

# NUSTEM TECHNOLOGIES, INC.

## Cord Blood Stem Cells *The Second Miracle of Birth*



**NuStem Technologies, Inc.**  
**5250 Neil Road, Suite 210**  
**Reno, NV 89502**  
**775.825.2700**

The information in this Business Overview is supplied on the understanding that it will be confidential and will not be duplicated, transmitted, or disclosed to third parties without prior written consent from NuStem Technologies, Inc. This overview has been prepared for internal use only and does not constitute an offer to sell or a solicitation of an offer to buy any securities of the Company. The information contained herein is compiled solely for the purpose of informing any and all interested persons of the mission, operations, and projected financial performance of the Company, and to give a general overview of the product and market conditions regarding umbilical cord blood stem cell storage and transplantation therapy as interpreted by the Company. This overview may be updated periodically.

## Disclaimer

This Business Overview (the “Overview”) has been prepared by NuStem Technologies Inc. solely for informational purposes from information supplied by NuStem Technologies, Inc. (sometimes referred to herein as the “Company”) and is being furnished through NuStem Technologies, Inc., as the exclusive authorized agent, solely for use by prospective parties in considering a financing transaction with the Company. **This Overview is neither an offer to sell, nor a solicitation to buy securities.** If a prospective party indicates a continuing interest in considering a financing transaction with the Company after reviewing the Overview, a more comprehensive offering memorandum will be prepared and delivered to such party. This Overview and additional information will only be provided to parties who qualify as an “accredited investor” within the meaning of Rule 501(a) of the Securities Act of 1933, as amended.

The information contained herein has been prepared to assist interested parties in making their evaluation of the Company and does not purport to contain all of the information that a party may desire. In all cases, interested parties should conduct and rely on their own investigation and analysis of the Company and the data set forth in this Overview. NuStem Technologies, Inc. does not make any representation or warranty, expressed or implied, as to the accuracy or completeness of this Overview and shall have no liability for any representations, expressed or implied, as to the accuracy or completeness of this Overview and shall have no liability for any representation, expressed or implied, contained in, or omissions from, this Overview or any other written or oral communications transmitted to the recipient in the course of the recipient’s evaluation of the Company.

The Overview includes certain statements, estimates, and projections with respect to the anticipated future performance of the Company. Such statements, estimates, and projections reflect various assumptions, which assumptions may or may not prove to be correct. No representations are made as to the accuracy of such statements, estimates, or projections. The Company does not undertake any obligation to provide additional information or to update any of the information set forth in this Overview.

By accepting this Overview, the recipient acknowledges and agrees that all of the information contained herein is confidential. Without limiting the generality of the foregoing: (1) the recipient will not reproduce this Overview, in whole or in part; (2) if the recipient does not wish to pursue this matter, it will return this Overview to NuStem Technologies, Inc. as soon as practical, together with any other materials relating to the Company which the recipient has received from NuStem Technologies, Inc.; and, (3) any proposed actions by the recipient which are inconsistent in any manner with the foregoing agreements will require the prior written consent of NuStem Technologies, Inc.

The Company reserves the right to negotiate with one or more prospective parties at any time and to enter into agreements with such parties without prior written notice to the recipient or other prospective parties. The Company reserves the right to terminate, at any time, any further participation of itself or any party in the investigation and consideration process of any party. Finally, NuStem Technologies, Inc. reserves the right to modify, at any time, any procedures relating to such process without assigning any reason therefore. The Company intends to conduct business in the ordinary manner; however, it also reserves the right to take any action, whether in or out of the ordinary course of business, including but not limited to, the sale of any property, which it deems necessary, prudent, or desirable in the conduct of such business.

No person on behalf of NuStem Technologies has been authorized to give any information or to make any representation other than those contained in the Overview, and, if given or made, such information and representation must not be relied upon as having been authorized by the Company. This Overview does not constitute an offer to sell or is it a solicitation of any offer to buy any securities of the Company.

The Overview is submitted solely for informational purposes and may not be reproduced or issued for any other purpose without the written authorization of NuStem Technologies, Inc., and is to be returned to NuStem Technologies, Inc. upon request. This Overview and the information herein contains statements that constitute “forward-looking statements” with the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934. Those statements appear in a number of places herein and includes statements regarding the intent, belief or current expectations of the Company, its directors or its officers with respect to, among other things: (i) trends affecting the Company’s financial condition or results of operations; (ii) the intended and current product development efforts; (iii) the Company’s business and growth strategies; and (iv) the Company’s industry, market, and marketing efforts. Participants and shareholders are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected as a result of various factors.

## **TABLE OF CONTENTS**

<b>PREFACE.....</b>	<b>1</b>
<b>WHY NUSTEM? .....</b>	<b>3</b>
<b>I. EXECUTIVE SUMMARY.....</b>	<b>6</b>
<b>II. THE COMPANY AND ITS MISSION.....</b>	<b>12</b>
<b>III. BUSINESS MODEL .....</b>	<b>12</b>
<b>IV. THE BLOOD STEM CELL MARKET.....</b>	<b>14</b>
<b>V. STRATEGIES: CORPORATE, AND MARKETING AND SALES.....</b>	<b>16</b>
<b>VI. COMPETITION AND COMPETITIVE ADVANTAGE .....</b>	<b>19</b>
<b>VII. OPERATIONS AND TECHNOLOGY .....</b>	<b>22</b>
<b>VIII. ETHICAL AND LEGAL ISSUES, GOVERNMENT REGULATION, LITIGATION.....</b>	<b>29</b>
<b>IX. HUMAN RESOURCES SUMMARY.....</b>	<b>31</b>
<b>X. FINANCIAL INFORMATION .....</b>	<b>33</b>

## **APPENDICES**

A. RISK FACTORS .....	37
B. HUMAN RESOURCES.....	41
C. EXTERNAL ADVISORS.....	46
D. DISEASES TREATED WITH UMBILICAL CORD BLOOD STEM CELLS .....	46
E. CORPORATE HISTORY .....	48
F. GLOSSARY .....	49
G. FINANCIAL PROJECTIONS.....	52

## PREFACE

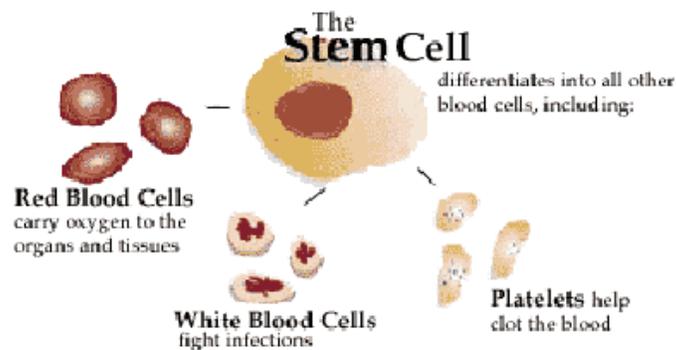
### THE SECOND MIRACLE OF BIRTH

The baby's first cry trumpets the *miracle of birth*. The umbilical cord is severed and the baby is wiped down in preparation for return to the mother, while the umbilical cord and placenta are cleared away for disposal as waste. In this case, as in the vast majority of all cases, *the second miracle of birth* will not achieve a single shred of its amazing promise. A rich harvest of potentially life saving blood stem cells, dispersed throughout the umbilical cord, is about to be incinerated.

#### *What's So Valuable About Stem Cells?*

The blood stem cell is the “mother” of all blood cells. Among its many roles, the blood stem cell has a critical role as a life sustaining precursor cell that develops into red and white blood cells, and platelets. When one hears of a person needing a “bone marrow transplant,” it is the blood stem cells that are being sought. Blood stem cells are absolutely necessary because they produce:

- **Red blood cells** that carry oxygen throughout the body
- **White blood cells** that fight infection
- **Platelets** that aid in clotting



Without blood stem cells, the body's immune system would collapse and its entire blood system would cease to exist. Additionally, blood stem cells are used – to the extent of their highly limited availability and the difficulties of finding a match - as an essential component in the effective treatment and cure of numerous diseases. Unfortunately, the need for blood stem cells vastly exceeds their supply, causing much suffering, the premature and preventable loss of life, and the stifling of development of new therapies of radically positive promise.

#### *What About Bone Marrow Transplants?*

Blood stem cells reside in the bone marrow. In a bone marrow transplant (BMT), the bone marrow, and its precious blood stem cells, are transplanted into a dying patient. The

sole reason this medical procedure is successful is that, after transplantation, the donor's blood stem cells create their own manufacturing plant in the patient. The donor's blood stem cells continue to produce red blood cells, white blood cells and platelets throughout the patient's life.

Unfortunately, the process of harvesting blood stem cells from bone marrow is highly invasive and painful with long (several weeks) time for full recovery. The process involves repeated insertions of a large-bore needle into the hipbone of the donor to extract the marrow over a period of an hour or more. This together with extensive administrative requirements greatly reduces donor enthusiasm. This is understandable since donors are asked to donate for the use of someone they do not know – at the cost of great personal discomfort and inconvenience. Thus, today's shortages of “donor” bone marrow blood stem cells.

### ***OK, What's So Valuable About Cord Blood Stem Cells?***

As already indicated, the blood found in the umbilical cord of a newborn, healthy baby has a rich supply of medically valuable blood stem cells, and this offers several advantages over bone marrow as a source of stem cells:

- Non-invasive collection; painless to the donor at the time of collection and causes no ongoing, post-collection discomfort and limitations.
- Conversion of a “waste” material to fill unmet needs for the unique, life saving therapies provided by blood stem cells.
- Less mature than bone marrow stem cells which makes cord blood stem cells more adaptable, e.g. they have a less demanding matching requirement than bone marrow stem cells and, therefore, they make the probability of finding a match much greater.
- Immediate availability because of cryogenic storage well in advance of use. This eliminates the long (and frequently unsuccessful) search for a bone marrow match – with all the anxiety and likely ultimate disappointment
- experienced by the patient and his or her loved ones in the search period.
- Lower risk of transmitting infectious diseases to the patient.
- Significant reduction of the incidence and severity of graft versus host disease (GVHD) – the battle of the donor's immune system versus that of the patient. GVHD is the leading cause of morbidity and mortality following a conventional BMT.
- Considerably less expensive when compared with all bone marrow donor-related costs.

*“The potential benefits of cord blood include immediate availability, absence of donor risk, and very low risk of transmissible infectious diseases.”*

*Lancet Medical Journal*

## WHY NUSTEM?

### ***Allogeneic Cord Blood Banking by NuStem***

NuStem will collect, analyze, process, register and store cord blood stem cells from donors unrelated to the eventual recipient at the Company’s own cost. Suitably matched cord blood units will be sold to Transplant Centers and Research Laboratories generating gross revenues for NuStem.

### ***Market Size***

The worldwide served and unserved markets for blood stem cells are estimated to total about \$57 billion. If worldwide demand for the unserved BMT market alone were met at current prices, the global market is estimated to be in the range of \$1.4 billion. Actual gross market revenues presently are about \$320 million due to the lack of availability of bone marrow stem cells that match the search requirements. The U.S. unserved market for BMTs is about one third of the worldwide total, or \$500 million.

These market estimates do not take into account any growth in current areas of demand that would be stimulated by growth in supply at lower cost than BMTs, nor growth due to new uses encouraged by blood stem cell availability – which growth is stifled by the current dearth of supply.

### ***Closing the Matching Gap***

Each year about 40,000 new patients worldwide fail in their search for bone marrow stem cells. By meeting the patient’s desperate objective to get matching blood stem cells from cord blood, NuStem can save lives, while enjoying a rapid growth in earnings and attractive returns on investment.

### ***Financial Projections***

NuStem projects breakeven in the fourth quarter of year two with gross revenues of slightly less than \$20 million for the year. As a result of an average revenue growth rate of 145% per annum over the ensuing period, gross revenues are expected to approach \$300 million in year five and earnings to exceed \$159 million. Increased early investment will result in more attractive gross revenue growth and higher absolute earnings and returns on investment.

### ***Worldwide Collection and Distribution***

From its professional contacts, the Company has established commitments with a domestic and international array of twelve obstetrical practices representing the ethnic diversity of the world's population. NuStem's Collection Center network is unique among cord blood banks.

### ***Greatest Genetic Diversity***

NuStem's Collection Centers will maintain a richly diverse inventory. Specific Centers around the world will conduct their operations so as to maintain an inventory that enables a high success rate in matching requests.

### ***Inventory Plans – First Three Years***

Due to the extensive medical contacts of the Company's senior management and advisors, NuStem anticipates that it will be able to build its proprietary cord blood banking inventory to about 1,050 units within year one, over 15,700 units by the end of year two, and approximately 44,800 units by the end of year three. These inventory levels will make NuStem the largest cord blood bank in the world after two years of operations. This will result in dramatic improvements in the likelihood of finding a match for patients in need of blood stem cells.

