



Cord Blood Bank Business Plan

A sample of how to create a new program

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BACKGROUND

Scientists have stated that we are entering the “age of the cell”, in which virtually every field of medicine will see direct application of cell therapies for both generalized and personalized cures. Degeneration of tissues and organs due to aging or injury is the most common cause of morbidity and mortality in society today. New and innovative cellular therapies in the field of regenerative medicine, which use stem and progenitor cells for tissue and organ repair, are being developed throughout the world at an unprecedented rate.

Stem and Progenitor Cells are early-stage cells which possess the capacity to differentiate into numerous cell and tissue types as they mature in their natural biologic setting or niches. The ability to develop into many tissue types makes stem cells ideal for use in proven and novel clinical therapies as well as for research. Stem and progenitor cells provide the foundation for cell therapy and regenerative medicine.

Recent data demonstrate that umbilical cord blood is rich in stem cells. However, cord blood is routinely discarded as hospital waste along with the umbilical cord and placenta following birth. Umbilical cord blood can be collected, processed, tested and banked for future therapeutic use. There are two types of umbilical cord blood banks. Public banks ask mothers to donate their umbilical cord blood for future use by anyone who may be a potential match. Private or “family” banks will store umbilical cord blood for future use by the donor or matching family members for an average fee of \$2,000 plus an annual storage fee. Historically, public banks have been not-for-profit while private or family banks have been for-profit enterprises. *This proposal focuses on a not-for-profit public cord blood bank.*

VISION

The vision is to establish an Umbilical Cord Blood Bank to be used as a resource in our own state as well as nationally and internationally for treatment of devastating diseases such as leukemia, lymphoma and others. In addition, a repository of cord blood stem cells, DNA and serum will be established to be used for researchers in our state and around the world. Further value will be added to these resources by associating the biological samples with additional information from the vast databases that exist here.

Why this state?

There are approximately 26,000 births per year within a relatively restricted geographic footprint.

	Normal Newborns
Medical Center A	9,056
Hospital B	3,671
Hospital C	3,459
Hospital D	3,343
Hospital E	2,788
Regional Medical Center F	3,880
Total Area Births in 2008	26,197

The high birthrate and relative healthy nature of the babies born in our state make it an ideal location to collect umbilical cord blood. The enthusiasm of our residents to contribute to medical discovery and advancement has been proven by their willingness to volunteer and participate in research studies and clinical trials throughout decades of investigation. As a result, more discoveries revealing the cause of devastating diseases have been determined in this compared to any other state. The existence of vast, long-standing databases promises to add value to collected biosamples. Finally, we have strong leadership and support for cord blood banking and research from different sources X and Y.

NEED

Over the past 20 years, research has demonstrated that cord blood is an alternative to bone marrow for blood and marrow transplantation. Historically, cord blood as a substitute for bone marrow was useful primarily in infants and young adults due to the lower number of stem cells present in the small volume of cord blood available compared to the relatively large volumes of bone marrow that can be obtained. However, recent data demonstrate that by transplanting two, instead of one, cord blood units to an adult, a successful outcome can be achieved. Such approaches will greatly increase the utility of cord blood transplants to adults, as well as children, resulting in a significant increase in need of cord blood units.

In 2006 the Institute of Medicine estimated the number of cord blood units needed in the US alone to be 150,000. Recently that number was increased to 400,000. The existing inventory is less than 50,000. To date, over 20,000 cord blood transplants have been performed worldwide for treatment of over 70

diseases. Indications for cord blood transplantation continue to expand yet the current supply of banked cord blood units does not meet the demand.

Figure 1 illustrates an algorithm created to estimate the need for cord blood units for transplantation over the next 10 years. The data were prepared by Avalere Health, LLC at the request of the National Marrow Donor Program. The algorithm takes into account such pertinent information as number of patients diagnosed with transplantable diseases, the likelihood of having a matched sibling donor and the possibility of using bone marrow versus cord blood as the graft source.

