6.2 Strategy Integration and Communication

INTRODUCTION

Having assembled all of the complex components required to build a successful medtech company, at least one essential step remains: being able to explain the vision and plan for the company in a compelling enough way to rally potential investors, partners, advisors, and employees. The process a company goes through to integrate its functional strategies with the operating plan, craft a compelling "story," and prepare to share it with the world was traditionally based on writing a business plan. In today's medtech environment, having a formal business plan is not nearly as important as it used to be. However, the exercise of developing a holistic view of the business, clearly articulating what it is trying to achieve, and outlining how it will execute against its plans is still essential. In most cases, the way a company now communicates this information is through a pitch, which acts as a management tool for the leadership team and provides the rationale for others to commit their time and money to the project.

A company's pitch provides an integrated summary of all of the in-depth strategy and planning work that has been completed to this point in the biodesign innovation process. Among other information, it describes the clinical need, the product's value proposition, the market potential, and the development and commercialization pathway. By putting this material in writing, as part of one cohesive overview, innovators are forced to crystallize their thinking about how they will communicate with internal and external audiences and the story they will tell about the ways in which their business will create and sustain value. They are also forced to identify *key questions* – the few most important unknowns or risk factors that must be addressed in sequence on the way to bringing an innovation to market. Having to articulate a clear, compelling story further helps innovators prepare for important interactions with prospective employees, investors, and customers (whether or not the pitch is directly shared with these audiences), and it can be used as a mechanism for aligning the goals of everyone who is involved in making the business a reality. While the development of the pitch should not take on a life of its own and eclipse the importance of staying focused on the execution of the

OBJECTIVES

- Appreciate how a company's functional strategies come together with the operating plan to form an integrated view of the business.
- Understand the purpose and function of pitch development, both internally in managing the new venture and externally in communicating with potential investors, partners, and employees.
- Learn to identify and develop the main components of a pitch to address the key questions and other information the target audience is most interested in knowing.
- Recognize that a strong pitch does not guarantee funding, but it helps innovators rigorously prepare to present and defend the opportunity to potential investors.

functional strategies and operating plan, the disciplined thinking and integrated view of the business that it imposes on the team can be invaluable.

See ebiodesign.org for featured videos on strategy integration and communication.

STRATEGY INTEGRATION AND COMMUNICATION FUNDAMENTALS

In the past, innovators were advised to develop a detailed business plan to use for three primary purposes: planning, management, and communication. As a planning tool, the business plan was meant to outline the steps that a company would take in order to bring its product to market and become financially viable. It also integrated the functional strategies behind the venture and the detailed steps that supported the execution of those strategies, along with the required resources. As a management tool, the plan set a short list of important goals to be achieved and the expected timetable, including both near-term and longer-term objectives. It could then be used to monitor progress toward achieving the company's greater goals. Finally, the plan provided a tool for framing and guiding communications, both internally and externally. Internally, it could facilitate cross-functional interactions and help maintain the alignment of objectives and activities across the different departments within the company. Externally, it could be used for recruiting purposes, to convince other businesses to enter into strategic partnership, and to persuade investors to provide capital.

To create the business plan, innovators traditionally started with the operating model and financial plan developed as part of chapter 6.1, and then integrated additional information and materials from the research and planning they completed as part of the strategy development stage of the biodesign innovation process. Typically, all of this information was assembled at a detailed level into a narrative form (e.g., a Word document) that ranged from 40–60 pages in length.

In some cases, this business plan was actively referred to and maintained by the management team and successfully shared with prospective partners and investors to get them interested in the opportunity being pursued by the company. But, with increasing frequency, traditional business plans have been under-utilized (at best) and overlooked (at worst). In parallel, important **stakeholders** in the external environment, such as investors, no longer want to see lengthy, text-heavy descriptions of the business. Rather than full-fledged business plans, they are asking for concise "**pitch** decks" and/or executive summaries that convey much of the same information in a more targeted manner.

Given this important shift, the bulk of this chapter is devoted to what goes into developing an effective pitch. However, there are a few essential points that innovators should understand:

- Companies are no longer required to develop a traditional business plan, but they still must complete the in-depth business planning exercise that integrates the operating plan and the functional strategies.
- Many elements of the traditional business plan are directly relevant to the pitch.
- The pitch is only as strong as the research and analysis that supports it.
- Just as with a business plan, investors, partners, and even prospective employees can all be expected to validate aspects of the pitch through "**due diligence**" before committing resources to the company.

As the author of one article effectively summarized:[1]

> *I completely agree that old fashioned 30–50 page business plans are relics of the past. But I think that sometimes, when people have this idea that they are only pitching and not planning, they are really just changing the vocabulary. Planning should be nimble. Planning should focus on just the*

information you need to run your business, and planning should be an ongoing process to help you understand where you are doing well, and where you may be headed into trouble – before it happens. The more information you can gather and understand about your business and how it relates to your market, competition, pricing, bottom line, and cash, the more successful you are likely to be.

The good news for innovators following the biodesign innovation process is that most of the required research and analysis to support the pitch has already been completed. As noted, the detailed **operating plan** and **financial model** serve as the foundation of the business planning exercise (and will feature prominently in the pitch). The functional strategies that have been developed in areas such as R&D, regulatory, **clinical trials**, **reimbursement**, marketing, and sales, will also provide important inputs. The primary challenge that remains is to integrate these strategies and communicate the company's path forward.

About the pitch

Every invention and every company has a story. The key is to figure out how to articulate it effectively and learn to tell it well to attract talent, funds, and other resources to the project. Generally, innovators must force themselves to shift their focus from thinking about the solution in terms of "how it works" to explaining "what it does" to address the **need** and deliver **value** to important stakeholders.

At an overarching level, the pitch puts forth a cohesive argument for why the company is viable. Many innovators mistakenly believe that the primary driver of business success is the underlying technology, especially its unique aspects. However, there are other considerations that are equally important to establish in the pitch, and these should be based on what is most important to the target audience. For example, consider a pitch developed to raise funding from investors. The innovators should recognize that investors are more willing to put their money into market- or customer-driven companies than those primarily driven by technology (assuming, of course, that the underlying technology is viable). Accordingly, it may be more important to make a compelling case regarding the size and growth of target markets, potential sales, and expected profitability than it is to educate the audience on the detailed features of the innovation. Investors will also want substantial information about the critical financial projections and capital requirements of the business. On the other hand, if the pitch is to be used to seek input on the idea from expert clinicians, then more emphasis might be placed on the need, how the technology will improve the delivery of care, and other related subjects. A pitch delivered to employees may devote more attention to the company's vision, along with the key milestones outlined in the operating plan that the team needs to work together to achieve. In all of these scenarios, the innovators should explain or avoid terminology or in-depth concepts that might be unfamiliar or off-putting to the target audience. The most effective pitch decks demonstrate an understanding of the audience's priorities, issues, and questions, and address them in a straightforward and comprehensive manner.

It is also important for a pitch to be action oriented. In addition to communicating the company's vision and overarching strategy, the pitch should detail the tactical and operational activities that demonstrate how the innovation will be developed and commercialized. It also should instill confidence in the audience that the team has done its homework, has a clear understanding of what is required to get to market, and that the members have the capabilities to make it happen. As Mir Imran, serial inventor, entrepreneur, and founder of InCube Labs, put it, "I have learned that good ideas are a dime a dozen. It's the execution that matters."[2] According to one guideline, innovators should develop plans that are 10 parts implementation for every one part strategy.[3]

One of the most important ingredients to building confidence in the target audience relates to the issue of risk. Most audiences appreciate that any effort to develop and commercialize a new medical technology is inherently risky. That said, an effective pitch must identify and address the project's greatest risks head on rather than trying to side-step them. Innovators should be honest about the main challenges their company faces, primarily because these issues almost always become apparent in a

pitch or presentation. Investors will be particularly interested in understanding how the innovators intend to tackle risks in a sequence so that funding can be staged to match the company's requirements as the plan is proven. Again, every project faces risks – the key is to identify them early and outline the decisive steps the team is taking to mitigate them.

