6.1 Operating Plan and Financial Model

INTRODUCTION

Engineers to design, prototype, develop, and manufacture a new product. Clinicians to run clinical trials. Statisticians to analyze the data. Executives to develop marketing and sales strategies. Reimbursement consultants to secure codes, coverage, and payment. Sales people to get the technology into the hands of customers. Key opinion leaders to promote its adoption. All of these individuals are essential to the development and commercialization of a medical device. Yet, without a carefully integrated plan that captures and coordinates these complex, interdependent efforts, innovators cannot fully understand whether the effort required to develop and commercialize the offering will justify the associated investment.

Through the operating plan and financial model, innovators will gain an understanding of the time and money necessary to develop and commercialize their new solution. This information will be used both to assess the viability of pursuing the proposed solution and to provide a blueprint for implementing the company's business strategy, realizing its vision, and monitoring the results it achieves.

To prepare an operating plan, innovators specify precisely who will execute the various strategies defined through the strategy development stage of the biodesign innovation process, when and in what order key activities will be performed, and with what resources. This information is then translated into costs and consolidated into an integrated financial model that also includes a detailed revenue plan for capturing a share of the potential market. By comparing the revenue projections to the detailed cost estimates that stem from the operating plan, the innovators can confirm whether or not the potential market justifies the financial requirements for developing and commercializing the product.

See ebiodesign.org for featured videos on preparing an operating plan and financial model.

OBJECTIVES

- Understand how to develop an operating plan, cost projections, and revenue model and then integrate them into a unified financial model that can be used to validate an opportunity and support business planning.
- Appreciate how to make and validate medtech-specific assumptions to support the creation of an operating plan and financial model.
- Learn to identify the most important strategic and tactical issues that should be reflected in the operating plan and financial model.
- Understand how to perform a proxy company analysis to validate all components of the operating plan and the financial model against a more established company with attributes similar to the new venture.

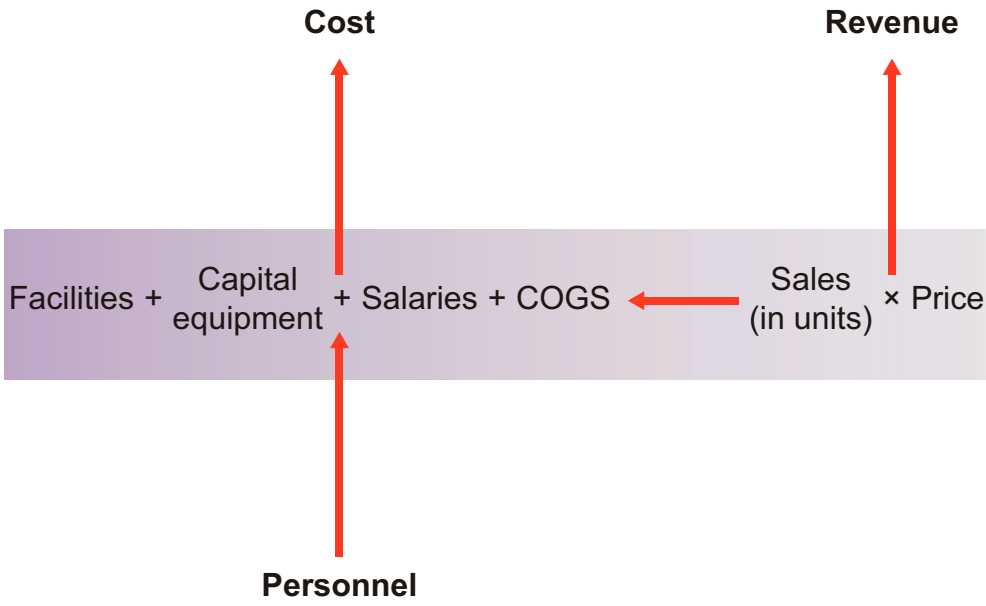

FIGURE 6.1.1
Cost and revenue are the fundamental drivers of any financial model.

OPERATING PLAN AND FINANCIAL MODEL FUNDAMENTALS

Thomas Fogarty, innovator and founder of more than 30 **medtech** companies, highlighted the diversity of the skills required to bring a new device to the market:[1]

> *Particularly in this day and age, you need people from different disciplines – you need intellectual property attorneys, you need corporate attorneys, you need regulatory experts, you need good engineers . . . and you need different types of engineers. You need the person who can conceptualize, the one who can* ***prototype****, the production engineers, and then what I call a "finisher." To bring this whole team together, you have to understand* ***value*** *allocation. All of these people create value. They bring something different to the table. If you think, just because you had the idea, you brought all the value, you're not going to be successful. Somebody has to implement your idea, and one individual can't do it.*

A **financial model** for a new venture is a detailed, quantitative articulation of Fogarty's statement. Until this point, innovators largely have been thinking about important activities and costs related to specific steps in the biodesign innovation process, first through landscaping and competitive scanning and then through more focused approaches. Now it is time to bring that information together and integrate it into a cohesive plan so that they can establish a comprehensive understanding of the magnitude of time, effort, and money required to bring the solution to market. In the US, it is not uncommon for a company to require more than three years and $4–$15 million to get a **510(k)** product to market. Technologies on the **PMA** pathway are more likely to take seven to 10 years and anywhere from $50 million to $120 million. Getting a **CE mark** product to market is still significantly more efficient, at roughly two years and $4 million. Of course, these estimates can vary dramatically from project to project, but they underscore the point that medtech development and commercialization is resource-intensive. More than anything, innovators need a realistic, practical understanding of what will be required, and the operating plan and financial model can provide it.

This exercise begins with the company's operating plan, tracking the cost of developing and commercializing the innovation, along with market revenue, over a period of five to seven years. For at least the first three years (and, ideally, the first five years), the model tracks costs and revenue on a quarterly basis and, after that, on an annual basis.

Costs include salaries, capital equipment, supplies, facility expenses, and cost of goods sold (**COGS**), which is the total material cost for manufacturing[2] Revenue is total units multiplied by sales price. Figure 6.1.1

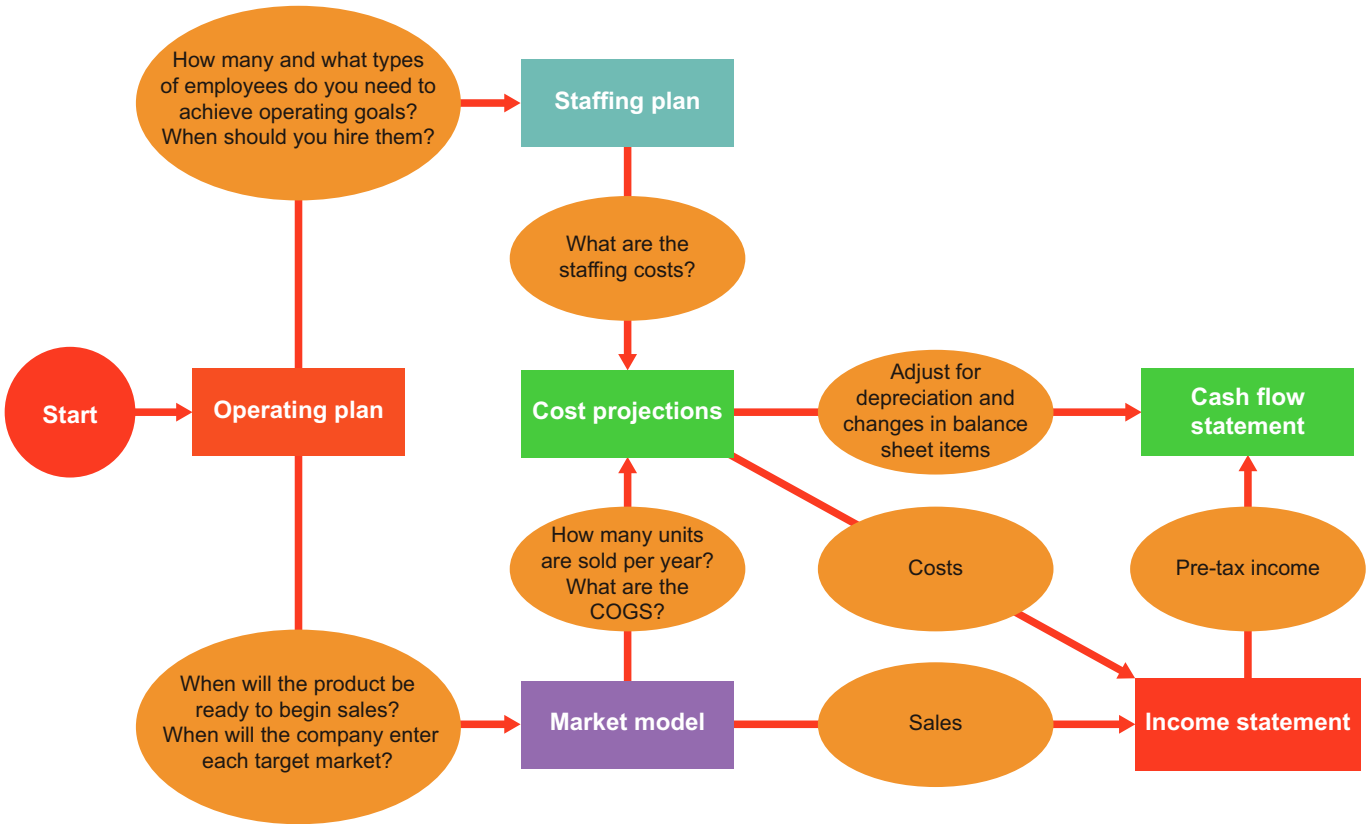

FIGURE 6.1.2
The six primary components of a financial model and how they work together.

provides a simplified view of these basic drivers of the financial model.