### ***Virtually Assured Global Matching Capabilities***

NuStem plans to build its bank to a maximum of 110,000 units by the end of year five and maintain that inventory level by replacing cord blood units that have been shipped for transplant. This inventory level will allow a global matching capability in excess of 90% with volume increases in the total number of units stored being driven by rising demand.

### ***Internet Based Searches for Matches***

NuStem will build a state-of-the-art interactive Internet website ([www.nustem.com](http://www.nustem.com)) to provide global access for on-line queries to identify genetic matches from NuStem's inventory. Access will be provided free of charge to any patient or medical institution.

### ***Multiple Strategic International Relationships for Market Development***

NuStem has begun developing strategic international relationships that will provide new markets and access to the inventories of other international cord blood banks. NuStem will also formalize relationships with institutions performing BMTs to allow these key players to achieve greater success in finding matches and more immediately available delivery of blood stem cells to patients.

### ***Donor and Patient Confidentiality***

The Company will employ state-of-the-art safeguards fully compliant with FDA and NIH protocols that are designed to ensure donor and patient confidentiality at all times.

### ***International Education***

NuStem will provide on-going education to leading institutions and their staff about cord blood banking and transplantation. Additionally, influential blood stem cell specialists and medical leaders will be invited to an annual Cord Blood Stem Cell Biology and Transplantation Symposium designed to expand the Company's industry standing and relationships, ensure awareness of and access to new research data, and to promote information exchange.

## I. EXECUTIVE SUMMARY

### *The Company*

NuStem Technologies, Inc. is a privately held company focused entirely on all aspects of cord blood banking – from collection to delivery to Transplant Centers or Research Laboratories. The Company was incorporated in Nevada in 2000 and is headquartered in Reno, where it is in the process of establishing its first laboratory for the receipt, processing, cryogenic storage, retrieval and delivery of cord blood stem cells to its target markets. The Company is seeking a minimum equity placement of \$10 million to enter commercial operations and will place up to \$40 million in this round of funding, subject to terms and market conditions.

### *Mission*

NuStem's Mission is to build the most genetically diverse cord blood bank in the world, allowing it to achieve unparalleled genetic matching capabilities. The Company seeks to become the recognized leading source of cord blood stem cells and to do so at competitive prices for the patient while earning highly attractive financial returns for NuStem.

### *Business Model*

The key components of the Company's Business Model are:

- Collections
- Packaging, Identification, and Shipping
- Processing and Testing
- Storage and Retrieval
- Tissue Matching
- Fulfillment

NuStem is in the business of obtaining cord blood units from donors under the soundest ethical principles and, thereafter, performing certain operations on those units through each stage of handling so as to deliver an uncompromised product to the Company's end users. To operate the Business Model's components effectively while maintaining overall integration of the business, the following tools will be used:

- Corporate governance practices
- Information gathering, analysis and strategic planning
- Budgeting and performance monitoring
- Operational control formulation, training and implementation
- Information technology
- Financial management and control
- Internal and external audit

## ***Blood Stem Cell Market***

The following table outlines the Company's markets as described by the number of patients per year for whom a properly matched allogeneic transplant of blood stem cells would appear to be highly advisable or essential to prolonging the life of the recipient.

<b>Annual Stem Cell Market</b>	US	Global*	%	Cost of Procurement (\$000's)	Gross Global Market (\$billions)
<b>BMT Market</b>					
Served **		8,500		\$38***	\$0.3
Unserved		<u>36,500</u>	0.1%	\$38	<u>\$1.4</u>
		45,000			\$1.7
<b>Total Cancer Market****</b>					
<b>Blood Related Cancers</b>					
Incidences	109,500	328,500	8.6%	\$15	\$4.9
<b>Non-Blood Related Cancers</b>					
Incidences	<u>1,158,500</u>	<u>3,475,500</u>	91.4%	\$15	<u>\$52.1</u>
<b>Total *****</b>	1,268,000	3,804,000	100.0%	\$15	\$57.0
(*BMT procedure or incidence) / (** Served market is the number of transplants per year)					
(***)Average cost of Bone Marrow procurement - low of \$30,175 to high of \$58,900)					
(**** Source of data is the American Cancer Society BMT market) / (***** Includes BMT market)					

As can be seen above, the Company's Mission addresses a vast, largely unserved global market of approximately \$57 billion, of which the US represents about \$20 billion. The overwhelming majority of this market is currently unserved due to the lack of available blood stem cells that match a potential patient's requirements.

Initially, NuStem plans to focus on the unserved BMT market (\$1.4 billion) for the treatment of:

- inherited and acquired blood diseases
- cancers of the blood, and
- as a "rescue" therapy allowing high dose chemotherapy (with or without radiation) as a treatment for cancer.

As the Company gains market stature over its first two years of operation, it will also be preparing the market for the early use of blood stem cells in treating solid tumors, a vastly larger market (\$52 billion) than the current areas for blood stem cell therapies established by the use of bone marrow.

### ***Initial Markets***

The total number of patients in need of an unrelated (not from a family member) allogeneic BMT of blood stem cells is estimated to be over 45,000 per year. Of these, the total number of patients who cannot locate a donor is in excess of 36,000 (source: worldwide and US donor registries). The Company is forecasting completion of over 21,000 matches in year five.

The Company's forecast of completed matches is based on the unserved bone marrow market today and does not take into account the increase in demand for cord blood stem cells as a replacement for bone marrow in existing markets (\$300 million), nor the solid tumor market (\$52 billion), nor the essentially certain advances of current and pending research that can be anticipated in this period (unquantified, but expected to be large).

### ***Strategies: Corporate, and Marketing and Sales***

Superior strategy formulation and execution require sound experience in strategic planning melded with managerial excellence and a thorough knowledge of the underlying business.

The Company's leaders know how to use all the tools required to integrate strategic and operational planning and achieve the execution required for success in a zero-defect business, e.g. the Company's Standard Operating Procedures ("SOP") Manual is fully compliant with NIH requirements because NuStem's Vice Chairman for Scientific and Medical Affairs was the head of blood diseases at NIH when NIH's protocols were designed and completed.

The Company's primary initial strategy is to establish priorities in each area of the Business Model, and to move quickly to get into business by accomplishing these priorities. This is already underway: Collection Centers are identified and presold; leading Transplant Centers have also been approached with excellent early indications; the intermediate steps between collection and fulfillment are thoroughly documented, understood, and ready to be implemented as a result of years of experience in such activities.

All components of the Business Model already have strategic outlines and established priorities, which will be enriched as the staffing of key positions proceeds.

On-going strategy will evolve from an annual strategic planning process from which budgets and operating plans will be constructed to guide the following year.

### ***Competition***

The majority of the Company's competitors are undercapitalized, nonprofit organizations, with small inventories. The blood stem cell market is immature and the Company sees this is an unusually attractive opportunity to gain the industry's leadership role and to enhance barriers to entry.

Whereas competition may arise as a result of the Company's success, NuStem knows of no party planning the market assault envisioned in this plan - and so desperately needed by patients throughout the world.

The Company believes that the best barrier to entry is to establish a commanding position while gaining the respect of industry leaders as the premier cord blood bank

### ***Operations and Technology***

NuStem's success does not depend upon new technology. The Company's technologies and procedures are adapted from those of the FDA and NIH. These technologies and procedures have been in use for many years and are proven to be the safest and most effective in the industry. NuStem's technologies and procedures are fully described in the Company's 200-page SOP Manual that will be provided to investors of serious intent, should they wish to review it as part of their due diligence process. An outline of the Company's technologies and procedures appears below:

- Informed consent
- Donor confidentiality
- Collection procedure
- Shipping technology (from Collection Centers to NuStem)
- Infectious and genetic disease testing and HLA typing
- Cord blood processing
- Cryopreservation
- Shipping technology (from NuStem to Transplant Centers and Research Laboratories)

### ***Human Resources***

The Company's Board of Directors includes a distinguished group of individuals with medical and business experience relevant to the Company's market penetration objectives, product development and intellectual property priorities.

The origins of the Company arise from the efforts of Mark Cullen, M.D., beginning in 1995. Dr. Cullen has subsequently worked closely with Dr. Alan Levine and Dr. Esmail Zanjani. This team evolved the initial concepts that led to the firm establishment of NuStem's current development plans for cord blood banking. The Company's technologies are based on decades of collective experience by its senior technical team and Scientific Advisory Board members in the fields of obstetrics and hematology - backed by the extensive senior executive experience of Mark Cullen, M.D., Chairman, the managerial and financial experience of Robert P. Jenks, President and Chief Executive Officer, and the counsel of Hyman P. White, Director.

NuStem also has access to a network of leading doctors, research scientists in academic and medical institutions, and private practice. Further biographical information on the Company's senior management, directors and Scientific Advisory Board members appears in Appendix B.

***Financial Projections***

Per the selected financial data below, the Company is projecting gross revenue of about \$500 thousand in year one and approaching \$200 million in year five. Sales in year five represent about a 15% penetration of the unserved current BMT market. Profitable operations are expected by the second quarter of year two and positive cash flow by the third quarter of the year two.

The Company is seeking to place equity from a minimum of \$2 million upwards to \$10 million in its current round of funding and estimates its total requirement over the five-year period to be in the range of \$25 million. The use of proceeds is described further in Section X.

Selected Financial Data (\$ millions)

**Statement of Operations Data:**

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 5</b>
<b>Revenue</b>	<b>0</b>	<b>19.9</b>	<b>89.9</b>	<b>199.5</b>	<b>297.3</b>
<b>Cost of Goods Sold</b>	<b>0</b>	<b>1.7</b>	<b>6.3</b>	<b>13.1</b>	<b>18.9</b>
<b>Operating &amp; Other Expenses</b>	<b>7.6</b>	<b>24.8</b>	<b>54.9</b>	<b>111.0</b>	<b>118.7</b>
<b>Net Income (Loss)</b>	<b>(7.6)</b>	<b>(6.6)</b>	<b>28.7</b>	<b>75.4</b>	<b>159.7</b>

**Statement of Cash Flow Data:**

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 5</b>
<b>Acquisition of Property and Equipment</b>	<b>1.5</b>	<b>1.9</b>	<b>3.2</b>	<b>3.5</b>	<b>3.0</b>
<b>Net Increase (Decrease) in Cash</b>	<b>(11.0)</b>	<b>(21.7)</b>	<b>2.2</b>	<b>43.6</b>	<b>133.3</b>

**Statement of Balance Sheet Data:**

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 5</b>
<b>Cash</b>	<b>4.0</b>	<b>2.3</b>	<b>4.5</b>	<b>48.0</b>	<b>181.4</b>
<b>Inventory</b>	<b>0.8</b>	<b>12.6</b>	<b>35.8</b>	<b>64.1</b>	<b>87.4</b>

**Note: Appendix K includes a financial model of the annual revenue and expense projected over five years.**

## II. THE COMPANY AND ITS MISSION

### THE COMPANY

NuStem Technologies, Inc is a privately held company focused exclusively on all aspects of cord blood banking – from collection to delivery to Transplant Centers and Research Laboratories.

Originally organized through an existing corporation, Saratech, Inc., the Company was reincorporated in Nevada in 2000. A brief corporate history appears in Appendix I.

NuStem is headquartered in Reno, Nevada, where it occupies 1,700 square feet of administrative and laboratory space. The Company has its first cryogenic cord blood storage unit in place in its Reno headquarters' laboratory. NuStem is in the process of completing the fitting out of this first laboratory for the receipt, processing, storage, retrieval, and dispatch of cord blood stem cells to Transplant Centers and Research Laboratories worldwide.

The Company believes that rapid occupation of market space can lead, equally rapidly, to dominance in the \$57 billion total global market for bone marrow and cord blood transplants. The unserved portion (no available supply) of this global market is around \$54 billion or 95 %. The Company's projections indicate a total investment need of approximately \$40 million within its first 24 months of operation to meet its market penetration objectives. NuStem currently seeks a minimum of \$10 million to enter commercial operations and will place up to \$40 million of equity in this round of funding, subject to terms and market conditions.

### MISSION

NuStem's Mission is to build the most genetically diverse cord blood bank in the world, allowing it to achieve unparalleled genetic matching capabilities – well in excess of 90%. The Company seeks to become the recognized leading source of cord blood stem cells and to do so at competitive prices for the patient while earning highly attractive financial returns for NuStem.