Through the development of their functional strategies, innovators identified specific risks in each core area (technical risk, clinical risk, regulatory risk, reimbursement risk, adoption risk, etc.). However, at this point, as they integrate strategies into a single view of the business, they must think more holistically about risk. The idea behind identifying *key questions* is to consider all of the risks facing a company and then organize them in sequence, with an emphasis on determining the one or two most critical issues that must be addressed *first* in order for the project to remain viable. For instance, if the company is still uncertain whether the primary mechanism of action for its technology will function as intended in human anatomy, this risk needs to be retired before substantially more time and effort is invested in the further development of clinical and regulatory strategies and the mitigation of their related risks. Key questions are often, but not always, technical in nature. For example, the team may determine that physician willingness to adopt a new device is on the company's critical path before it invests more time and money into development. The point is that not all risks are created equally, and they do not all require the same level of attention from the team at the same time. Strategic integration is a mechanism through which the innovators explicitly recognize which risks are on their immediate critical path, devise plans for addressing them in the nearterm so that the company's larger goals can be achieved in the longerterm, and think about the optimal way to communicate and manage expectations in these areas.

One more important factor worth considering in pitch development is that the strongest presentation typically makes an emotional connection with the audience and communicates the passion that the team has for addressing its chosen need. Every pitch must display clear logic and a realistic, rational approach, but those that add an emotional element to their vision can often stand out. In many cases, an emotional appeal can be a good way to capture attention and draw in the audience. In healthcare (compared to other industries), demonstrating passion and a desire to help others is usually not difficult for teams, but this aspect of the pitch should not be overlooked. As an example, healthcare pitches will often feature a "day in the life" portrayal of a patient experience as a way to make the problems being solved more tangible and meaningful to the audience.

An effective pitch can range in length from 10 to 50 slides, with 15 to 30 slides often considered optimal. The appropriate number of slides varies based on the target audience and the purpose of the presentation. For example, when using the pitch to recruit a key staff member, 10 slides may be adequate to provide a high-level overview of the business. When sending the pitch to an investor with the hope of securing a first meeting, 10 to 20 slides may be needed to more fully explain the opportunity. In the first meeting with an investor, the innovators may want a 50-slide version of the presentation so they have access to back-up information that can be used to address important questions that arise.

Innovators usually create their pitch decks in PowerPoint (or another presentation software program). While the quality of the content is definitely more important than the form the presentation takes, appearances can make a difference. More than anything, innovators should ensure that the pitch appears professional and projects the image of the company they intend to build. The use of features such as interesting graphics, video testimonials, or animations to help communicate complex subjects is certainly not required, but it can enhance understanding and help build excitement about the proposed venture. Just keep in mind that some audiences can respond negatively if a pitch looks too "slick" or as though the team spent an excessive amount of money to prepare it. Striking an appropriate balance is important.

A few additional guidelines for improving the readability and appeal of a pitch are outlined in Table 6.2.1.[4]

Developing the pitch

While each pitch is unique, most cover a similar set of topics. These topics are outlined in the sections that

Table 6.2.1 Paying attention to small details can make a big difference when it comes to the caliber of a pitch (based, in part, on J. Skyler Fernandes, "The 'Best' Start-Up Pitch Decks & How to Present to Angels/VCs," One Match Ventures, July 2013).

Be succinct – Emphasize quality and clarity over length. Don't use too many words on any given slide. Keep each slide uncluttered and easy to read. Make sure text is not too small (font size 20 or larger).
Be specific – Avoid generalizations. Address important issues directly and in sufficient detail to demonstrate preparedness and mitigate major concerns.
Show, don't tell – Emphasize progress and results to date. Include customer input as appropriate. Do not self-aggrandize. Let the facts speak for themselves.
Keep it simple – Make each slide self-explanatory. Avoid content (including graphics) that requires a complex description.
Double check everything – Be sure the pitch is well written (e.g., appropriate in tone and style). Carefully check for typos and the accuracy of all calculations and citations. Be consistent in the use of punctuation and capitalization.

follow.[5,6] To simplify the descriptions, the primary focus is on a pitch targeted at investors for the purposes of raising early-stage funding for a company.

Cover slide

On the cover slide, include the name of the company and/or its logo, the purpose of the presentation (e.g., investor presentation), and the date. Sometimes innovators also include "Copy number ___" in an upper or lower corner of whatever hard copies are produced and shared to help manage and track distribution. This approach can also reassure investors that the plan has not been shared with too wide an audience.[7]

Elevator statement

In an "elevator pitch," innovators try to capture the essence of the business they are developing in just one to two sentences. This concise statement should include the core problem the company is seeking to address, what the solution is that it has developed, and the benefits it will deliver to its target customers. The time and effort innovators have invested in developing both their **value propositions** and **need statement**s will be useful in crafting the elevator statement for a pitch.

The clinical need

Provide a brief overview of the disease state and the medical need that the innovation is intended to treat. Focus on evidence that confirms the need is real and significant, including opinions of key clinical advisors. Use competitive analysis of existing solutions to make a strong case demonstrating the gap in the existing solution landscape.

Figure 6.2.1 provides a sample from the pitch deck of a start-up called Ciel Medical, founded by Kate Garrett and Dan Azagury. Ciel is developing a series of novel solutions for ventilated patients. Its first product, called the C.L. Bougie, facilitates optimal endotracheal tube placement to prevent complications associated with malpositioning. Its second and third products are targeted at preventing aspiration, which can lead to ventilator-associated pneumonia (VAP). These solutions include the BronchoGuard aspiration barrier and the Sora suction catheter. The Ciel team recognized the importance of clearly and professionally communicating its key messages and worked with consultant Devesh Khanal to develop its pitch.

The solution

Describe the innovation, emphasizing what it does for key stakeholders and the value it delivers to them. Use a short demo to show how the product works, but do not spend too much time here. (Many innovators embed videos in their pitches, but this can create a negative perception if the video fails to work.) Provide evidence that potential **users** find the product compelling by including preliminary results from user studies, quotes from user interviews, or a story from a new or potential user.