The financial model has six components, which correspond to the six steps in its development. The **operating plan** provides an overview of the activities that must be performed to develop the technology, their timing, and the key milestones they support. The **staffing plan** specifies the personnel needed to execute the operating plan. The **market model** includes revenue and market share projections, as well as a preliminary assessment of the sales force required to achieve these forecasts. **Cost projections** then integrate all costs together: salaries, facilities, equipment, supplies, and COGS from product manufacturing. The **income statement** subtracts all costs from revenue to generate an accounting income statement. An important distinction is that, with accounting income, the cost of capital equipment is not subtracted in the year the equipment is purchased. Instead, it is spread across the lifetime of the equipment. However, the capital necessary to acquire the equipment is needed in the year of the purchase. Cash flows reflect this distinction and are calculated by subtracting the actual cash expenditures from the cash revenue recorded during a given time period. The cash flow analysis then provides the basis for estimating a company's funding needs. Each of these components is explained in more detail in the sections that follow. Figure 6.1.2 provides an overview of how these elements work together.

Throughout this chapter, an example will be referenced to illustrate each of the components of the financial model. The example focuses on a fictitious business developing a relatively traditional medical device. The major components of the operating plan and financial model for other types of offerings should be similar, although details may vary significantly. For instance, for a mobile health (**mHealth**) application, products are typically faster to prototype and can be moved into user testing more quickly. Additionally, while the overall capital requirements for their development is likely to be lower, the corresponding spend on marketing will be higher.

	Quarter																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Phase 1: Proof of concept																				
Hire CEO																				
Initial catheter prototyping																				
Generator prototyping																				
Clinical proof of concept testing																				
Phase 2: Final product development																				
Finalize catheter design																				
Finalize generator design																				
Complete manufacturing design																				
Phase 3: FDA approval																				
Complete animal and bench top testing																				
First in human																				
510k approval process																				
Finalize manufacturing processes																				
FDA approval																				
Phase 4: Reimbursement																				
Payer engagement																				
Preparation of payer materials																				
Payer communication																				
Reimbursement support																				
Phase 5: Market availability																				
Initial sales force hires																				
Design training program																				
Limited pilot study and availability																				
Product generally available																				

FIGURE 6.1.3
Sample operating plan for a hypothetical ablation catheter business.

This particular example focuses on a product intended to treat atrial fibrillation (AF), a cardiac rhythm abnormality that causes the atria (the upper chambers of the heart) to contract irregularly. This condition creates a number of undesirable side effects ranging from palpitations and fatigue to the potential for a debilitating stroke. One way to treat AF is to destroy, or ablate, certain areas of the heart responsible for the initiation and perpetuation of electrical signals underlying the disease. Ablation is achieved through the use of an ablation catheter, which can be advanced into the heart via the blood vessels where it can be used to deliver energy to ablate the cardiac tissue (see 2.1 Disease State Fundamentals and 2.2 Existing Solutions for more information).

Operating plan

To prepare an operating plan, innovators should start with the high-level milestones a company chooses to chart its progress. Many of these early milestones are related to research and development (R&D), as explained in 5.2 R&D Strategy. Specific milestones vary from company to company. However, at a high level, they might include:

1. Proof of **concept**
2. Product development progress
3. Manufacturing feasibility
4. **First-in human** studies, **clinical trials**, and **FDA** submission
5. **Reimbursement** progress
6. Development of scalable manufacturing
7. Marketing and sales (US, Europe, Asia)

A detailed operating plan would break down these high-level milestones into additional granularity (e.g., reimbursement initiatives could be divided by **payer** type). Figure 6.1.3 shows a sample operating plan by quarter for the hypothetical ablation catheter business (assuming a 510(k) regulatory pathway and reimbursement under existing codes).

Innovators often would like to think that the operating plan does not change. However, at some point, most ventures face significant technical or clinical challenges that force the team to reconsider its plans and milestones. For example, the company featured in online Appendix 6.1.1 (Cardica, Inc.) faced a formidable set-back when the FDA changed the clinical trial requirements in the middle of its clinical studies as a result of safety problems with a competitor's product. The appendix explains how the company modified its strategy and operating plan in response to the unanticipated change.

Staffing plan

The staffing plan outlines the number of employees that need to be hired over time. The staffing plan is a direct outgrowth of the steps in the operating plan, since staffing requirements should be determined by the company's strategic and operating decisions. Essentially,

	Quarter																				Year	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	6	7
Manufacturing team																						
Engineers	0	0	0	0	0	0	0	0	1	2	3	4	6	6	6	6	9	9	9	9	9	12
Manufacturing assemblers	0	0	0	0	0	0	0	0	2	2	2	2	5	5	5	5	10	10	10	10	18	35
R&D																						
Catheter team																						
Engineers	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2	3	5
Techs	2	2	2	4	4	4	4	4	4	4	4	6	6	6	6	6	6	6	6	6	7	10
Generator team																						
Engineers	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	5
Techs	2	2	2	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	7	10
SG&A																						
Salesforce	0	0	0	0	0	0	0	0	0	0	0	4	4	8	12	12	12	12	12	12	25	50
Marketing, business development, and reimbursement	0	0	0	0	0	1	1	1	1	1	2	2	3	3	3	3	3	4	4	4	5	5
Clinical advisor	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	2	2
Regulatory	0	0	0	0	0	0	0	1	1	1	1	1	2	4	4	4	4	5	5	5	5	5
Administrative asst.	0	0	0	0	0	1	1	1	1	1	1	1	1	1	2	2	2	3	3	3	4	5
Management	1	1	1	1	2	2	2	2	2	2	2	4	4	4	4	6	6	6	6	6	8	8

FIGURE 6.1.4
A sample staffing plan.

an innovator needs to figure out the types of employees (in terms of skill sets or function) and overall number of employees required to achieve the milestones set forth in the operating plan. The strategies developed in earlier chapters provide critical input to these estimates.

Figure 6.1.4 shows a sample staffing plan that is driven by the operating plan shown in Figure 6.1.3. The staffing plan is divided into three components: manufacturing, R&D, and **SG&A** (selling and general administrative) expenses. The levels in the staffing plan should directly correspond to the milestones in the operating plan. For instance:

- R&D staffing starts from the first quarter but it increases as product launch approaches in the 12th quarter (Q12). The company hires a second catheter team R&D engineer in Q10 to support R&D activities related to the development of the manufacturing process. This should match the achievement of a specific milestone in the operating plan (e.g., completion of manufacturing design and initiation of the development of manufacturing process).
- The completion of manufacturing design (under Phase 2) is finalized in Q10 and manufacturing processes are finalized in Q11 and Q12. Accordingly, manufacturing employees are hired in Q9, to participate in finalizing the manufacturing process before manufacturing actually begins.
- FDA approval is targeted for Q11, which is why the first members of the sales force are hired in Q12, since it would not make sense to hire them prior to having a product to sell. In this example, a focused direct sales model (selling directly to the physician or facility customer) is assumed. The peak sales force size assumed (50) is relatively small for direct sales force and should be rationalized based on a more detailed model (the method used to develop such a model is discussed as part of the **bottom-up market model** later in this chapter). Other sales models, such as using distributors, would require a smaller in-house sales team and these numbers would be reflected in the staffing plan accordingly.

In general, staffing numbers will vary based on factors such as the regulatory pathway, reimbursement environment, and sales model that have been chosen. For example, a direct sales force can require as many as 100 to 200 sales representatives at a peak, while a two- to three-person sales team might be sufficient to support an **indirect sales model**. Additionally, the size of the target physician population (e.g., a smaller specialty as compared to the large numbers of primary care doctors) can significantly affect the required sales force. Reimbursement may require a team of up to ten people if a multinational reimbursement effort is anticipated and a high level of support is desired. On the other hand, one or two consultants may be sufficient if favorable **coding**, **coverage**, and **payment** decisions are already in place.

One way to roughly check if the number of employees reflected in the staffing plan is reasonable is to use commonly accepted staffing ratios and formulas. For example:

- **SG&A to R&D** – Typically, the ratio of SG&A employees to R&D employees is roughly three to one in a mature medical device company. (It is important to note that this ratio may be very different in the early phases of a business as a product is being developed.)
- **Product units per assembler** – If the company intends to assemble or build the product in-house, it must be sure to have enough assemblers to meet demand for the product. Calculate the total number of units produced by each assembler to make sure it is a reasonable match to anticipated demand and a reasonable quantity for an assembler to achieve in a given time period. If either of these are not the case, more or fewer assemblers may be needed. The number of assemblers is linked to the market model, which defines the number of units that need to be produced for a given time period.