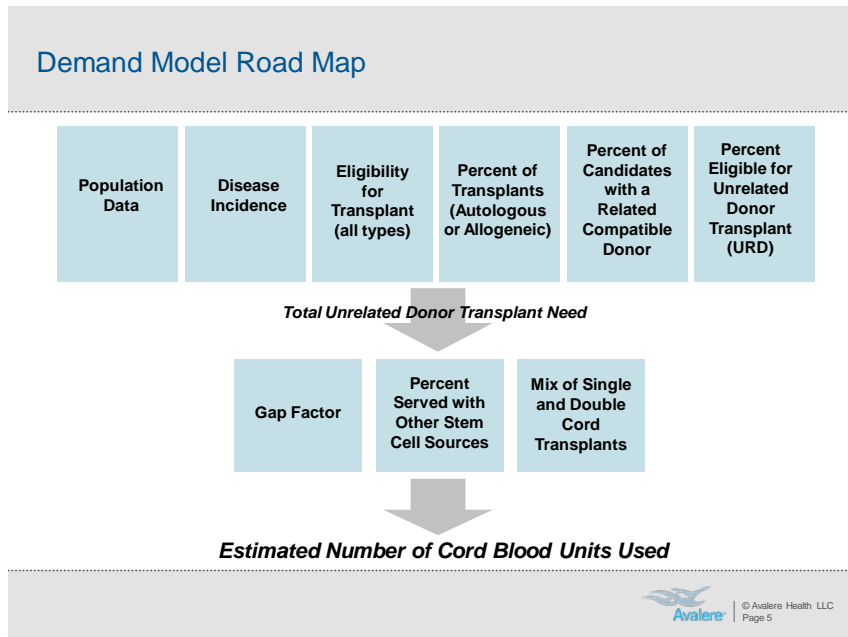


Figure1. Algorithm used to determine the number of cord blood units needed vs. those that are available.

Provided by the National Marrow Donor Program (NMDP)

Using the algorithm in Figure 1, the estimated number of cord blood units expected to be utilized as standard-of-care for transplantable diseases recognized in 2009 exceed 11,000 cord blood units (Figure 2). The inventory needed to facilitate acceptable tissue matching for the recipients is much greater.

Base Case: Demand for Cords To Increase 2.5 Times Over Ten Years

	United States			International		
	2008	2013	2018	2008	2013	2018
Total Disease Incidence	4,511,285	4,686,627	4,855,824	29,970,587	31,729,588	33,256,794
# Eligible for Transplant	32,636	39,885	47,295	200,803	253,981	311,286
# Eligible for Allo (Sib, haplo, or MUD)	20,070	25,612	31,541	124,805	169,274	215,235
Number of Patients in Need of Unrelated Donor Transplant	11,314	15,549	19,397	70,509	103,400	133,241
Gap Factor	60%	57.5%	55%	87%	85.8%	84.5%
Estimated Realized Demand for URD Transplant	4,526	6,609	8,728	9,166	14,734	20,652
Estimated Number of Realized URD Transplants Served with BM or PBSC	3,258	4,428	5,499	7,333	11,051	14,870
Remaining Served with Cord Blood	1,267	2,181	3,230	1,833	3,684	5,783
Mix of Single:Double	82.8%	70.3%	57.8%	82.3%	76.1%	69.8%
Estimated Number of Cords Used	1,485	2,556	3,785	2,158	4,566	7,529