The market

Define the initial target market for the innovation. Outline the size of the market, as well as its projected growth and other important trends. Explain key characteristics of

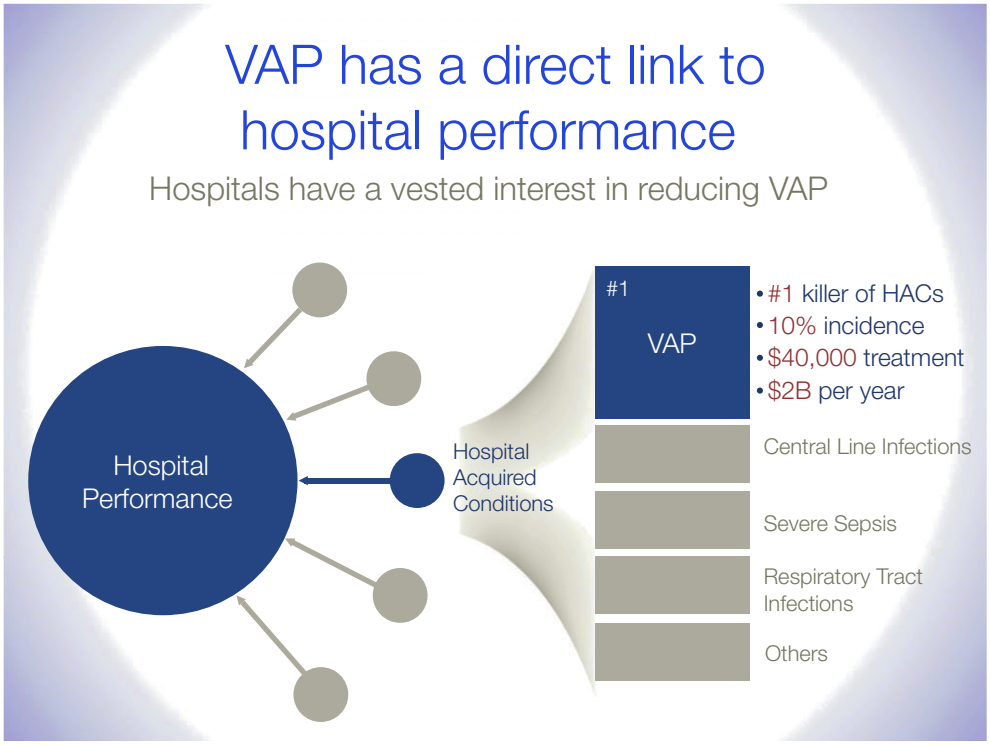


FIGURE 6.2.1
One of the slides used to establish the need for a solution to address VAP (courtesy of Ciel Medical).

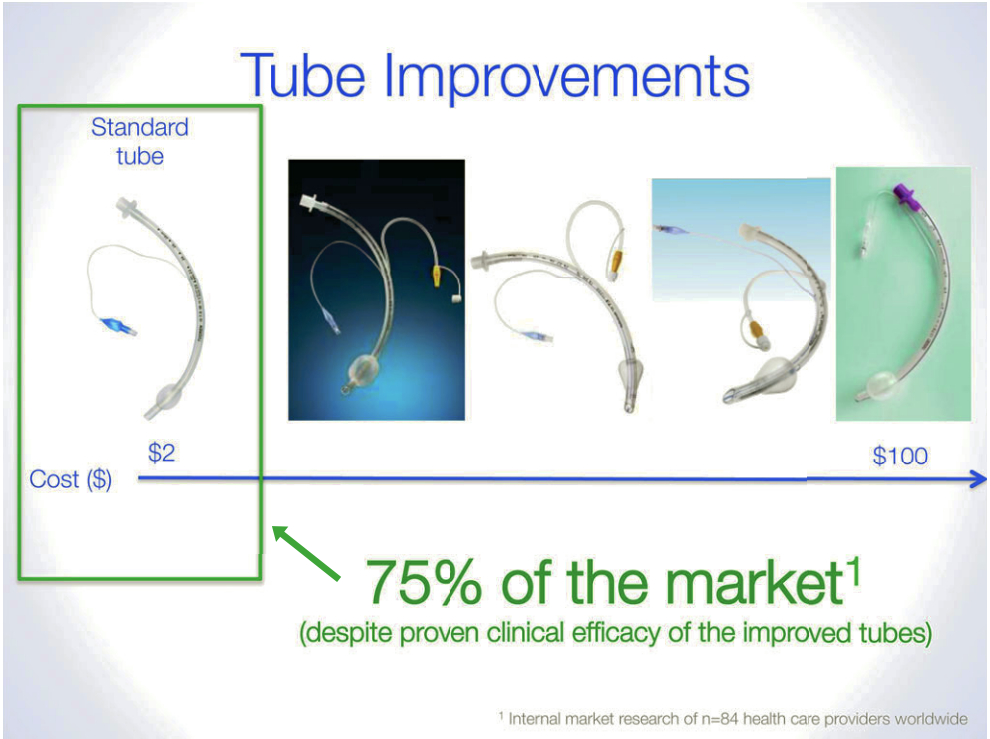


FIGURE 6.2.2
This slide from the Ciel Medical pitch is part of the story describing the competitive landscape for endotracheal tubes (courtesy of Ciel Medical).

the market, including how buying decisions are made, **market segmentation**, important aspects of the competitive landscape (see Figure 6.2.2), and what kind of market position is most appropriate for the innovation. Describe mitigation strategies for addressing the most critical market risks (e.g., how to differentiate the innovation from existing alternatives or how to defend the innovation against second-generation products if it is

the first to market) and the competitive landscape. Touch on potential market expansion strategies.

Intellectual property (IP)

If intellectual property is an important aspect of the proposed business, as it is for most **medtech** start-ups, then it is important to address this issue. However, a sophisticated audience will appreciate that detailed IP discussions should normally not occur without the protection of attorney–client privilege. Despite the fact that most pitches are labeled as "confidential," the innovators should assume that the contents of the pitch could potentially be accessed in the course of IP litigation and keep commentary on claims and prosecution strategy out of the presentation. If the company has issued or licensed IP that is already public it can be listed on the slide together with a summary of relevant facts (for example, the total number of pending applications). A more detailed discussion of IP-related aspects of the plan can be handled during due diligence.

R&D

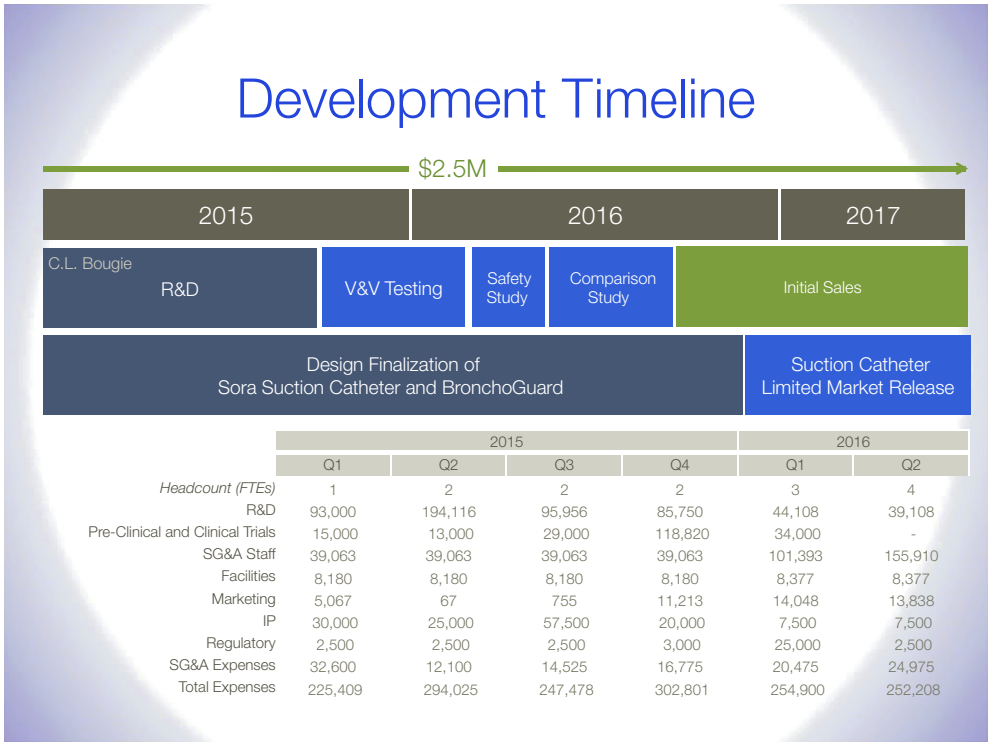
If the innovation is still under development, outline how much additional research and development is needed, describe and characterize the technical risks, and cover risk mitigation mechanisms. Timelines are important. Including an R&D Gantt chart can help to rapidly communicate key milestones on the path to commercialization (see Figure 6.2.3). Note, however, that this R&D Gantt is normally a simplified version of what would be used to manage the R&D process itself. This is also true for the two sections that follow – regulatory and clinical.