Market model

As described in 2.4 Market Analysis, there are two ways to approach market models: top-down or bottom-up. While **top-down models** have been useful to this point in developing "back of the envelope" market estimates, innovators are encouraged to develop a market model from the bottom-up for inclusion in the financial model. This approach helps to ensure that the cascade of assumptions relied upon to develop the numbers are fundamentally sound and well understood. It lends credibility to the model and provides innovators with confidence when asked to defend it. And, it gives them an opportunity to think through the sales process in depth and develop a better understanding of challenges related to capturing market share. These challenges are not apparent in a rough top-down model. That said, both types of models can be useful in different circumstances and are therefore covered in more detail in the sections that follow.

Top-down model

A top-down market model forecasts projected yearly revenue by outlining the segments of the market that will be addressed and by determining how many customers the company intends to service (the number of patients that will be treated, hospitals/offices that will be sold to, etc.), then multiplying the number of customers by the price of the innovation. This approach is useful for quickly confirming how attractive the market is to pursue. Figure 6.1.5 shows a sample market model; a detailed description of the calculations follow the figure.

As noted, a top-down market model is based entirely on a number of statistical assumptions. Innovators can find many relevant statistics in scientific journals and analyst reports, but they will almost certainly be required to make "educated estimates" when no specific references are available. Developing reasonable assumptions

Key Assumptions

Assumption	#	Source
# of paroxysmal AF patients	960,000	American Heart Association
Population growth rate	2%	US pop stats - baby boomers
% drug refractory	28%	New England Journal of Medicine
Average selling price (ASP) of ablation catheter ($)	2000	Company research
% annual decrease of ASP	1%	Estimate

US Market Model

Year	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Key milestones			FDA Approval				
Paroxysmal AF patients	960,000	979,200	998,784	1,018,760	1,039,135	1,059,918	1,081,116
% drug refractory	28%	28%	28%	28%	28%	28%	28%
Refractory AF patients	268,800	274,176	279,660	285,253	290,958	296,777	302,712
% of refractory patients treated	*2.5%*	*4.5%*	*7.5%*	*15.0%*	*25.0%*	*30.0%*	*35.0%*
Procedures per patient	1.15	1.12	1.10	1.08	1.07	1.06	1.05
Total ablation procedures performed	7,728	13,818	23,072	46,211	77,831	94,375	111,247
Total market size ($)	**15,456,000**	**27,498,756**	**45,683,536**	**91,042,470**	**152,572,428**	**184,078,320**	**215,901,728**
% Market share of ablation patients	*0.0%*	*0.0%*	*0.1%*	*1.0%*	*5.0%*	*12.0%*	*20.0%*
Total units sold	-	-	23	462	3,892	11,325	22,249
Average selling price ($)	2,000	1,990	1,980	1,970	1,960	1,950	1,941
Revenue ($)	**-**	**-**	**45,684**	**910,425**	**7,628,621**	**22,089,398**	**43,180,346**

FIGURE 6.1.5
A sample top-down market model.

is part of the process of constructing a financial model and something that innovators need to become comfortable doing. Remember that these estimates can always be improved as additional data become available. Where references do exist, cite these sources to enhance the credibility of the projections. Also, draw on the early work completed as part of 2.4 Market Analysis.

To develop this particular top-down market model, the first step was to calculate the number of paroxysmal AF patients per year, starting with 960,000 in year 1 and increasing by 2 percent per year. The number of paroxysmal AF patients per year was then multiplied by the percent of patients who are drug refractory (i.e., not responsive to pharmaceutical therapy) and, therefore, are candidates for ablation (28 percent). This represented the total number of patients who can be treated with ablation. That number was next multiplied by the percentage of drug refractory AF patients who are actually treated to get the number of patients treated per year. These percentages were taken from a Frost & Sullivan research report (it is always a good idea to incorporate published statistics where applicable).

Because patients may need multiple procedures, the number of patients treated was then multiplied by the number of procedures per patient to produce the total number of procedures performed per year. The number of procedures performed per year was multiplied by the average selling price (ASP) per procedure ($2,000) to determine the total market size in dollars. To address the fact that the company will capture a fraction of this market, market share projections were multiplied by the total number of procedures per year to produce the target number of procedures per year, which corresponds to the total number of units sold per year. (Note that if more than one device was used per procedure, this would also need to be taken into account.) Finally, the total number of units sold per year was multiplied by the average selling price to produce the revenue target per year.

When determining market share, bear in mind that market share growth depends on a number of factors, including how innovative or unique the technology is, as well as how likely physicians are to adopt it. Factors such as how aggressive the company's sales plan is and how many sales representatives will be hired should also be taken into account. Finally, consider the number of competitors already in the market and the extent of their resources.

Experts caution that one should not be overly aggressive when modeling market penetration. In most cases, it is unlikely for a product to gain more than 1 percent market share in the first year unless there is substantial pent-up demand and the sales channel is already well established. Although there are some notable exceptions, innovators should also assume that, in the long-run, competition will join the market (if not already present) and that portions of the market will not necessarily be accessible. As a result, a long-term market share forecast of 15–30 percent is a realistic outcome, even in a successful scenario.

Bottom-up model

The bottom-up model takes a different approach to assessing the market as described in the seven steps listed below:

1. **Determine the fundamental unit of business** – In this first step, the key is to determine what drives business in the market. For a company selling capital equipment, the "unit of business" is the number of facilities that purchase the machine. For other medtech companies, however, physicians may be the key unit of business because they are the ones that directly use a device within a specific procedure. If the company is working on an over-the-counter or fee-per-use business model (see 4.4 Business Models), then the patient may serve as the fundamental business unit.
2. **Consider the sales cycle** – The sales cycle involves all of the time and expense required to sell one unit of business. This includes the time and cost of raising the buyer's awareness of the technology, getting him/her interested, and closing the deal. If the buyer is a facility or hospital, standard purchasing processes and cycles must be taken into account, which can require as much as six months to a year to complete. If the buyer is a physician, the time and cost of training him/her to use the device may also need to be calculated, along with any follow-up

training. For new sales reps, a learning curve must also be factored in to these calculations – it can take three to six months (or more) before a new rep is trained and closes a first sale.

3. **Consider the adoption curve** – The adoption curve refers to the rate at which the buyer will utilize or consume the technology. For devices that present a relatively low risk and/or obvious benefits, the number of devices used over a given unit of time may grow relatively steadily. However, for higher-risk devices or technologies perceived as being more experimental, utilization may grow more gradually. For instance, a physician may perform a first procedure using the technology and then wait for several months to see how that preliminary patient responds before performing another. Certain facilities and medical specialties have a tendency to adopt new technologies faster than others, which should also be taken into account when developing the adoption curve. The key is to derive the anticipated utilization rate for a single unit of business on day one, day two, etc., to get a sense of how quickly the company will be able to build its sales volume. Some typical metrics that can be used to capture utilization include the percentage of the case volume of the business unit that utilizes the venture's products, the number of physicians trained in the use of the product (see the Cardica case example), or the number of individual physicians within the staff who are considered active (repeat) **users** of the product.
4. **Build the commercial effort** – At this point, innovators stop thinking about what is required to make individual sales to a single unit of business and start thinking about how many sales reps should be hired to build a reasonable business. From step 1, the innovators can determine how many units of business exist within the target market. From step 2, they understand how much total effort is required and expected to make each sale. From step 3, they have estimated a realistic adoption rate. Now, the challenge is to pull these factors together to determine how many sales reps are needed to grow the business at an appropriate, realistic pace. The key is to balance the innovators' desire for "reward" with their tolerance for risk. Hiring too many sales reps at once can be a costly mistake until key assumptions regarding the sales cycle and adoption curve have been tested in the market. On the other hand, the company needs to be able to drive enough sales within a realistic time frame to sustain its operations and keep its commitments to investors. It is common practice to pilot the proof of the sales model – that is, to size the initial sales force to a handful of representatives and postpone expansion (scale up) until the assumptions built into the plan can be validated by actual field experience. Typically, it is advisable to run multiple scenarios (what would it look like to start with 5 sales reps? 10 sales reps? 15 sales reps?), then choose the one that produces the best risk/reward ratio.
5. **Consider market development factors** – The next step is to consider other factors in external environment that have the ability to affect the overall market model. For example, reimbursement coverage can have a major effect on market adoption. If reimbursement has not yet been achieved, this could affect the size of the initial sales force that is appropriate. Similarly, if professional societies have not yet endorsed the technology or key data have not been published, it may be wise to start with a smaller sales force focused on converting early adopters until some of these other factors have been put into place to support more widespread sales. Importantly, the top-down market model does not explicitly take these types of factors into account, which is one of its inherent weaknesses.
6. **Factor in product evolution** – If the innovator anticipates that subsequent versions of the technology will become available within a one-to-three year time frame, this should be reflected in the market model. New versions of a technology have the potential to increase utilization based on the improvements made and/or features added that potentially make the technology relevant to a greater number of procedures, or provide the opportunity to raise the selling price to reflect added value.

7. **Consider other factors** – Finally, an innovator should look closely at the market, the buyer, and the technology to determine if there are any other factors that might affect sales. For example, some medical specialties are more seasonal than others (e.g., orthopedics is busiest in the winter and the summer when people participate in seasonal sporting activities). Buying behavior in certain medical specialties can also be influenced by major medical conferences that occur at a certain time of year (when physicians and hospital administrators convene to check out new technology in the field). These types of considerations should be factored into the overall market model and the timing of key market decisions.