## III. BUSINESS MODEL

NuStem is in the business of obtaining cord blood units from donors - using the soundest ethical principles - and, thereafter, performing certain operations on those units through each stage of handling so as to deliver an uncompromised, zero-defect product to the Company's clients - Transplant Centers and Research Laboratories. Accordingly, the key components of the Company's Business Model have been carefully selected to focus on all aspects of the process of obtaining cord blood stem cells and their careful handling through to delivery to NuStem's clients. These Business Model components are:

- Collections
- Packaging, Identification, and Shipping

- Processing and Testing
- Storage and Retrieval
- Tissue Matching, and
- Fulfillment

To operate the Business Model’s components effectively while maintaining overall integration of the business, NuStem’s senior management has given the highest priority to the use of the following “tools” (single examples are generally given, rather than comprehensive sub-points for each tool):

**Corporate governance practices**

e.g. setting a standard of excellence at the highest level

**Information gathering, analysis and strategic planning**

e.g. gathering information on Transplant Centers by various criteria such as size, location, NuStem affiliations with senior administrators, etc.; analyzing priorities in terms of market development objectives; forming strategies for achieving marketing success, and; integrating the Transplant Center strategy with overall Corporate strategic planning and the strategies being implemented in other Business Model component areas

**Budgeting and performance monitoring**

e.g. preparation of annual Business Model component budgets consistent with the overall strategic plan and Corporate budget; monthly and quarterly reviews of results versus budget; and corrective action, including strategy reassessment

**Operational control formulation, training and implementation**

e.g. ensuring that the Company’s SOP Manual, which is fully FDA and NIH compliant, is understood by all necessary parties and that its protocols are strictly observed

**Information technology excellence**

e.g.. ensuring that the Company’s web site database of available units is maintained accurately and efficiently; applying excellent IT to all relevant administrative requirements of the executive, marketing and sales, and technical operations of NuStem.

**Financial management and control**

e.g. complete professionalism at all levels from fund raising to fulfillment invoicing, all under scrupulous accounting practice

**Internal and external audit**

e.g. independent verification of the Company’s conduct of business The Business Model,

in conjunction with its tools of operation, is the means by which the Company believes it can best fulfill its Mission.

#### IV. THE BLOOD STEM CELL MARKET

As can be seen in the Table that follows, the Company’s Mission addresses a vast, largely unserved global market of approximately \$57 billion, of which the US represents about \$20 billion. The overwhelming majority of this market is currently unserved due to the lack of available blood stem cells that match a potential patient’s requirements.

<b>Annual Stem Cell Market</b>	US	Global*	%	Cost of Procurement (\$000's)	Gross Global Market (\$billions)
<b>BMT Market</b>					
Served **		8,500		\$38***	\$0.3
Unserved		<u>36,500</u>	0.1%	\$38	<u>\$1.4</u>
		45,000			\$1.7
<b>Total Cancer Market****</b>					
<b>Blood Related</b>					
<b>Cancers</b>					
Incidences	109,500	328,500	8.6%	\$15	\$4.9
<b>Non-Blood Related</b>					
<b>Cancers</b>					
Incidences	<u>1,158,500</u>	<u>3,475,500</u>	91.4%	\$15	<u>\$52.1</u>
<b>Total *****</b>	1,268,000	3,804,000	100.0%	\$15	\$57.0
(*BMT procedure or incidence) / (** Served market is the number of transplants per year)					
(***)Average cost of Bone Marrow procurement - low of \$30,175 to high of \$58,900)					
(**** Source of data is the American Cancer Society BMT market) / (***** Includes BMT market)					

#### **Market Priorities**

Initially, NuStem plans to focus on the unserved BMT market (\$1.4 billion) for the treatment of:

- inherited and acquired blood diseases
- cancers of the blood, and
- as a “rescue” therapy allowing high dose chemotherapy (with or without radiation) as a treatment for cancer.

As the Company gains market stature over its first two years of operation, it will also be preparing the market for the expanded use of blood stem cells in treating solid tumors, a vastly larger market (\$52 billion) than the current areas for blood stem cell therapies established by the use of bone marrow.

### ***The BMT Market / Projected Income / Market Size Assumptions***

The total number of patients in need of an unrelated (not from a family member) allogeneic BMT of stem cells is estimated to be over 45,000 per year. Of these, the total number of patients who cannot locate a donor is in excess of 36,000 (source: worldwide and US donor registries). The Company is forecasting completion of over 21,000 matches in year five.

The Company's forecast of completed matches is based on the unserved bone marrow market today and does not take into account the increase in demand for cord blood stem cells as a replacement for bone marrow in existing markets (\$300 million), nor the solid tumor market (\$52 billion), nor the essentially certain advances of current and pending research that can be anticipated in this period (unquantified, but expected to be large). As a result of the foregoing, NuStem regards its projections of successful matches in year five as being highly conservative.

*"...more than 50% of patients (are) unable to access bone marrow for transplant and, in this context, umbilical cord blood has emerged as an attractive alternative and rich source of hemopoietic stem cells for transplant."*

*MJA, Vol 166, 2 June 1997*

### **BROAD CATEGORIES OF DISEASES TREATED WITH STEM CELL TRANSPLANTS**

The following is a list of the currently identified broad categories of diseases that can be treated with umbilical cord blood stem cells.

- Malignancies of the blood and immune systems
- Blood diseases
- Genetic diseases of metabolism
- Immunodeficiency diseases

### ***Possible Future Applications***

- Solid tumors
- AIDS, multiple sclerosis, rheumatoid arthritis, lupus
- Ex vivo expansion
  
- Stem cell plasticity

Given the painful, administratively complex and anonymous nature of bone marrow collection, the Company foresees no way in which collections can be increased to meet the huge need for blood stem cells. Cord blood stem cells are the only answer and, in any event, have characteristics significantly superior to bone marrow stem cells as already described herein. In summary:

- the gap between supply and demand is huge and can only be filled by cord
- blood stem cells
- the needs of patients are great, usually life-threatening, and
- the opportunity to save lives – at lower cost to the patient while enjoying high financial returns for NuStem – is exceptionally attractive.

Further details on existing and potential applications appear in Appendices D and E.

## V. STRATEGIES: CORPORATE, AND MARKETING AND SALES

Superior strategy formulation and execution require sound experience in strategic planning and execution, melded with managerial professionalism and a commanding knowledge of the operating and technical requirements of the underlying business.

The Company's leaders know how to use all the tools required to integrate strategic and operational planning and achieve the execution required for success in a zero-defect business, e.g. the SOP Manual is fully compliant with NIH requirements because NuStem's Vice Chairman for Scientific and Medical Affairs was the head of blood diseases at NIH when NIH's protocols were designed and completed.

The Company's primary initial strategy is to establish priorities in each area of the Business Model, and to move quickly to get into business and occupy market space by accomplishing these priorities. This process is already underway:

- Collection Centers are identified and pre-sold.
- Leading Transplant Centers have also been approached with excellent early indications.
- The intermediate steps between collection and fulfillment are thoroughly documented, understood, and ready to be implemented as a result of years of experience in such activities.
- All components of the Business Model already have strategic outlines and established priorities that will be enriched as the staffing of key positions proceeds.

As outlined in the Markets section, market focus is initially based on meeting the unserved demand for allogeneic donor bone marrow to treat:

- inherited and acquired diseases
- cancers of the blood, and use as a

- “Rescue” therapy allowing high dose chemotherapy (with or without
- radiation).

Longer term (three years out and beyond) the Company’s strategies are based on projections of increased demand for cord blood stem cells, as it becomes a replacement for the served – as well as unserved - bone marrow market, as the use of rescue therapy widens and deepens into an immense area of diverse cancers, as a treatment for non-cancerous diseases, as the immense solid tumor market gathers pace, and as other uses arise from research accelerated by availability.

On-going strategy will evolve from an annual strategic planning process from which budgets and operating plans will be constructed to guide the following year. The Company’s seniors have many years of experience in effective use of these essential tools of management.

## MARKETING AND SALES STRATEGY

### *Collection and Fulfillment*

The Company does not manufacture a product for sale and distribution. u NuStem’s product comes from the umbilical cords of full-term, healthy newborn babies – donated by their mothers – who have the legal power to do so under the laws of almost all countries.

These donations must be obtained in the strictest ethical manner and will not occur without the complete confidence of the respective obstetric practice, the hospital, and with the fully informed consent of the donor mother. Accordingly;

- NuStem must present (“sell”) itself to both the practice and the mother in a highly effective and totally correct manner.

In exchange for fee income, NuStem will provide blood stem cells to Transplant Centers and Research Laboratories. Accordingly;

- NuStem must present (“sell”) itself to both the Transplant Centers and Research Laboratories in a highly effective and totally correct manner.

This aspect of the Company’s Business Model means that, in effect, NuStem addresses two “markets” for which it requires “sales” strategies. These markets are:

- The collection market, and
- The fulfillment market

### *Collections Marketing and Sales Strategy*

Under the norms of medical ethics it is not possible to purchase umbilical cords from mothers before, during or after birth. The mother must donate the umbilical cord to a

chosen recipient if it is not discarded.

The twelve Collection Centers currently prepared to work closely with NuStem in fostering “informal consent” procedures for the collection of blood stem cells from the umbilical cord of births occurring in their institutions have been influenced to undertake these commitments primarily due to the following factors:

- Respect for the professionalism of NuStem’s senior medical and scientific team.
- NuStem’s absolute commitment to FDA and NIH protocols that is unique in the world of blood stem cell banking.
- NuStem’s standard operating procedures thoroughly documented in the Company’s SOP Manual and covering all aspects of cord blood banking from collection to fulfillment.
- NuStem’s Donor Education Program as to be conducted by the Company’s Cord Blood Collections Management Teams dedicated to each specific Collection Center.
- An anticipated special relationship between NuStem and the Collection Center’s staff with respect to professional interchange.

As the Company progresses, a dedicated sales team will gather on-going information on the collection market and analyze it to set priorities to further develop and service this aspect of the Company’s business.

***Fulfillment Marketing and Sales Strategy.***

There are hundreds of bone marrow transplant (BMT) centers in the United States. Initially, the Company plans to implement an aggressive campaign to develop relationships with selected BMT centers.

NuStem’s cord blood sales forecasts are based on the number of BMT centers times the number of queries times the probability of finding a match. Consequently, there is a strong linkage between the Company’s collection strategies, fulfillment strategies, and the ability to find a match.

NuStem’s marketing and sales strategy for the fulfillment market has two primary elements: (1) Direct marketing and sales (“M&S”) and (2) Database M&S.

As the Company progresses, a dedicated sales team will gather on-going information on the fulfillment market, and analyze it to set priorities to further develop and service this aspect of the Company’s business. All of the sales points used to develop the collection market (other than the Donor Education Program) will be relevant to the fulfillment market.

Database sales will be based on a state-of-the-art interactive Internet-based system to provide on-line queries to identify matches from the Company’s inventory of cord blood samples. This system will integrate the NuStem central database with the database from the ThermoGenesis Bioarchive® cryogenic freezer system (see Section VII. Operations

and Technology).

Access to data will be in real time to allow HLA matching without delay and with 100% accuracy. The information will be kept in an historical database to provide for ad hoc queries and to report on trends and demographics.

The existence of the Company's Internet based database will be promoted through trade journal advertising, direct mail, and direct contact with potential sources of sales by the fulfillment sales team. Inquiries are expected to come from worldwide sources and to grow as the Company's inventory acquires greater depth and breadth in terms of ethnic diversity and blood characteristics.

Data based matching should become the main source of NuStem's fulfillment sales within a reasonably short period of time (two to three years).

## VI. COMPETITION AND COMPETITIVE ADVANTAGE

At mid-2001, there are about forty unrelated donor cord blood banks in operation Here is a profile of these organizations:

- Half located outside the US
- Large majority are non-profit organizations
- Undercapitalized
- Small, undiversified inventories
- Modest market share
- Largely unregulated
- Other than NuStem, no for-profit cord blood bank complies with all FDA and NIH protocols, processing techniques and storage equipment specifications.

The following is a summarized list of cord blood banks and, if known, their total inventory as of April 2001.

<u>Country</u>	<u>Approximate No. of CB Banks/Registries</u>	<u>Total Inventory</u>	<u>Largest Individual Inventory</u>
USA	18	33,300	12,000
Europe	16	33,300	8,731
<u>All others</u>	<u>4</u>	<u>6,000</u>	<u>5,327</u>
Total	38	72,600	N/A

There are two types of cord blood banks:

### *Autologous Banks*

In an autologous bank, the family of the baby from which the blood is being collected pays to “bank” the baby’s cord blood for the private use of the family in the event that the baby, or a close relative, needs a blood stem cell transplant in the future. Families typically pay a front-end fee of \$1,500 to bank the cord blood, plus an annual maintenance fee of approximately \$100.