Regulatory strategy

Describe the regulatory pathway for the innovation and other key aspects of the regulatory strategy (see Figure 6.2.4). Provide the current status of all regulatory efforts, outline any regulatory risks, and share planned mitigation strategies.

Clinical studies

Describe what testing has been completed to date, including bench-top validation and animal studies. Detail the clinical studies the company proposes to sponsor. Include information about the endpoints, sample sizes, duration, and location, as well as key investigators. Provide evidence to support integration of studies with regulatory, reimbursement, and marketing efforts, along



	2015				2016	
	Q1	Q2	Q3	Q4	Q1	Q2
Headcount (FTEs)	1	2	2	2	3	4
R&D	93,000	194,116	95,956	85,750	44,108	39,108
Pre-Clinical and Clinical Trials	15,000	13,000	29,000	118,820	34,000	-
SG&A Staff	39,063	39,063	39,063	39,063	101,393	155,910
Facilities	8,180	8,180	8,180	8,180	8,377	8,377
Marketing	5,067	67	755	11,213	14,048	13,838
IP	30,000	25,000	57,500	20,000	7,500	7,500
Regulatory	2,500	2,500	2,500	3,000	25,000	2,500
SG&A Expenses	32,600	12,100	14,525	16,775	20,475	24,975
Total Expenses	225,409	294,025	247,478	302,801	254,900	252,208

FIGURE 6.2.3
This slide illustrates at a high level the development timelines for the three products in the Ciel Medical portfolio (courtesy of Ciel Medical).

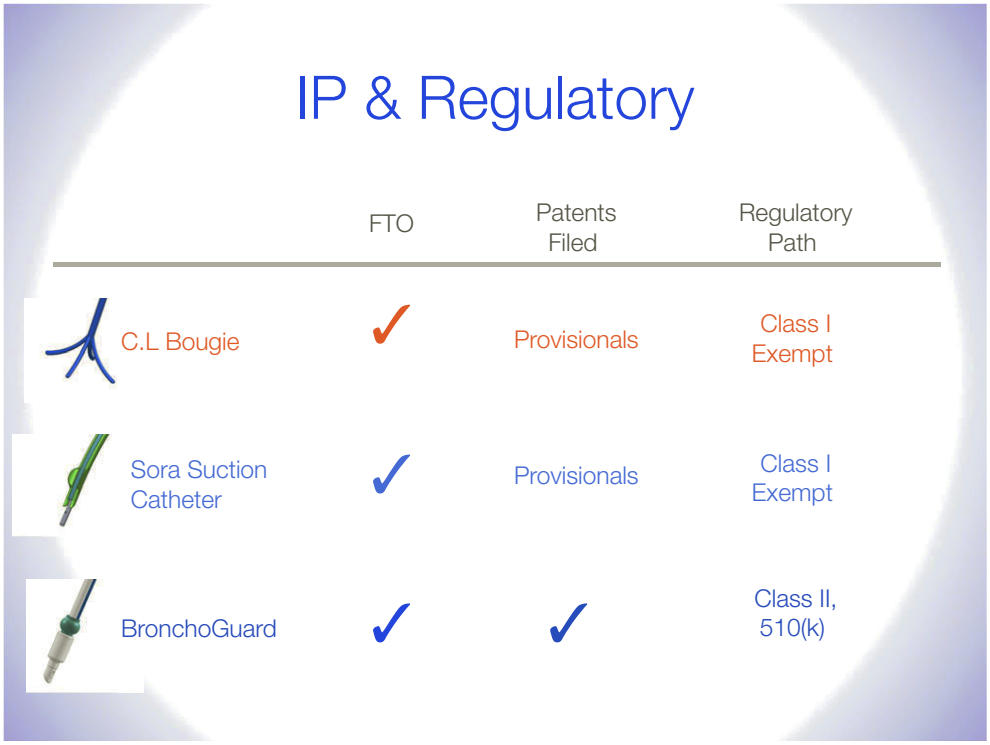


FIGURE 6.2.4
This slide clearly and simply communicates the regulatory pathway for the Ciel products, as well as the status of their IP (courtesy of Ciel medical).

with information demonstrating that the company has (or can access) the necessary expertise to successfully conduct the trials.

Reimbursement

Describe the reimbursement strategy for the product. Outline the likelihood of (and justification for) receiving reimbursement. Provide examples of the reimbursement codes to be used if they exist, or outline the status of efforts to secure reimbursement to date. Outline reimbursement risks and planned mitigation strategies.

Business model

Highlight how the company will make money, including its anticipated pricing and margins. Justify the type of business model chosen, where the company's key revenue stream(s) will come from, the timing and frequency of revenue realization, and the volume of business needed to make the model viable.

Marketing and sales

Clarify the company's competitive advantage and value propositions for the offering. Outline planned sales and marketing efforts. Be certain to address the costs associated with sales and promotional activities and provide a convincing explanation of how the chosen methods will result in the greatest return for the most reasonable investment.

Financial information

Include a one-page summary of financial forecasts covering at least the next two to three years of operations, as well as an indication of funds needed and how they will be used. Refer to 6.1 Operating Plan and Financial Model for more detailed information on what specific financial information should be provided.

Exit scenarios

Indicate the pathways through which investors may achieve a **liquidity event** for their investment. Investors are interested in knowing how their financing is most likely to be monetized and in what timeframe that might occur (see Figure 6.2.5). It is highly unusual for a medtech company to return capital investment to investors through **dividends**. Instead, the two most common paths to liquidity – or an **exit** – are the initial public offering (**IPO**, rare in recent years) and the trade sale. A trade sale, which involves the merger or **acquisition** of the