The following example on Cardica, Inc. demonstrates how a bottom-up market model is developed in practice within a medical device start-up. More details about Cardica and a more complete financial model for the company can be found in online Appendix 6.1.1 on **proxy company** analysis.

FROM THE FIELD CARDICA, INC.

Developing a bottom-up market model for a direct sales force focused on CABG

Cardica, Inc. was co-founded by Bernard Hausen and Steve Yencho, PhD, in 1997 in order to design and manufacture proprietary products that automate the connection, or anastomosis, of blood vessels during coronary artery bypass graft (CABG) surgery. In CABG procedures, veins or arteries are used to construct "bypass" conduits to restore blood flow beyond closed or narrowed portions of coronary arteries. This is typically accomplished by suturing one end of the vein or arterial conduit to the aorta and the other end to the coronary artery at a site beyond the blockage. Cardica's product portfolio included two products by 2004: the C-Port® Distal Anastomosis System (referred to as C-Port; see Figure 6.1.6) and the PAS-Port® Proximal Anastomosis System (referred to as PAS-Port). The C-Port product was used to connect a bypass graft to the coronary arteries while PAS-Port was to automate the connection of the graft to the aorta. In November 2005, Cardica received 510(k) clearance for C-Port, but PAS-Port was deemed to require a PMA and a **randomized clinical trial** (more details are provided in the proxy example analysis in online Appendix 6.1.1). As a result, management expected a potential three-year delay between the US commercial launch of its C-Port and PAS-Port systems.

FIGURE 6.1.6
Cardica's C-Port xA distal anastomosis system (courtesy of Cardica, Inc.).

Early in the biodesign innovation process, Cardica's management team made the decision to develop a direct sales force. As Bob Newell, Cardica's CFO explained, "A key metric we use to measure progress in our business is the number of trained surgeons using the product. In

the US there are about 3,000 surgeons performing approximately 250,000 CABG surgeries per year in 1,000 hospitals; but about 225 hospitals perform 50 percent of all procedures. So we can go after these higher volume facilities with a targeted sales force. Our sales force doesn't have to be really huge, like it would be if we were in interventional cardiology. In addition, we do not need to target all surgeons in these hospitals. There are two primary segments: on-pump and off-pump CABG surgery. On-pump is the traditional way of doing bypass surgery where the heart is stopped and the patient is on a bypass machine, which filters their blood and keeps the blood flowing while the heart is stopped. About 75 percent of the market still does bypass surgery that way. A newer method of doing bypass surgery is called off-pump, or beating heart surgery, which means that the surgery is performed on a heart that has not been stopped – it continues to beat and the blood is not bypassed out into a bypass machine. Beating heart surgeons tend to be early adopters, so most of our first customers are likely to be beating heart surgeons."[3] Cardica's management estimated that 225 surgeons performed the overwhelming majority of beating heart surgeries.

Cardica's basic sales strategy was to first train surgeons based on the use of the C-Port device. The company's goal was to have many high-volume beating heart surgeons trained by the time the PAS-Port product was approved and launched. This gave the company three years from the time of C-Port's launch to train its first adopters. Newell estimated that the main expense in educating a surgeon was the time it took the sales person to deliver the training. After a four-to-six hour initial instruction at the company's facilities, which included a brief excursion to the wet lab, a Cardica sales representative would attend the first five to six cases performed by the surgeon. Once a surgeon was trained, it could take anywhere between two to nine months to reach steady-state sales for that customer.

Cardica management estimated that C-Port would have a theoretical total US market of 875,000 units based on an average of 3.5 distal anastomoses per procedure and a total number of 250,000 procedures. Of this amount, the beating heart segment would be about 25 percent or a total available theoretical market of just over 200,000 units. PAS-Port, on the other hand, would potentially have a total theoretical market of 375,000 units based on an average of 1.5 proximal anastomoses per procedure. (The difference between the average number of distal and proximal anastomosis is because some of the arterial bypass conduits, such as the internal mammary artery, are used with their proximal blood flow site intact and thus no proximal anastamosis is required.) The price for C-Port was set at $800 per anastomosis, while PAS-Port was $600 per anastomosis. Using these numbers, management estimated that the total theoretical annual US sales with 100 percent penetration would be $700 million for C-Port (250,000 procedures $\times$ 3.5 devices per procedure $\times$ $800 per device) and $225 million for PAS-Port (250,000 procedures $\times$ 1.5 devices per procedure $\times$ $600 per device) The corresponding numbers for the beating heart segment were: $170 million and $56 million (all numbers rounded to the nearest million).

The company then estimated that a sales person would cost between $350,000 and $400,000 per year (including benefits) and each one could generate a maximum of $1.5 to $2.5 million in annual sales. Once a sales person reached that threshold, a new sales person would be needed in the territory to cover additional surgeons. It would take Cardica two to three months to train a sales person, and the company anticipated that each sales person could bring in and train three new surgeons per quarter.

To develop a bottom-up market model based on this information requires two phases of effort. Phase I covers the initial period between C-Port and PAS-Port launch. Phase II covers PAS-Port launch and beyond.

The goal of phase I is to train early adopters at the rate of 25 to 30 per quarter and to have as many as 250 to 300 or more surgeons trained and using C-Port by the time PAS-Port is approved. Assuming a two-thirds retention rate over a three-year period, this translates into roughly

	C-Port® Launch						PAS-PORT® Launch	
Quarter	1	2	3	4 …..	9	10	11	12
Direct Sales Force	3	3	3	10	10	10	10	10
Physicians Trained in Current Quarter	10	10	10	10	30	30	30	30
Physicians Trained (and retained) in Prior Q		7	7	7	20	20	20	20
Physicians Trained (and retained) Two Qs Ago			7	7	20	20	20	20
Fully Trained & Retained Physicians				7	80	100	150	140
Total Trained Physicians	10	20	30	40	190	220	250	280
Total C-Port Sales		37,037	111,111	222,222	1,666,667	2,000,000	2,333,333	2,666,667
Total PAS-Port Sales								
Total Sales		37,037	111,111	222,222	1,666,667	2,000,000	2,333,333	2,666,667
Quarterly Sales per Sales Rep		12,346	37,037	22,222	166,667	200,000	233,333	266,667
Total Sales Force Costs	300,000	300,000	300,000	1,000,000	1,000,000	1,000,000	1,000,000	1,000,000

FIGURE 6.1.7

The phase I market model. Notes: (1) The line item "total trained physicians" reflects the cumulative number of physicians trained, ignoring the two-thirds retention rate; (2) the delay in sales following the launch of both products reflects the need for physician training time.

180 to 200 retained surgeons by Q12. This calculation implies that about 10 new surgeons can be trained each quarter in the first year. A reasonable target in Q5 to Q12 is 30 new trained surgeons per quarter (which translates into a direct sales force of 10 reps). The model in Figure 6.1.7 outlines the details (each row in the model represents a quarter and the cost for a fully loaded sales person is $400,000 per year or $100,000 per quarter).

A small sales force of three sales people is in place for the first three quarters, until it increases to ten in the fourth quarter. The model assumes a quarter of training for new sales people; therefore, after training for one quarter, the additional sales people allow Cardica to reach the target surgeon training level of 30 in Q5. The model keeps track of the number of surgeons trained in the current quarter, as well as in the previous two quarters in order to capture the three to nine months it takes for newly trained surgeons to reach steady-state sales. The calculation of total sales assumes surgeons trained in the current quarter do not perform any procedures, while surgeons trained in previous quarters perform increasingly more procedures until reaching 10 percent of their case volume nine months after they complete training. The model indicates that the sales force will generate enough sales to cover its expenses by Q8 (not shown).

The next step is to consider phase II: PAS-Port launch and beyond (see Figure 6.1.8). With an established base of 180 trained and retained off-pump surgeons (140 fully trained with more than two quarters of experience, plus 40 trained and retained for at least one or two quarters) by Q12, one would expect a successful launch and potentially a rapid, "hockey stick" pattern of adoption for PAS-Port. Cardica's management estimated that all retained C-Port surgeons could be trained on the PAS-Port within two quarters after the PAS-Port launch, given their familiarity and use of a Cardiac device and relationship with a Cardiac sales person. New surgeons would continue to be trained at the rate of 30 per quarter on both and C-Port and PAS-Port.

FIGURE 6.1.8

PAS-Port proximal anastomosis system (courtesy of Cardica, Inc.).

Further, management believed the penetration of PAS-Port into the surgeon's case volume would be more rapid than C-Port due to more accepted clinical benefit (one of the benefits of PAS-Port is that it eliminates the need to clamp the aorta, which can lead to a stroke, and is required in manual procedures). They felt that it would be reasonable to expect a 25–50 percent penetration rate within three quarters from launch (the model shown below assumes penetration of 35 percent). Under these assumptions, Cardica's total quarterly US sales would be expected to exceed $8 million by Q17. This sales growth would strain the sales force of 10. Therefore, Cardica would need to build its sales force in anticipation of this growth. The following model assumes that recruitment and training for the sales force happens early in Q11 with a modest increase from 10 to 13 to anticipate the new, additional needs of the existing trained base. The sales force will then increase again to 17 by Q16. The model also assumes that sales territories are split and new sales people are added when the existing sales of a sales person reaches the target $1.5 to $2.5 million per year, and that each new sales person requires one quarter of training. The model in Figure 6.1.9 starts from Q10 and modifies the sales people row to capture the increased needs due to the PAS-Port product launch.