MUD: Matched Unrelated Donor

Avalere © Avalere Health LLC Page 6

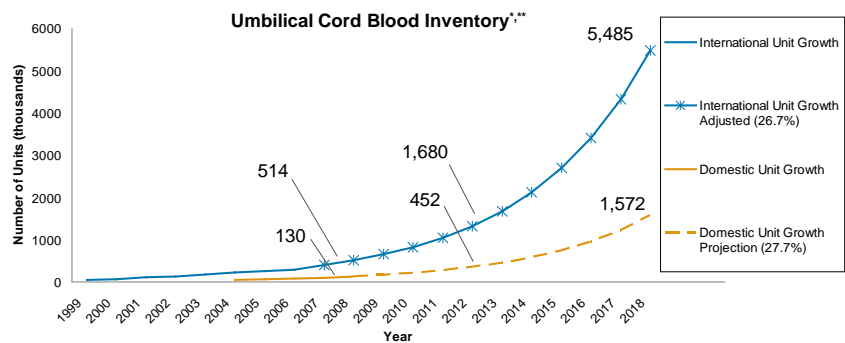
Figure 2. The estimated 10-year demand for Cord Blood Units in the United States and Internationally. Provided by the NMDP

In addition to the use of cord blood as a stem cell source for transplantation, it is further speculated that stem cells derived from cord blood have the potential to be cultured in the laboratory to create a variety of healthy tissue types to replace degenerating tissues of multiple organs. Therefore, the therapeutic potential of cord blood may far exceed use for transplantation and may someday benefit individuals with neurodegenerative disease, diabetes, heart disease, kidney failure, lung damage, spinal cord injury, bone degeneration, limb ischemia, ophthalmic anomalies and others.

Figure 3 demonstrates the extrapolated inventory for cord blood units through 2018 as determined by historical usage. It is noteworthy that the demand for cord blood units will rise independently of inventory levels until all patients receive a transplant.

Scenario 1: Continued Growth Based on Historical Rates

Growth Category	Projected Unit Growth in Perpetuity
Adjusted International Unit Growth	26.7%
Domestic Unit Growth Based on Historical Data	27.7%



Sources:
 * Historical years: World Marrow Donor Association, "Stem Cell Donor Registries Annual Report 2007," Page 15, 2007 and National Marrow Donor Program, Cord Blood Analysis Reports for Officers, March 31, 2008.
 ** Future years - Avalere projections. Note all projections based on total inventories, including units < 90 TNC.

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Cord Blood Unit Distribution

When a transplant center determines that an individual requires a stem cell transplant, and a “matched” relative is not available to donate stem cells from bone marrow or mobilized peripheral blood, a search for a matched unrelated bone marrow or cord blood donor is undertaken. Transplant centers search established registries for matched donors. In the United States, the primary registry searched is the National Marrow Donor Program. Once a transplant center locates an appropriate matched unit (or units in the case of double cord transplants), it requests that the units be shipped immediately. *Cord blood banks charge transplant centers an average of \$30,000 per cord blood unit.*

Cord blood banks must build an inventory of 500 units and register with the FDA before they can seek accreditation from the American Association of Blood Banks (AABB).

SAMPLE

CREDENTIALS AND QUALIFICATIONS

In a two-phase expansion between years 2005-2008, this University funded a **\$2.5M** build-out of a 20,000 sq ft state-of-the-art Cell Therapy Facility (CTF). CTF currently provides access to a variety of human stem and progenitor cells, stem cell technologies, cell manufacturing and tissue engineering services to academic and industry partners, supporting projects ranging from basic research to clinical trials. Cell therapy clinical trials are still in early stages and their success depends upon access to a reliable, high-quality, well-characterized source of biomaterials. CTF has both access to and expertise in processing, banking and storing biomaterials including stem and progenitor cells. The facility has the extra capacity to house an umbilical cord blood bank.