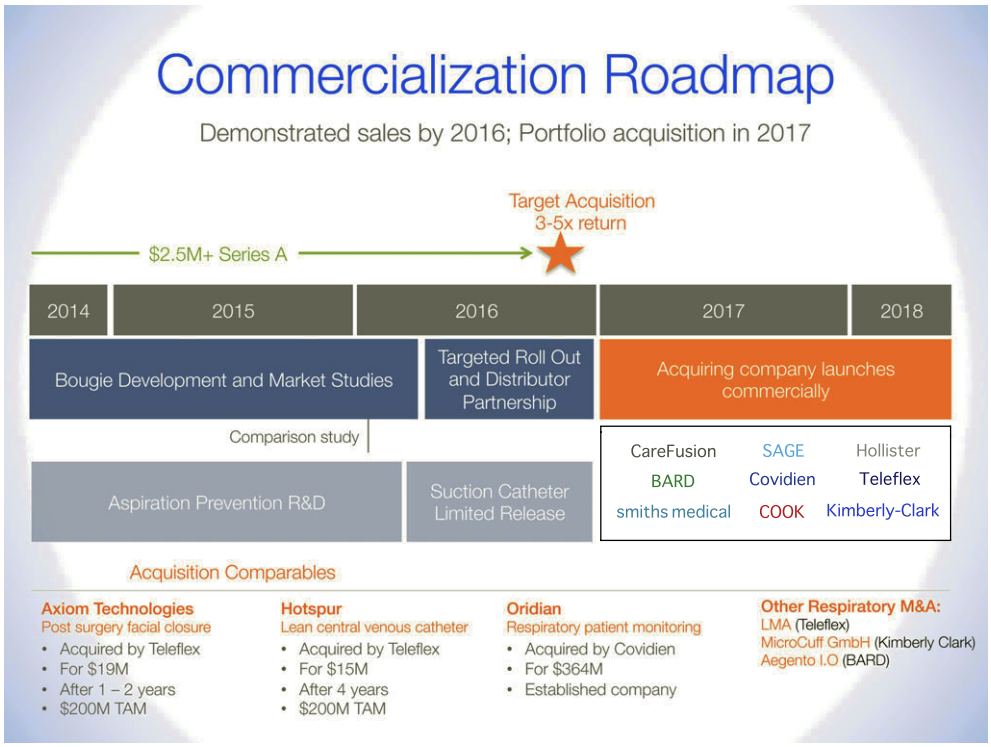


FIGURE 6.2.5
This slide provides an overview of Ciel Medical's commercialization and exit targets, as well as relevant information about comparable exits (courtesy of Ciel Medical).

new venture into a larger company, is by far the most common path. When presenting their opportunity, innovators should be prepared to identify and discuss which of the established medtech companies might be interested in acquiring the business and according to what timeline. If comparable exits have occurred previously, it is helpful to include that data (see 6.3 Funding Approaches for more information about exit scenarios).

The ask

This slide clearly states the objective of the pitch. In many cases, the ask will be for a specific amount of funding. If so, the pitch should outline how much capital is required, specifically how it will be used, and what progress/milestones it will allow the company to achieve.

Management team

Profile key members of the company's management team, highlighting relevant experience, leadership successes, and business accomplishments. It can also be helpful to include advisors or board members if they are well known and respected in the field. Include details about the company's organizational structure and staffing plans, if they are relevant to the team's ability to execute on the strategy outlined in the pitch.

Closing slide

The closing slide should reiterate the company name and provide contact information, even if just the name, phone number, and email address of the CEO. Innovators frequently create pitch decks with too little information about how the company can be contacted for questions and additional information. The closing slide may also propose an actionable and specific next step that drives the process forward (e.g., reconvene within two weeks for a follow-up meeting), although some innovators prefer to leave this topic open for discussion to give them the chance to interact with the investor in deciding what happens next. The process of reaching agreement on next steps can serve as a great preview of future management styles for both parties.

While the sections of the pitch do not need to be presented in this specific order, this organization represents a logical flow that is used by many companies. That said, innovators should feel free to experiment with slide

placement, ultimately deciding on an approach that best supports their story.

Importantly, with even one slide on each of these listed topics, a team would already have a 17-page deck. And, it is quite possible that some topics will require more than one slide to clearly capture the team's most important messages and communicate progress in an area to date. One approach is to develop all of the slides needed to clearly tell the company's story and then combine those slides in different ways to address the specific needs and interests of different audiences, using the ones that are most relevant and leaving out those that are not. A list of typical back-up or appendix slides is shown in Table 6.2.2.

To get started in developing the pitch, it can often be helpful for innovators to answer the series of questions captured in Table 6.2.3. These questions can help them think through all of the work they have performed to date and begin identifying some of the most important ideas and information to include within their presentation.

Another approach is to force the "story" onto a single page with no more than four or five main points. This exercise can help the innovators better appreciate which information is needed to support their argument and which information is interesting, but not as essential. Innovators sometimes make the mistake of assuming that they build credibility based on sharing all of the details of what they have done in each of the functional areas related to building the business. However, in truth, they often receive more "credit" for selectively using the facts they now possess to support a solid argument. If investors are interested in the project, the team will have ample opportunity to impress them with its command of the details during due diligence (see 6.3 Funding Approaches for more information about due diligence).

An alternate approach is to quickly create a crude first draft with no more than 15 slides. With the deck in this "rough draft" form, the team can review the slides and ask, "Why are we sharing these data and what point are we trying to make with them?" Always remember that everything in the pitch deck should support the company's overarching story.

Table 6.2.2 Innovators can find it helpful to create a series of back-up or appendix slides that are not included in the main pitch but can be referenced when addressing stakeholder questions (J. Skyler Fernandes, "The 'Best' Start-Up Pitch Decks & How to Present to Angels/VCs," One Match Ventures, July 2013).

Timeline: History, milestones, and prior funding
Detailed value propositions for key stakeholders
Detailed financials (revenue and expense breakdown)
Break-even analysis (base-case versus bare bones case)
Pipeline of potential clients (with likelihood of closing each one and potential revenue)
Capital structure (ownership of founders and current investors)
Competitors (capital raises/investors)
Headcount (number of employees, projections, key hires needed)
Proprietary aspects not included in core deck

Creating an executive summary

In addition to the pitch deck, many innovators find it useful to create a one- or two-page executive summary that summarizes the most important aspects of the business in a short narrative form. Some investors may request an executive summary as a first step prior to scheduling a meeting, although not all require one. The executive summary can also be helpful in communicating with partners, advisors, and other stakeholders.

Some experts suggest writing a draft of the executive summary to help guide the development of the pitch. Others suggest saving the executive summary for last, after the pitch has been complied. In either scenario, it is essential to make sure the executive summary is concise, well-written, and compelling.

As the innovator begins to prepare an executive summary, the following guidelines may prove useful:

- **Opening** – Start with the elevator statement, which is a compelling statement about the clinical need, proposed solution, and market opportunity.
- **Body** – Provide the most important high-level information about each of the most relevant topics

Table 6.2.3 The major sections of the pitch can be mapped to specific steps in the biodesign innovation processes. Innovators should consider all of the questions listed here; however, not all of the answers will be included in the pitch deck. Focus is key.

Major sections	Questions to address	Relevant activities in the biodesign innovation processes (from which to pull information)
Elevator statement	• What is the core problem the business is trying to solve? • What is the solution it has developed? • What key benefits will the solution deliver to its target customers?	5.7 Marketing and Stakeholder Strategy 5.9 Competitive Advantage and Business Strategy
The clinical need	• What is the need being addressed? • Why is this need important? • How is the need currently being addressed (if at all)? • In what ways are current solutions inadequate?	1.3 Needs Statement Development 2.1 Disease State Fundamentals 2.2 Existing Treatments 2.5 Needs Selection
The solution	• What is the proposed solution to the need? • How will it be used (and by whom)? • How does it better address the need than what is currently available? • What is the value proposition?	5.7 Marketing and Stakeholder Strategy
The market	• Who is the target customer? • What is the market size? • How fast is it growing? • Who are the primary competitors? • How will the company differentiate itself from the competition? • What are the barriers to entry?	2.4 Market Analysis 5.7 Marketing and Stakeholder Strategy 5.9 Competitive Advantage and Business Strategy
Intellectual property	• How will the company protect its IP? • How strong is its IP position?	4.1 Intellectual Property Basics 5.1 IP Strategy
R&D strategy	• How will the company prove (or has it proven) that the solution is technically feasible? • What are the risks that must be addressed and how will they be mitigated? • How will the product be manufactured and where?	4.5 Concept Exploration and Testing 5.2 R&D Strategy 5.5 Quality Management
Regulatory strategy	• How will the company get its product cleared/approved for the market? • What will be required to demonstrate safety and efficacy?	4.2 Regulatory Basics 5.3 Clinical Strategy 5.4 Regulatory Strategy

