Appendix 6.1.1
Proxy Company Analysis

This example presents an overview of how to analyze and reconstruct an operating plan using only publicly available information about a proxy company. The analysis reflects information available as of March 2008, although the Cardica Post-IPO section draws from public sources accessible as of early 2014. The insights of the Cardica management, captured in the Working Example boxes, are shared throughout the document but were not used to perform the analysis.

- **Company Name** – Cardica, Inc.
- **Founded** – 1997
- **Description** – Cardica designs and manufactures proprietary automated anastomotic systems used by surgeons to perform coronary artery bypass surgery. In coronary artery bypass grafting, or CABG, procedures, veins or arteries are used to construct "bypass" conduits to restore blood flow beyond closed or narrowed portions of coronary arteries. Cardica's first two products, the C-Port® Distal Anastomosis System, referred to as the C-Port system, and the PAS-Port® Proximal Anastomosis System, referred to as the PAS-Port system, provide cardiovascular surgeons with easy-to-use, automated systems to perform consistent, rapid and reliable connections, or anastomoses, of the vessels, which surgeons generally view as the most critical aspect of the CABG procedure.[1]

Performing Proxy Company Analysis

Table 6.1.1-1 presents the main components of proxy company analysis and how they can be used to inform a financial model and plan.

Table 6.1.1-1 – These components work together to inform an effective proxy company analysis.

Component of Proxy Analysis	How To	Purpose
High Level Operating Plan – Timeline of key operating milestones	Evaluate benchmarks from: Prospectus VentureXpert (Thompson ONE) VentureSource	To validate the company's own operating plan in terms of timeline and staffing requirements.
Financing Milestones – Timeline of major financing events and valuations	Evaluate benchmarks from: Prospectus VentureXpert (Thomson ONE) VentureSource	To validate the company's own financing needs and potential valuations.
Clinical Trials History	Evaluate benchmarks	To validate the company's

Component of Proxy Analysis	How To	Purpose
– Timeline of clinical trials, including duration, location, number of patients enrolled, and important regulatory events	from: Prospectus Medline Search Clinicaltrial.gov	clinical strategy and match the clinical and regulatory strategies to financing milestones and the operating plan.
Other Milestones – Additional milestones, such as sales and signed distribution agreements	Evaluate benchmarks from: Prospectus	To identify other relevant milestones and embed them into an operating plan.
Operating Costs and Staffing Levels – Historical operating expenses and staffing levels by employee type	Use staffing levels and operating cost information from prospectus. Fit these levels into a more refined operating cost model. Divide broader categories of employees reported in the prospectus into specific sub-categories using relevant ratios. Iterate to develop a complete model, including reasonable assumptions about staffing costs.	To help the company develop its own operating expenses analysis, including detailed staffing levels and salary information.
Clinical Trials Costs – Estimate of cost per person of the clinical trials process	Obtain total clinical trial costs and divide by number of patients to get rough estimate of clinical trial cost per enrolled patient.	To help the company estimate the cost of its own clinical trials.
Cash Flow – Cumulative cash flows	Examine financial statements of proxy companies and make adjustments for unusual items such as grants of stock options.	To help the company develop its own cash flow models.

The end goal of this analysis is to refine and validate the company's own business plan, and in particular its operating expenses model, financial model, and funding requirements. The analysis of proxy companies should enable the company to:

1. Confidently state that its plan is reasonable (i.e., expenses and timelines are reasonable and appropriate, and the clinical strategy is relevant).

2. Identify reasonable financing milestones and potential valuation points.
3. Identify potential risk factors (based on challenges faced by proxies) and integrate risk mitigation strategies into the business plan.

To achieve these objectives, the company may wish to examine between one and four proxy companies. Try to include companies with various levels of success in this analysis for a diversity of perspectives and lessons learned.

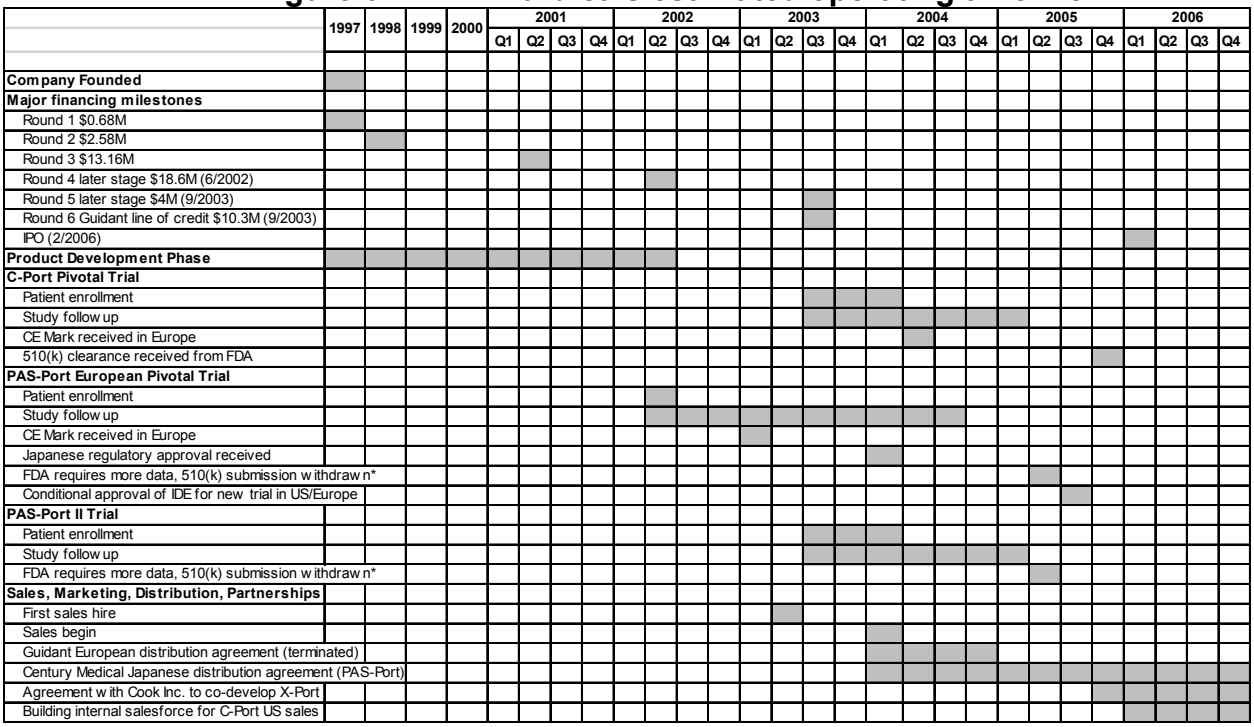
High-Level Operating Plan

In preparing the Cardica proxy company analysis, the first step was to identify the key operating milestones achieved by the company. The primary source of information for this step was the company prospectus. The section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations summarized the key milestones achieved by the company to date.

As stated in the prospectus, 1997-2002 "consisted primarily of start-up activities, including developing the C-Port and PAS-Port systems, recruiting personnel and raising capital."[2] The prospectus did not contain any details about the intermediate milestones between the company's founding in 1997 and the start of clinical trials in 2003, so this period was designated as the product development phase. During this time frame, the team was probably quite small and focused on core R&D activities to develop the company's initial products and prepare for clinical trials. 2003-2005 included all clinical trials, start of sales, and development of R&D and sales distribution partnerships.

Figure 6.1.1-1 contains an operating timeline of key company milestones, including major financing events, clinical trials history and outcomes, and sales and distribution milestones. As discussed in the main body of this chapter and also in 6.3 Funding Approaches, key operating milestones and financing milestones (which are discussed in more detail below) often go hand in hand. For example, Cardica's first clinical trial, the PAS-Port European clinical trial, began in quarter 2 (Q2) 2002, which is the same quarter that the company completed its 4th round of financing ($18.6 million). The C-Port and PAS-Port II trials both began in Q3 2003, the same quarter that the company closed its 5th and 6th rounds of financing (together worth $14 million). In each case, the cash infusion may have been a necessary prerequisite for the company to launch each clinical trial.

Figure 6.1.1-1 – Cardica's estimated operating timeline.



Financing Milestones

VentureXpert and VentureSource were used to identify Cardica's funding rounds. VentureXpert reported three funding rounds along with their post-money valuations. However, the earliest reported round occurred in 2001, four years after the company's founding. Since Cardica's income statement revealed that the company had spent several million dollars to get to this point, this data seemed incomplete. The VentureSource database revealed a total of five venture funding rounds. This case illustrates the importance of double-checking information when possible.