In 2007 CTF established an Umbilical Cord Blood Collection program funded by the University Hospitals and Clinics. The purpose of the program is to collect umbilical cord blood units in hospitals throughout the area and contribute them to the National Cord Blood Inventory, a public cord blood registry maintained by the National Marrow Donor Program. The cord blood units are used to treat patients primarily with leukemia and lymphoma. To date, the program is very successful and is currently collecting cord blood at University Hospital A and Regional Hospital B. A contract was signed in October 2009 and it is anticipated that four hospitals will be opened in 2009 and 2010. *Presently, the cord blood units collected in the state for clinical use are not banked in the state but rather sent to collaborating banks in other states. It is advantageous to establish an Umbilical Cord Blood Bank in our own state.*

In 2007, Dr. Welby Kirk-Spock received a \$125K Center of Excellence Grant from the Governor's Office of Economic Development to establish a proof-of-concept cord blood repository for research. A specific goal of this project was to collect 100 cord blood samples and process them into different components to be made available for research. Dr. Kirk-Spock has recently accomplished this goal and made samples available to researchers interested in all areas of stem cell biology including stem cell transplantation, orthopedics, neurology, cardiology, ophthalmology, medicine, nephrology, oncology, aging and bioengineering.

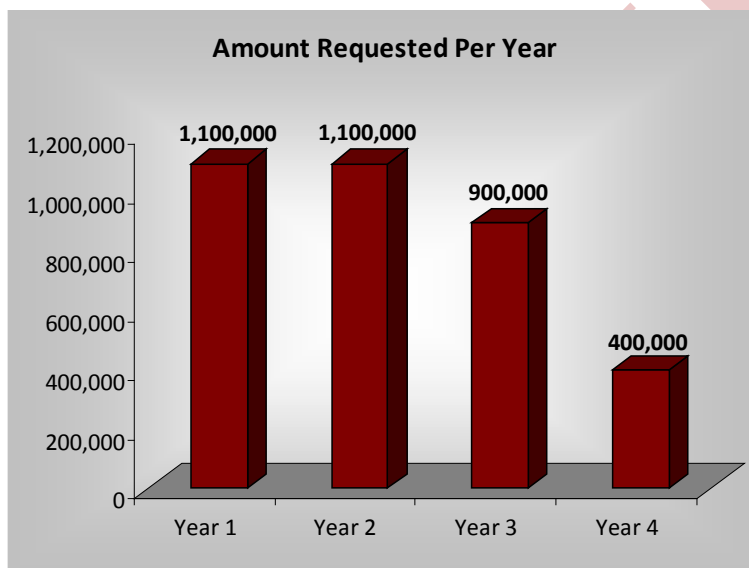
Importantly, Dr. Kirk-Spock has also recently received approval to link the cord blood samples collected to date, whether collected for clinical use or research, to the state's unique databases. Linkage to these databases allows us to relate information about donor and family medical history to assess the likeliness that a sample may be associated with other inheritable diseases.

ECONOMICS OF CORD BLOOD BANKING

Funding to create and sustain the bank will be sought from local sources as donations or gifts. A gift in the amount of \$3.5M, \$1.1M over the first two years, \$900K in the third year and \$400K in the fourth year, will fund start-up costs and allow the bank to reach a level of self sustainment. The pro forma below shows a detailed breakdown of the revenue, costs and inventory levels for years 1-7. Cord blood demand growth rates were obtained from Figure 3, above.

\$1.1M will be used in the first year to build an inventory of 500 banked cord blood units. The monies will be used for collection, processing, testing and storage of the cord blood units. The Cord Blood Bank must establish an inventory of 500 units before the units can be listed with the NMDP for distribution. Once the units are distributed for use to a transplant recipient, the bank will be reimbursed approximately \$30K per unit by the recipient's insurance company.

An additional \$1.1M, \$900K and \$400K (\$2.5M total) will be used in years 2, 3 and 4 respectively to continue to expand the inventory to allow the bank to acquire a critical volume of units to facilitate exports in order to support the cost of running the bank.