Table 6.2.3 (*cont.*)

Major sections	Questions to address	Relevant activities in the biodesign innovation processes (from which to pull information)
Clinical studies	• How will the company collect safety and efficacy data? • Where will the studies be performed and who will be the key investigators? • What other endpoints will be studied (and why)?	5.3 Clinical Strategy
Reimbursement	• What is the reimbursement pathway? • What codes will be used? • How much resistance is anticipated?	4.3 Reimbursement Basics 5.6 Reimbursement Strategy
Business model	• How will the company make money, including its anticipated pricing and margins? • What will be the timing and frequency of revenue realization? • What volume of business is needed to make the model viable?	4.4 Business Models 5.7 Marketing and Stakeholder Strategy 6.1 Operating Plan and Financial Model
Sales and marketing	• Why will customers be compelled to use the product? • How will the company close sales? • How will the product reach customers?	5.7 Marketing and Stakeholder Strategy 5.8 Sales and Distribution Strategy
Financial information	• What are the company's financing needs? • What does it intend to do with the money raised (according to what timeline)? • How (and when) will it generate a return for investors?	6.1 Operating Plan and Financial Model 6.3 Funding Approaches
Exit scenarios	• How are investors most likely to achieve liquidity for their investment? • When is an exit most likely to occur?	6.1 Operating Plan and Financial Model 6.3 Funding Approaches
Management team	• Who are the key individuals that make up the company? • What specific qualifications do they bring to bear?	6.1 Operating Plan and Financial Model

outlined in the pitch, focusing on actions that have been taken and results that have been achieved to date. Include evidence to support claims about the extent of the need and the likelihood that the solution will address the need. Describe key risks and propose mitigation strategies. Use headings to make the organization of the summary intuitive and clear. Make sure the text flows smoothly from one section of the overview to the next, using transitions as needed.

- **Conclusion** – Conclude the executive summary with a clear statement of the purpose of pitch (e.g., "The

purpose of this presentation is to raise $2 million in funds to establish the technical feasibility of the product and perform animal testing . . .”). If the company clearly articulates its capabilities and needs in the executive summary, it will have a significantly greater chance of engaging the reader.

Just like the pitch, the innovators should always develop the executive summary with the intended reader in mind.

The following case example demonstrates how one team developed a pitch and executive summary and successfully used them with investors to raise preliminary funding.

FROM THE FIELD SIMPIRICA SPINE

Putting together a pitch

Colin Cahill, Ian Bennett, and Louie Fielding, three student innovators in Stanford University’s Biodesign Program, worked on the need for *a way to stabilize the spine without compromising mobility*. Over time, they invented a minimally invasive implant to help relieve early-stage degenerative disc pain, an area with a vast unmet need (see Figure 6.2.6). The device had a clear mechanism of action, was simple, and would not necessitate large axial loads, reducing the risk of mechanical failure. In combination, these factors caused the team’s mentor, spine surgeon Todd Alamin, to recommend that they further develop the idea.

After completing the formal Biodesign Program, the team began an exploratory period to determine how they should proceed. Because Cahill and his colleagues perceived the market to be highly competitive, they decided to work in “stealth mode.” This meant they were relatively conservative in terms of sharing information about the device. “At first we were paranoid, because the idea was very raw. We were very careful about which people we talked with about the **concept**,” he said.[8]

One top priority during their exploration was proving the technical viability of the idea. “We applied for and were granted some **seed funding**, so we could advance our prototyping and testing,” explained Cahill. They outsourced the development of some technical components, but were careful never to reveal how the components would be used or how they fit into the larger design.

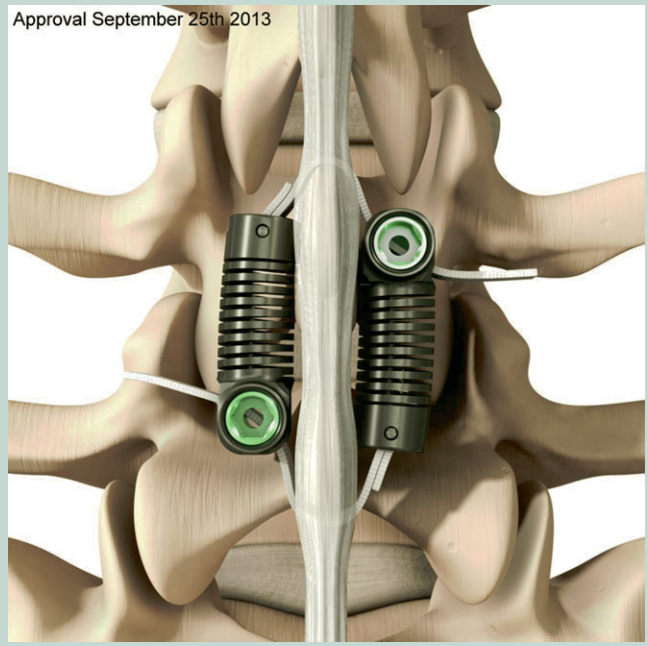


FIGURE 6.2.6
The LimiFlex™ Paraspinous Tension Band (courtesy of Simpirica Spine).

Another priority was ensuring that the solution was truly unique and could be protected with a strong intellectual property (IP) position. Toward this end, the team filed core **patents** early, engaged the services of an outside IP attorney, and used a non-disclosure agreement (**NDA**) to help keep the idea confidential when talking with third parties.

In parallel, they investigated whether the solution was clinically valuable enough to warrant bringing forward. To

address this challenge, they leaned heavily on Alamin and also conferred with a small group of trusted spine surgeons to continue to vet the idea. “We didn’t want to start a company if it didn’t make sense. We had other options – we could have considered it a project and tried to publish a paper, or we could have licensed the idea to a larger company,” Cahill stated.

After about a year of hard work, the output of these three work streams started to come together. The data from the team’s preliminary tests looked highly promising, the IP position appeared strong, and feedback from advisors was positive. In addition, several events in the external environment related to spinal technologies (such as an IPO filing by St. Francis Medical, a company working on a different type of spinal implant) indicated that the market was ripe for innovative spine-related interventions. “We were also approached by several seasoned entrepreneurs who told us that if we decided not to build a business around the company, they would be interested in taking it on,” Cahill remembered. With all of these factors reflecting positively on the opportunity, he said, “We decided to go for it.” Cahill, Bennett, Fielding, and Alamin incorporated the company as Simpirica Spine, with Cahill becoming its full-time CEO.

One of their first challenges, once formally committed to pursuing the concept, was to raise additional funding. In preparation, Cahill and team formally began thinking about how to optimally communicate their idea to investors. Instead of developing a traditional business plan, which Cahill suspected would not be fully utilized, they focused on creating a 20-slide overview presentation that covered the company’s vision, the need, an overview of the current treatment landscape, a description of the new technology and its value proposition, pre-clinical results to date, and the team, including key project advisors. “We’d been thinking about our ‘story’ from very early in the project, so what we were really doing was filling in the blanks with more robust data,” Cahill described. Much of these data stemmed from the team’s operating plan and financial model, the diligence it had completed around IP, the pre-clinical results it had collected, and other related information. Essentially, the team’s exploratory period had equipped Simpirica with a great deal of information that would help it back up its pitch. “If we hadn’t felt like it was a plan that could work, or if there had been a massive piece of the story missing, we wouldn’t have gone ahead,” Cahill noted.