In August 2003, Guidant extended a $10.3 million line of credit to Cardica, as described in the company's prospectus:

> In August 2003 Guidant extended a line of credit to Cardica for $10.3 million. The company has drawn down this line of credit and currently has a long-term loan of $10.3 million outstanding from Guidant, due in August 2008. Interest of 8.75 percent per year accrues during the life of the loan and is due at maturity.[3]

Combined with Guidant's participation in Cardica's 4th and 5th venture rounds, the company has received a cumulative total of $14 million from Guidant. Table 6.1.1-2 shows a summary of all of the company's financing events.

Table 6.1.1-2 – Cardica's financing activity.

Round	Date	Amount Raised	Post-Money Valuation	Stage	Investors
1st	1997	$0.68 million	$4.94 million	Early stage	Individual investors
2nd	1998	$2.58 million	$10.64 million	Early stage	Individual investors
3rd	June 14, 2001	$13.16 million	$31.43 million	Early stage	Sutter Hill Ventures Allen & Co.
4th	June 13, 2002	$18.6 million	$62 million	Later stage	Sutter Hill Ventures Allen & Co. Guidant Corp.
5th	September 30, 2003	$4 million	$85 million	Later stage	Guidant Corp.
6th	August 2003	$10 million	N/A	Line of credit	Guidant Corp.
IPO	February 2006	$35 million	$110 million (post-IPO) $75 million (pre-IPO)	IPO	N/A

Clinical Trials History

The clinical trial history shown in Table 6.1.1-3 was obtained from the IPO prospectus:[4]

Table 6.1.1-3 – Cardica's clinical trial history.

Study	Number and Location of Sites	Enrollment Start Date	Enrollment Completion Date	Number of Patients	Objective	Length of Follow-Up
C-Port Pivotal Trial	5 European sites	July 2003	February 2004	133	Determine safety and efficacy of distal anastomotic device	12 months
PAS-Port European Pivotal Trial	3 European sites	June 2002	September 2002	55	Determine safety and efficacy of proximal anastomot	24 months

					ic device	
PAS-Port II Trial	4 European sites	July 2003	February 2004	54	Increase data pool for study and efficacy with an improved PAS-Port device	12 months

The prospectus also showed regulatory results to date, which are captured in Table 6.1.1-4.

Table 6.1.1-4 – Cardica's regulatory history.

Product	Date	Result
C-Port	April 2004	CE Mark received in Europe
	Nov 2005	510(k) clearance received in U.S.
PAS-Port	March 2003	CE Mark received in Europe
	Jan 2004	Japanese regulatory approval received
	Ongoing	510(k) clearance has proved elusive. Submitted results of 3/6-month follow-up data in application for 510(k) clearance in April 2003. After FDA redefined objective performance criteria for safety/efficacy of anastomosis products, company resubmitted pooled data from two PAS-Port trials. In April 2005, FDA panel decided it required more robust data, and company withdrew 510(k) submission. Received IDE for a new randomized prospective clinical trial to be conducted in U.S. and Europe.

As noted, Cardica has had difficulty obtaining U.S. regulatory approval for its PAS-Port product. Initially expecting a one-year trial process, the company submitted the results of two years' worth of trial data. Ultimately, the FDA required more robust data and Cardica withdrew its 510(k) submission. This seems to have been a blow to Cardica and may have contributed to lowered expectations and a reduced valuation heading towards its IPO.

Working Example
Cardica Management Perspective: FDA Approval Difficulties

Bernard Hausen, co-founder and CEO of Cardica, Inc., explained how changes in the FDA requirements stalled product approval after Cardica's clinical trials had been completed: "At the time, there was a competitive product to the PAS-Port already approved called the Symmetry device from St. Jude Medical. It was approved by the FDA with hardly any clinical data and was selling very well. Suddenly, some patients started coming back six to nine months after surgery with symptoms of angina, which was indicative of occlusions or narrowing of the blood vessels in the connections that this device created. The FDA realized that it had approved the Symmetry device with far too little clinical data and that any similar products, such as ours,

would have to pass through a very different hurdle than the one St. Jude had to pass." To help determine specifically what manufacturers with a product in this space would have to prove to receive approval, the FDA convened a panel of experts who redefined the standards. The impact of the new requirements on Cardica was that "the clinical data we had accumulated at that point was not sufficient to convince the FDA to approve us, which meant we had to start all over again with that product." This development, which Cardica saw as largely outside of its control, was a central factor in reducing Cardica's valuation for its IPO, as well as in forcing the company to raise more capital in order to fund these additional clinical trials.

Other Milestones

Cardica entered into the following sales and distribution partnerships:

- **Cook License Agreement –** In December 2005, Cardica entered into a license, development and commercialization agreement with Cook Incorporated, related to development of the X-Port Vascular Access Closure Device, a product candidate in preclinical animal model studies as of early 2007.

- **Guidant European Distribution Agreement –** Cardica entered into an agreement with Guidant Corporation for European distribution of the C-Port and PAS-Port systems. The agreement was signed in May 2003, amended in Jan 2004, and ultimately terminated in Sept 2004. This agreement accounted for 48 percent of total revenue in fiscal year 2004 and 50 percent of total revenue in fiscal year 2005.

- **Guidant Development/Supply Agreement –** Cardica entered into a development/supply agreement with Guidant in December 2003 to develop an aortic cutter for Guidant's Heartstring product, and manufactured the first 10,000 aortic cutters. Guidant subsequently outsourced future production of the aortic cutter to a third-party contract manufacturer. Cardica would receive a modest royalty for each aortic cutter sold beyond 2005, but does not expect these royalties to contribute significantly to revenue.

- **Century Medical Distribution Agreement –** Cardica distributes the PAS-Port system in Japan through an exclusive distributor, Century Medical Inc. Sales to Century produced 33 percent of fiscal 2005 net revenue. Century is responsible for development of the anastomotic device market in Japan, possessing a direct sales organization of 16 reps and providing clinical training and support for end users in Japan. Cardica provides promotional support and clinical training to Century. Agreement expired in June 2008, but was renewed.

Working Example
Cardica Management Perspective: Partnership Agreements

Unlike most medical device start-ups, which try to get one product into the market before developing another, Cardica decided early on to diversify its product portfolio. In addition to developing both the C-Port and the PAS-Port systems in parallel, the company pursued a number of other smaller projects (e.g., Cardica's aortic cutter). Hausen saw this strategy as more of a biotech approach that involved focusing the company on developing a core

competency from which it could create many potential products. He explained: “It made sense for us to take our core competency, which is in developing these miniature stapling devices, and see where else in the human body they could be used and how they could be developed into additional products. This would give us not just two legs to stand on, but three, four, or five legs in case one of them was to get cut away.”

While this diversification strategy had some advantages (e.g., allowing the company to begin generating revenues from the sale of its C-Port product when it was forced to re-group around the FDA approval requirements for the PAS-Port), it proved to be expensive. When Cardica did not have the cash to continue developing the various products in its project pipeline, William Younger, a managing director of Sutter Hill Ventures and a member of the Cardica board of directors, saw partnerships as a potential solution to this problem. “As a young company, Cardica could not afford to sustain development on all these products and still afford the distribution when we eventually got a product approval,” he said. “So there had to be sponsorship and a distribution arrangement that got the company royalties.” It was this necessity, driven by Cardica’s approach to diversification that led to formation of the partnerships listed above.

Cumulative Sales

As of Sept 2005, Cardica sold over 250 C-Port systems and 2,400 PAS-Port systems worldwide. Sales began in fiscal year 2004. Lacking information about individual 2004 and 2005 unit sales, for the purposes of financial modeling, the assumption was made that Cardica sold 100 C-Port and 700 PAS-Port systems in 2004 and 150 C-Port and 1,700 PAS-Port systems in 2005, for a total of 800 systems in 2004 and 1,850 systems in 2005 (a 2005 to 2004 ratio of 2.3). This assumption was guided by the ratio of historical total 2005 revenue ($2,056,000) to total 2004 revenue ($836,000).

Operating Costs and Staffing Levels

One of the key objectives in analyzing Cardica as a proxy company was to infer its historical operating costs and staffing levels so that these figures could be used to validate a bottom-up financial model for a new enterprise. Two key pieces of available data were especially useful in this regard: (1) 2005 staffing levels and (2) 2001-2005 operating cost information (both retrieved from the prospectus).

Note: When presenting snapshots from the company’s financial model or financial data from Cardica’s prospectus, fiscal years are used throughout. Fiscal years for this company run from July of a given calendar year to June of the next calendar year. For example, fiscal 2003 is July 2002 through June 2003.