This model demonstrates that by Q18 a sales force of 17 will be able to cover 300 trained and retained surgeons, which represents about 17 surgeons per sales person. Sales activities will include a mixture of supporting existing surgeons and bringing new surgeons on board. Total sales of $8.6 million per quarter will be reached in Q18. The reader will notice that despite the markedly increased sales force, the number of new trained physicians per quarter remains constant. This is because most of the sales people are now spending more of their time maintaining and supporting existing surgeons and a smaller fraction of their time recruiting new surgeons. The assumptions made in the model include the following:

- 3,000 surgeons performing CABG surgeries in the US in 1,000 hospitals.
- 225 hospitals perform roughly 50 percent of all procedures.
- Of the 250,000 CABG surgeries annually in the US, approximately 25 percent are "off pump" or beating heart procedures.
- Surgeons performing off-pump CABG surgeries will be most of the company's first adopters.
- Cardica's goal is to train 300 or more surgeons on the use of C-Port by the time PAS-Port is approved for commercial use.
- The company anticipates that it will take approximately three years (Q1–Q12) from the time of the C-Port commercial launch to the approval of PAS-Port.
- Once a surgeon is trained, it takes two to nine months to achieve a steady-state sales volume.
- Approximately two-thirds of trained surgeons are "retained," or continue to use the product.

		PAS-PORT® Launch						
Quarter	**11**	**12**	13	14	15	16	17	18
Direct Sales Force	13	13	13	13	13	17	17	17
Physicians Trained in Current Quarter	30	30	30	30	30	30	30	30
Physicians Trained (and retained) in Prior Q	20	20	20	20	20	20	20	20
Physicians Trained (and retained) Two Qs Ago	20	20	20	20	20	20	20	20
Fully Trained & Retained Physicians	120	140	160	180	180	220	240	260
Total Trained Physicians	250	280	310	340	370	400	430	460
Total C-Port Sales	2,333,333	2,666,667	3,000,000	3,333,333	3,666,667	4,000,000	4,333,333	4,666,667
Total PAS-Port Sales				964,286	2,142,857	3,937,500	3,937,500	3,937,500
Total Sales	2,333,333	2,666,667	3,000,000	4,297,619	5,809,524	7,937,500	8,270,833	8,604,167
Quarterly Sales per Sales Rep	179,487	205,128	230,769	330,586	446,886	466,912	486,520	506,127
Total Sales Force Costs	1,300,000	1,300,000	1,300,000	1,300,000	1,300,000	1,700,000	1,700,000	1,700,000

FIGURE 6.1.9
The phase II market model.

- C-Port would be used in approximately 10 percent of the CABG procedures with an average of 3.5 anastomoses per procedure at $800 each.
- PAS-Port would be used in 25–50 percent of all beating heart procedures and 5–10 percent of on-pump procedures with an average of 1.5 anastomoses per procedure at $600 each.
- The cost of a Cardica direct sales rep would be approximately $350,000 to $400,000 per year, fully burdened.
- Each sales rep has the capacity to generate $1.5–$2.5 million in sales per year.
- Once a sales person reaches that threshold, a new rep would have to be hired and the territory divided.

Discussion of the Cardica bottom-up model

This model is only a starting point. The company can experiment further with its core assumptions, especially with respect to the ramp-up in Q12, training requirements for existing surgeons on PAS-Port, and the training of new surgeons once C-Port and PAS-Port are both in the market. Other considerations that could be included in the model are outlined below.

Reimbursement

A shortfall of this analysis is that it does not factor in the effect of reimbursement, if any, on sales. In reality, product adoption can be significantly influenced by the status of reimbursement coverage and should be incorporated into such models.

Expansion in indications

While the model focuses primarily on adoption of C-Port and PAS-Port among surgeons performing beating heart surgeries, Cardica's management team believes that both devices will eventually be used in non-beating heart CABG surgeries and also believe there may be potential applications in other vascular grafting procedures.

Changes in the business environment

The model can also be used to monitor changes in the external environment and progress within the business to determine if the company's targets remain attainable. Such a model should never be static. Management must actively monitor conditions and then factor them into the model in order to determine the best time to expand the sales force or divide sales territories

The sales organization

The current model does not provide details about how the initial sales territories will be organized. Typically, this kind of analysis should be complemented by a preliminary design of sales territories, since different regions are likely to generate different levels of sales. In the US, it is common for companies to focus their preliminary sales effort in major, high-volume metropolitan areas such as New York, Boston, Chicago, San Francisco, Los Angeles, San Diego, Denver, and Miami. Utilization data from Medicare and the Dartmouth Atlas of Health Care[4] can be used to determine the highest-volume areas for purposes of designing the initial territories.

Reconciliation with the top-down model

As mentioned, a quick back-of-the-envelope calculation shows that the total US markets for beating heart CABG surgeries in which C-Port and PAS-Port could be used were estimated to be $170 million and $56 million, respectively. Assuming a 10 percent penetration for C-Port and a 35 percent penetration for PAS-Port into the total caseload of beating heart CABG surgeries (both are assumptions made in the bottom-up model), this brings the estimated annual US sales to $17 million and $20 million for total annual sales of $37 million, or slightly more than $9 million per quarter. It is reassuring that this quick, back-of-the-envelope, calculation is consistent with estimated quarterly sales of $8.6 million by Q18 in the bottom-up model. It should be noted that both of these sales estimates do not necessarily represent the final steady-state sales for Cardica but rather steady-state sales in the first adopter market segment of beating heart surgeries.

Cost projections

Cost projections (also called the operating statement) calculate the estimated costs of the business, including **manufacturing costs** and operating expenses (**OpEx**). Manufacturing costs include both material costs (COGS), as well as manufacturing labor, facilities, and equipment. They capture how much it costs for the company to make the products it sells. OpEx captures all other costs not included in manufacturing costs, including R&D, sales staff, general and administrative functions, and non-production facilities costs.

A **cost analysis** can be performed at varying levels of detail. It is up to the innovator to decide how much detail is required to satisfy the target audience for the financial model.

Salary analysis

Using the ablation catheter example, the creation of cost projections begins with an employee salary analysis, which includes three main components:

1. Summarize the staffing plan by calculating the average number of hires per year by type.
2. Outline annual salary assumptions, or how much the company will have to pay in salary by employee type, for each position type.
3. Calculate fully **burdened cost** per employee per year by position, taking into account employee healthcare and other benefits, insurance, computers, desk chairs, equipment, etc. for each employee. The fully burdened cost represents the total annual cost for each employee.

Benchmarks for average annual salaries are widely available. Table 6.1.1 provides some sample data based on a 2012 salary survey.[5]

Rather than figuring out the exact fully burdened cost of compensation, many experts use a back-of-the-envelope factor of two-times the annual salary for each employee (e.g., the fully burdened cost of an R&D employee would be $100,500 × 2 = $201,000). The 2× multiplier, used to account for benefits, insurance, etc., applies to all employees except manufacturing employees, for which a 1.5× multiplier should be used. Additionally, do not forget to take into account annual salary increases, as well as the need to offer stock to attract and retain high-caliber talent.

Table 6.1.1 Medtech salaries can vary by geographic location and stage of the company's development, but generally fall within standard ranges (based on the Medical Device and Diagnostic Industry Salary Survey 2012, unless otherwise noted).

Job title	Median annual salary	Median annual total compensation (including bonuses)
General and corporate management	$145,600	$190,300
Regulatory and legal affairs	$126,600	$163,000
Research and development	$100,500	$120,000
Production and manufacturing	$100,00	$125,000
Product design and engineering	$94,200	$100,000
Quality assurance and quality control	$93,100	$110,000
Medical device sales	$78,489[6]	$150,890[7]
Consultants	$1,000 to $2,500 per day[8]	NA

Figure 6.1.10 shows a sample salary analysis that builds on the staffing plan in the model. (Note that the salaries reflect prevailing rates at the time the model was constructed for the first edition of this text.)

Manufacturing costs

Manufacturing costs have at least three primary components: manufacturing labor costs, manufacturing facilities costs, and raw materials costs (COGS). Figure 6.1.11 shows a sample model for capturing these data.

