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SURGICAL MEDICAL EQUIPMENT BUSINESS PLAN

BIORING SA

Executive Summary

Bioring SA produces niche-specific rings for cardiac valve repair. It has its main office in Lonay (CH) and maintains a small manufacturing and assembly plant in Lonay, Switzerland. Its products are to be sold through single or multiple distributors.

- This business plan is part of our regular business planning process. We revise this plan every quarter and it is placed under change control.
- In the next two years we intend to develop two new products and to improve revenues.
- Our keys to success and critical factors for the next year are, in order of importance:
    - Product approval: CE mark.
    - Sales to dealers in volume.
    - Financial control and cash flow planning.

- **Objectives**

1. To give Bioring SA the market presence needed to support marketing and sales goals, and to attract distributors of new Bioring products.

2. To develop two new Bioring products by the end of year four.
3. To increase sales to reach $312,500 monthly sales by the end of year two, and $830,000 monthly by the end of month eight of year three.
4. To control expenditures to serve the best dividends to the shareholders.

- **Mission**

Bioring SA addresses the surgical repair techniques which are implemented in open heart surgery. This business is based on a product owned by the company, which is a cardiac implant more precisely called "Kalangos Biodegradable Ring."

We intend to make enough profit to generate a fair return for our investors and finance continued growth and development in quality products. We also maintain a friendly, fair, and creative work environment, which respects diversity, new ideas, and hard work.

Market Analysis Summary

The market for annuloplasty rings is worth an estimated $250 million at end-user value in 2001, and is projected to grow at 3% per year according to professional forecasts published in specialized issues in 2000. Sources included The European Heart Institute and The National Center for Health Statistics in the USA.

1. **Market Segmentation**

The rings for annuloplasty belong to the heart valve repair industry.

We prefer segmentation by addressed patients. This incorporates some of the product type differences, but in a more practical sense:

- The pediatric market, which is a potential market of 40,000 rings implanted per year.
- The adult market, which is a potential market of 200,000 rings implanted per year.

MARKET ANALYSIS							
		YEAR 1	**YEAR 2**	**YEAR 3**	**YEAR 4**	**YEAR 5**	
Potential Customers	Growth						CAGR
New-born and infant market	0%	2,000	6,000	10,000	14,000	18,000	73.21%
Adult market	0%	2,000	10,000	14,000	20,000	22,000	82.12%
Other	0%	0	0	0	0	0	0.00%
Total	77.83%	4,000	16,000	24,000	34,000	40,000	77.83%

2. **Target Market Segment Strategy**

- **Market Needs**

We understand that our target market needs more than just standard rings covered with a polyester mesh. The need grew out of the special needs of neonate cardiac surgery. Our target customer wants to have this new possibility which they consider as a major improvement. There is a need for high-quality prostheses which solves patient and surgeon problems. We don't just sell a ring; we sell a new concept and a new surgical procedure.

- **Market Trends**

Our market has finally grown towards more sophisticated techniques of valve repair, where the surgeon will try to repair a portion a faulty valve. In the past years, he would have replaced the total valve. Fine repair of cardiac valve is the new trend.

- **Market Growth**

According to The European Heart Institute, (Cardiovascular Device Update, August 98, page 2) the number of congenital heart defects treated in Europe in 1995 represented 24,400 procedures, which represent a rate of 48 surgical procedures per million. In 2002, it is projected to perform

28,000 surgical procedures (50 procedures per million). This market is growing at a annual rate of 1.9%.

3. Industry Analysis

A recent article published in Cardiovascular Device Update, (December 2000), shows that the European and the U.S. market are practically the same size. The same issue of this paper indicated that the present potential U.S. market for cardiac abnormalities repairs amounted $215 million per year, and that the congenital heart defects repair amounted for $149 million per year.

- **Industry Participants**

The major players in this industry are international companies. It is a concentrated industry in which there are a few major players.

We are mentioning: Baxter Corporation (U.S.), Boston Scientific (U.S.), Cryolife (U.S.), Edwards Corporation (U.S.), Guidant (U.S.), Medtronic (U.S.), St Jude Medical (U.S.), Sulzer Medica (Switzerland).

- **Distribution Patterns**

Distribution channels are of two types:

- Distribution through a national dealer.
- Distribution through a large multi-national company.

The cost of marketing a new class III device is becoming a serious barrier to enter a market. For Bioring type of company, the best choice is to deal through national dealers in Europe and a major company in USA.