Autologous cord blood banking is very controversial in the medical community because of the low probability that the banked cord blood will ever be needed.

- Estimates have shown that there is a 1 in a 100,000 chance (with a range of 1 in 10,000 to 1 in 300,000) that the child will develop a disease curable by blood stem cell transplantation.
- Many professionals believe that blood from another person (allogeneic) has benefits over one’s own blood (autologous). If a person carries a stem cell defect that causes the need for a blood stem cell transplant, that person’s blood cannot be used.

For these reasons, NuStem does not intend to be involved in autologous banking, i.e. cord blood banks that operate in the miniscule autologous market will not be in competition with NuStem.

### ***Allogeneic Banks***

An allogeneic bank collects cord blood from donors who have no familial relationship to the recipient. No attempt is made to store cord blood for a specific individual or family – matching is done on HLA typing only.

NuStem’s senior team believes that establishing the largest and most diverse allogeneic cord blood bank in the world will provide the greatest opportunity for sustainable profitability while saving lives. The principal factor in preventing existing competition from building a successful allogeneic cord blood bank is:

- The lack of capital investment resources, which in turn leads to
- Shallow inventory formation.

Most cord blood banks are non-profit, government-supported entities that depend on donated funds to develop their inventory. Consequently, many cord blood banks contain an inventory of only 1,000 to 3,000 units. The New York Blood Center is currently the largest allogeneic cord blood bank in the world with about 12,000 units stored. Initially funded by the NIH, the New York Blood Center is no longer receiving these funds.

NuStem plans to invest approximately \$40 million dollars over its first two years to create a cord blood bank with 110,000 units. Within one year of beginning commercial operations, the Company plans to be one of the largest cord blood banks in the world. By the end of the third year of operation, NuStem’s bank is projected to contain over 45,000 units, nearly four times the size of the New York Blood Center.

### ***Genetic Diversity***

As the number of banked cord blood specimens increases, the probability of finding a suitable match increases. Despite the small number of cord blood specimens banked to date, cord blood matches have been identified in many cases when no donor could be found in bone marrow registries.

This ability to provide close HLA matching will be enhanced as NuStem's cord blood bank develops its genetic diversity through collecting blood from a wide range of ethnic donors.

Most cord blood banks are affiliated with one hospital or a group of hospitals in their immediate area. The genetic diversity of these cord blood banks is limited to the genetic diversity of the babies born in the respective hospital(s). This will usually be limited to the ethnic diversity of the cord blood bank's local collection areas.

NuStem has identified and pre-marketed to a worldwide network of Collection Centers specifically to provide a wide variety of donors representative of all classes and groups. The Company will manage its network to develop an effective genetic mix in its blood bank, to build the most genetically diverse blood bank in the world. This diversity will help NuStem achieve the highest probability of providing a suitable match, resulting in a sustainable competitive advantage.

### ***Standards of Practice***

The NIH and the FDA have established a standard methodology of protocols for effective cord blood collection and banking. NuStem is the only cord blood bank committed to operating under all NIH and FDA standards and protocols. Additionally, NuStem will achieve accreditation from the American Association of Blood Banks and the Foundation for Accreditation of Hematopoietic Cell Therapy.

### ***Strategic Relationships***

NuStem has relationships with leaders in the field of hematology and has developing relationships with international organizations that have demonstrated great interest in NuStem's proposed cord blood bank. The Company's senior team is committed to building additional strategic relationships with bone marrow Transplant Centers and international specialists through, among other initiatives, its hosting of an annual Symposium on Cord Blood Stem Cell Biology and Transplantation.

### ***Scientific Leadership***

NuStem's Vice Chairman for Scientific and Medical Affairs is the former head of blood diseases at the NIH. He also has the primary responsibility, in conjunction with other members of senior management, for the development of the Company's Scientific Advisory Board ("SAB") working in close cooperation with the SAB's Chairman, Dr.

Esmail Zanjani.

It is the Company's intention to expand the SAB by the addition of acclaimed leaders in hematology, oncology, stem cell biology and transplantation. Among these scientific leaders will be specialists in laboratory procedures, blood banking techniques, and the use of cord blood stem cells for transplantation, as well as experts in the use of hematopoietic stem cells. All of the Company's Scientific Advisors will be at the forefront of on-going research.

## VII. OPERATIONS AND TECHNOLOGY

### BUSINESS MODEL PROCESSES

NuStem's "Operations" would, in the broadest sense, cover the infrastructure required to support all of the Company's activities and, therefore would include such topics as:

- Premises strategy and planning, acquisition, build out and maintenance.
- Equipment acquisition and maintenance of all types, e.g. furniture, computers of all sizes, Company vehicles. etc. in addition to the laboratory equipment described later herein.
- Payroll systems.
- Staff attendance tracking.
- Invoicing systems.
- Records maintenance systems.
- Web site operations etc.

This discussion of Operations will be limited to the key operational steps required to obtain custody of the blood stem cells which are present in the umbilical cord of a full term, healthy baby (a blood stem cell "unit") and to handle them through to delivery to the custody of a NuStem client.

#### ***Patient Education, Informed Consent, and Confidentiality***

Custody over a unit will never occur without the informed consent of the mother. NuStem regards this step as an essential part of its cord blood handling operations. The following describes the collection process:

- At each Collection Center, NuStem will establish a Cord Blood Collection Management Team, consisting of a nurse and an assistant, who will be responsible for managing all aspects of the collection process.
- The Collection Team will make available to the hospital, birthing center, or physician's office, brochures detailing the services provided.
- Each Cord Blood Collections Management Team will be thoroughly trained in the uses and advantages of cord blood banking.
- NuStem's Informed Consent Form is modeled after NIH protocols and will be

subject to the complete scrutiny and approval of all appropriate hospital committees at the Collection Center.

- The Collections Management Team will meet each obstetrical patient (mother/donor) and share with her materials and information about the program
- Education of the mother/donor will begin early in the pregnancy and continue to the time of delivery.
- After a very specific informed consent procedure, each mother/donor will have the option to donate or discard her baby's cord blood sample.
- Protection of the identity of the mother and infant donor is of the highest priority for NuStem. The Company's SOP manual describes in extensive detail NuStem's policies and procedures for maintaining confidentiality.

Near the time the cord blood is collected, a qualified member of the Collection Management Team will interview the mother to obtain a detailed medical and social history in the same manner as would occur for any blood donor. In addition, a sample of blood will be drawn from the mother for subsequent testing.

### ***Packaging, Identification, And Shipping***

NuStem will provide the Collection Centers with special cord blood collection kits, bar code labels and readers, so that collection and processing of the cord blood unit and the associated paperwork will proceed as efficiently as possible with very little risk of error.

NuStem uses labels bar coded with the standardized ISBT-128 system. The Company's bar code labels are printed in sets with each set having a unique bar code number. Various labels within the set are specially sized to fit on laboratory tubes, basins, blood bags, and all data forms. Labels will be tracked at the Collection Centers and at the respective NuStem Cord Blood Bank Laboratory.

The Collection Management Team will be responsible for strict application of all NuStem protocols in the collection and packaging process. The protocols recommended by the companies that developed the cryogenic storage units and the packaging materials, (i.e. ThermoGenesis and MedSep) are proprietary and will also be rigorously followed. NuStem will use only those protocols and equipment that have been approved by the FDA and NIH and this will remain corporate policy throughout the Company's period of operation.

At the time of delivery, the placenta will be taken to a nearby clean area, the puncture site of the umbilical cord will be sterilized, and the stem cells removed to a sterile, special purpose container for shipment marked with a bar code providing appropriate information as to donor, baby, date, location, etc.

The sample will then be shipped via special courier directly to a NuStem Blood Bank Laboratory for processing, testing and storage. Demographic data on the mother and baby will be recorded and entered into NuStem's database.

Shipping containers that have been specially designed to transport blood cells will be

used to ship cord blood units from the Collection Center to the NuStem Cord Blood Bank Laboratory. Temperature stabilizing gel packs will maintain the shipping container at the optimal temperature for ensuring cell viability. Special temperature measuring devices will be used to ensure that the internal temperature of the shipping container is maintained throughout shipping.

### ***Processing and Testing***

The practice of timely processing, and the strategic location of the respective Cord Blood Bank Laboratory will be essential. As the sample is removed from the shipping container, a separate small portion of the sample will be sent to an independent, accredited, specialty laboratory for additional testing. The tests that will be performed on the sample include:

- HLA typing: A, B, DR, medium resolution,
- HIV and other infectious disease testing,
- Blood typing, and
- Genetic testing for common genetic diseases such as sickle cell anemia

The remainder of the blood will be spun down in a centrifuge to isolate the progenitor blood stem cells from the other components of the whole blood. Once the processing is complete, all data will be input into the database. The sample to be stored will be mixed with a freezing agent and placed in the specially developed container to preserve the unit in a cryogenic state when introduced into the storage device.

### ***Safe Storage and Retrieval of Cord Blood Samples***

NuStem has in place a FDA approved cryogenic storage device – and will use only such devices in the future. Engineered and produced by ThermoGenesis of Sacramento, California, the BioArchive™ is a computer-controlled system for storage and for controlled rate freezing and thawing of cord blood units. The freezer is maintained at -320° F (-185° C) using liquid nitrogen.

The maximum capacity of the BioArchive is 3,600 units at any one time. Since this special freezer does not have to be opened to introduce or remove a sample, the internal temperature is strictly maintained and computer monitored 24 hours per day. Samples are placed in the BioArchive by a robotic periscope arm.

The cord blood sample is first placed in a separate quarantine area of the BioArchive until the infectious disease results are obtained and verified. The computer then instructs the robotics to remove the cord blood sample from quarantine and “archive” it into the long-term storage area of the freezer. Retrieval of the cord blood unit is also accomplished with the BioArchive’s computer-controlled robotic system. The unique controlled freezing and thawing programs have been designed to maximize cell viability at all times.

### ***Retrieval, Thawing and Shipping***

Once a match has been found in the database and an order placed, the robotics of the cryogenic storage unit select the sample and guide it through a slow-thaw process. The device is capable of retrieving a sample completely frozen in the event it must be shipped frozen to another location. Special containers for either frozen or thawed shipping are used to protect the sample until it reaches its destination. These shipping containers maintain the blood at less than  $-120^{\circ}\text{C}$  for up to eight days.

### ***Treatment Follow-up & Research Data***

The Company will follow up on the results of each transplant at timely intervals. The data collected will be used to provide efficacy tracking on the performance of all NuStem cord blood units that are used for transplantation. This information will also provide statistical information allowing comparison of the success of cord blood transplants versus those of bone marrow transplants.

## TECHNICAL BACKGROUND

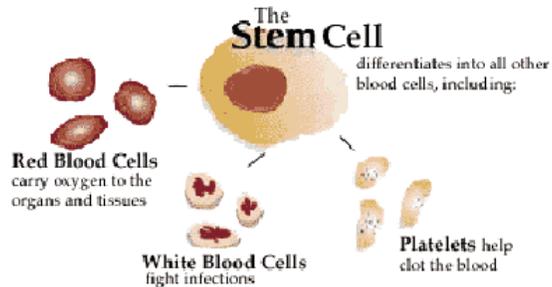
### ***Introduction***

Cord blood stem cells are obtained from the umbilical cord following the birth of a full-term, healthy baby. **CORD BLOOD STEM CELLS ARE NEVER OBTAINED FROM AN EMBRYO.** There is no moral dilemma or controversy regarding the collection or use of cord blood stem cells. The blood stem cell is the “mother” of all blood cells, and the precursor cell from which all blood cells, as well as the key components of the body’s immune system are derived. The blood stem cell can reproduce itself unless circumstances damage or destroy it.

### ***The Second Miracle of Birth***

Blood stem cells circulate freely in the blood of babies before, and just after they are born. An unusually rich supply is then available to be harvested from the umbilical cord following the birth of a full-term, healthy baby. Umbilical cords and their precious blood stem cells have historically been regarded as medical waste that has been discarded. When one hears of a person needing a “bone marrow transplant,” it is the blood stem cells that are being sought. Blood stem cells are absolutely necessary because they produce:

- **Red blood cells** that carry oxygen throughout the body
- **White blood cells** that fight infection
- **Platelets** that aid in clotting



Stem cells are an essential component in the effective treatment of many diseases. In some cases, such as cancer, chemotherapy and radiation destroy not only malignant cancer cells but also the body's blood stem cells. Without a replenishment of the blood stem cells, the body cannot make the blood components necessary for life.