In this analysis, to calculate manufacturing labor costs, engineers per year (from the staffing model) were multiplied by their fully burdened salary cost to produce a

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Manufacturing team							
Engineers	0	0	3	6	9	9	12
Manufacturing assemblers	0	0	2	5	10	18	35
R&D							
Catheter team							
Engineers	1	1	2	2	2	3	5
Techs	3	4	5	6	6	7	10
Generator team							
Engineers	1	1	1	1	1	3	5
Techs	2	4	4	4	4	7	10
SG&A							
Salesforce	0	0	1	9	12	25	50
Marketing, business development, and reimbursement	0	1	2	3	4	5	5
Clinical advisor	1	1	1	1	2	2	2
Regulatory	0	0	1	4	5	5	5
Administrative asst.	0	1	1	2	3	4	5
Management	1	2	3	5	6	8	8

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

Fully burdened salary - per employee ($)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Engineering	260,000	266,500	273,163	279,992	286,991	294,166	301,520
Technicians	100,000	102,500	105,063	107,689	110,381	113,141	115,969
Clinical, regulatory & QA	260,000	266,500	273,163	279,992	286,991	294,166	301,520
Sales, marketing, bus. development	200,000	205,000	210,125	215,378	220,763	226,282	231,939
Administration	70,000	71,750	73,544	75,382	77,267	79,199	81,179
Manufacturing	52,500	53,813	55,158	56,537	57,950	59,399	60,884
Management	400,000	410,000	420,250	430,756	441,525	452,563	463,877

FIGURE 6.1.10
A sample salary analysis.

total engineer cost. The total number of labor employees (e.g., assemblers, processors, testers) per year was similarly multiplied by their fully burdened salary cost to produce total manufacturing labor cost. These two figures were added together, providing the total manufacturing labor cost.

To calculate manufacturing facilities costs, the analysis started with an estimate for the cost of facilities space per square foot. The model assumed $25 per square foot per year, inflated at 2.5 percent per year. However, a more current estimate for Silicon Valley office space is roughly $31 per square foot per year,[9] and R&D space in the area can be leased for approximately $18 per square foot per year.[10] Many medical device start-ups lease R&D space in order to conserve funds, and because it can accommodate multiple functions under one roof, including business operations, lab space, clean rooms, machine shops, manufacturing, shipping/receiving, and so on.

Next, space per employee was calculated by assuming 250 square feet per employee. This estimate can be reduced over time to 210 square feet per employee as manufacturing processes become more efficient.

Then, the total space required was determined by multiplying the space per employee by the number of manufacturing employees.

Manufacturing labor	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
# of engineers	-	-	2.5	6.0	9.0	9.0	12.0
Fully loaded employee cost ($)	260,000	266,500	273,163	279,992	286,991	294,166	301,520
# of direct labor	-	-	2.0	5.0	10.0	18.0	35.0
Fully loaded employee cost ($)	52,500	53,813	55,158	56,537	57,950	59,399	60,884
Manufacturing labor cost ($)	**-**	**-**	**793,222**	**1,962,633**	**3,162,424**	**3,716,676**	**5,749,180**
Manufacturing facilities	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Cost per sq. foot ($)	25.00	25.63	26.27	26.92	27.60	28.29	28.99
Inflation	n/a	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Sq. footage / employee	250	250	250	240	230	220	210
# of manufacturing employees	-	-	4.5	11.0	19.0	27.0	47.0
Sq. footage required	-	-	1,125	2,640	4,370	5,940	9,870
Projected sq. footage	-	-	3,000	3,000	15,000	15,000	15,000
Manufacturing facilities cost ($)	**-**	**-**	**78,797**	**80,767**	**413,930**	**424,278**	**434,885**
Raw materials	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Units sold	-	-	23	462	3,892	11,325	22,249
Raw material costs per unit ($)	-	-	600	540	486	437	394
% improvement	n/a	n/a	n/a	10%	10%	10%	10%
Raw material & packaging costs (COGS) ($)	**-**	**-**	**13,843**	**249,539**	**1,891,298**	**4,953,558**	**8,758,685**
Manufacturing costs	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Manufacturing labor cost ($)	-	-	793,222	1,962,633	3,162,424	3,716,676	5,749,180
Manufacturing facilities cost ($)	-	-	78,797	80,767	413,930	424,278	434,885
Cost of Goods Sold ($)	-	-	13,843	249,539	1,891,298	4,953,558	8,758,685
Total ($)	**-**	**-**	**885,862**	**2,292,939**	**5,467,652**	**9,094,512**	**14,942,750**

FIGURE 6.1.11
A sample model for estimating manufacturing costs.

Additional assumptions were made about projected facilities space. For instance, the model assumes that the company can lease facilities space in blocks and always has more facilities space than needed, but employee moves are limited to a reasonable number. In this example, the first two years of manufacturing (years 3 and 4) are satisfied by 3,000 square feet. A move is made in year 5 to a 15,000 square foot facility. Finally, the projected facilities space was multiplied by the cost of facilities space to produce the manufacturing facilities cost.

To calculate raw material costs, the total units forecast to be sold (taken from the market model) was multiplied by the cost of raw materials per product. In the model, it is assumed that the cost of raw materials drops by 10 percent per year as production volume increases to reflect learning and volume discounts ($600 in year 3 down to $394 in year 7).

Finally, these three cost elements were summed and the result was taken as the total manufacturing cost. It should be emphasized here that the process of developing a manufacturing cost model is tightly coupled with the company's R&D and manufacturing strategy. Answers to the following questions must be available before an accurate model can be developed: What will the manufacturing process be? Where will manufacturing be done (in-house, outsourced in the US or outsourced outside the US)? What components can be made in-house and what components can be purchased or outsourced? Who will be the suppliers of the outsourced components and who will supply the raw material(s)? What kind(s) of equipment will be needed? What are the cost projections for these components?

OpEx

OpEx refers to the following components in the model: R&D staff costs, clinical trials costs, SG&A staff costs, and non-manufacturing facilities costs. Figure 6.1.12 shows a sample of an OpEx analysis.

R&D	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Staff costs							
# of engineers	2.0	2.0	2.8	3.0	3.0	14.0	30.0
Fully loaded employee cost ($)	260,000	266,500	273,163	279,992	286,991	294,166	301,520
# of techs	4.5	8.0	8.5	10.0	10.0	28.0	46.0
Fully loaded employee cost ($)	100,000	102,500	105,063	107,689	110,381	113,141	115,969
Staff costs	970,000	1,353,000	1,644,228	1,916,865	1,964,787	7,286,269	14,380,198
Clinical trials costs							
Est. # of patient-years in each year	0	50	100	0	0	0	0
Cost per patient-year	15,000	15,000	15,000	15,000	15,000	15,000	15,000
Total cost of trials	0	750,000	1,500,000	0	0	0	0
R&D costs ($)	970,000	2,103,000	3,144,228	1,916,865	1,964,787	7,286,269	14,380,198
SG&A	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Staff costs							
# of sales reps	0.0	0.0	1.0	14.0	27.5	70.0	140.0
Fully loaded employee cost ($)	200,000	205,000	210,125	215,378	220,763	226,282	231,939
# of clinical, regulatory & QA	1.0	1.3	2.0	4.5	6.5	9.0	18.0
Fully loaded employee cost ($)	260,000	266,500	273,163	279,992	286,991	294,166	301,520
# of marketing & bus. development	0.0	0.8	1.5	4.0	4.8	12.0	20.0
Fully loaded employee cost ($)	200,000	205,000	210,125	215,378	220,763	226,282	231,939
# of administrative assistants	0.0	0.8	1.0	1.5	2.8	8.0	10.0
Fully loaded employee cost ($)	70,000	71,750	73,544	75,382	77,267	79,199	81,179
# of management	1.0	2.0	2.5	5.0	8.0	12.0	12.0
Fully loaded employee cost ($)	400,000	410,000	420,250	430,756	441,525	452,563	463,877
Staff costs	660,000	1,360,688	2,195,806	7,403,623	12,729,722	27,266,938	48,915,868
Facilities costs							
Cost per sq. foot ($)	25.00	25.63	26.27	26.92	27.60	28.29	28.99
Inflation	n/a	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Sq. footage / employee	200	200	200	200	200	200	200
# of employees	8.5	14.0	17.8	38.0	57.8	141.0	256.0
Sq. footage required	1,700	2,800	3,550	7,600	11,550	28,200	51,200
Projected sq. footage	3,000	3,000	15,000	15,000	15,000	60,000	60,000
Facilities cost ($)	75,000	76,875	393,984	403,834	413,930	1,697,112	1,739,540
SG&A costs ($)	735,000	1,437,563	2,589,791	7,807,457	13,143,652	28,964,050	50,655,409
Operating costs	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
R&D costs ($)	970,000	2,103,000	3,144,228	1,916,865	1,964,787	7,286,269	14,380,198
SG&A costs ($)	735,000	1,437,563	2,589,791	7,807,457	13,143,652	28,964,050	50,655,409
Total operating costs ($)	**1,705,000**	**3,540,563**	**5,734,019**	**9,724,322**	**15,108,439**	**36,250,319**	**65,035,607**

FIGURE 6.1.12
A sample OpEx model.

To calculate OpEx, estimate R&D staff spending by multiplying the number of R&D-related employees per year by their fully burdened salary for each type of employee for a given year. In this example, engineers and technicians are considered R&D employees. All employee data are taken from the staffing plan and salary analysis used in the model.

Next, estimate clinical trials costs as follows. First, review the operating plan and 5.3 Clinical Strategy to determine the length of the clinical trials and the number

of patients. The trial length and strategy should be determined early, as part of the overall operating strategy. In this example, the trials will be completed in six quarters: quarters 7 through 12. Therefore, year 2 will include two quarters or 0.5 years of clinical trials (quarters 7 and 8) and year 3 will include all four quarters or a full year of trials. The number of patients participating in the clinical trials is assumed to be 100. Since year 2 includes 0.5 years of clinical trials, it includes 50 patient-years. Similarly, year 3 includes 100 patient-years. Another assumption was made about the cost per patient-year, $15,000, which is a reasonable (but somewhat optimistic) estimate for invasive medical device clinical trials. (Cost per patient-year is the cost of one patient participating in a clinical trial with one-year follow-up.) Multiply the patient-years by the cost per patient-year and sum over the years involved, in this case years 2 and 3, to yield the total clinical trials cost.