- **Competition and Buying Patterns**

In the high-end specialty market, particularly in our niche, features are very important. Our target customer is not making selections based on price. The high-tech, innovative aspect, the easy-to-implant aspect, the reduced time of procedure, the anatomical shape, the physiological process and the clinical results are more important than pricing.

- **Main Competitors**

In the field of cardiac surgery prostheses, the general trend is to develop anatomical and physiological mimetic implants. The ergonomic of the implant is also important.

In the field of pediatric surgery, as previously mentioned, there is no real competitor. Therefore the strategy of the company is to enter the market together with a well-known market leader, to avoid to be considered as a weak company by the market leaders.

Financial Plan

The financial picture is quite encouraging. Sales are projected to start slowly, but this is due to the necessity of receiving CE mark. We need a second round of financing in April 2000 to start the sales on the market. The company has financed all machinery and tools and does not have any credit line. The original investors have been financing the development

1. **Important Assumptions**

The financial plan depends on important assumptions, most of which are shown in the following table.

GENERAL ASSUMPTIONS			
	YEAR 1	**YEAR 2**	**YEAR 3**
Plan Month	1	2	3
Current Interest Rate	6.00%	6.00%	6.00%
Long-term Interest Rate	5.00%	5.00%	5.00%

Tax Rate	11.67%	10.00%	11.67%
Other	0	0	0

2. Break-even Analysis

Our Break-even Analysis is based on running costs, the "burn-rate" costs we incur to keep the business running, not on theoretical fixed costs that would be relevant only if we were closing. Between payroll, rent, utilities, and basic marketing costs, we think the number shown in the table is a good estimate of fixed costs.

BREAK-EVEN ANALYSIS	
Monthly Units Break-even	38
Monthly Revenue Break-even	$23,710
Assumptions:	
Average Per-Unit Revenue	$625.00
Average Per-Unit Variable Cost	$35.00
Estimated Monthly Fixed Cost	$22,382

3. Projected Profit and Loss

We expect sales to hit $2,500,000 for this year. It should increase to $10 million by the second year of this plan, as net earnings increase steadily. Our high sales volume has lowered our cost of goods and increased our gross margin. This increase in gross margin is important to profitability.

PRO FORMA PROFIT AND LOSS			
	YEAR 1	**YEAR 2**	**YEAR 3**
Sales	$2,500,000	$10,000,000	$15,000,000
Direct Cost of Sales	$140,000	$560,000	$840,000
Production Payroll	$14,730	$70,200	$74,500

Other	$0	$0	$0
TOTAL COST OF SALES	**$154,730**	**$630,200**	**$914,500**
Gross Margin	$2,345,270	$9,369,800	$14,085,500
Gross Margin %	93.81%	93.70%	93.90%
Operating Expenses			
Sales and Marketing Expenses			
Sales and Marketing Payroll	$65,250	$78,000	$181,250
Advertising/Promotion	$0	$35,000	$50,000
Travel	$6,000	$24,000	$35,000
Miscellaneous	$13,500	$20,000	$30,000
TOTAL SALES AND MARKETING EXPENSES	**$84,750**	**$157,000**	**$296,250**
Sales and Marketing %	3.39%	1.57%	1.98%
General and Administrative Expenses			
General and Administrative Payroll	$29,115	$65,500	$359,000
Sales and Marketing and Other Expenses	$0	$0	$0
Depreciation	$72,000	$96,000	$96,000
Patent fees for PCT	$10,000	$70,000	$70,000
Utilities	$3,150	$5,400	$6,000
Insurance	$9,000	$12,000	$13,000
Rent	$33,300	$444,400	$45,000
Payroll Taxes	$27,274	$75,925	$178,688
Other General and Administrative Expenses	$0	$0	$0
TOTAL GENERAL AND ADMINISTRATIVE EXPENSES	**$183,839**	**$769,225**	**$767,688**

General and Administrative %	7.35%	7.69%	5.12%
Other Expenses:			
Other Payroll	$0	$90,000	$100,000
Consultants	$0	$0	$0
Royalties Dr. A.Kalangos	$0	$125,000	$493,750
TOTAL OTHER EXPENSES	**$0**	**$215,000**	**$593,750**
Other %	0.00%	2.15%	3.96%
Total Operating Expenses	$268,589	$1,141,225	$1,657,688
Profit Before Interest and Taxes	$2,076,681	$8,228,575	$12,427,813
EBITDA	$2,148,681	$8,324,575	$12,523,813
Interest Expense	$0	$0	$0
Taxes Incurred	$207,668	$822,858	$1,449,911
Net Profit	$1,869,013	$7,405,718	$10,977,901
Net Profit/Sales	74.76%	74.06%	73.19%

4. Projected Cash Flow

We expect to manage cash flow over the next three years with $100,000 of new investment in April 2000.