2005 staffing levels were outlined accordingly:

> As of November 30, 2005, we had 42 employees, including 16 employees in manufacturing, one employee in sales and marketing, four employees in clinical, regulatory and quality assurance, and five employees in general and administrative and 16 employees in research and development.[5]

2001-2005 operating cost data (each fiscal year ending in June) were taken from Cardica's income statement and shown in Table 6.1.1-5**.**

Table 6.1.1-5 – Excerpt from Cardica's income statement (2006 Cardica prospectus; reprinted with permission).

Operating Costs and Expenses (in 000s)					
Cost of product revenue (includes related-party costs of $1.377, $1,180, $306, and $0 in fiscal 2004, fiscal 2005, and [three] months ended September 30, 2004 and 2005, respectively)				2,105	2,478
Research and development	5,058	5,765	6,698	5,826	6,289
Selling, general and administrative	1,166	1,635	1,936	1,809	3,753
Total operating costs and expenses	6,224	7,400	8,634	9,740	12,520

The goal was to use these pieces of available data, along with Cardica's operating plan, to estimate the company's staffing levels and overall costs on an annual basis, from 1997 through 2005. This was done in two steps.

Step 1 – Structure the Operating Cost Model

The objective of this step was to define the specific elements of the operating cost model so that they accurately reflect the company being analyzed. These elements include cost line items and employee types.

Define Costs

The line items underlying Cardica's cost model included: (1) R&D, (2) SG&A, and (3) COGS. In most medical device company financial models, employee costs account for most of the first two categories. However, upon reading the Cardica prospectus, it seemed appropriate to include additional cost line items. Under R&D, "cost of clinical trials" and "capital expenditure" was added. Under SG&A, "other SG&A expenses" were added. A section for "facilities" also was included under SG&A. All of these additions are explained in the section below entitled Cost Line Items Added. The operating cost model used here was based on the general model described earlier in this document.

Bear in mind that different companies have different costs and the cost model should reflect the specific business being analyzed. Also note that the analysis can get as detailed as needed in this area, depending on how carefully the prospectus is reviewed. Just be careful not to spend too much time modeling costs that are unique to the company being analyzed and will not generalize to another venture.

Define Employee Types and How They Are Categorized Within the Income Statement

There were five general employee types mentioned in the prospectus: (1) manufacturing, (2) sales and marketing, (3) clinical, regulatory, and quality assurance (QA), (4) general and

administrative, and (5) R&D. To begin the analysis, manufacturing was divided into the employee types of manufacturing engineer and manufacturing technician. Engineering management and clinical management were also added as types within R&D, reflecting the fact that two senior managers (the vice president (VP) of clinical and regulatory affairs and the VP of research and development), had been categorized in the income statement within the R&D line item and not within a more general management line item (senior management positions were identified from the Management section of the prospectus). This allowed for the definition of a higher salary category for these two positions.

Table 6.1.1-6captures how each employee type was mapped to an income statement category.

Table 6.1.1-6 – Cardica staffing estimates.

Employee Type (from prospectus excerpt)	Cardica Income Statement Category
Manufacturing engineer	Cost of product revenue
Manufacturing technician	Cost of product revenue
R&D engineering manager (VP R&D)	Research and development
R&D engineer	Research and development
R&D technician	Research and development
Clinical management (VP Clinical)	Research and development
Clinical, regulatory and quality assurance	Research and development
General management (CEO, CFO)	Selling, general and administrative
Sales and marketing (VP)	Selling, general and administrative
Administrative assistant	Selling, general and administrative

Step 2 – Assign Staffing and Costs to the Model

The objective of step two was to arrive at a reasonable estimate of annual staffing levels and costs. The general strategy here was to start from actual available data, assign estimates to each of the other unknown items, and then iterate until all items seemed reasonable alongside one another and the costs seemed to reflect the known operating milestones on an annual basis. The analysis should begin in a year where both staffing levels and total costs are known. In the case of Cardica, only 2005 staffing levels were available from the prospectus, so the analysis began with 2005 and was performed backwards.

<u>Define Number and Type of Employees in 2005</u>

Since the prospectus only stated the number of employees within each of five broad employee types, it was necessary to make judgments about how these numbers should be divided across the more specific employee types:

- The 16 manufacturing employees mentioned in the prospectus were divided into groups of 5 engineers and 11 technicians. The general trend is that as a company is

defining its manufacturing processes, there is a roughly equal number of technicians and engineers, or there are slightly more technicians. As manufacturing processes become streamlined, the ratio of technicians to engineers increases substantially, up to 3 or more manufacturing technicians per engineer.

In this case, the company's manufacturing labor and materials costs were nearly the same in 2004 ($2,105,000) and 2005 ($2,478,000), despite a significant increase in unit sales from 2004 to 2005. (Note that while the common accounting convention used in text is to include only material costs in the calculation of COGS, the Cardica prospectus includes both manufacturing staff and materials costs as part of COGS.) This suggests that the company made a large investment in manufacturing staff and capabilities when it began manufacturing in 2004. Nevertheless the company was only about a year into manufacturing, and therefore past the initial stage but still ramping up sales and refining its manufacturing processes. In 2004, the company had reallocated some of the engineering costs from the R&D category to manufacturing, suggesting that the manufacturing team was still being fully developed. Therefore, an allocation of 11 manufacturing technicians to 5 engineers seemed reasonable.

- The 16 employees referred to as R&D employees in the prospectus were allocated as follows: 1 engineering manager (VP R&D), 4 engineers, and 11 technicians. This engineer to technician ratio is roughly equivalent to the ratios described in this document, or roughly 1 to 3 R&D technicians per R&D engineer.

- The 4 employees referred to as clinical and regulatory staff in the prospectus were divided into a VP position and 3 clinical staff.

- The 6 employees referred to as SG&A in the prospectus were allocated into 1 VP position for sales and marketing, 2 administrative assistants, and 3 general managers (CEO, CFO, and one additional manager).

Assign 2005 Employee Salaries by Employee Type

First, salary levels were defined for each employee type. The initial values chosen were based on standard industry values (provided in chapter 6.1, Table 6.1.1 of the *Biodesign* textbook). Factors for the fully burdened salaries (to account for benefits, equipment, etc.) were defined using standard medical device industry values: 1.5x for manufacturing employees and 2x for all other employee types. Finally, the salary levels and factors were used to produce fully burdened salaries for each employee type as well as totals for 2005 R&D staff costs, SG&A staff costs, and manufacturing staff costs.

Use 2005 Known Operating Costs to Estimate Additional Cost Line Items

Now that estimates for the total 2005 R&D, SG&A and manufacturing staffing costs were understood, the only unknown cost items remaining were the additional cost line items defined in step one. Estimates could be assigned to these additional line items within each category such that each of the projected totals nearly matched the actual 2005 historical total operating cost values.

Tweak the 2005 Estimates

Some experimentation was required with the employee salaries by type and the cost line items to make the projected 2005 operating costs seem realistic while remaining in alignment with the actual 2005 historical costs.

Assign 2001-2004 Staffing Levels and Cost Items

With 2005 staffing levels and costs estimated, 2001-2004 estimates were assigned next. The 2005 staffing levels and costs served as a guidepost, since 2001-2004 values should have increased reasonably towards 2005.

One of the most challenging aspects of creating this model was assigning staffing levels by employee type to years 2001-2004. The staffing levels for each year had to make sense relative to the key operating milestones (clinical trials progress in 2002-2004, start of sales in 2004, etc.), as well as to 2005 staffing levels. Once staffing levels were assigned and corresponding fully burdened costs calculated, values could be assigned to the additional cost line items for each year so that the total projected costs aligned with the historical costs from 2001-2004.

Iterate

The steps outlined above were repeated and the model was revised until the figures made sense alongside each other. Examples of some of the key considerations used to tweak the cost model included:

- The 2001-2005 costs projected by the model had to approach the actual 2001-2005 historical costs. In the spreadsheet, there is a line under each section called “discrepancy” which indicates the variance between the two sets of figures.
- The year-to-year increase in staff needed to reflect key company milestones. These milestones included the closing of the 1st major round of financing, as well as the start of sales and manufacturing.
- The company could not go bankrupt in any year. In other words, post-financing cash in the bank (under cash flow) had to be positive in each year. Because the company fundraising was minimal until its first major cash infusion in 2001, the projected staffing levels until 2001 were also quite low.