In other cases, a genetic malfunction cripples the blood stem cells and results in the production of defective blood components. An example of such a genetic disease is sickle cell anemia. Replacing the body's defective blood stem cells with stem cells that function properly can cure many of these diseases.

### ***Bone Marrow Transplantation (BMT)***

Bone marrow is the site in the body where blood cells are produced. The spongy tissue of the bone marrow is found inside the bones and this is where blood stem cells are found. Bone marrow is obtained by withdrawal of the marrow from the donor's body. A large-bore needle is repeatedly inserted into the donor's hipbone to withdraw the marrow. The procedure requires over one hour to obtain sufficient marrow for a transplant (about a quart).

In a bone marrow transplant procedure, the patient's bone marrow is first destroyed in order to eliminate the damaged or diseased blood stem cells. Healthy blood stem cells from the donor are then infused intravenously into the patient's blood stream. In a successful transplant, the new blood stem cells migrate to the cavities of the large bones where they engraft and begin to produce normal blood cells again.

### ***Genetic Matching***

In allogeneic transplants, matching is not absolutely perfect because no two people are genetically identical (except identical twins). The donated stem cells must match the genetic makeup of the patient as closely as possible. There are various degrees of matching, and a less than perfect match must often be accepted. Graft versus host disease, a very serious and frequently lethal side effect of stem cell transplantation, is minimized when there is a better match.

### ***Graft versus Host Disease (GVHD)***

In a BMT, the donor's stem cells (the graft), which include the donor's entire blood and immune systems, is transplanted into the patient. The immune cells of the donor (the

graft) perceive the patient's body (the host) as "foreign" material and the donor's immune cells begin to attack or "reject" the patient. This is called GVHD. GVHD may range from a mild skin rash to major internal organ involvement. It occurs in 40-70% of patients after a BMT. Up to 40% of patients who develop GVHD (16% to 28% of all BMT recipients) will die from this very common side effect of a BMT. However, because of the immunologically naive nature of cord blood stem cells, the requirements for precision matching are not as demanding as in bone marrow transplants. (The immature nature of the immune systems of babies is why baby bottles have to be sterilized.)

Aside from the painless method of acquiring cord blood stem cells and their ample supply - if correct policies and practices are followed in future - cord blood stem cells' superior performance versus BMTs with respect to GVHD is an exceptionally important advantage.

### ***Cord Blood Stem Cell Transplantation***

There is a major opportunity for NuStem's cord blood banking initiative to provide an additional and alternative source of blood stem cells to fulfill the unmet need for matched blood stem cells and circumvent the shortcomings of bone marrow donation. The barriers and difficulties BMT patients experience include the following:

- the lack of suitable donors, especially for minorities and ethnic groups
- if a suitable donor is available, it takes too long to locate the donor and arrange for the BMT
- the high incidence of post-transplant infections, and
- Graft-versus-host disease (GVHD).

Other important considerations include:

- Cord blood is routinely disposed of as medical waste.
- Collection of cord blood stem cells is completely safe and non-invasive to the mother and infant.
- Time required for a donor search is reduced tremendously, saving many lives, and avoiding the anxiety of a long and potentially fruitless search.
- The shortage of donors in ethnic minority populations is alleviated.
- Cord blood stem cell transplants are safer than BMTs.
- Decreased risk of transmitting deadly infectious diseases.
- Lower cost to the patient in comparison with BMTs, while offering attractive returns on investment to NuStem.

### ***Other Technical Considerations of Cord Blood Transplantation***

Ounce-for-ounce, cord blood is a much richer source of stem cells than bone marrow. The average volume of a cord blood unit is about three ounces. The volume of bone marrow needed to perform a transplant is up to one quart. The actual number of blood stem cells in the cord blood unit is less than in a quart of marrow. Since fewer cells are

transplanted, two limitations exist:

- It may take somewhat longer for the patient’s cell counts to return to normal following a cord blood stem cell transplant.
- Some cord blood units may not contain a sufficient number of cells to successfully transplant a large person.

Nevertheless, many adults weighing over 200 pounds have been successfully transplanted with cord blood, and technologies now exist to “expand” the volume of a cord blood unit to handle ordinary weight, adult patients.

Additionally, NuStem believes that the widely varying freezing and thawing protocols that are utilized by many of the already established cord blood banks are a cause of decreased cell viability and degraded engraftment characteristics. Unlike most other cord blood banks, NuStem uses the most accurate, state-of-the-art, calibrated, computer controlled technology to freeze, thaw, and monitor the temperature of the freezer at all times. This, together with the Company’s other rigorous quality control procedures, will assure that the blood stem cells that the Company provides for transplant will be of the highest quality and viability.

The above is substantiated by a paper by Dr. Mary Laughlin in the New England Journal of Medicine:

***“In summary, the results of this study demonstrate that HLA mismatched umbilical-cord blood from unrelated donors is a feasible alternative source of hematopoietic stem cells for transplantation in adults. ”***

Laughlin MJ, Barker J, Mambach B, Koc ON, Rizzieri DA, Wagner JE, Gerson SL, Lazarus HM, Cairo M, Stevens CE, Rubinstein P, Kurtzberg J. Hematopoietic engraftment and survival in adult recipients of umbilical-cord blood from unrelated donors. *New England Journal of Medicine*, 2001; 344:1815-1822.

In an accompanying editorial in the same issue of that publication, Dr. Eliane Gluckman provided additional insight and opinion on Dr. Laughlin’s study.

***“In this issue of the Journal, Laughlin et al. present the remarkable results of transplantation of HLA-mismatched cord blood in 68 adults with life-threatening disorders...These results in patients who have advanced disease and lack an HLA-identical donor are very encouraging, and they compare favorably with results obtained with transplantation of marrow from unrelated donors or peripheral blood stem cells from haploidentical donors.”***

Gluckman E. Hematopoietic stem-cell transplants using umbilical-cord blood. *New England Journal of Medicine* [Editorial] 2001; 344:1860-1861.

## Summary

Despite some limitations, the use of cord blood stem cells harvested, maintained and delivered under the strictest FDA and NIH protocols is a technology which can save lives and provide uniquely beneficial therapies at an improved cost to the patient while offering the prospect of highly attractive returns to NuStem.

## VIII. ETHICAL AND LEGAL ISSUES, GOVERNMENT REGULATION, LITIGATION

### ETHICAL ISSUES

The following discussion of the legal and ethical issues of cord blood banking pertains only to allogeneic (unrelated) cord blood banking. A different set of legal and ethical issues, which are not relevant to the Mission of NuStem, arise with respect to autologous (related) cord blood banking, and will not be discussed here.

#### ***Blood Donation:***

The donation of cord blood for transplantation can be viewed in the context of either organ donation or blood donation. The issues and practices that society considers acceptable and even legal for blood donation may not be acceptable for organ donation. Donating umbilical cord blood, a lifesaving substance that would otherwise be disposed of as medical waste, must be viewed in the same context as blood donation.

***“In my view, the organ transplantation analogy is dysfunctional and misleading. Adopting the blood transfusion analogy may help us to more properly conceptualize the real issues involved in the collection, storage, and use of placental blood...The blood donation model would also put the Food and Drug Administration (FDA)...in charge of regulating placental blood safety. The FDA’s proposed regulations have already been subjected to critical legal commentary.”***

George J. Annas, J.D., M.P.H. Health Law Department Boston University School of Public Health Annas GJ, *Waste and longing – the legal status of placental blood banking*. New England Journal of Medicine, 1999; 340:1521-1524.

#### ***Ownership and Informed Consent:***

The norms of medical ethics and the legal systems of virtually all developed nations have given the mother the legal right and the responsibility to make decisions regarding the child’s medical affairs and property, including the medical wastes of childbirth. For the purpose of informed consent, it is appropriate to consider the mother as the donor. Consistent with this, NuStem has adopted the elaborate procedures and Informed Consent Form developed by the NIH.

#### ***Privacy:***

For various reasons the names of the mother and baby need to be “linked” to the cord blood unit and this may pose a risk to the privacy of the baby and the mother. Cord blood must be screened for a variety of infectious and genetic diseases, and extensive family histories and social practices are recorded in order to determine whether the cord blood unit is safe for transfusing into another person. NuStem’s SOP Manual, modeled after the NIH protocols, has appropriate policies and procedures in place regarding the mother’s consent for testing and for sharing of results.

It is important for the safety of the patient who will eventually receive the cord blood to have some information about the medical history and health status of the donor or baby. As modeled after the NIH protocols, NuStem will obtain a signed Informed Consent to check the baby’s medical record at six-months and at one year of age. After one year from birth, it becomes an unreasonable invasion of privacy to continue to monitor the baby’s health.

Only the Medical Director of NuStem, a position to be filled, will have access to the secure area of the Company’s database that contains medical information on the mother and baby. The necessity to maintain privacy cannot be overemphasized, and NuStem considers this to be of the utmost importance.

***Conflict of Interest:***

According to NuStem’s standard operating procedures, informed consent must be obtained by a specially trained individual who follows a strict protocol for providing information to the mother/donor in a completely impartial manner so as to avoid any potential conflict.

***Timing of Informed Consent:***

Informed consent should not be obtained during labor, delivery, or immediately following delivery of the baby. The most suitable time to approach the mother/donor for the process of obtaining informed consent would be during prenatal care. This is the time that is set forth in NuStem’s SOP Manual.

***Cord Blood Collection:***

Cord blood collection should not be done in complicated deliveries, and the cord blood stem cell collection program should not alter routine practice for the timing of umbilical cord clamping. The task of collecting the cord blood and the presence of collection personnel in the delivery room should in no way detract from the health and well being of the mother and baby. The welfare of mother and baby must be of the highest priority in the delivery room.

***Commercialization:***

The economics of cord blood banking should be viewed in the same way as the pharmaceutical industry’s activities, profits, and life saving products are viewed. It is also

important to keep in mind that the cost to the patient for cord blood is less than bone marrow donor-related costs while still allowing for highly attractive returns on investment.

## GOVERNMENT REGULATION

In 1997, the FDA announced regulations of cellular and tissue-based products that include stem cell regulation. The regulations required the licensing and registration of tissue processing facilities, but blood products that are not genetically manipulated received little regulation. Due to concerns regarding the activities of unregulated cord blood banks, and general concern over the lack of protection of the public, the FDA resolved to act decisively early in 2001.

On January 19, 2001, the FDA issued Rules and Regulations entitled “Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing.” NuStem is committed to following these FDA guidelines and practices and all other guidelines established by the NIH. Additionally, **NuStem will not use any embryo or fetal tissue, or by-products, from aborted fetuses either within or outside the USA.**

## LITIGATION

NuStem is not involved in any current or pending litigation, nor is the management of the Company aware of any fact or circumstance that could give rise to any litigation at the present time.

## IX. HUMAN RESOURCES SUMMARY

NuStem is committed to excellence in every facet of its operations. An example of this commitment is reflected in the experience, prominence, and reputation of the personnel it has assembled for its Officers, Board of Directors, and Scientific Advisory Board. A detailed biography of personnel can be found in Appendix B.

## MANAGEMENT

***Mark T. Cullen, M.D.***  
***Chairman of the Board***

Dr. Mark T. Cullen is the Company’s founder. He is also the President, CEO and Director of SulphCo, Inc. Reno, Nevada, and a Director of Adrian Oil and Gas, Inc., Geneva, Switzerland.

Dr. Cullen received his B.S. degree in Chemistry in 1979 and received his M.D. degree in 1982. Subsequently, Dr. Cullen did post graduate work at Yale University, School of Medicine, first as a post-doctoral Research Fellow, then as a Resident and Fellow in the Department of Obstetrics and Gynecology.

Dr. Cullen has established a professional network of obstetricians located at medical centers and hospitals worldwide. This obstetrical network is an integral part of NuStem's cord blood Collections Centers strategies.

***Robert P. Jenks***  
***President and Chief Executive Officer***

Mr. Jenks is founder and CEO of Intelesis Technologies Corporation in San Diego, CA. He has broad senior corporate and management experience with commercial and government organizations and programs and more than 20 years technical experience in: management consulting information system design, system integration, management of software development, data base development, test and evaluation, IV&V and ILS. Mr. Jenks is a graduate of the United States Naval Academy and a retired Naval officer. He also has earned an MBA and is an excellent communicator and team leader.

***Mark N. Steele***  
***Chief Information Officer***

Mr. Steele (B.S., M.S. Computer Science) has thirty-five years of experience in systems engineering, test and evaluation, operational training, systems analysis, systems programming, project management, and computer science instruction. He has taught programming languages and application development at several colleges. In addition, Mr. Steele is an experienced network engineer and integrator.