STATE CORD BLOOD BANK PRO FORMA

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Units Stored	500	500	500	300	300	300	300
Cumulative Inventory	500	1,000	1,500	1,800	2,100	2,400	2,700
Cord Units Sold	-	-	15	23	32	36	41
Selling Price	30,000	30,000	30,000	30,000	30,000	30,000	30,000
Cord Bank Revenue	-	-	450,000	675,000	945,000	1,080,000	1,215,000
Gifts	1,100,000	1,100,000	900,000	400,000	-	-	-
Income from Previous Year	-	36,800	73,600	248,775	425,948	432,186	530,171
TOTAL REVENUE	1,100,000	1,136,800	1,423,600	1,323,775	1,370,948	1,512,186	1,745,171
Recruitment Costs	421,000	421,000	442,050	354,990	372,740	391,376	410,945
Processing Costs	438,000	438,000	459,900	289,737	304,224	319,435	335,407
Storage Costs	30,500	30,500	32,025	20,176	21,185	22,244	23,356
Overhead Costs	123,700	123,700	129,700	141,200	148,200	156,200	163,200
Distribution Costs	-	-	1,150	1,725	2,414	2,759	3,104
Equipment	50,000	50,000	20,000	-	-	-	-
New Employee Training Costs	-	-	90,000	90,000	90,000	90,000	90,000
TOTAL COSTS	1,063,200	1,063,200	1,174,825	897,827	938,762	982,015	1,026,012
COST PER UNIT SOLD	NA	NA	78,322	39,903	29,802	27,278	25,334
NET INCOME	36,800	73,600	248,775	425,948	432,186	530,171	719,158
Margin	3%	7%	21%	47%	46%	54%	70%

**Conditional upon support from the Hospital or University as illustrated in Appendix A*

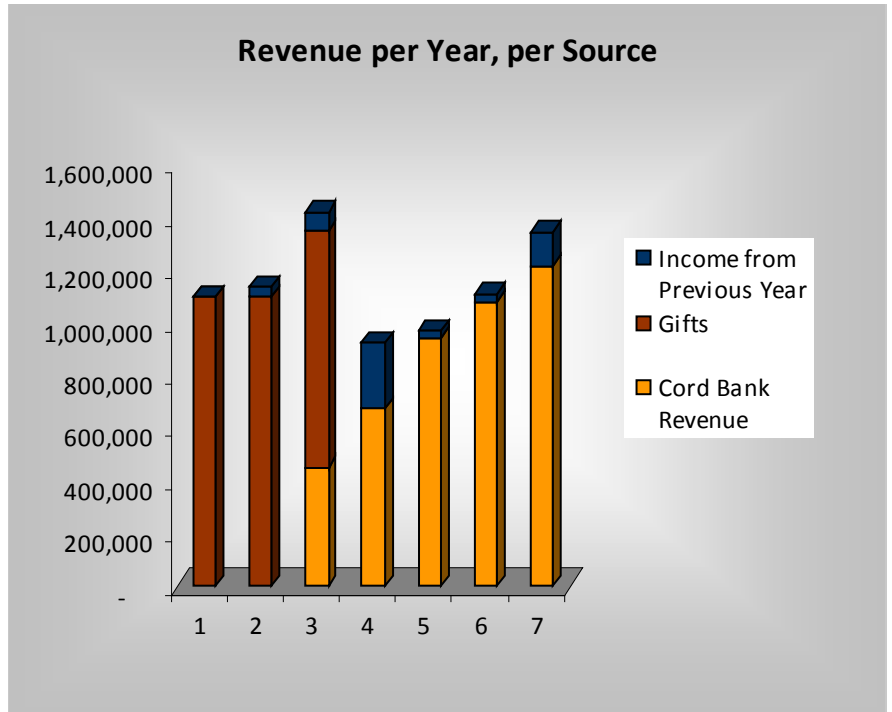
Pro forma Explanation and Assumptions

Revenue

- **Units Stored:** # of Units that are banked. The cord blood collection program has collected over 2 years of data including the number of births, number of collected units and # of units banked. We used this data set to determine the # of units that can be banked.

- **Cumulative Inventory:** Total number of units banked for all years

- **Cord Blood Units Sold:** Number of cord blood units sent out for transplant and reimbursed by insurance companies. Sales data from SPECIFIC Cord Blood Bank shows that 1% of inventory will be sold when inventory is less than 2000 units; 2% of inventory at >2000 units; 3% of inventory at > 4000 units. To be conservative we choose to estimate that 1.5% of our inventory would be sold at >2000 units



- **Selling Price:** The range of insurance reimbursement is \$30K-\$35K. We choose \$30K to be conservative.