PRO FORMA CASH FLOW			
	YEAR 1	**YEAR 2**	**YEAR 3**
Cash Received			
Cash from Operations			
Cash Sales	$625,000	$2,500,000	$3,750,000
Cash from Receivables	$1,414,063	$6,117,188	$10,328,125
SUBTOTAL CASH FROM OPERATIONS	**$2,039,063**	**$8,617,188**	**$14,078,125**
Additional Cash Received			
Sales Tax, VAT, HST/GST Received	$0	$0	$0
New Current Borrowing	$0	$0	$0

New Other Liabilities (interest-free)	$0	$0	$0
New Long-term Liabilities	$0	$0	$0
Sales of Other Current Assets	$0	$0	$0
Sales of Long-term Assets	$0	$0	$0
New Investment Received	$100,000	$0	$0
SUBTOTAL CASH RECEIVED	**$2,139,063**	**$8,617,188**	**$14,078,125**
Expenditures	Year 1	Year 2	Year 3
Expenditures from Operations			
Cash Spending	$109,095	$303,700	$714,750
Bill Payments	$333,104	$2,128,248	$3,167,861
SUBTOTAL SPENT ON OPERATIONS	**$442,199**	**$2,431,948**	**$3,882,611**
Additional Cash Spent			
Sales Tax, VAT, HST/GST Paid Out	$0	$0	$0
Principal Repayment of Current Borrowing	$0	$0	$0
Other Liabilities Principal Repayment	$0	$0	$0
Long-term Liabilities Principal Repayment	$0	$0	$0
Purchase Other Current Assets	$0	$0	$0
Purchase Long-term Assets	$0	$100,000	$200,000
Dividends	$0	$0	$0
SUBTOTAL CASH SPENT	**$442,199**	**$2,531,948**	**$4,082,611**
Net Cash Flow	$1,696,864	$6,085,240	$9,995,514
Cash Balance	$1,725,864	$7,811,104	$17,806,618

5. Projected Balance Sheet

As shown in the balance sheet in the following table, we expect a healthy growth in net worth. The monthly projections are in the appendix.

PRO FORMA BALANCE SHEET			
	YEAR 1	**YEAR 2**	**YEAR 3**

Assets			
Current Assets			
Cash	$1,725,864	$7,811,104	$17,806,618
Accounts Receivable	$460,938	$1,843,750	$2,765,625
Inventory	$19,250	$77,000	$115,500
Other Current Assets	$0	$0	$0
TOTAL CURRENT ASSETS	**$2,206,051**	**$9,731,854**	**$20,687,743**
Long-term Assets			
Long-term Assets	$280,000	$380,000	$580,000
Accumulated Depreciation	$72,000	$168,000	$264,000
TOTAL LONG-TERM ASSETS	**$208,000**	**$212,000**	**$316,000**
TOTAL ASSETS	**$2,414,051**	**$9,943,854**	**$21,003,743**
Liabilities and Capital	Year 1	Year 2	Year 3
Current Liabilities			
Accounts Payable	$61,038	$185,123	$267,111
Current Borrowing	$0	$0	$0
Other Current Liabilities	$0	$0	$0
SUBTOTAL CURRENT LIABILITIES	**$61,038**	**$185,123**	**$267,111**
Long-term Liabilities	$0	$0	$0
TOTAL LIABILITIES	**$61,038**	**$185,123**	**$267,111**
Paid-in Capital	$742,500	$742,500	$742,500
Retained Earnings	($258,500)	$1,610,513	$9,016,231
Earnings	$1,869,013	$7,405,718	$10,977,901
TOTAL CAPITAL	**$2,353,013**	**$9,758,731**	**$20,736,632**
TOTAL LIABILITIES AND CAPITAL	**$2,414,051**	**$9,943,854**	**$21,003,743**
Net Worth	$2,353,013	$9,758,731	$20,736,632