***Raymond S. Plevyak***  
***Chief Financial Officer***

Mr. Plevyak (BS, MBA) has over 20 years of financial management experience with banking, services, product, and manufacturing-based firms. He is an experienced designer, integrator, and manager of a variety of systems for financial reporting, budgeting and strategic planning, general accounting, and cash management. He is experienced in due diligence, planning, and venture funding of firms in all stages, including start-ups, IPO candidates, mid- and large-capitalization companies. Mr. Plevyak is a Certified Management Accountant.

***Alan Levine Ph.D.***  
***Vice Chairman for Scientific and Medical Affairs, and Director***

Twenty-five years of experience at the National Institutes of Health where he was the Director of the Blood Diseases Program in the National Heart, Lung, and Blood Institute. Dr. Levine has been involved in organizing multicenter, multimillion-dollar programs in stem cell biology and transplantation and cord blood research since its inception.

***Esmail Zanjani, Ph.D., Chairman of Scientific Board***  
***Professor of Medicine/Physiology, Veterans Administration Medical Center, Reno, NV***

World's foremost expert in the field of blood stem cell research and blood stem cell transplantation. Developed the world's only in vivo assay that is capable of determining the ability of blood stem cells to continue producing blood cells for many years after they are transplanted. Dr. Zanjani has pioneered the field of in utero blood stem cell transplantation to cure genetic diseases in the womb. He holds the only FDA Investigational New Drug (IND) application to process cells for in utero transplantation and gene therapy.

#### **NUSTEM TECHNOLOGIES' SCIENTIFIC ADVISORY BOARD**

The Scientific Advisory Board has been established to provide NuStem with the advice and leadership of leading experts in the field of blood banking, tissue transplantation and progenitor cell identification and separation.

**Esmail Zanjani, Ph.D., Chairman**

*Professor of Medicine/Physiology, Veterans Administration Medical Center,  
Reno, NV*

(See above.)

**Joao Ascensao. MD, Ph.D., F.A.C.P.**

*Professor of Medicine and Director, Bone Marrow Transplant Program,  
University of Nevada, Reno*

Dr. Ascensão is a Professor of Medicine, Oncology/Hematology Division, the Director of the Bone Marrow Transplantation Program, and the Associate Chairman for Research in the Department of Medicine at the University of Nevada School of Medicine in Reno, Nevada. He is also the Co-Director of Hematology Research at the Veterans Administration Medical Center in Reno and he has an active grant-supported research program in hematology, stem cell biology, and transplantation.

Dr. Ascensão received a M.D. degree with honors and a Ph.D. degree from the University of Lisbon Medical School in Portugal. He was a Fellow in Clinical Immunology and Immunology at the Memorial Sloan-Kettering Cancer Center in New York where he studied under Dr. Bob Good, the world renowned "father" of bone marrow transplantation.

Upon completion of the Company's current round of funding, NuStem plans to enlarge the Scientific Advisory Board with a series of prominent additions. These plans are a key element in gaining widespread acceptance of the Company and its product in the medical community and in the market place.

#### **X. FINANCIAL INFORMATION**

The Company's income statement and cash flow projections are based on achieving the funding objectives outlined in the Executive Summary. The Company is projecting no gross revenues in year one, but revenues approaching \$300 million in year five. The

Company's revenue, expenses and net income projections are constructed on what the Company believes to be well-founded assumptions for the five-year period.

Key Assumptions used are:

- The number of Collection Centers, and cord blood samples collected at each.
- The number of Transplant Centers, and searches made.
- The number of Internet based searches made.
- Successful matches in correlation to the size of inventory
- Pricing for delivery of a cord blood unit to the Company's clients.
- Staffing requirements in the laboratories as a function of the number of samples processed.
- Laboratory capital expenditures as required by projected capacity requirements.
- Capital set up expenses per employee level.
- Marketing materials expenditures as they relate to sales or other dependent factors.

Appendix G is a financial model available under separate cover.

#### USE OF PROCEEDS

The net proceeds of the Company's initial \$10 million funding round are expected to be used as follows (amounts are estimates and in \$ millions)

• Inventory buildup .....	\$0.52
• Collection Center expansion .....	\$0.40
• Processing and storage of samples .....	\$0.77
• Development of databases and modules .....	\$0.93
• Capital expenditures .....	\$1.51
• Salaries and wages .....	\$1.77
• Operations and overhead .....	\$2.48
• Total use of funds .....	\$8.38

The use of proceeds outlined above is subject to change based upon actual rather than estimated expenses and changes in business conditions. Pending such use of the proceeds, as described above, the net proceeds will be invested in bank deposits and short term investment grade securities, including government obligations and money market instruments.

## CAPITAL STRUCTURE

As of June 30, 2001 the capital structure of the Company was as summarized in the table below. A detailed description of the Company's ownership structure can be found in Appendix H

<b>Company Ownership</b>	<b>Outstanding</b>	<b>Number of Holders</b>
<b>Common Stock</b>	<b>12,204,400</b>	<b>93</b>
<b>Warrants</b>	<b>517,000</b>	<b>66</b>

Warrants to purchase the Company's Common Stock are currently exercisable at \$5 per share.

Note 1. Included in this amount are 7,700,000 shares of Common Stock that have been issued to Company Management, Members of the Board, and Members of the Advisory Board at an average price per share of \$0.001

## NuStem Technologies, Inc.

### Financial Projections

#### Condensed Statement of Operations

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 5</b>
<b>Revenue</b>		\$19,890,000	\$89,880,000	\$199,485,000	\$297,345,000
<b>Cost of revenue</b>	45,000	1,740,600	6,267,600	13,050,000	18,936,000
<b>Gross margin</b>	(45,000)	18,149,400	83,612,400	186,435,000	278,409,000
<b>Operating expenses</b>					
Processing & collections	1,676,144	7,649,945	13,416,241	17,656,403	22,244,315
Sales & marketing	1,362,037	9,984,476	18,825,971	29,840,417	41,457,852
General & administrative	4,521,633	7,169,786	11,569,865	16,428,419	23,263,600
<b>Total operating expenses</b>	<b>7,559,814</b>	<b>24,804,207</b>	<b>43,812,077</b>	<b>63,925,239</b>	<b>86,965,767</b>
<b>Profit (loss) from operations</b>	<b>(7,604,814)</b>	<b>(6,654,807)</b>	<b>39,800,323</b>	<b>122,509,761</b>	<b>191,443,233</b>
<b>Interest income/(expense)</b>	<b>17,643</b>	<b>31,142</b>	<b>12,004</b>	<b>281,066</b>	<b>1,488,668</b>
<b>Net profit (loss) before income taxes</b>	<b>(7,587,171)</b>	<b>(6,623,665)</b>	<b>39,812,327</b>	<b>122,790,827</b>	<b>192,931,901</b>

Taxes			11,157,620	47,418,332	33,279,759
<b>Net profit (loss) from operations</b>	<b>(\$7,587,171)</b>	<b>(\$6,623,665)</b>	<b>\$28,654,707</b>	<b>\$75,372,495</b>	<b>\$159,652,142</b>

**Condensed Statement of Cash Flows**

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 5</b>
<b>Cash flows from operating activities</b>					
Net profit (loss)	(\$7,587,171)	(\$6,623,665)	\$28,654,707	\$75,372,495	\$159,652,142
Changes in operating assets and liabilities					
Inventory	(840,000)	(11,772,800)	(23,228,800)	(28,267,200)	(23,303,200)
<b>Net cash used in operating activities</b>	<b>(8,427,171)</b>	<b>(18,396,465)</b>	<b>5,425,907</b>	<b>47,105,295</b>	<b>136,348,942</b>
<b>Cash flows from investing activities</b>					
Acquisition of property and equipment	(1,526,000)	(1,943,500)	(3,202,500)	(3,540,000)	(3,035,000)
<b>Net cash used in investing activities</b>	<b>(1,526,000)</b>	<b>(1,943,500)</b>	<b>(3,202,500)</b>	<b>(3,540,000)</b>	<b>(3,035,000)</b>
<b>Net increase (decrease) in cash</b>	<b>(9,953,171)</b>	<b>(20,339,965)</b>	<b>2,223,407</b>	<b>43,565,295</b>	<b>133,313,942</b>
Net investment	13,950,000	18,600,000			
<b>Net cash at end of period</b>	<b>\$3,996,829</b>	<b>\$2,256,864</b>	<b>\$4,480,271</b>	<b>\$48,045,566</b>	<b>\$181,359,508</b>

## **APPENDICES**

### **A. RISK FACTORS**

In addition to the other information in this Business Plan, the following risk factors should be considered carefully in evaluating the Company with regard to possible investment.

#### ***Development Stage Company; History of Losses; Uncertain Profitability***

The Company is a development stage company with no sales of its proposed product - units of cord blood stem cells. Consequently, the Company has experienced operating losses and negative operating cash flow since its incorporation in 2000. At June 30, 2001, NuStem had an accumulated deficit of approximately \$650,000

The Company will have difficulties normally encountered by a new enterprise in its development stage, many of which are beyond the Company's control, and there is nothing at this time upon which to base an assumption that the Company's proposed business plans will either materialize or prove successful.

The development of NuStem's cord blood bank will require the commitment of further resources to commercialize its products. There can be no assurance NuStem will achieve significant commercial revenues or profitability in future.

#### ***Uncertainty of Market Acceptance***

Although the markets for blood stem cells are large, actual sales of the Company's products may be much less than the potential of these markets. Market acceptance of the Company's products will depend in large part upon the Company's ability to demonstrate the advantages and cost effectiveness of its products.

There can be no assurance that the Company's products will achieve full market acceptance. Failure to achieve market acceptance would have a material adverse effect on the Company business, financial condition and results of operations.

#### ***Limited Sales, Marketing and Distribution Experience***

The Company, as a legal entity, has no experience in sales, marketing and distribution. The Company currently intends to sell products throughout the world to Transplant Centers and Research Laboratories. Therefore, NuStem plans to expand its human resources to include dedicated marketing and sales staff following completion of its funding plans.

There can be no assurance that the Company will be able to build such a marketing and sales team, that establishing such a team will be cost effective, or that the Company's sales and marketing efforts will be successful.

## ***Competition***

Given the dearth of supply of stem cells, the limitations of bone marrow collection, and the undercapitalized, not-for-profit, resource constrained nature of current competition, it is unlikely that existing stem cell banks will present a serious competitive threat to the Company.

However, success by NuStem could foster competition from larger, multi-product competitors with far greater resources than NuStem. Therefore, new competitors may arise with the objective of capturing the dominant role in cord blood banking and, to that end, develop resource intense strategies to place NuStem's existence in peril.

There is no assurance that NuStem will be able to effectively compete with such competitors, should they materialize. Competitive developments could have a material adverse effect on NuStem's business, financial condition and results of operations.

## ***Technological Changes Resulting in Product Obsolescence, and Dependence on a Single Technology***

The initial focus on cord blood banking and its attendant technologies makes the Company vulnerable to the development of superior competing therapies and/or changes in technology which could eliminate the demand for the Company's products.

Furthermore, while the Company believes there will be continuous, robust growth in the foreseeable future in demand for the Company's therapies and the desirability of those products, the Company's products could be rendered obsolete as a result of future innovations in therapies for the diseases NuStem addresses. Such developments would have a material adverse effect on the Company's business, financial condition and results of operations.

## ***Dependence on Voluntary Donors, Collection Centers, Transplant Centers, and Research Laboratories***

The ethics and practices of the medical industry present special challenges to the construction of durable commercial relationships.

In the event that the supply of umbilical cords is interrupted for any reason, arrangements with other Collection Centers, and their potential donor/mothers, to reinstate the Company's access to cord blood stem cells may prove unsuccessful. Alternative supplies may not be immediately available in sufficient volume to meet the Company's needs.

Similarly, in the event that the demand for cord blood stem cells is interrupted due to reduced or severed relationships with Transplant Centers and Research Laboratories, arrangements to reinstate the Company's ability to place cord blood stem cells may prove unsuccessful. Alternative demand may not be available in sufficient volume within the time required to meet the Company's needs. Any interruption in supply or demand could have a material adverse effect on the Company.

### ***Ability to Manage Growth***

NuStem intends to pursue a strategy of rapid growth. The Company plans to significantly expand marketing and sales, and to devote substantial resources to building the largest and most genetically diverse cord blood bank in the world. There can be no assurance that NuStem will be able to attract qualified personnel or successfully manage such expanded operations. The failure to properly manage growth could have a material adverse effect on the Company.

### ***Lack of Intellectual Property Protection***

The Company does not yet have defensive intellectual property by which to defend against competitive threats based on copying the exact way in which it conducts its business and may not obtain such protection.