Then calculate SG&A staff spending in the same way as R&D staff spending. In this example, SG&A employees include sales reps, marketing and business development, clinical and regulatory employees, administrative assistants, and managers. Determine non-manufacturing or SG&A facilities costs using a method similar to that applied to manufacturing facility costs but using a higher initial cost per square foot. Finally, take the R&D, SG&A, and facilities expenses and sum them to calculate the company's total OpEx. It is worth noting that clinical and regulatory staff is sometimes categorized under R&D staff and sometimes under SG&A. In this example they are allocated under SG&A.

Be aware that clinical trial costs can vary widely, depending on the invasiveness of the device and length of study follow-up. Trials for non-implantable therapeutic devices and diagnostics with a short follow-up period can cost as little as $2,000 per patient-year (or $3,500 per patient on average). However, these costs can climb to as much as $100,000 per patient for an implantable or therapeutic device, which typically requires a lengthy follow-up period. Trial expenses may also depend on whether some of the costs for treating the patient (e.g., physician and facility reimbursement) will be covered by Medicare or private payers.[11] Additionally, the number of patients in the trial should be based on the number of patients statistically needed to establish a particular clinical result. Clinical trial strategy and planning is discussed in more depth in 5.3 Clinical Strategy.

Income statement

The income statement brings together all of the elements of the financial model into a unified view of the company's expected financials. It is also known as an earnings statement, statement of operations, or profit and loss (P&L) statement, and includes the line items shown in Table 6.1.2.

Constructing the income statement is quite simple, since it only requires the innovators to pull together their previous calculations. Figure 6.1.13 shows a sample of an income statement.

When investors examine an income statement, they typically apply a series of guidelines to check and see if

Table 6.1.2 The elements of an income statement.

Item	Description
Revenue (sales)	Total sales for the year.
Manufacturing costs	Total cost of the products *actually* sold by the company. In the case of ablation catheters, this includes cost of raw materials and labor to assemble the device and any other component that went directly into the production of the device. Does *not* include expenses such as marketing, sales costs, management salaries, etc.
Operating (gross) margin	Revenue minus manufacturing costs.
OpEx	All the other expenses associated with running the business that were not incorporated into COGS. Includes items such as R&D, facilities rentals, SG&A, company functions, etc.
Operating income	Operating margin – operating expenses.

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Revenue ($)	**-**	**-**	**45,684**	**910,425**	**7,628,621**	**22,089,398**	**43,180,346**
Manufacturing costs ($)	-	-	885,862	2,292,939	5,467,652	9,094,512	14,942,750
Gross margin ($)	-	-	(840,178)	(1,382,514)	2,160,969	12,994,886	28,237,595
Gross margin (% of sales)	N/A	N/A	N/A	-152%	28%	59%	65%
Operating expenses							
R&D costs ($)	970,000	2,103,000	3,144,228	1,916,865	1,964,787	3,348,968	5,334,590
% of sales	N/A	N/A	6883%	211%	26%	15%	12%
SG&A costs ($)	735,000	1,437,563	2,458,463	6,165,199	8,408,295	13,492,043	19,708,990
% of sales	N/A	N/A	5382%	677%	110%	61%	46%
SG&A facility costs ($)	75,000	76,875	262,656	269,223	275,953	707,130	724,808
% of sales	N/A	N/A	575%	30%	3.6%	3.2%	1.7%
Total operating expenses	**1,705,000**	**3,540,563**	**5,602,691**	**8,082,064**	**10,373,082**	**16,841,011**	**25,043,579**
% of sales	N/A	N/A	12264%	888%	136%	76%	58%
Pre-tax operating profit ($)	**(1,705,000)**	**(3,540,563)**	**(6,442,869)**	**(9,464,578)**	**(8,212,112)**	**(3,846,125)**	**3,194,016**
Operating margin	N/A	N/A	N/A	N/A	N/A	-17%	7%

FIGURE 6.1.13
A sample income statement for the hypothetical catheter ablation business.

the financial plan is realistic. The following are principles that apply to mature medical device companies:

- A typical gross margin at maturity should be around 70 percent (gross margin equals revenue less manufacturing costs). Many companies target a 60 percent gross margin in their initial financial models.
- R&D is roughly 10–15 percent of sales at maturity.
- SG&A expenses are roughly 15–30 percent of sales (higher at first and then declining over time).
- While not usually highlighted as a separate line on the income statement, SG&A facility expenses are roughly 1 percent of sales.

Double check the income statement against these ratios to help anticipate how it will be received by potential investors, and/or make adjustments. In this example, the only expense category that deviates from medical device norms is SG&A. Therefore, innovators should examine carefully that component of the income statement and either rationalize it or determine ways to reduce it.

In the ablation catheter business example, the business loses money for the first six years due to important early investments in R&D, clinical trials, etc. In general, it takes longer for device companies to become profitable than it did in the past due to the changing, more competitive environment. The operating margin for the sample company reaches 7 percent in year 7, which is modest for a medical device company.

Cash flow statement

At this point, the innovators are ready to determine the exact cash needs of the business. These are not the same as the net result of the income statement. The discrepancy can be due in part to an accounting concept called depreciation. Sometimes when a business spends cash, it does not record it as a cost on the income statement right away. For example, the company may purchase a computer for $1,000 which has a useful life of three years. On the income statement, the company may record a cost of $333 per year, representing the expended value of the computer each year. However, it still requires $1,000 cash up-front to make the purchase. Similarly, the company will need to spend cash on raw materials to build its product, but it will take time before the products are sold (and therefore recognized as sales on the income statement). In this way, as the company produces more product to support its future sales, it will begin to generate an inventory of finished product and work in process. This, too,

consumes cash and needs to be reflected in the calculation as a use of funds. As a result, cash will move out of the hands of the company before the company recognizes the corresponding revenue. A similar adjustment for changes in payables and receivables (or net working capital over time) is not shown in the model but may be needed since it can be another driver of sources and uses of cash in the **cash flow statement**.

When a company's cash is equal to zero, the business is essentially bankrupt. For this reason, having a cash requirements plan is extremely important. Such a plan can also help the company balance the need to be frugal with the need to allow appropriate spending to support the growth of the business – a delicate but essential balance that every company must strike.

Figure 6.1.14 shows a **cash flow statement**, incorporating financing. To complete a cash requirements plan, the innovator needs to begin with an actual pre-tax **operating profit** (or loss) from the income statement. Then, elements representing cash flow "out the door" can be added in, which are not immediately deducted from the income statement. This includes (as shown in the model used here) capital equipment purchased in three categories:

- Cost of capital equipment per employee. This includes the cost of computers, phones, desks, etc. In the model, it is estimated to be $7,500/employee.
- Cost of clean rooms in the years that manufacturing facilities are developed.
- Cost of manufacturing equipment.

Next, consider raw materials costs (taken from manufacturing analysis when developing cost projections) needed to build up inventory. In this example, this is estimated to be 35 percent of the total raw material costs.

Subtract these elements from the pre-tax operating profit (loss) to produce total cash flow per year.

Next, add cumulative cash flow from the prior year (presumably $0 prior to year 1) to total cash flow from the current year to produce cumulative cash flow for the current year. Prior to any financing, the cash balance listed under cash needs will be the same as cumulative cash flow.

Cash balance and financing needs

Once the cash flows are calculated, the innovators can determine the company's financing needs (i.e., funds it needs to raise) and cash balances over time. The cash

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Pre-tax operating profit (loss) ($)	**(1,705,000)**	**(3,540,563)**	**(6,442,869)**	**(9,464,578)**	**(8,212,112)**	**(3,846,125)**	**3,194,016**
Capital equipment purchased							
# of non-mfg employees	8.5	14.8	21.8	41.5	52.8	78.0	117.0
Cost of computers, phones, desks / employee ($)	7,500	7,500	7,500	7,500	7,500	7,500	7,500
Total cost of computers, phones, desks ($)	63,750	46,875	116,250	195,000	200,625	384,375	493,125
Clean room ($)	0	0	300,000	0	0	600,000	0
Manufacturing equipment ($)	0	150,000	150,000	300,000	150,000	300,000	200,000
Total capital equipment purchase ($)	**63,750**	**196,875**	**566,250**	**495,000**	**350,625**	**1,284,375**	**693,125**
Raw material costs ($)	0	0	13,843	249,539	1,891,298	4,953,558	8,758,685
Factor	0.35	0.35	0.35	0.35	0.35	0.35	0.35
Inventory build ($)	**0**	**0**	**4,845**	**87,339**	**661,954**	**1,733,745**	**3,065,540**
Total cash flow from the year ($)	(1,768,750)	(3,737,438)	(7,013,964)	(10,046,917)	(9,224,692)	(6,864,245)	(564,649)
Cumulative cash flow ($)	(1,768,750)	(5,506,188)	(12,520,152)	(22,567,069)	(31,791,760)	(38,656,006)	(39,220,655)
Cash needs	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Cash balance ($)	(1,768,750)	(2,506,188)	2,479,848	(7,567,069)	10,208,240	3,343,994	2,779,345
Suggested amount financed ($)	3,000,000	12,000,000		27,000,000			
Post-financing cash in the bank ($)	1,231,250	9,493,813	2,479,848	19,432,931	10,208,240	3,343,994	2,779,345

FIGURE 6.1.14
A sample cash flow statement.

balance will always need to be positive so financing must occur before the cash balance becomes zero. By looking at the cash requirements based on cumulative cash flow (i.e., what is the minimum cash infusion that would make the cumulative cash flow positive), the innovators can input various amounts representing the financing to be raised. The choice of how much money to raise and at what milestones (or points in time) are key strategic decisions (see 6.3 Funding Approaches). Implicit in this decision is also how long each financing round will allow a company to have a positive cash flow.