Some additional considerations are discussed in the section entitled Additional Cost & Staffing Considerations. This process required several iterations until all considerations were met and the model was determined to be sound.

Figure 6.1.1-2 contains the actual version of the cost model. Some of the key considerations in selecting reasonable values for staffing levels and costs are outlined in Figures 6.1.1-3 through 6.1.11.

Figure 6.1.1-2 – Cardica's actual financials (2006 Cardica prospectus; reprinted with permission).

Actual Financials ($)	1997	1998	1999	2000	2001	2002	2003	2004	2005
(from prospectus)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
Revenue								836,000	2,056,000
Manufacturing costs	-	-	-	-	-	-	-	2,105,000	2,478,000
Total capital expenditures							757,000	914,000	882,000
R&D					5,058,000	5,765,000	6,698,000	5,826,000	6,289,000
Selling, general & administrative					1,166,000	1,635,000	1,936,000	1,809,000	3,753,000
Total operating expenses (excl. manufacturing costs)					6,224,000	7,400,000	8,634,000	7,635,000	10,042,000
Total operating expenses					6,224,000	7,400,000	8,634,000	9,740,000	12,520,000
Total operating loss							**8,634,000**	**8,904,000**	**10,464,000**

Figure 6.1.1-3 – Estimated staffing levels.

Staffing	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
Manufacturing									16
Engineers	0	0	0	0	0	0	0	5	5
Assemblers	0	0	0	0	0	0	0	11	11
Research & development									16
VP, research & development	0	0	0	0	1	1	1	1	1
Engineers	1	1	1	1	8	8	8	4	4
Technicians	0	0	1	1	11	11	11	11	11
VP, clinical and regulatory affairs	0	0	0	0	1	1	1	1	1
Clinical, regulatory and QA	0	0	0	0	3	3	3	3	3
Sales, general & administrative									6
VP, sales & marketing	0	0	0	0	0	0	1	1	1
Administrative assistant	0	1	1	1	1	1	1	1	2
General mgmt (CEO, CFO, other)	1	1	1	1	2.1	3	3	3	3
Total	**2**	**3**	**4**	**4**	**27**	**28**	**29**	**41**	**42**

Figure 6.1.1-4 – Salary assumptions.

Salary assumptions (2005)	Factor	Salary ($)
Engineering	2	130,000
Technicians	2	50,000
Clinical, regulatory & QA	2	130,000
Sales & marketing	2	100,000
Administration	2	35,000
Manufacturing	1.5	35,000
Management	2	200,000
Yearly salary increase	2.5%	

Fully burdened salary ($)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
Engineering	213,394	218,729	224,197	229,802	235,547	241,436	247,472	253,659	260,000
Technicians	82,075	84,127	86,230	88,385	90,595	92,860	95,181	97,561	100,000
Clinical, regulatory & QA	213,394	218,729	224,197	229,802	235,547	241,436	247,472	253,659	260,000
Sales & marketing	164,149	168,253	172,459	176,771	181,190	185,720	190,363	195,122	200,000
Administration	57,452	58,889	60,361	61,870	63,417	65,002	66,627	68,293	70,000
Manufacturing	43,089	44,166	45,271	46,402	47,562	48,751	49,970	51,220	52,500
Management	328,299	336,506	344,919	353,542	362,380	371,440	380,726	390,244	400,000

Figure 6.1.1-5 – R&D expenses.

Operating Expenses (Op Ex)									
	1997	1998	1999	2000	2001	2002	2003	2004	2005
R&D spending	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**
Staff costs									
# of engineering management	0	0	0	0	1	1	1	1	1
Fully loaded employee cost ($)	328,299	336,506	344,919	353,542	362,380	371,440	380,726	390,244	400,000
# of engineers	1	1	1	1	8	8	8	4	4
Fully loaded employee cost ($)	213,394	218,729	224,197	229,802	235,547	241,436	247,472	253,659	260,000
# of technicians	0	0	1	1	11	11	11	11	11
Fully loaded employee cost ($)	82,075	84,127	86,230	88,385	90,595	92,860	95,181	97,561	100,000
# of clinical management	0	0	0	0	1	1	1	1	1
Fully loaded employee cost ($)	328,299	336,506	344,919	353,542	362,380	371,440	380,726	390,244	400,000
# of clinical, regulatory, QA	0	0	0	0	3	3	3	3	3
Fully loaded employee cost ($)	213,394	218,729	224,197	229,802	235,547	241,436	247,472	253,659	260,000
Total R&D staff costs	213,394	218,729	310,427	318,188	4,312,325	4,420,133	4,530,637	3,629,268	3,720,000
Cost of clinical trials ($)	0	0	0	0	400,000	950,000	1,700,000	1,600,000	2,000,000
Capital expenditure (0.6 of total in 03-05) ($)	50,000	65,000	80,000	100,000	350,000	400,000	469,340	566,680	546,840
Proj. annual R&D expenses ($)	**263,394**	**283,729**	**390,427**	**418,188**	**5,062,325**	**5,770,133**	**6,699,977**	**5,795,948**	**6,266,840**
Discrepancy ($)					**-4,325**	**-5,133**	**-1,977**	**30,052**	**22,160**

Figure 6.1.2-6 – SG&A expenses.

	1997	1998	1999	2000	2001	2002	2003	2004	2005
SG&A spending	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**
Staff costs									
# of sales & marketing	0	0	0	0	0	0	1	1	1
Fully loaded employee cost ($)	164,149	168,253	172,459	176,771	181,190	185,720	190,363	195,122	200,000
# of admin assistants	0	1	1	1	1	1	1	1	2
Fully loaded employee cost ($)	57,452	58,889	60,361	61,870	63,417	65,002	66,627	68,293	70,000
# of management	1	1	1	1	2	3	3	3	3
Fully loaded employee cost ($)	328,299	336,506	344,919	353,542	362,380	371,440	380,726	390,244	400,000
Total SG&A staff costs	328,299	395,395	405,280	415,412	824,415	1,179,321	1,399,167	1,434,146	1,540,000
Facilities costs									
Cost per sq. foot ($)	25.00	25.63	26.27	26.92	27.60	28.29	28.99	29.72	30.46
Inflation	n/a	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Sq. footage / employee	250	250	250	250	250	250	250	250	250
# of employees	2	3	4	4	27	28	29	41	42
Sq. footage required	500	750	1,000	1,000	6,775	7,000	7,250	10,250	10,500
Projected sq. footage	3,000	3,000	3,000	3,000	12,000	12,000	12,000	12,000	18,000
Total facilities cost ($)	75,000	76,875	78,797	80,767	331,144	339,422	347,908	356,606	548,281
Other SG&A spending ($)						130,000	200,000	0	1,700,000
Proj. total SG&A spending ($)	**403,299**	**472,270**	**484,076**	**496,178**	**1,155,559**	**1,648,744**	**1,947,075**	**1,790,752**	**3,788,281**
Discrepancy ($)					**10,441**	**-13,744**	**-11,075**	**18,248**	**-35,281**

Figure 6.1.1-7 – Total operating expenses.

Operating expenses (excl. manufacturing costs)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
Proj. annual R&D expenses ($)	263,394	283,729	390,427	418,188	5,062,325	5,770,133	6,699,977	5,795,948	6,266,840
Proj. total SG&A expenses ($)	403,299	472,270	484,076	496,178	1,155,559	1,648,744	1,947,075	1,790,752	3,788,281
Total operating expenses (excl. manufacturing costs) ($)	**666,693**	**755,999**	**874,503**	**914,366**	**6,217,884**	**7,418,877**	**8,647,052**	**7,586,700**	**10,055,121**
Discrepancy ($)					**6,116**	**(18,877)**	**(13,052)**	**48,300**	**(13,121)**

Figure 6.1.1-8 – Total manufacturing costs.

Total Manufacturing Costs									
	1997	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Manufacturing labor	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**
# of engineers	-	-	-	-	-	-	-	5	5
Fully loaded employee cost ($)	213,394	218,729	224,197	229,802	235,547	241,436	247,472	253,659	260,000
# of direct labor	-	-	-	-	-	-	-	11	11
Fully loaded employee cost ($)	43,089	44,166	45,271	46,402	47,562	48,751	49,970	51,220	52,500
Manufacturing labor cost ($)	-	-	-	-	-	-	-	1,831,707	1,877,500
	1997	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
COGS	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**
Units sold	-	-	-	-	-	-	-	800	1,850
Raw material costs per unit ($)	-	-	-	-	-	-	-	340	340
% improvement	0%	0%	0%	0%	0%	0%	0%	0%	0%
Raw material & packaging costs ($)	-	-	-	-	-	-	-	272,000	629,000
	1997	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Manufacturing Costs	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**
Manufacturing labor cost ($)	-	-	-	-	-	-	-	1,831,707	1,877,500
Raw material & packaging costs ($)	-	-	-	-	-	-	-	272,000	629,000
Total manufacturing costs ($)	-	-	-	-	-	-	-	2,103,707	2,506,500
Discrepancy ($)	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1,293**	**(28,500)**

Figure 6.1.1-9 – Total sales.