- **Cord Bank Revenue:** That number of cord blood units sold multiplied by the selling price.

- **Gifts:** Donation amount.

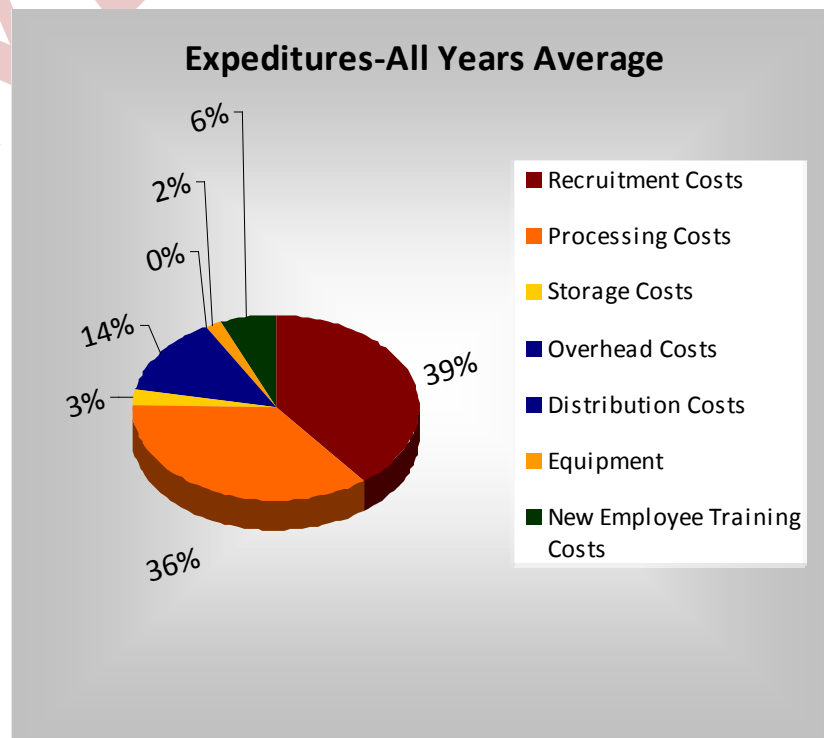
- **Total Revenue:** Cord Bank Revenue plus Gifts.

Expenditures

- **Recruitment Costs:** The cost per cord blood unit collection. Includes collection of all units not just those banked. Includes salaries, supplies and other direct collection costs.

- **Processing Costs:** The cost per cord blood unit processed. Includes processing of all cord blood units processed not just those banked. Includes salaries, supplies and other direct processing costs.