With the slide presentation and a two-page executive summary, Simpirica was nearly ready to begin meeting with investors. However, before taking this step, the team shared its materials with trusted advisors and practiced delivering its pitch. This resulted in valuable feedback that helped the members strengthen their approach. And, although the core messages remained the same, they learned to tailor the presentation to the audience to maximize its effectiveness. “The final pitch was a combination of the dream, the vision for the company, and our ability to execute on that vision,” Cahill said.

When asked how they handled concerns about **public disclosure** when talking with prospective investors, Cahill stated that they did not ask these individuals to sign NDAs. “We’d been told that a venture capitalist would never sign an NDA, which isn’t necessarily true. But it seemed like a better approach to develop the presentation in such a way that we’d be comfortable if it ended up on the Internet, which it never did,” he said.

They did, however, mark CONFIDENTIAL on every slide and, more importantly, made sure all of their IP filings were in place before “going public” with the idea. Reflecting on the disclosure issue, Cahill commented that perhaps he and his teammates were too conservative at first. “As long as you’ve secured your IP, talking to a lot of people can be a good thing. Use your best judgment about people’s character when you meet them, but err on the side of disclosing more rather than being paranoid.” Sometimes, he explained, one conversation can lead to another, with new connections and contacts contributing valuable input to the project.

On a related note, Cahill suggested engaging with investors early and potentially talking with them multiple

times. "At Simpirica, we didn't want to pitch anyone too early," he said. "But building familiarity with key contacts and showing progress against your milestones before it's time for anyone to make a decision can be valuable, particularly now that there's less capital to be raised in medtech markets. I think the value outweighs the risk."

Finally, he acknowledged that preparing and delivering a pitch and undergoing diligence could be nerve racking. "But if you have all of your ducks in a row and are well prepared, there shouldn't be too many surprises," Cahill advised.

Using its preliminary pitch, the Simpirica team raised **angel investor** funding, followed rapidly by a venture-backed series A round. In 2014, the Simpirica implant was on the market in Europe where it had been used to treat more than 1,500 patients. In the US, the company was initiating a pivotal trial to support a **PMA** application to the **FDA**.

More about pitching and funding

Some medtech innovators erroneously believe that the most important reason to develop a pitch is to raise funds. Even if this is one of the team's primary objectives, the real value of creating the pitch is that it forces the innovators to carefully think through how they will build a business (in combination with the activities described in 6.1 Operating Plan and Financial Model). That said, the pitch is certainly an important tool that helps facilitates conversations with investors and can lead to funding. Investors expect to see a well-constructed pitch and may rapidly eliminate projects from consideration if the caliber the presentation is lacking.

Of course, funding from external investors will not sustain a new venture indefinitely. A company needs profitable, revenue-generating products to become sustainable. As investors are required in the current investment environment to commit increasingly large sums of money over a longer time horizon to reach an exit, they have higher expectations (and perform more stringent due diligence) related to a company's operational capabilities. A compelling pitch demonstrates how a company will become profitable, as well as the management team's ability to run the business for as long as necessary for investors to generate a return.

One of the most common mistakes innovators make in developing a pitch for investors is to understate important costs (or overstate market estimates). Not only does this cause projections to be blatantly inaccurate, but it can result in the team losing credibility with prospective investors. Studying how other companies of the same size or in the same field have expanded and how their sales figures have grown over time can provide an effective check on whether the figures outlined in the company's financial projections are truly realistic (refer to online Appendix 6.1.1). Innovators should also recognize that despite their efforts to provide realistic estimates, investors will sometimes discount sales projections by as much as 50 percent and may also inflate costs. By varying sales and/or expenses in the financial model, innovators can study the impact of these assumptions and provide investors comfort that the plan remains viable. Showing investors the results of the analysis over the range of assumptions is called a "sensitivity analysis" and can help build confidence and credibility in the investor audience.

Approaching investors

When seeking funding, it is preferable to use one's connections to gain access to investors. Cold calling, blind mailings, or online submissions of a business plan rarely lead to positive results, and may actually hurt a company's chances of being funded in some cases. Referrals to investors can be gained through any number of different sources. Other innovators, as well as service providers (attorneys, consultants), can be rich sources of leads. If innovators do not have direct contacts in the industry, they should network to find them. For example, if the innovators know a venture capitalist or angel investor who works in the high technology sector, that person might be able to make a referral to another venture capitalist or angel who works in the healthcare or medical device field. Be assertive, but respectful in

networking and pursuing referrals. If the innovators have no choice other than to make a cold contact, they should be sure to focus on investors or firms whose criteria seem appropriate to the business. Names and relevant information about potential investors can be found through online directories.

Once potential targets are identified, innovators should next conduct thorough research to understand everything they can about the investors, including their existing portfolios, track records, investment criteria, management styles, and other factors that can help determine if there is a good fit between the company (and its technology) and the interest of the investors. Seek out interviews with founders that the investors have previously supported to gain an understanding of their investment approach and management style. Remember, fit is very important. The questions in Table 6.2.4 can help in this assessment.

Before making contact with prospective investors, the innovators should at least have their elevator statement ready and a sense of the company's funding requirements. Having the pitch and/or the executive summary available to share is even better.

Table 6.2.4 Innovators should spend nearly as much time screening investors as investors spend screening investment opportunities.

Questions for screening investors
At what stage does the individual or firm usually invest?
What is the typical investment level over the life of a company?
What is the typical amount invested in each round?
For VCs, when was the current fund started? (If > 5 years ago, then there may not be adequate funds remaining for additional financing rounds.)
For individuals, how did the investor earn his/her money? How many other companies is s/he involved in?
How much time will be spent with the company? What expectations does the investor or firm have regarding involvement?
What prior deals has the individual or firm done in the industry?
Does the company have references (other innovators with whom it has worked) who can be contacted?

Preparing to deliver the pitch

In an ideal world, what most investors are seeking is an attractively valued company with a strong, experienced management team that can implement a well thought-out business model to sell a proprietary technology or service in a large, worthwhile market, and grow a substantial, profitable company over a short time frame with a clear exit strategy for the investors. In other words, they are seeking huge rewards with limited risk.[9]

Rodney Perkins, founder of multiple companies including ReSound Corporation, Laserscope, Collagen Corporation, Novacept, and Pulmonx, offered this advice to innovators as they prepare to address investor questions:[10]

> *When you're talking with [investors], any complexity makes them nervous. You want to describe a very straightforward, single product; you're going to sell it to a known market, this is the development risk, this is the regulatory risk, and make sure that these are clearly understood.*

Many investors make preliminary inquiries in six primary areas: (1) technology or service concept; (2) market size and dynamics; (3) management team; (4) business model and financial requirements; (5) exit scenarios; and (6) **valuation** and deal structure. Table 6.2.5 provides examples of the types of specific questions they may ask in each of these areas when assessing an opportunity. Innovators should develop answers to these questions in advance, in preparation for delivering their pitch. That said, they should also expect that investors will ask at least some questions that they will not be able to answer. During the pitch and diligence process, investors sometimes use their questions as a way to probe whether the team is willing to admit the limits of its own knowledge and how comfortable they are recognizing the never-ending need to seek out ways to get better answers from others. Simply put, every innovation initiative starts off with more assumptions than knowledge and the innovators will be asked to demonstrate their understanding of that reality.

Table 6.2.5 Common questions asked by professional investors (based on Ross Jaffe, "Introduction to Venture Capital," October 6, 2004; reprinted with permission).

