hematopoietic Stem Cell Laboratory (HSCL) in the School of Medicine, the laboratory responsible for processing bone marrow for transplants. Dr. Jane Doe took over responsibility for the Hematopoietic Stem Cell Laboratory in year X. She began with a staff of two in a 500 sq ft laboratory located in the basement of the School of Medicine building and fully supported and funded by the University Hospital.

As the uses for and sources of hematopoietic stem cells grew and non-hematopoietic stem cells began being considered for therapy, major expansions of BNCCTRM were undertaken in year X, year X and most recently in year X.

Current Operations

In year X, revenue generated by the BNCCTRM was slightly under dollar amount X. Projected revenue for the fiscal year X is over dollar amount X.

Activities of the BNCCTRM can currently be divided into three primary key areas:

- Stem cell processing for transplants
- Manufacturing
- Stem cell and tissue collection

Stem Cell Processing for Transplants

Processing stem cells for transplants represents the majority of BNCCTRM's revenues today. The BNCCTRM currently processes stem cells from bone marrow, umbilical cord blood, and peripheral blood for transplants for patients at the Hospital A, Hospital B, and Hospital C.

The number of stem cell transplants in A-C Hospitals has grown steadily over the past five years. In fiscal year X, there were 90 stem cell transplants at A-C hospitals. In year X, the number of transplants had grown to 193. The number of transplants at A hospital has more than tripled over the past five years. This growth has been primarily due to the initiation of a program for the treatment of disease X. At Hospital B, the number of transplants has more than doubled in 5 years. In the same period, revenues from processing stem cells for transplants grew from approximately dollar amount X to just over dollar amount X.

Manufacturing

In year X the BNCCTRM agreed to assist two local biotechnology start-ups in developing manufacturing processes for their therapeutics based upon stem cells. The BNCCTRM entered an agreement with Biotech Company A to transfer technology for

manufacture of cells X for treatment of disease X. The BNCCTRM entered an agreement with Biotech Company B, for the growth, expansion and characterization of human bone marrow-derived mesenchymal stem cells for pre-clinical and clinical studies for treatment disease X.

BNCCTRM is currently manufacturing pre-clinical supplies for both companies and expects to manufacture Phase 1 clinical supplies as well. CEOs of both companies have been generous with their praise toward BNCCTRM and have been quick to point out that they have benefited greatly from having a local manufacturer with whom to work.

In addition to acting as sole manufacturer for local companies, BNCCTRM also acts as the local processing laboratory for major pharmaceutical companies who work with local investigators to conduct clinical trials for stem cell therapies in the state. Indeed, it would not be possible for local investigators to participate in clinical trials utilizing autologous stem cells without the participation of the BNCCTRM as the only FDA approved facility in the state.

Stem Cell and Tissue Collection

Recognizing the growing importance of stem cells derived from umbilical cord blood (UCB), in year X the BNCCTRM entered an agreement with one of the world's largest UCB banks, Bank X, Inc. to collect umbilical cord blood at hospitals A-C. BNCCTRM currently employs 6 full-time employees who collect UCB immediately following births at the Hospitals A-C. BNCCTRM expects to add other area hospitals by the end of the year. Eventually, the BNCCTRM will collect cord blood at most major hospitals in area X.

Approximately 40% of the units collected prove eligible. Target hospitals recorded slightly over 19,000 normal births in year X. BNCCTRM is currently working to identify the ideal staffing and collecting model to maximize income from this business arrangement and will continually assess the program to ensure profitability.

Proposal

Dr. Doe has outlined various challenges facing the program and the University Hospital has also expressed the need for a change to the program. The following topics are proposed for review and discussion:

- **Management Support & Structure:**

Dr. Doe has produced a white paper outlining several new business models:

- Operate independent of the University and the University Hospital, but will maintain as a key objective the advancement of patient care and research in the state. All employees of BNCCTRM will be employees of the new enterprise, and not the University Hospital. Investors will be sought and University Hospital will be compensated for its original investment.
- Operate independent but be owned by the University.

- Operate as a service line and be managed by a Core Committee of physicians, scientists and administrators.
- Spin off Regenerative Medicine and/or Cord Blood as private companies. Retain the Stem Cell Laboratory as is.
- **HR Policies** (Improvement of Hiring and Termination Processes):
Seek best practices within the University to enhance and expedite HR Practices.
- **Equipment Acquisition**
This could be divided into the program sections
 - Hospital Related: Current practices in place
 - Research/Manufacturing Related: Seeking input and examples from other University programs to determine best practices.
- **Contract/Legal Review**
The Cell Therapy Program has an active contract review process. The need to efficiently review contracts for compatibility, profitability, resource requirement and timing is required. A contract review process is needed.
- **Medical Directorship**
A determination of the appropriate medical director leadership and support will be needed to outline the role for each section on leadership to the program.
- **Financial Expertise and Review**
Currently there is no stable financial support or financial platforms for expense and pricing structure. The program has some support but structure and performance guidelines are being sought.

Conclusion

More effective business models exist for BNCCTRM that will address the issues faced by the program and the University Hospital. The program requests that a small group of physicians, scientists and administrators convene to discuss an action plan addressing each topic.

We would like to acknowledge the major contributions of Nicole Omer in the preparation of this document.

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