### ***Risk of Product Liability***

NuStem faces an inherent risk of exposure to product liability claims in the event that the use of its products is alleged to have resulted in harm. Before sale of cord blood units begins, the Company will attempt to arrange a general insurance policy that includes coverage for product liability claims.

There can be no assurance that the Company will not be subject to product liability claims, that any claim will be successfully defended, or if the Company is found liable, that the claim will not exceed the limits of the Company's insurance, should NuStem have such coverage, at the time of final legal judgment.

There is no assurance NuStem will be able to obtain product liability insurance on commercially reasonable terms or at all. Consequently, a product liability claim or other claim with respect to uninsured liabilities could have a material adverse effect on the Company's business, financial condition and results of operation.

### ***Need for Additional Capital***

NuStem's liquidity and capital requirements following completion of its current round of funding will depend upon numerous factors including increasing cord blood unit acquisition, laboratory and administration premises and fitting out costs, expansion of the Company's marketing and sales team, and future acquisitions or investments.

There is no assurance that NuStem will not need to raise additional capital or that capital will be available on acceptable terms, if at all. Future financings will result in dilution to holders of the Company's equity securities.

### ***Dependence on Key Personnel***

The Company is highly dependent on the principal members of its executive officers and certain scientific advisors. The loss of the services of any of the Company's key personnel

could have a material adverse effect on the Company.

## **B. HUMAN RESOURCES**

### SENIOR MANAGEMENT

***Mark T. Cullen, M.D.***  
***Chairman of the Board***

Dr. Mark T. Cullen is the Company's founder. He is also the President, CEO and Director of SulphCo, Inc. Reno, Nevada, and a Director of Adrian Oil and Gas, Inc., Geneva, Switzerland.

Dr. Cullen received his B.S. degree in Chemistry in 1979 and received his M.D. degree in 1982. Subsequently, Dr. Cullen did post graduate work at Yale University, School of Medicine, first as a post-doctoral Research Fellow, then as a Resident and Fellow in the Department of Obstetrics and Gynecology.

Following his work at Yale School of Medicine, Dr. Cullen was director of The Fetal Diagnostic Program at the University of Florida at Jacksonville and Director of Obstetrics and Gynecology, Florida Hospital. Dr. Cullen has also served as Associate Clinical Professor at the University of Nevada and Medical Director of Obsterix, Inc. Nevada. (NASD). Dr. Cullen has authored 26 peer reviewed papers and contributed to several chapters in medical books. He is a member of Sterling's Who's Who. Dr. Cullen is certified by the American Board of Obstetrics and Gynecology and he has a sub-specialty certification in Maternal-Fetal Medicine

Dr. Cullen has established a professional network of obstetricians located at medical centers and hospitals worldwide. This obstetrical network is an integral part of NuStem's cord blood Collections Centers strategies.

***Robert P. Jenks***  
***President and Chief Executive Officer***

Mr. Jenks is founder and CEO of Intelesis Technologies Corporation in San Diego, CA. He has broad senior corporate and management experience with commercial and government organizations and programs and more than 20 years technical experience in: system design, system integration, management of software development, data base development, test and evaluation, IV&V and ILS. Mr. Jenks is a retired Naval officer and graduate of the United States Naval Academy. He also has earned an MBA and is an excellent communicator and team leader.

***Alan Levine, Ph.D.***  
***Chief Scientific Officer***

Dr. Levine received a B.S. degree from Monmouth University in 1966 and a Ph.D. in chemistry from the University of Delaware in 1971. After a post-doctoral research associateship at the University of Kansas, Department of Pharmaceutical Chemistry, in

1972 he began his twenty-five year career at the National Institutes of Health (NIH), the world's leading biomedical research institution. At the NIH, after four years of laboratory research in the area of hematology and sickle cell anemia, Dr. Levine moved into a position where he eventually became the Director of the Blood Diseases Program in the NIH's National Heart, Lung and Blood Institute. In this capacity, Dr. Levine was responsible for directing the federal government's overall efforts in hematology research.

At the NIH, Dr. Levine was responsible for a \$100 million per year basic and clinical biomedical research program. He participated in the formulation of overall program policy and development relating to hematology research. He served as the Institute's liaison to NIH committees, to professional and lay organizations, and committees dealing with hematology and blood diseases in order to help coordinate federal, academic, and private research efforts. His responsibilities also included developing new research programs and directing, reviewing, and evaluating national and international biomedical research programs encompassing basic, applied, and clinical research in the areas of hematology and blood diseases, especially in blood stem cell biology and transplantation.

Examples of national and international scientific programs developed under Dr. Levine's direction include: Genes Determining Stem Cell Self-Renewal and Commitment; Pathobiology of Bone Marrow Suppression in AIDS (\$10 million/5 years); Stem Cells for Transplantation: Blood Cells for Transfusion (\$9 million/4 years); *In Utero* Stem Cell Transplantation for Genetic Diseases (\$6.0 million/4 years); Basic Research in Hematopoietic Stem Cell Biology (\$3.4 million/4 years); Hematologic Consequences of HIV Infection of Stem Cells (\$8.1 million/5 years); Human Stem Cell Sources and Transplantation Biology (with a focus on cord blood, \$6.4 million/4 years); Clinical Trial of Bone Marrow Transplantation for Sickle Cell Disease; and Specialized Centers of Research in Hematopoietic Stem Cell Biology (the NIH flagship program in basic and clinical research on cord blood and other stem cells, \$52.8 million/10 years).

Dr. Levine organized and presided over numerous Federal conferences and workshops including; NIH Workshop on the Standardization of *In Vitro* Hematopoietic Culture Techniques, NIH Symposium on the Stromal Regulation of Hematopoiesis, NIH Workshop on Hematopoietic Stem Cell Purification and Biology, NIH Working Group on Butyrate Therapy for Thalassemia and Sickle Cell Anemia, NIH Workshop on *In Utero* Hematopoietic Stem Cell Transplantation for Genetic Diseases, and the First and Second International Conferences on *In Utero* Hematopoietic Stem Cell Transplantation and Gene Therapy.

Dr. Levine is credited with playing a major role in developing the field of *in utero* stem cell transplantation and gene therapy and umbilical cord blood research and he has received numerous honors and awards in recognition of his success in directing national multicenter programs in hematology research. Dr. Levine is a member of the American Society of Hematology, the International Society for Experimental Hematology, the American Association of Blood Banks, and the American Association for the Advancement of Science. Dr. Levine is listed in Who's Who in Medicine and Healthcare, American Men and Women of Science, Who's Who in Science and Engineering, Who's Who in the World, Who's Who in Government, Who's Who in the East, and Who's Who

Among Human Services Professionals. Dr. Levine has published numerous peer review articles and has edited several books on blood stem cell technology.

***Mark N. Steele***  
***Chief Information Officer***

Mr. Steele (B.S., M.S. Computer Science) has thirty-five years of experience in systems engineering, test and evaluation, operational training, systems analysis, systems programming, project management, database development and computer science instruction. He has taught programming languages and application development at several colleges. In addition, Mr. Steele is an experienced network engineer and integrator.

***Raymond S. Plevyak***  
***Chief Financial Officer***

Mr. Plevyak (B.S., MBA) has over 20 years of financial management experience with banking, services, product, and manufacturing-based firms. He is an experienced designer, integrator, and manager of a variety of systems for financial reporting, budgeting and strategic planning, general accounting, and cash management. Experienced in due diligence, planning, and venture funding of firms in all stages ...including start-ups, IPO candidates, mid- and large-capitalization companies. Also experienced in managing and training corporate and divisional accounting staffs.

**OUTSIDE MEMBERS OF THE BOARD OF DIRECTORS**

***Hyman P. White***

Mr. White is Executive Chairman of the Board of Advanced DNA Technologies, Inc., and Founder and President of Organ Transport Systems, Inc. Both early stage companies with a combined total market projected to be \$3.5 billion by the year 2005. He has over 30 years of marketing, sales, executive management and financial experience in the medical field.

Mr. White is widely experienced in all phases of new technology development. He has developed international strategic alliances and partnerships in marketing, manufacturing and distribution. Mr. White has also established relationships with business and government leaders in North America, Asia, Europe, Africa, and the Middle East. He has extensive international speaking experience.

Prior to his current responsibilities, which began three years ago, Mr. White was Vice President of Corporate Development for Immortality, Inc., an internet service provider. Previously, Mr. White developed the corporate strategies for two companies, which treated infectious medical waste at the hospital in an earth friendly fashion. Earlier Mr. White worked with Xanadu Securities as regional manager financing large hospital equipment purchases. At that time, he also did the master medical plans for the countries of Indonesia and Malaysia.

The first entries into the medical markets for Mr. White after graduation from university were with the Hyland Division of Baxter-Travenol and the urological surgical division of C.R. Bard. With the introduction of CT Scan and MRI technology, Mr. White combined leasing and securities sales through Xanadu Securities for large systems acquisitions.

Mr. White has raised over \$120 million in capital investments for start-up ventures and corporate growth. He led a team in the development of master health care plans for Malaysia and Indonesia. He has developed domestic and international marketing networks with market values exceeding \$50 million. Mr. White has been responsible for acquiring approvals for new technologies domestically and in the European Community.

Mr. White's schooling began at Kilgore College with two years of pre-med work. It was interrupted when Mr. White was drafted immediately following the assassination of John F. Kennedy. Thereafter, he was a member of the US Air Force in top-secret work for four years. Mr. White then earned a degree in marketing and finance from the University of North Texas.

#### SCIENTIFIC ADVISORY BOARD

***Esmail Zanjani, Ph.D.***

Dr. Zanjani received a B.A. in 1964, an M.S. in 1966, and a Ph.D. in 1969 from New York University. He then had further post-doctoral training at NYU under the direction of Professor Albert Gordon, a renowned hematologic physiologist.

Dr. Zanjani joined the faculty Mt. Sinai School of Medicine in New York in 1970. In 1977, he became a Professor of Medicine and Physiology at the University of Minnesota School of Medicine and a Research Career Scientist at the Veterans Administration (VA) Medical Center in Minneapolis. In 1987, Dr. Zanjani was appointed Professor of Medicine and Physiology at the University of Nevada School of Medicine in Reno, and Senior Research Career Scientist at the Reno VA Medical Center.

Dr. Zanjani has been a member and chairman of many NIH, American Society of Hematology, and Veterans Administration peer review, human subjects, and advisory committees. He has served on the editorial boards of scholarly journals such as Stem Cell, Blood, Journal of Cell Cloning, Journal of Laboratory and Clinical Medicine, and the Journal of Pathobiology. He is currently the Associate Editor of two journals, Experimental Hematology and the Journal of Hematotherapy and Stem Cell Research.

Dr. Zanjani has been the recipient of numerous NIH and VA grants. He currently holds several NIH research grants, including the coveted NIH MERIT Award, which is bestowed to only the most honored scientists. He is a member of the American Society of Hematology, the International Society for Experimental Hematology, the Central Society for Clinical Research, the European Hematology Society, and the American Society of Gene Therapy. Dr. Zanjani was recently elected President of the International Society for Experimental Hematology for a term beginning in 2002.

Dr. Zanjani is a world-renowned expert in blood stem cell biology and he has led the

development of the field of *in utero* stem cell transplantation and gene therapy as a means for curing genetic diseases prior to birth. He developed the protocols for *in utero* stem cell transplantation in humans and holds the only IND for *in utero* gene therapy granted by the FDA.

Dr. Zanjani has developed the fetal sheep model for studying human blood cell development and transplantation. This is the world's only large animal model for studying human blood cell formation and for performing assays for the blood stem cell. He has written over 200 publications in scholarly journals, almost 50 book chapters, and has edited several books.

***João L. Ascensão, M.D., Ph.D., F.A.C.P.***

Dr. Ascensão is a Professor of Medicine, Oncology/Hematology Division, the Director of the Bone Marrow Transplantation Program, and the Associate Chairman for Research in the Department of Medicine at the University of Nevada School of Medicine in Reno, Nevada. He is also the Co-Director of Hematology Research at the Veterans Administration Medical Center in Reno and he has an active grant-supported research program in hematology, stem cell biology, and transplantation.

Dr. Ascensão received a M.D. degree with honors and a Ph.D. degree from the University of Lisbon Medical School in Portugal. He was a Fellow in Clinical Immunology and Immunology at the Memorial Sloan-Kettering Cancer Center in New York where he studied under Dr. Bob Good, the world renowned "father" of bone marrow transplantation. He completed internal medicine training and received a fellowship in Oncology/Hematology at the University of Minnesota School of Medicine.