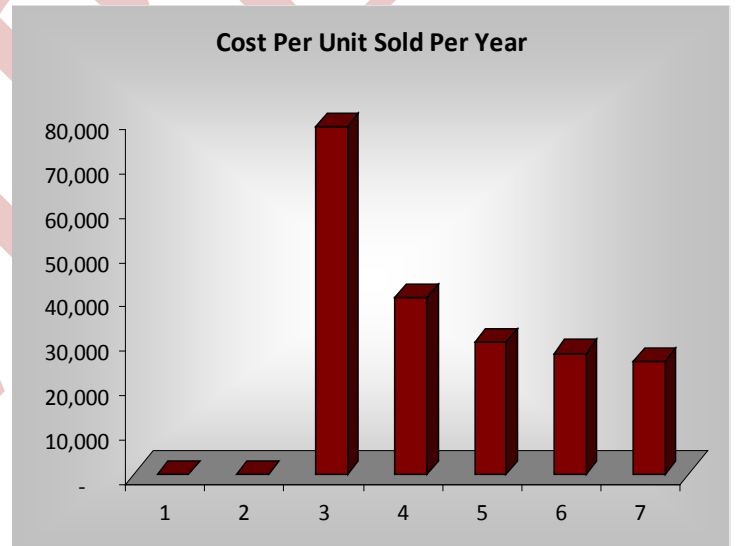
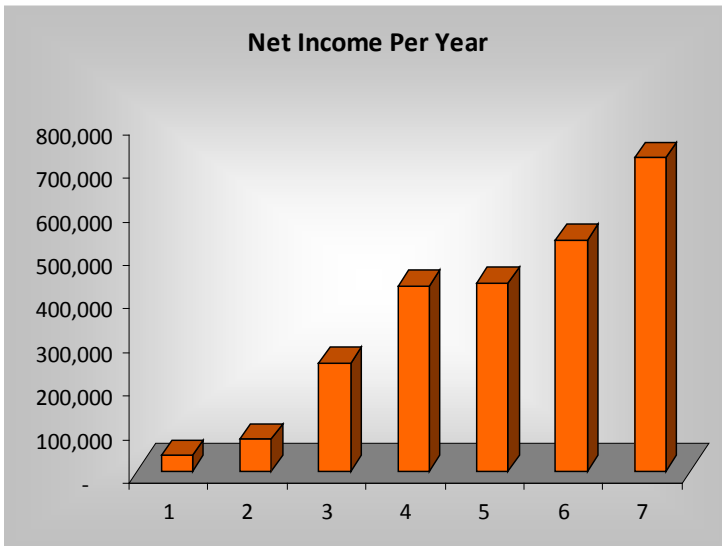
- **Storage Costs:** The costs of storing banked units.



- **Overhead Costs:** Includes quality assurance, travel, phone and other indirect costs.
- **Distribution Costs:** The costs of sending a unit out for transplant.
- **Equipment:** The bank requires 4 pieces of major equipment. Two processing devices at \$50K per device and two freezers at \$20K. One freezer has already been purchased and the second freezer will not be needed until inventory reaches 2000 units. The two processing devices can be purchased separately in the first two years because inventory growth will not require two until year 3.
- **New Employee and Training Costs:** The cost of new employees and training costs.
(A 5% increase per year for all costs has been added starting in year 3).

Totals

- **Total Costs:** Total of all costs.
- **Cost Per Unit Sold:** Cost per banked unit sold.
- **Net Income:** Total revenue minus total costs.
- **Cumulative Net Income:** Revenue total for all years.
- **Margin:** Difference between total revenue and total costs.



CONCLUSIONS

The impact of this program is significant in that it gives our state a unique position in the stem cell field that other academic institutions or states do not and can not provide. Having a stem cell source that can be used for research or clinical therapies that is linked to an extensive medical history uniquely positions the State to make a significant contribution to the field.

SAMPLE

APPENDIX A

Support requested from the Hospital and/or University for the Cord Blood Bank

University Hospital has invested over \$1M dollars in the Cord Blood Program, not including the investment it has made into the Cell Therapy Facility, mentioned above. The Hospital has supported collection and regulatory activities as well as overhead expenses. Most of these expenses are shared with other departments as a means of leveraging resources such as highly skilled employees including quality assurance and administrative staff and state-of-the-art facilities. These resources are required to run the Cord Blood Bank. It is requested that the Hospital or University support these resources to provide for the other departments that rely on these resources, as well as show continued good faith towards this project and potential donors.

The amount requested is shown below for Years 1-7. It is assumed that in Year 8 the Cord Blood Bank will take over these costs. These costs have not been included in the Pro forma above.

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Rent	180,000	180,000	189,000	198,450	208,373	218,791	229,731
Quality Assurance	45,000	45,000	46,350	48,668	51,101	53,656	56,339
Administrative Support	35,000	35,000	36,050	37,132	38,245	39,393	40,575
TOTAL COST	260,000	260,000	271,400	284,249	297,719	311,840	326,644