The spreadsheet in Figure 6.1.14 shows how, starting with the desired financing, the innovator can calculate the post-financing cash in the bank by adding the (pre-financing) cash balance to the current year financing. All subsequent year (pre-financing) cash balances must be adjusted by adding the cash flows to the cash balance. This will need to be repeated for each year until the company has sufficient pre-tax operating profits (based upon revenue) to independently keep cash flow positive.

The financing milestones (i.e., when to raise money from investors) are a critical output from the financial model. In some cases, it becomes evident that not enough important milestones occur within a certain time frame to align investor interest with the funding needs of the business. As a result, it may be necessary to either raise more money upfront to cover the company through these periods, or reconsider the operating plan to allow for a more continuous flow of value-building milestones (milestones that demonstrate the reduction of risk and/or measurable progress towards the market). See 6.3 Funding Approaches for more information.

When developing the cash flow model, innovators undoubtably realize that the process of building a company involves working on an extremely tight budget. This can be a challenge, but Mir Imran, founder and CEO of InCube Labs, pointed out the silver lining:[12]

> *I really believe that the good part of not having sufficient capital is that it really forces you to think through your expenses more clearly and spend the money less frivolously.*

A note on profitability

In developing a financial model, it is important to determine a realistic profit goal. This profit goal will directly affect the company **valuation** (i.e., how much the company will be worth) since the valuation is a function of earnings (the higher the earnings, the higher the valuation – see chapter 6.3). Other considerations that impact the business' valuation include:

- **Revenue ramp** – How quickly the company expects to grow its revenue, sometimes referred to as its "growth rate."
- **Time to profitability** – How long it will take the company to break even, and then turn a consistent operating profit.
- **Operating profit percent** – What operating profit the company expects to achieve as a percentage of revenue.
- **Competitive benchmarks** – Benchmarks and comparable data related to the type of business model the company has chosen (e.g., disposable, reusable, capital equipment; see 4.4 Business Models) and the sector/industry within which the company operates (e.g., devices, genomics, pharmaceuticals).

A reasonable operating profit benchmark is approximately 30 percent of pre-tax income in the long term. However, how the company achieves this goal will depend upon its go-to-market strategy. A company might choose a direct sales strategy, in which case it would not have to share revenue with distributors, resulting in high gross margins; but it would have to hire a large sales force, resulting in high sales costs. Alternatively, the company could choose to use distribution partners, resulting in lower gross margins, but lower sales costs. Another option is to blend the two strategies, employing distributors in some markets and direct sales in others. To determine a likely profit model/goal, examine comparable companies to gain insights into reasonable revenue and cost projections. In the example presented here, the operating profit margin in year 7 was relatively low, reflecting the high cost of building a direct sales force. As part of developing the financial model, the innovators should consider the implications of different strategic choices (e.g., direct sales force versus hybrid).

Proxy companies

Proxy companies, also known as comparable companies, are those whose operations resemble what is required to commercialize a product. The concept of **comparables analysis** is that historical precedents can be used as a basis for validating a financial model. In the broadest sense, comparables will include other medical device companies. Further refinement would narrow comparable companies to ones that have, or went through, similar development challenges, clinical and regulatory pathways, are focused on the same disease state, and/or have similar products.

In analyzing a proxy company, there are three primary objectives:

- Determine the milestones that the company selected and/or achieved in developing its business.
- Identify the main risk factors that the company faced in developing its business and devise a plan to mitigate similar risk.
- Reconstruct the company's operating plan and financial model from the details that have been uncovered so that they can be used as a benchmark.

Investors, as well as innovators, use proxy companies to determine appropriate valuations for a new venture using the valuation models outlined in 6.3 Funding Approaches. Therefore, an added benefit of proxy company analysis is that it can help innovators be better prepared in their negotiations with investors since proxy companies play an important role in reaching a fair, market-driven valuation for the company.

This analysis can be performed at a high level or in great detail, depending on the needs of the innovators. A thorough analysis will enable a new enterprise to benchmark and modify its plans against multiple comparable companies, learning from their successes and failures. A high-level or more narrowly focused analysis will provide an innovator with directional information or the answer to a specific question (e.g., how long did comparable companies spend in clinical trials? What are reasonable fund-raising goals and milestones?).

While innovators can learn from the assessment of almost any proxy company, it is most helpful to look for those companies that have been considered a success.

Table 6.1.3 Typical markers for proxy company identification.

Timing	Company focus
Years 1 and 2	• Product development • Intellectual property (IP) filing • Pre-clinical discovery
Years 3 and 4	• Clinical value established • Product defined after multiple iterations • Regulatory approval complete • IP issued
Years 5 and 6	• Revenues ramping up • Franchise established • Pipeline of iterations • Clinical utility established

When the innovators can select from multiple proxy companies they can use the markers in Table 6.1.3 to determine which of these companies will more closely resemble their proposed venture.

See online Appendix 6.1.1 for a sample proxy analysis.

A note on intrapreneurship

Financial models for a new technology that will be developed and commercialized by an established company (this type of development is often referred to as "intrapreneurship") have the same basic components as the model described in this chapter for start-up companies. However, there are at least two key differences to consider.

Leveraging existing resources

Unlike innovators starting a new stand-alone venture, **intrapreneurs** may be able to leverage existing resources within their organization to manage some of the costs. This can involve engaging existing R&D engineers, using existing capital equipment, and/or leveraging the existing sales force. Accordingly, one of the first questions to be resolved is whether any of these existing resources can be accessed for the project. Even if established resources *can* be used, however, they are not cost-free and they should not necessarily always be employed. The finance department of the organization can provide guidance on

the cost of existing resources. Another consideration is timing. With multiple projects competing for the attention of limited internal resources, progress may be slower than desired. Therefore, the intrapreneur should develop multiple financial models involving different degrees of reliance on internal resources, and use them to make a recommendation to senior management about the extent to which internal resources should be used.

Complementarities with existing products and company strategy

The financial model should explicitly account for complementarities with existing product portfolios and company strategy and should also provide an assessment of the impact of the project on the company's financial statement. Questions to address include whether the new project will defend existing market share or be used to increase market share. In both cases, the financial benefits to the organization should be articulated. In the defensive case, the market model should explain how market share may decrease without the new innovation. In the offensive case, the market model should highlight how the new innovation will increase revenue without cannibalizing existing sales, and whether the increase in revenue will be significant enough to make a difference.

Online Resources

Visit www.ebiodesign.org/6.1 for more content, including:

Activities and links for "Getting Started"

- Develop detailed bottom-up financial model
- Identify proxy companies
- Develop proxy company analysis
- Compare and rationalize bottom-up and top-down approach

Videos on operating plan and financial model

An appendix that provide an extensive example of proxy company analysis

CREDITS

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NOTES

1 From remarks made by Thomas Fogarty as part of the "From the Innovator's Workbench" speaker series hosted by Stanford's Program in Biodesign, January 27, 2003, http://biodesign.stanford.edu/bdn/networking/pastinnovators.jsp. Reprinted with permission.

2 Walter T. Harrison and Charles T. Horngren, *Financial Accounting* (Prentice Hall, 2007).

3 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.

4 The Dartmouth Atlas of Healthcare, http://www.dartmouthatlas.org/ (February 24, 2014).

5 "Medical Device and Diagnostic Industry Salary Survey 2012: Data Tables," http://www.mddionline.com/article/mddi-salary-survey-2012-data-tables (February 20, 2014).

6 "2013 Medical Device Sales Salary Report," MedReps.com, http://www.medreps.com/medical-sales-careers/2013-medical-device-sales-salary-report/ (February 20, 2014).

7 Ibid.

8 Broad estimate by the authors based on informal input from experienced device executives.

9 "Silicon Valley Office," Kidder Matthews Real Estate Market Review, Fourth Quarter 2013, http://www.kiddermathews.com/downloads/research/office-market-research-silicon-valley-2013-4q.pdf (February 20, 2014).

10 Ibid.

11 "Medicare Coverage: Clinical Trials," Centers for Medicare and Medicaid Services, http://www.cms.hhs.gov/clinicalTrialPolicies/Downloads/finalnationalcoverage.pdf (February 24, 2014).

12 From remarks made by Mir Imran as part of the "From the Innovator's Workbench" speaker series hosted by Stanford's Program in Biodesign, April 28, 2004, http://biodesign.stanford.edu/bdn/networking/pastinnovators.jsp. Reprinted with permission.