LESSONS LEARNED AS PRESIDENT/CEO BRINGING A COMPANY FROM OBSCURITY TO "MEDICAL DEVICE COMPANY OF THE YEAR"

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INTRODUCTION

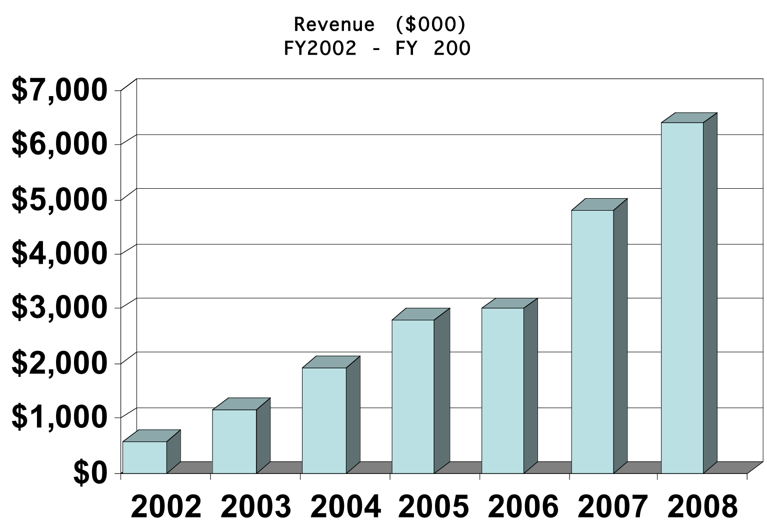
The lessons learned and described here are from first hand experience when the author assumed his new role as Director, President and Chief Executive Officer of Pyng Medical Corp, headquartered in Vancouver, BC. He held this position from November 2006 until March 2009 and today holds no office with the company, but remains a shareholder. In the previous two years, the Company revenues were flat and operating profits were just above break-even. During his tenure, the business more than doubled in revenues, profits increased 12-fold - reaching almost a million dollars, share price rose from 40 cents to a high of 95 cents, commercial products expanded three-fold, assets quadrupled and two new products were developed for submission to regulatory authorities. In the spring of 2008, Pyng was recognized for their achievements, as the Life Sciences BC Medical Device Company of the Year. This article looks at some of the many challenges facing medical device companies in Canada and provides an example of dramatic growth over a relatively short two year period. The "lessons learned" include illustrative examples of success and failure which should be instructive to others faced with similar challenges.

SINGLE PRODUCT COMPANY

Pyng had built a marginally profitable company on a single product that had remained relatively unchanged since it received FDA clearance in 1997. As with many new medical devices, the product, brand named FAST1 and generically known as an intraosseous infusion device, had been slow to gain clinical acceptance. The device, originally developed and prototyped at the British Columbia Institute of Technology, represented a significant break-through in achieving rapid vascular access for patients in dire circumstances, such as complete cardiac arrest or severe hypovolemia. Some first responders, such as paramedics and medics, had initially embraced the product, but subsequently a well-funded American competitor entered the market and took much of the business in the civilian market, leaving Pyng in a dominant position only in the military market. The mandate for the Company now was to expand and diversify the business, by pursuing new products, new geographic markets and new vertical markets

PATHS FORWARD

Assessing the strengths, weaknesses, opportunities and threats, the management team through a strategic planning process, quickly determined that their first priority must be to re-invent the core product because of customer complaints related to some limitations with the original design. Given that the Company only had in-house capabilities in manufacturing and post-production engineering, an outside medical device design house, Starfish Medical in Victoria, BC, was contracted. They were given two key tasks – improve the current product to address a perceived product deficiency and create an entirely new product that would address any and all limitations of the existing product. In parallel with this, the search for new distribution partners and complementary products began in earnest. The goal was to accelerate Pyng's revenue, create sustainable profitability and diversify the business by adding new revenue streams. The path forward followed major milestones in five key areas: 1) strengthening distribution; 2) finding complimentary products; 3) financing the expansion; 4) completing a strategic acquisition; 5) launching the next generation of the Company's core product.