Sales	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**
C-Port units	-	-	-	-	-	-	-	100	150
PAS-Port units	-	-	-	-	-	-	-	700	1,700
C-Port average selling price (ASP) ($)	-	-	-	-	-	-	-	800	800
PAS-Port average selling price (ASP) ($	-	-	-	-	-	-	-	800	800
C-Port revenue ($)	-	-	-	-	-	-	-	80,000	120,000
PAS-Port revenue ($)	-	-	-	-	-	-	-	560,000	1,360,000
Total revenue ($)	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**640,000**	**1,480,000**

Figure 6.1.1-10 – Clinical trial expenses.

Clinical Trials	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**	**Total**
C-Port pivotal trial patient-years	0	0	0	0	0	0	66.5	133.0	33.2	
PAS-Port European trial patient-years	0	0	0	0	0	0	55.0	55.0	13.8	
PAS-Port II trial patient-years	0	0	0	0	0	0	0.0	40.5	13.5	
Total # of patient-years	-	-	-	-	-	-	121.50	228.50	60.49	410
Total clinical trial cost ($)										6,650,000
Cost per patient-year ($)										**16,200**
Total # of patients enrolled										242
Cost per patient ($)										**27,479**

Figure 6.1.1-11 – Income statement and cash flow.

Income Statement	1997	1998	1999	2000	2001	2002	2003	2004	2005
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
Revenue ($)	-	-	-	-	-	-	-	836,000	2,056,000
Total manufacturing costs ($)	-	-	-	-	-	-	-	2,103,707	2,506,500
Gross margin ($)	-	-	-	-	-	-	-	(1,267,707)	(450,500)
Total operating expenses (excl. manufacturing costs) ($)	666,693	755,999	874,503	914,366	6,217,884	7,418,877	8,647,052	7,586,700	10,055,121
Pre-tax operating profit ($)	(666,693)	(755,999)	(874,503)	(914,366)	(6,217,884)	(7,418,877)	(8,647,052)	(8,854,408)	(10,505,621)
Discrepancy ($)							**(13,052)**	**49,592**	**(41,621)**

Cash Flow	1997	1998	1999	2000	2001	2002	2003	2004	2005
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
Cash balance (= operating profit) ($)	(666,693)	(742,691)	962,805	48,440	(6,169,445)	(428,321)	9,524,627	670,219	4,164,598
Amount financed ($)	680,000	2,580,000	-	-	13,160,000	18,600,000	-	14,000,000	-
Post-financing cash in the bank ($)	13,307	1,837,309	962,805	48,440	6,990,555	18,171,679	9,524,627	14,670,219	4,164,598

Cost Line Items Added

The following information explains the cost line items added to the operating cost model:

Clinical Trials Expenses

While employee costs generate most R&D expenses, an additional line-item was needed under R&D to reflect the actual clinical trials cost. This excerpt from the prospectus indicated that the clinical trial process accounted for a significant portion of R&D costs:

> Research and development expenses fluctuate with the stage of development of, the timing of clinical trials related to, and the status of regulatory approval of our products.[6]

Once this line-item was added, 2001-2005 clinical trial costs were assigned: $400,000 in 2001, $950,000 in fiscal 2002, $1,700,000 in 2003, $1,600,000 in 2004, and $2,000,000 in 2005. It was assumed that the company incurred some pre-trial preparatory costs in 2001, and that 2002 trials costs were lower than the following years since the trials began toward the end of 2002. From 2003-2005, relatively constant clinical trial costs were assumed, with a slight increase in 2005. There is no way to deduce from the prospectus a precise timeline of how the costs were incurred. The costs may have been highest at the start of the trials reflecting registration fees or upfront payment to trial service providers, or may have been spread evenly over time. In this model, it is assumed that the bulk of the trial costs are incurred during 2003-2005 when most of the trial activity occurs.

Working Example
Cardica Management Perspective: Additional Clinical Trial Expenditures

In 2005, after the FDA rejected Cardica's existing clinical trial data and required the company to complete an additional study, Cardica found itself facing clinical trial expenses that it had not anticipated in its operating plan, nor built into its financial model. This setback required a two-pronged approach. First, Cardica negotiated with the FDA on a shorter time frame for its new trial. "Our original trial had six-month data," Hausen explained. "The FDA wanted one-year data, and we were able to convince them to compromise on nine-month data for the new trial." This compromise has been estimated by the authors to lead to direct clinical trial savings of about half a million dollars, as well as enabling Cardica to come to market in the United States three months sooner than it would have otherwise. Second, this change forced Cardica to use more of the proceeds from its IPO to fund clinical trials, rather than committing them to marketing expenses. While this change would obviously negatively impact IPO pricing, the ability to change strategies quickly enabled Cardica to make the best of a bad situation. In the medical device world, which is ever-changing, it is critical to be able to change directions when necessary and refrain from lamenting over lost opportunities.

Capital Expenditures

This line item was added to R&D to reflect the costs of capital equipment necessary to perform the R&D process. The company statement of cash flows indicated that the company spent $757,000 in fiscal 2003, $914,000 in 2004, and $882,000 in 2005 on total purchases of property and equipment. To estimate what portion of these values were allocated to R&D equipment, Note 4 (p. 127) was referenced, which provided an estimate of the proportion of company capital equipment value represented by "machinery and equipment," namely $1,899,000 out of $3,040,000 (62 percent) in 2004, or $2,832,000 out of $3,833,000 (74 percent) in 2005.[7] The 62 percent figure was used to determine the estimates for R&D capital expenditures in 2003, 2004 and 2005 (see Table 6.1.1-7). Estimates for 1997 to 2000 were ramped up gradually over time, followed by a sizable jump from 2000 to 2001 to reflect a substantial increase in staffing and financing in 2001.

Table 6.1.1-7 – Excerpt from prospectus detailing company equipment asset values in 2004-2005 (2006 Cardica prospectus; reprinted with permission).

	2004	2005
Computer hardware and software	$362	$375
Office furniture and equipment	$144	$154
Machinery and equipment	$1,899	$2,832
Leasehold improvements	$461	$461
Construction in process	$174	$11
	$3,040	**$3,833**

Facilities

A facilities section was added under SG&A costs. The following excerpt from the prospectus detailed the current facilities situation:

> We currently lease approximately 29,000 square feet in Redwood City, California, containing approximately 19,000 square feet of manufacturing space,

> 7,000 square feet used for research and development and 3,000 square feet devoted to administrative offices. Our facility is leased through August 2008. We believe that our existing facility should meet our needs for at least the next 24 months.[8]

All facilities expenses were allocated under SG&A, rather than broken up across SG&A, R&D, and manufacturing, for the following reasons: (1) Cardica only possessed one facility which the various departments shared, and the amount of space used by any one of the three departments was small, and (2) the company had only recently begun sales, and cumulative sales figures were low, so the cost of goods attributable to facilities costs would probably be quite low.

Other SG&A Expenses

This line item was added under SG&A costs to reflect additional non-staff costs. This was originally motivated by a sizable increase in SG&A expenses of $2 million, from $1.8 million in 2004 to $3.8 million in 2005, due to a non-cash stock-based compensation expense related to loans made to three directors to purchase shares in Cardica's common stock. This was not an operational expense but had to be accounted for in order to derive an accurate estimate of operational SG&A expenses in 2005. This line item also captured non-cash stock-based compensation, travel, and professional services expenses.

Additional Cost & Staffing Considerations

The following were additional considerations in setting costs and staffing levels:

R&D

As noted above, in assigning values to the cost of clinical trials line item, every effort was made to match the progress of the clinical trials from 2003 through 2005. This line item included filing and regulatory costs, consulting costs, as well as the cost of producing the units of the products used in the trial. An analysis of clinical trials is provided in a separate section below.