From 1981-1984, Dr. Ascensão was on the faculty of the University of Minnesota School of Medicine. From 1984-1989, he was an Associate Professor of Medicine and Associate Director of the Bone Marrow Transplant Program at New York Medical College in Valhalla, New York. From 1989-1991, Dr. Ascensão was an Associate Professor of Medicine and Laboratory Medicine, the Director of the Bone Marrow Transplant Program, and Co-Director of the Connecticut Cancer Institute at the University of Connecticut Health Center in Farmington.

Dr. Ascensão is board certified in internal medicine and he has sub-specialty certifications in Medical Oncology and in Hematology. He is also certified by the European Board of Medical Oncology. He is a member of the American Association for Cancer Research, American Society of Hematology, American Federation for Medical Research, International Society for Experimental Hematology, American Society of Clinical Oncology, American Association of Immunology, Portuguese Society of Immunology, European Society for Medical Oncology, Clinical Immunology Society, American Society for Blood and Marrow Transplantation, American Association of Blood Banks, International Society for Hematotherapy and Graft Engineering, and he is a Fellow of the American College of Physicians.

Dr. Ascensão is the author of over 61 peer reviewed articles, 25 book chapters and

medical review articles, and he is the editor of three books on cancer, blood diseases, stem cell biology and transplantation. Additionally, Dr. Ascensão has organized numerous national and international scientific conferences and symposia in various aspects of stem cell biology and transplantation. Dr. Ascensão received a Fellowship Award from the Instituto de Alta Cultura- Ministry of Education, Lisbon, Portugal, a Fellowship Award from the J.M. Foundation, a Research Career Development Award from the US Veterans Administration, the Charles H. Revson Foundation Award, and a NIH Young Investigator Award. Dr. Ascensão is currently the Treasurer of the Nevada Oncology Society. He has held elected offices in the International Society for Experimental Hematology including the Chairman of the Scientific Program Committee, Chairman of the Membership Committee, Chairman of the Nominating Committee, Councilor and the Board of Trustees.

Dr. Ascensão has served on the Editorial Board of the journal, Experimental Hematology, and he served as the Chairman of the Hematology Merit Review Board of the Department of Veterans Affairs in Washington, DC. Dr. Ascensão has served on several NIH peer review committees throughout his career and has served as a peer reviewer for the following medical journals: Blood; Journal of Cell Physiology; British Journal of Cancer; Cancer; Journal of Clinical Investigation; and, Clinical Immunology & Immunopathology.

### **C. EXTERNAL ADVISORS**

#### ***Legal Advisors***

Jeffrey L. Grausam  
Morgan, Lewis and Bockius, LLP  
300 South Grand Avenue, 22<sup>nd</sup> Floor  
Los Angeles, CA 90071-3132

#### ***Accountants***

Phil Smith  
Considine and Considine  
1501 5<sup>th</sup> Avenue, Suite 400  
San Diego, CA 92101-3297

#### ***Bankers***

Wells Fargo Bank

### **D. DISEASES TREATED WITH UMBILICAL CORD BLOOD STEM CELLS**

#### **MALIGNANCIES**

Acute-Lymphocytic Leukemia (ALL)  
Acute Myelogenous Leukemia (AML)  
Acute Nonlymphocytic Leukemia (ANL)  
Chronic Lymphocytic Leukemia (CLL)  
Chronic Myelocytic Leukemia (CML)

Ewing Sarcoma  
Germ Cell Tumors  
Hodgkin's Disease  
Juvenile Myelomonocytic Leukemia (JML)  
Myelodysplastic Syndrome (MDS) Multiple Myeloma  
Neuroblastoma  
Non-Hodgkin's Lymphoma  
Rescue Therapy (does not treat the disease directly but “rescues” the patient from the ultra-high, lethal doses of chemotherapy or radiation)  
Brain Tumors  
Breast Cancer  
Ovarian Cancer  
Small-cell Lung Cancer  
Testicular Cancer

#### BLOOD DISEASES

Aplastic Anemia  
Sickle Cell Anemia  
Amegakaryocytic Thrombocytopenia (AMT)  
Blackfan-Diamond Anemia  
Congenital Cytopenia  
Evan Syndrome  
Fanconi's Anemia  
Kostmann's Syndrome  
Thalassemia

#### GENETIC DISEASES OF METABOLISM

Adrenoleukodystrophy  
AL Amyloidosis  
Bare-Lymphocyte Syndrome  
Dyskeratosis Congenita  
Familial Erthrophagocytic Lymphoistiocytosis  
Gaucher's Disease  
Gunter Disease  
Hunter Syndrome  
Hurler Syndrome  
Inherited Neuronal Ceroid Lipofuscinosis  
Krabbe Disease  
Langerhans'-cell Histiocytosis  
Lesch-Nyhan Disease  
Leukocyte Adhesion Deficiency  
Osteopetrosis

#### IMMUNODEFICIENCY DISEASES

Severe Combined Immunodeficiency Disease (SCID)  
Chronic Granulomatous Disease (CGD)  
Wiskott-Aldrich Syndrome  
X-linked Lymphoproliferative Disease (XLP)

#### OTHER DISEASES (EXPERIMENTAL)

Solid tumors  
AIDS  
Multiple Sclerosis  
Rheumatoid Arthritis  
Systemic Lupus Erythematosus

### **E. CORPORATE HISTORY**

#### ***Lifecord, Inc.***

Lifecord, Inc. was incorporated in Nevada on February 12, 1997. The company was established by Dr. Mark Cullen as a preliminary vehicle for the operation of a cord blood stem cell collection and testing facility. Lifecord, Inc. issued no stock, had no shareholders and remained largely inactive. No business operations, employees, or facilities were initiated under this name.

#### ***Saratech, Inc.***

Saratech, Inc. was incorporated in Nevada on November 21, 1995. The company was selected to be the original vehicle for NuStem's business operations because of its existing base of over 400 shareholders.

Saratech changed its name to NuStem Technologies, Inc. on May 20, 2000. 11,350,000 shares of stock were issued to various individuals for services provided. Thereafter, a private placement was conducted in July 2000 whereby 485,000 shares of common stock were sold.

In September 2000, it was determined that the large shareholder base of Saratech, Inc. was not required. At directors' and stockholders' meetings held on September 25 and 26, 2000, it was agreed to form a separate entity, issue adjusted stock amounts to founders and key principals of Saratech, Inc. in the new entity, issue matching stock to investors, under the July, 2000 private placement, in the new entity, and continue the business of cord blood banking with the new entity, NuStem Technologies, Inc. New investors would receive stock in the new entity. The company's name would then revert to Saratech with the new Company taking the name of NuStem Technologies, Inc.

#### ***NuStem Technologies, Inc.***

NuStem Technologies, Inc. was incorporated in Nevada on September 28, 2000. The Company has an authorized capital of 23,000,000 shares of common stock, par value

\$0.001 per share, and 2,000,000 shares of preferred stock, par value \$0.001 per share. As of June 30, 2001, there were a total of 11,687,400 (517,000 warrants not included) shares of common stock issued and outstanding, held by 27 founders and 66 outside investors. The 66 outside investors are made up of the original private placement investors of Saratech / NuStem, together with investors who subscribed, to the July, 2000 private placement, following the incorporation of the new NuStem corporation.

In April 2001, a revised private placement memorandum was forwarded to all outside investors. All investors were offered, in addition to their previous investment, share purchase warrants totaling half of their original investment. An additional 100,000 Units, consisting of one share and one half-share purchase warrant were also authorized under the private placement memorandum. The share purchase warrants are for a two year period, expiring April 30, 2003, and allow the purchase of additional stock in NuStem at the price of \$5.00 per share.

## **F. GLOSSARY**

### **Adult Stem Cells**

A stem cell that has not been derived from an embryo or fetus. Stem cells that are obtained from the umbilical cord of a newborn baby are considered adult stem cells.

### **Allogeneic**

Taking bone marrow or cord blood cells from a healthy donor, other than the recipient, whose blood type and HLA factors match closely enough to the recipient for the transplant to be successful.

### **Anemia**

Low red blood cell counts that causes a deficiency in the ability of blood to carry oxygen throughout the body.

### **Aplastic Anemia**

A condition where the bone marrow is unable to make blood cells.

### **Autologous**

Related to self; derived from the same individual. In an autologous bone marrow or cord blood stem cell harvesting, the cells are taken from the individual to be used by that person at a later date in the event of disease requiring stem cell rescue.

### **Blastocyst**

A four day old embryo consisting of a spherical clump of about 40 cells; the outer layer develops into the placenta and the inner layer of embryonic stem cells are capable of developing into all the cells and tissues of the body.

### **Blood Bank**

A stored supply of human material or tissues (blood) for future use.

### **Blood Stem Cells**

A blood precursor cell. Produces all types of blood cells in the body.

**Bone Marrow**

Soft spongy material found in the cavities of the bones. Contains stem cells that produce blood cells for the body.

**Cancer**

A cellular tumor which, left untreated, can spread and cause death.

**Chemotherapy**

Drug treatment for cancer and other disorders. Aggressive chemotherapy can kill the stem cells that make all of the body's blood cells.

**Cryogenic**

Pertaining to or causing the production of low temperatures (frozen). Traditional methods use liquid nitrogen to create and maintain the low temperatures.

**Cryopreservation**

The maintaining of the viability of cells (blood), tissue, or organs by storing them at very low temperatures.

**Differentiate**

When a cell divides into two, more specialized cells, which are different from the original cell. A cell that has differentiated is said to be committed to making more specialized cells.

**DNA**

Abbreviation for deoxyribonucleic acid; the genetic material that makes up our genes.

**Embryo**

In a human, the developing baby is referred to as an embryo from the time of conception (fertilization of the egg by a sperm cell) until eight weeks of gestation.

**Embryonic Stem Cell**

The pluripotent stem cells that are contained in a four day old embryo.

**Gene**

The basic unit of heredity. A gene contains the sequence of DNA that encodes the instructions for cell operation and replication.

**Genetic Disease**

Disease caused by abnormalities in the gene structure of the body's cells. Often causes various diseases due to improper cell operations.

**Graft-Versus-Host-Disease (GVHD)**

A transplant complication resulting from the reaction between the immune system cells of a stem cell transplant recipient (host) and donor (graft). If the donor stem cells

perceive the body they were implanted in as hostile tissue, the new immune system produced by the stem cells will attack the body of the recipient.

### **HLA**

Human Leukocyte Antigen: Special identifying markers that are on all cells of the body. HLA markers must match fairly closely between donor and patient, or rejection may occur. HLA-identical means that two people have the same markers as each other (this can occur in twins or brothers and sisters).

### **Hematopoietic**

Refers to an agent or process that affects or promotes the formation of blood cells.

### **In utero therapy**

The prenatal treatment of diseases in a fetus while it is still in the womb or uterus.

### **Leukemia**

"Liquid" tumors. A progressive, malignant disease of the blood-forming NUSTEM TECHNOLOGIES, INC. A-27 organs that causes a type of white blood cell to grow uncontrollably. Names are given depending on which type of white blood cell is abnormal. More sudden types include Acute Lymphoblastic Leukemia (ALL), Acute Non- Lymphocytic Leukemia (ANLL) and Acute Myelocytic Leukemia (AML). More gradual types include Chronic Granulocytic Leukemia (CGL), Chronic Myelogenous Leukemia (CML), Chronic Myelomonocytic Leukemia (CMML) and Chronic Lymphocytic Leukemia (CLL).

### **Lymphomas**

Tumor of the white blood cells called lymphocytes. Different types include Hodgkin's (Follicular), Non-Hodgkin's (NHL), and Small Lymphocytic Lymphoma.

### **Myeloma**

Tumor of one of the types of white blood cells.

### **Platelets**

Cells in the blood that are assist in blood clotting.

### **Pluripotent**

Cells that can differentiate or transform themselves into other types of cells.

### **Relapse**

A disease that returns in spite of treatment.

### **Replicate**

The process whereby a stem cell divides into two identical stem cells.

### **Severe Combined Immunodeficiency (SCID)**

Immune disease where immune cells and special immune proteins needed to fight disease are missing. Untreated, many will die at a young age.

**Sickle Cell Disease**

Inherited blood disease with red blood cells shaped like sickles (crescents).

**Thalassemia**

Inherited blood disease resulting in insufficient production of hemoglobin, the red, oxygen-carrying protein in red blood cells; severe anemia results; includes alpha and beta thalassemia.

**Umbilical Cord**

The flexible, cordlike structure connecting the fetus at the navel with the placenta. It contains two umbilical arteries and one vein that nourish the fetus and removes the wastes.

**Umbilical Cord Blood**

Blood contained in the umbilical cord at the time of birth.

**G. FINANCIAL PROJECTIONS**

See document provided under separate cover.