EXPANSION AND DIVERSIFICATION

Strong US Distributor

Since launching their product in the US, Pyng had relied primarily on BoundTree Medical as their prime distributor. Management now turned their attention on developing this relationship, working with their key customers – such as the US Department of Defense, and demonstrating the Company's commitment to product development and new product creation. As well, they established a Canadian military distributor and began to work collaboratively with their overseas distributors to expand the business internationally. These efforts, combined with increased deployment of NATO forces in Iraq and Afghanistan, led to significant growth in sales volume.

Complimentary Products Identified

As the core business expanded and product development engineering continued on the existing product and the radically re-designed next generation of the core product, new complimentary products were identified. These products would be used by the same clinicians with the same patient population in the same markets that the core product was positioned in.

In parallel with all of the other initiatives underway, pursuit of these products began. The challenge was to build a relationship with the US company that owned the rights to these products and currently marketed them. Pyng management began to seek a way to make it worth their while to consider selling these products.

Biocybernetics International (BCI)

The company with these products was a small private California based company with other products that served the orthopedic market. The principals of BCI had invested in the trauma products that Pyng was interested in, since they represented a logical development of their core products and provided them with a degree of diversification. However, after a few years in the trauma business, they only represented about 10% of their total sales volumes, which their Board considered to be somewhat of a distraction. The trauma products included proprietary tourniquets, hip stabilizers and an emergency airway device – all used in the same life or death circumstance as Pyng's core product.

OPPORTUNITY FOR CHANGE

BCI management changes

In the summer of 2007, management changes at BCI created an opportunity for Pyng management to approach the new management, who had been brought in to build their core business in orthopedics. This created an opportunity to begin negotiations on the sale by BCI of their trauma products to Pyng. Now all that needed to be accomplished was an agreement on price.

Financing requirement

In order to proceed, Pyng needed to raise capital for the asset acquisition. At the time, the perception was that their stock, traded on the Toronto Venture Exchange as "PYT" was undervalued. Because of this and the risk of dilution to existing shareholders, the Company took the decision to finance the acquisition principally with debt, but also using some cash reserves and relying on vendor financing based on product development milestones for one of the BCI trauma products still in development. This resulted in Pyng changing banks, increasing their line of credit, securing a $1 million subordinated debt loan and forming a US subsidiary.

ASSET ACQUISITION CLOSES

By June of 2008, Pyng successfully closed a lengthy negotiation for the BCI trauma assets and took ownership of the three new products – two commercial and one still in development. All the products were synergistic with their core product and because of this; the two commercial products were immediately accretive to earnings.

FASTX CREATED

After a decade of in-field use, the FAST1 was fundamentally re-designed to create the FASTX, which today is CE marked. This next generation intraosseous infusion device addresses all of the concerns that customers perceived with the original design.

LESSONS LEARNED

Through the course of this fundamental transformation from a single product, no growth and marginally profitable business to a multi-product, fast growth business generating about 20% operating profit, the big engineering and management challenges were as follows.

1. Cultural shift – any company embarking on numerous significant new initiatives will experience cultural changes and this is particularly true if the business has cultivated status quo for some time. Know that all your best efforts may at times be unintentionally thwarted by cultural inertia.

2. Core competencies – if your organization does not have in-house capabilities in some area, like product design and engineering, then it will be difficult to turn this on overnight and you may wish to outsource to a service provider who is already set up for new product design.

3. Multiple initiatives – pursuing any one new initiative in a small company is challenging, multiple initiatives increases the challenges to the company dramatically. Know that your people will feel stretched and will require significant management leadership and support in order to execute successfully.

4. Financing constraints – early stage Canadian public companies in the medical device industry are often undercapitalized. Getting proper funding for new initiatives takes time, patience and a spirit of pragmatism, whether the money is raised through operations, equity or debt.

5. Pulling together – ensuring that your Board, management team, engineering and production staff and any outside service providers are in alignment with your vision for growth and diversification is critical. Any outliers can create a significant drag on the overall organizational change process.

CONCLUSION

Regardless of the strengths of your engineering team in building world-class products, the success of well-engineered products turns on the success of all the other functions of the business. The savvy biomedical engineer or engineering manager, understands the need to work effectively with the other functions in their organization, and this becomes particularly critical in small emerging companies in times of rapid growth and change. Know that even the best engineered products only succeed when combined with good business management practices. Even in the presence of such business competencies, any one deficiency can limit the growth and success of the products you have worked hard to create and develop.