According to the prospectus (p.40), R&D expenses decreased $872,000 between fiscal years 2003 and 2004, from $6.7 million to $5.8 million, "primarily attributable to the reallocation to cost of product revenue of $817,000 of personnel-related costs of manufacturing overhead included in research and development expenses in 2003."[9] In other words, Cardica reallocated some of its engineers from R&D costs to manufacturing in 2004. Staffing levels in the model reflect this change. From 2003 to 2004, R&D engineers decreased from 8 to 4 and manufacturing engineers increased from 0 to 5 (reflecting that 4 engineers were reallocated from R&D to manufacturing and 1 additional manufacturing engineer was hired in preparation for start of sales).

It was assumed that R&D engineering and technician staff remained small from 1997 to 2000 and jumped significantly in 2001, reflecting the significant round 3 financing it received and acceleration of product development efforts.

It was assumed that the VPs of R&D and clinical and regulatory were hired in year 5, upon completing round 3 financing and having the resources to put in place a more senior

management team. Clinical staff increased from 0 in 2000 to 3 in 2001, giving this staff a two-year head start to coordinate with the product team prior to beginning clinical trials.

Note that a fractional staffing level (e.g., 2.1) signifies that one of the hires was made midway through the year. Sometimes fractional staffing levels were assumed in the model in order to make the total costs approach the historical costs.

Working Example
Cardica Management Perspective: R&D Costs

As companies develop products and begin to focus on manufacturing and commercialization, many decide to decrease their R&D costs until they can develop solid revenues and prove that a market exists for their product. Cardica, however, continued to maintain high R&D expenditures as it began to roll out its C-Port and PAS-Port systems. Younger cited the company's physician stakeholders as one of the primary reasons Cardica needed to sustain its R&D expenditures: "We face a difficult market development problem because we have a very conservative customer base that is hard to please and will only use the best products." Hausen added, "Our R&D budget remains big because we need to keep making the product better and better, so that whenever physicians come up with a reason not to use our products, we overcome that resistance with a better offering." While each company must set an R&D spending level that is appropriate for its business (and stakeholders), it may be dangerous to automatically assume that such expenses costs will decrease dramatically over time.

SG&A
Since sales began in 2004, the VP of sales & marketing was not hired until 2003.

Manufacturing Costs
The manufacturing team, including one new engineer and 11 technicians, was not hired until 2004, the year sales began.

In setting raw materials costs, the number of units sold in 2004 and 2005 was estimated to be 800 and 1,850, respectively. The company prospectus states that it had cumulative sales through September 30, 2005 of 250 C-Port Systems and 2,400 PAS-Port systems worldwide, for a total of 2,650 systems. Lacking better information, the assumption was made that the two systems have the same raw materials costs. It was also assumed that of the 2,650 systems sold, 800 were sold in fiscal year 2004 and 1,850 in 2005.

No improvement in raw materials costs was assumed, since sales had only recently begun and sales levels were relatively low at the time of the IPO. Such improvements in costs are usually generated by high-volume production.

Revenue

Revenue for Cardica was difficult to model because the company had only two years of revenue at the time of their public offering and a significant portion was attributable to sales and development partnerships that had recently been terminated or downgraded. The Guidant European Distribution Agreement, which accounted for 48 percent of total 2004 revenue and 50 percent of fiscal 2005 revenue, had been terminated, and Cardica's role in supplying Guidant with aortic cutters had been downgraded from a manufacturing to a pure royalty relationship. Therefore, Cardica's revenue outlook heading into 2006 was unclear. A simple

model of C-Port and PAS-Port sales could be created, but no attempt was made to model the other revenue sources because they did not seem to reflect future sales. Because the revenue model did not account for all of 2004 and 2005 revenues, the discrepancy between historical sales and the model's projected sales was not calculated. When filling in the revenue line in the income statement, historical 2004 and 2005 revenues were used.

Working Example
Cardica Management Perspective: Redefining the Potential Market

While the problems with FDA approval delayed Cardica's launch of the PAS-Port in the United States and led to increasing clinical trial costs, Hausen viewed the FDA's change as a potential "blessing in disguise" with regard to potential, long-term revenue. He explained: "When we were initially in the middle of the FDA approval process, there were nine other companies competing for FDA approvals of similar products. This raising of the bar by the FDA and additional public scrutiny for our devices got rid of all of our competition virtually overnight. We suddenly became a company in a $1 billion-plus potential market, completely by ourselves." While Medtronic later began clinical trials for a competing product, this shift in market dynamics allowed Cardica to reevaluate its U.S. sales potential and model higher revenues in later years than was previously realistic.

Clinical Trials Cost

One of the objectives in analyzing Cardica was to develop a reasonable model for the cost of clinical trials in this sector. Previously, the cost of clinical trials per year was chosen so that the model's total R&D costs per year closely approximated the actual values in years 2001 through 2005. The next question to answer was how to use those clinical trial costs to calculate a reasonable cost per patient in the clinical trial.

First, the sum of the clinical trial costs was calculated in the model from years 2002 through 2005. This is the model estimate of the total spent on clinical trials ($6,650,000).

The start date and duration of each clinical trial was also examined to determine the number of patients actively involved in each clinical trial within each fiscal year. For example, in the case of the C-Port Pivotal trial, patient enrollment began in fiscal Q3 2003 and ended in Q1 2005 and there were 133 patients involved in that trial. 133 patients were assigned to each quarter between Q3 2003 and Q1 2005. This date range spanned half of fiscal year 2003 (Q3, Q4), all of fiscal year 2004, and a quarter (Q1) of fiscal year 2005. Therefore, 66.5 patient-years were assigned to 2003, 133 patient-years to 2004, and 33.2 patient-years to 2005 for the C-Port pivotal trial. This process was repeated for the other clinical trials to produce a total number of patient-years per fiscal year and per trial.

Finally, the model's estimate of the total spent on clinical trials was divided by the total number of patient-years to produce an estimate of the cost per clinical patient-year. The end result was $16,200 per patient-year.

Another metric for cost of clinical trials is the cost per patient, rather than the cost per patient-year. To calculate this, the total estimate for clinical trials cost ($6,650,000) was divided by the

total number of patients enrolled in the trials (242), yielding a result of $27,479 per patient (see Table 6.1.1-8).

Table 6.1.1-8 – Clinical trial analysis.

	2003	2004	2005	
	Year 7	Year 8	Year 9	Total
C-Port pivotal trial patient-years	66.5	133	33.2	
PAS-Port European trial patient-years	55	55	13.8	
PAS-Port II trial patient-years	0	40.5	13.5	
PAS-Port II trial patient-years	121.5	228.5	60.49	410
Total clinical trial cost				$6,650,000
Cost per patient-year				**$16,200**
Total # of patients enrolled				242
Cost per patient				**$27,479**

It is worth noting that because information was lacking about the timing of clinical trial costs, as well as the rate of patient enrollment, it did not seem reasonable to try to analyze the clinical trial costs on an annual basis. That is, the total clinical trial costs were analyzed as they related to the total number of clinical patient-years or the total number of patients. Also, bear in mind that the approach chosen here is quite rough.

Cumulative Cash Flows

In calculating cumulative cash flows, net income value was used without accounting for depreciation and other adjustments that would give a more precise number for cash flow. Examining the Cardica financial statements, it was clear that many of their adjustment items were details specific to Cardica that were not instructive to model. For example, in fiscal 2004, the net operating loss was $10,950,000 and net cash used was $7,417,000, an adjustment of $3,533,000. Yet $2,599,000 out of the $3,533,000 adjustment was due to stock-based compensation on grants of stock options to employees. Because the size and timing of this adjustment was specific to Cardica, it was not worth including in the model.

Figure 6.1.1-12 illustrates cumulative cash on hand, operating income (loss), and financing events over time.

Figure 6.1.1-12 – Financing events (financing data from VentureSource).

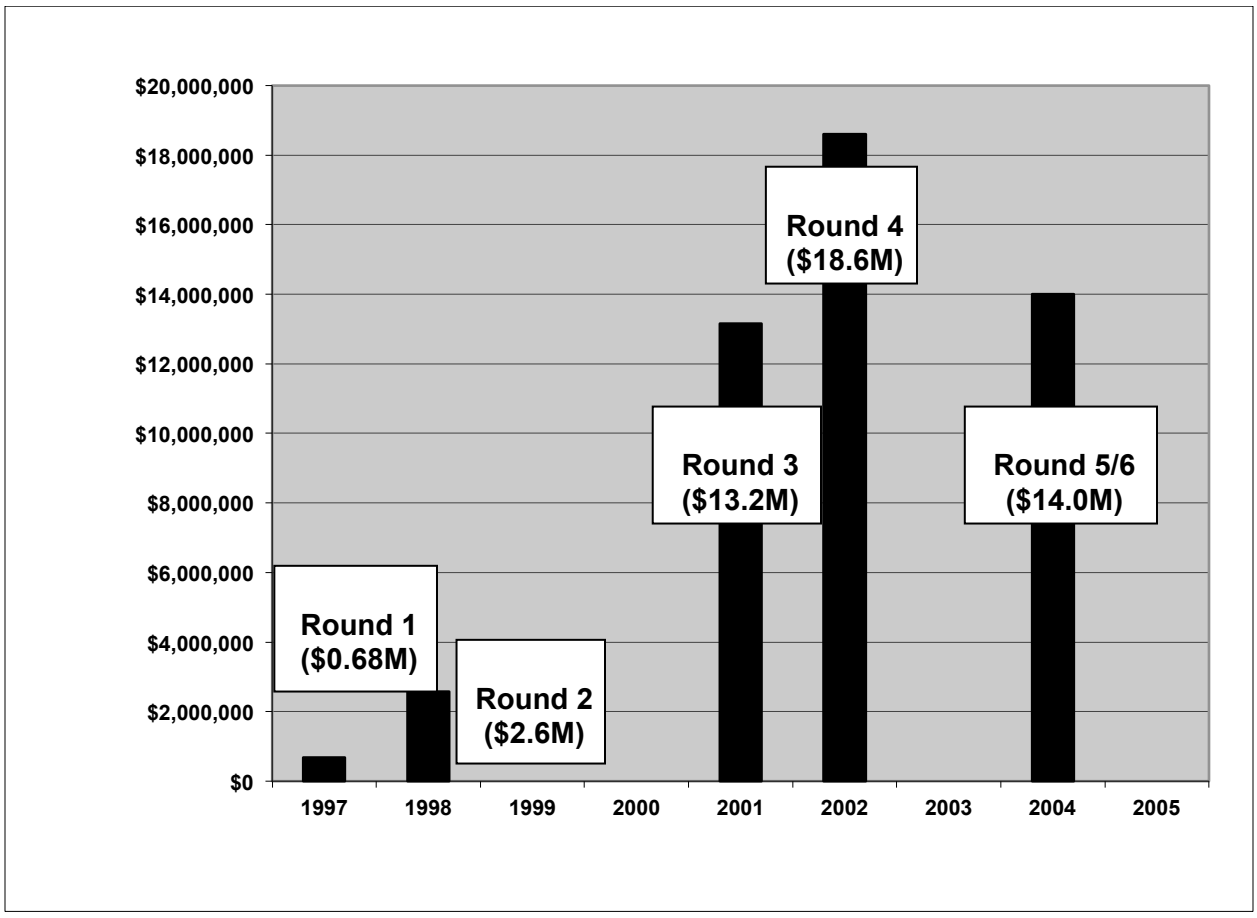
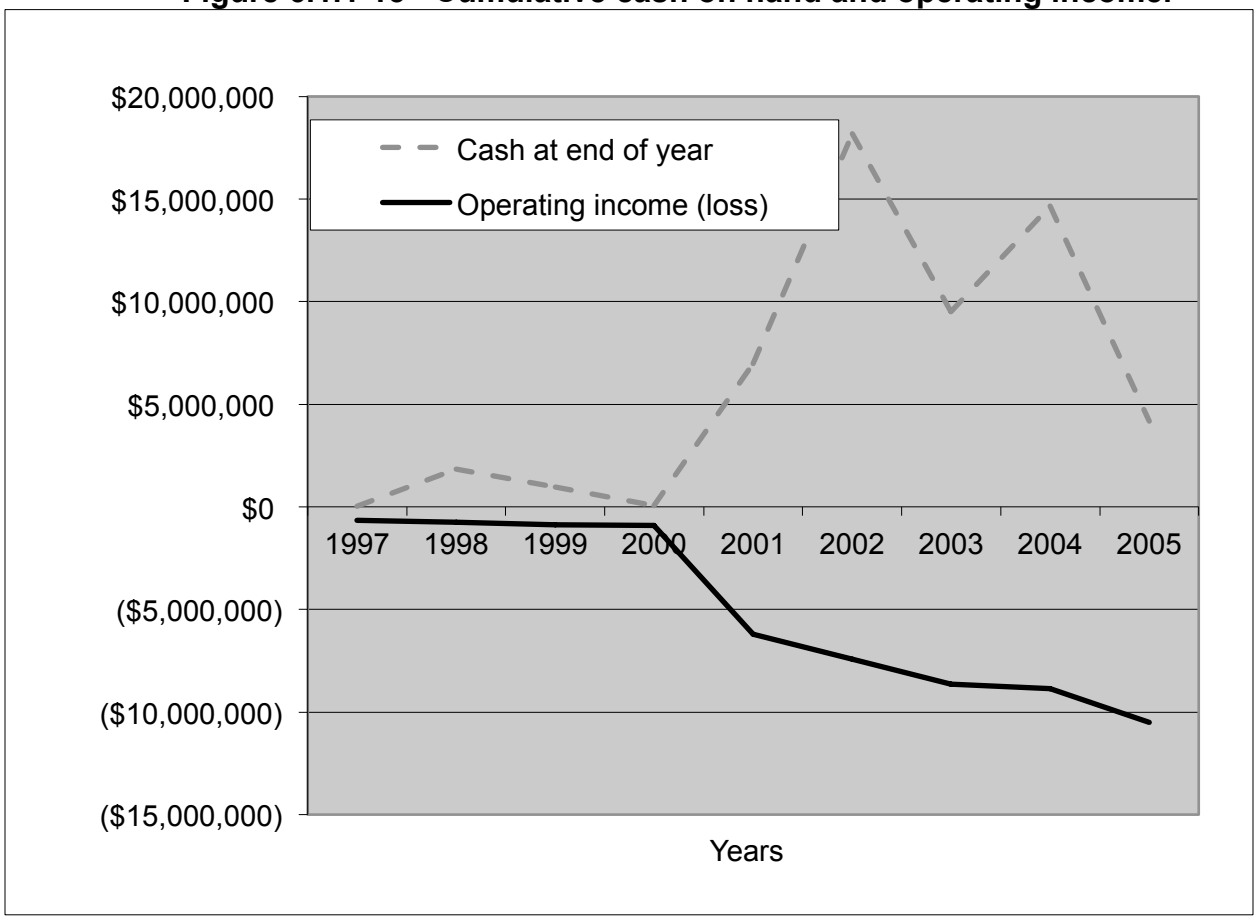


Figure 6.1.1-13 - Cumulative cash on hand and operating income.



Lessons Learned

Cardica faced significant hurdles at the time of its IPO:

- The company had so far failed to achieve FDA approval for its PAS-Port system, and only recently (November 2005) received FDA approval for its C-Port system.

- Sales had only begun in 2004, and 2005 revenues were limited.

- The termination of its European distribution agreement with Guidant in September 2004 was a setback, as the agreement accounted for 48 percent of total revenue in fiscal 2004 and 50 percent of 2005 revenue. At the time of its IPO, the company lacked a European distribution strategy and expected limited sales in Europe going forward.

- All of these factors probably contributed to Cardica's pre-IPO decrease in valuation. Between its 5th venture financing round in September 2003 and their prospectus filing on February 1, 2006, the company's valuation decreased from $85 million to $75 million.

Conventional wisdom in the field states that the proxy companies should have already reached profitability and achieved significant market penetration. In that respect, Cardica is not necessarily an ideal proxy company. On the other hand, the company appears to have persevered within a difficult and changing environment. Its approach and financial model can provide valuable lessons to innovators. Most ventures ultimately face challenges that may appear insurmountable. The ability of their management to work through the challenges in their path to the market is a critical success factor.

With that in mind, here are some lessons to take away from the proxy analysis:

- **FDA Regulatory Hurdles –** Cardica faced significant hurdles during the PAS-Port regulatory process. The FDA redefined the objective performance criteria in the middle of the process, requiring Cardica to resubmit data. Ultimately, the FDA required more robust data that required Cardica to withdraw its 501(k) application and embark on an entirely new clinical trial. If one were to develop a product similar to Cardica's, it would be important to further investigate these hurdles to understand what went wrong in the regulatory process.

- **Extraordinary Cost Items –** There may be some extraordinary cost items present in the income statement, such as stock options expenses or other non-operating expenses. For example in 2005, Cardica's SG&A expenses contained a $2 million stock compensation expense. Be aware of these expenses and account for them appropriately so that they are properly included in the operating expense estimates.

- **Focus on Relevant Costs –** When reconstructing the operating plan, try to focus on the cost items that will also likely apply to the company and spend less time on the items that are unique to the proxy company.

- **Identify Successful Companies in the Space –** Before picking apart a particular proxy company, identify proxy companies that have excelled and whose operating plans might be worth emulating.

Cardica Post-IPO

Cardica has had mixed success since going public in February 2006. Two additional versions of the C-Port system were developed and received 510(k) clearance in the U.S. in 2007. In September 2008, Cardica's PAS-Port device gained its long-awaited FDA approval in the U.S., following results from a 220-patient randomized clinical trial performed at multiple sites in the U.S. and Europe. The study met its primary endpoint of non-inferiority to hand-sewn anastomosis. This approval was granted five years after the company filed its original FDA application. PAS-Port was also approved for sale in Europe and Japan.

According to Hausen, not only did the delay in the FDA clearance process cause "significant delays in our commercial plans,"[10] but the company then encountered a series of other setbacks. Cardica had begun building a direct sales force between 2006 and 2008, but needed to expand it further because the cardiac surgeons that the company was relying on to adopt C-Port and PAS-Port had proven to be less receptive to the technology than anticipated. However, the global financial crisis of late 2008 and 2009 made it difficult for the company to

obtain the necessary funding. Despite a product portfolio of four anastomoses products, sales in the U.S. and overseas remained sluggish. As of Cardica's June 2010 10-K filing, the company had sold an aggregate of only 10,600 units of all the versions of its C-Port systems. Cardica had sold 19,500 PAS-Port systems, primarily in Japan and the United States. Total product sales of the C-Port and PAS-Port systems were $3.8 million, $6.8 million and $4.9 million for fiscal years ended June 30, 2010, 2009 and 2008, respectively. Hausen acknowledged that the company had expected cardiac surgeons to adopt its cardiovascular products "much more quickly and aggressively."[11]

Distribution & Sales

Cardica's exclusive distribution agreement with Century Medical Inc. to distribute the PAS-port system in Japan continued to generate good results (23 percent of PAS-port product sales for the fiscal year ended June 30, 2010).[12] However, Cardica was still without a European distribution partner after its Guidant agreement was terminated. The 2010 10-K report noted, "We expect to rely on third-party distributors for substantially all of our international sales. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenue and may not become profitable."[13] As Hausen observed, "Europe has lots of surgery, but no money," hypothesizing that the low reimbursement in Europe for heart surgery would prevent Cardica from generating substantial revenue in the region. In the same 10-K report, the company concluded, "We are continuing to sell to selected international customers and will continue to evaluate further opportunities to expand our distribution network in Europe and in other parts of the world where the healthcare economics are conducive to the introduction and adoption of new medical device technologies."[14]

However, the company did not anticipate that it would generate significantly higher product sales for the foreseeable future. "Sales of our C-Port and PAS-Port systems have not met the levels that we had anticipated, and to date our systems have had limited commercial adoption," noted the report. According to the 2010 10-K, sales of Cardica's total products and development activities generated only $4.0 million, $9.9 million and $7.6 million of revenue for fiscal years ended June 30, 2010, 2009 and 2008, respectively.[15]

New Direction

In response, the company was forced to pivot and take its stapling technology in a new direction. "The correction on our part was, well, if we can't get this group of surgeons to adopt our technology quickly enough to become profitable, then let's take the technology to surgeons who've already shown that they will adopt stapling technology and give them something they've been asking for so many years," said Hausen.[16] That "something" was a new microcutter line of products; smaller and more flexible versions of Cardica's proprietary miniaturized stapling technology that general and thoracic surgeons could use in minimally invasive (laparoscopic) surgery. In both of these markets, stapling was already "the gold standard." Cardica's goal would be to develop laparascopic stapling products that were significantly smaller than those currently available and so could be used through same size trocars used for other surgical tools. Accordingly, rather than try to increase the adoption of C-Port and PAS-Port, Cardica downsized its cardiac surgery sales force to four representatives and focused on raising funds to develop the microcutter products. "We use independent distributors and manufacturers' representatives to augment a small core direct sales team for our C-Port and PAS-Port systems in the United States to contain sales costs

while continuing to serve our customers and potential customers for our automated anastomosis product line," noted the 2013 10-K filing.[17]

Cardica continued to fund its operation through a variety of means, including a $10.2 million private placement of common stock in September of 2009,[18] and an August 2010 agreement with Intuitive Surgical in which Intuitive received with a worldwide, exclusive license to Cardica's intellectual property related to tissue cutting, stapling, and clip appliers for use in the robotics field. Intuitive paid Cardica $12 million for the license and an equity investment in approximately 1.25 million shares of Cardica's common stock.[19] In September 2011, Cardica signed an agreement with Century to distribute its microcutter products in Japan, and in exchange, Century agreed to loan Cardica up to $4 million, in $2 million increments, based on the achievement of milestones in the micocutter development. In addition, Century would also be responsible for securing regulatory approval from the Ministry of Health in Japan.[20]

As reported in its 2013 10-K report, the first product, the MicroCutter XCHANGE™ 30, received CE Mark in Europe in March 2012. Cardica made its first shipment to its distributor in Europe in December of 2012 and, as of the 10-K filing date, had agreements for the microcutter product line with four distributors in Europe covering eight countries. In January of 2014, Cardica received clearance from the FDA to begin commercial sales of the MicroCutter XCHANGE 30 device in the U.S. "This clearance…will allow us to initiate a selective commercial launch targeting key opinion leading accounts in the U.S," stated Hausen in a press release.[21] Cardica planned to introduce the MicroCutter XCHANGE 30 to a limited number of targeted clinical sites and learn the time and training required to achieve routine clinical adoption of the product. To support this strategy, the company planned to start with a small group of direct sales representatives who had extensive backgrounds in stapling products and laparoscopic procedures, as well as existing relationships with key surgeons and decision makers. Over subsequent quarters, Cardica intended to add additional sales representatives in new markets.

Revenues and Profits

Although the new product line holds promise, Cardica is still a long way from profitability. As noted in the 2013 10-K filing, as of June 30, 2013, Cardica had sold an aggregate total of 13,800 C-Port units in the U.S. and Europe, and 32,600 PAS-Port units in the U.S., Europe, and Japan.[22] Product and development revenues for fiscal year 2013 (ending June 30) totaled $3.5 million. This compares to operating costs in 2013 of $19.2 million, leading to continued large losses for the company. As stated in the 2013 10-K filing, "We have a history of net losses, which we expect to continue for the foreseeable future, and we are unable to predict the extent of future losses or when we will become profitable, if at all."[23]

Overall, Cardica's mixed record post-IPO has led to a stagnating stock price (roughly $1.16 per share in February 2014 compared to $10 upon opening in February 2008).

Reconciliation with the Bottom-Up Market Model

As this discussion illustrates, Cardica's actual performance varied substantially from the bottom-up market analysis performed as part of 6.1 Operating Plan & Financial Model. However, the example illustrates the unpredictable nature of a company's ability to achieve its financial projections and underscores the many risks that medical device companies face in

bringing a product to market. The effect of FDA delays and ongoing sales and distribution challenges, as well as the global financial crisis, impeded the company's progress. However, the greatest factor limiting Cardica's results was its failure to drive adoption among its target customers. It would seem that despite the clinical advantages offered by Cardica's anastomosis devices, their value proposition was not sufficiently compelling to persuade cardiac surgeons to change their established behavior. The company had some success in convincing a sub-segment of the population to become early, consistent users of the technologies, but failed to gain critical mass. As explained in Cardica's 2013 10-K filing, "Currently, the vast majority of anastomoses are performed with sutures and, for the foreseeable future, sutures will continue to be the principal competitor for alternative anastomotic solutions. The direct cost of sutures used for anastomoses in CABG procedures is far less expensive than the direct cost of automated anastomotic systems, and surgeons, who have been using sutures for their entire careers, have been reluctant to consider alternative technologies, despite potential advantages."[24] Quite possibly, while cardiac surgeons could appreciate the improvements offered by the new approach, they had other priorities (or needs) competing for their time, attention, and budgets. To be sure, adoption challenges such as these are difficult to anticipate. And they are even more challenging to address once in the market, which is precisely why this textbook places such great emphasis on issues related to needs exploration, stakeholder analysis, and market assessment so early in the biodesign innovation process.

Endnotes

[1] Drawn from Cardica Inc. S-1 Form, 2006, http://www.sec.gov/Archives/edgar/data/1178104/000116923205005200/d65698_s-1.htm (February 24, 2014). Reprinted with permission.
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