Area of inquiry	Technology or service concept
Technology or service concept	• Is the product/service concept clear? Does it make sense? • Is there sufficient proof of principle or evidence of feasibility? • Are there adequate proprietary aspects – patents, trade secrets, or other barriers to entry? • Can it be manufactured at a reasonable expense? • Are there regulatory issues?
Market size and dynamics	• How large is the market, realistically? What is the actual addressable population? • Does the company have realistic potential to obtain substantial revenues in the market? • Is the decision making of purchasers and users well understood? • Are there reasonable marketing and sales costs? Sales cycles? Distribution systems? • Are the business relationships between referral sources, purchasers, providers, and consumers well understood? • Does the company have a strong competitive position? • Is the technology/service consistent with market, regulation, and reimbursement trends?
Management team	• Is the management team smart? Are they knowledgeable about this business? • Does the management team have a proven record, particularly in this business? • Do managers have high levels of honesty and integrity? Can they be trusted? • Do they have reasonable expectations for the business, particularly for the difficulties of product/service development, rate of company growth, capital requirements, ultimate business size and profitability?
Business model and financial requirements	• What are realistic revenue and expense projections for the company? • How much capital will be required to reach positive cash flow? • What are realistic expectations for the timing and sources of this cash? • What are the realistic exit opportunities for investors in this deal?
Exit scenarios	• How are investors most likely to realize an exit? What scenario seems most likely? • For acquisition candidates, what companies are most likely to be interested? What other acquisitions have they made recently? Does the company have an established relationship with one or more of these companies? Why would these companies acquire a technology in the space rather than developing it themselves?[11] • What timeline is most realistic for achieving an exit? • What are the major factors likely to influence whether or not the exit is realized?
Valuation and deal structure	• Will the valuation of the investment in this deal afford a high probability of a substantial return (40 percent or greater internal rate of return)? • Will the deal allow for enough capital to be put to work to make the investment worth the time and effort? • Who will be the co-investors? Are these parties good to work with? • How can this investment be structured to minimize the technological and financial risk?

Even though all investors may be interested in information related to some or all of these questions, different types of investors may have different expectations about what the answers should be to attract their investment. Chapter 6.3 Funding Approaches provides an overview of various funding sources and how their priorities and expectations may vary.

Over and above preparing to address investor questions, innovators are advised to practice their presentations (many times over) to ensure that the flow, timing, transition, and tone are smooth and professional.[12] As suggested in the Simpirica story, it can be helpful to deliver the pitch to advisors and other mentors and actively seek constructive feedback.

The following story highlights other important information related to the investor's perspective and provides an example of how one medtech venture capitalist thinks about the hundreds of business pitches he sees each year.

FROM THE FIELD VERSANT VENTURES

The role of investors in screening new business opportunities

Versant Ventures is a leading venture capital firm focused on life sciences opportunities, including both diagnostic and therapeutic medical devices. The firm has invested in many of the major medtech success stories since its inception in 1999, including Acclarent (acquired by Johnson & Johnson) and St. Francis Medical (now part of Medtronic). Ross Jaffe, a managing director at Versant, focuses on medical device investments for the firm. He has worked in medtech investing for over two decades, bringing both his clinical training and business experience to bear.

When asked about the medtech funding landscape in 2014, Jaffe said, "We're in one of the most challenging environments for medical device investing I've seen in my career. And it's especially challenging to be an early stage investor in medical technology. We're at the lowest level of medical device **start-up funding** since 1995." Jaffe believes that the current situation is due, in part, to the general contraction in financial markets and longer-term cycles in the venture capital industry, but that is not the whole story. "Compared to the IT industry, healthcare is viewed as more complicated and complex because of the regulatory and reimbursement challenges we face. Fewer people are interested in taking on these additional risks," he explained.

The implications for innovators are stark, but not necessarily dire. Jaffe predicts a "Darwinian environment" where, he said, "Those companies that are truly outstanding and can adapt to the environment will be successful in raising venture capital. This environment will reward the scrappy entrepreneurs who can figure out how to get a lot done on very limited resources." Start-up companies with technologies that are highly attractive to potential acquirers will also do well since they have a clearer path to an exit. **Corporate investments** in early-stage medtech companies are on the rise but, according to Jaffe, this increase in corporate funding will not fully make up for the decline in venture investment in medical devices. "It's also critical to think about how new technologies fit into the evolving healthcare system," he advised. "Technologies that save costs as well as improve outcomes are more likely to succeed in this new paradigm." In contrast, "Incremental improvements that cost more but don't deliver improved outcomes or better economics are no longer compelling," added Jaffe. He also pointed out that the new environment will be challenging for companies developing truly novel technologies with long R&D cycles and no established business parallels.

Jaffe and his partners (see Figure 6.2.7) identify new ideas and technologies from a variety of sources, some higher-yield than others. "There is a hierarchy of where the best opportunities tend to come from," he said. The most promising ideas tend to come from the

FIGURE 6.2.7
Jaffe (center) at a partners meeting. (courtesy of Versant Ventures).

entrepreneurs they have worked with in the past and members of their network (i.e., trusted peers and service providers such as corporate attorneys, IP attorneys, regulatory consultants and the like). "We know their judgment about things, they know how we look at the world, and they often bring to us the highest quality deals. Projects from **incubators** that we generally work with are also in this category," Jaffe stated. Next are the opportunities that deal agents and investment bankers bring to Versant. The largest number of opportunities are the unsolicited proposals that come to Versant because of its reputation as an early-stage investor in the life sciences space, but they are not filtered through other knowledgeable people so the quality of the proposals can be highly variable. He added, "If you don't have direct relationships with venture capitalists yourself, having your proposal vetted by someone knowledgeable in the field who can give you feedback on ways to improve it and then forward the revised plan on to venture capitalists who they know increases the level of review your proposal will receive."

Through these three primary sources, the Versant team reviews 300–400 opportunities annually in the medical device sector. "But keep in mind that we can only invest in two to eight deals each year," Jaffe said. "So we're really trying to find the top one to two percent of opportunities with the top one or two percent of entrepreneurs that can make these ideas successful."

These days, entrepreneurs rarely send the firm a traditional business plan. Most start-ups submit a PowerPoint-based pitch. According to Jaffe, these presentations should provide a crisp picture of the clinical need, the size and characteristics of the market, the technology and how it solves the need, the key requirements to get to market and drive adoption (clinical, regulatory, reimbursement, and commercialization pathways), the knowledge and experience of the team, the strength of the intellectual property, the operating plan and resulting financial projections, and the financing strategy and exit opportunities for the company.

When he receives a pitch, Jaffe explained, "The first question I ask is: given the market opportunity and the amount of capital required, will the investment generate a return that justifies the risk, the time, and the money?" Importantly, he continued, "I can actually read one of these presentations in about five minutes and tell you whether I'd even consider investing in it or not." As a result, the pitch must be compelling. For Jaffe and many investors at well-known venture capital firms with high-volume deal flows, their time is a more limited resource than their capital. "So this may sounds a little harsh, but my goal is to get to 'no' as quickly as possible so that I can move on to find the most attractive opportunity available," he explained. "And I only need one reason to get to no. The pitch has to communicate why I should be excited about all the elements of the business, otherwise I'll set it aside."

Toward this end, Jaffe shared some tips on how to prepare a compelling pitch. First, he said, "Conciseness and pithiness matter." The pitch should be direct, complete, and clear, without being too wordy or long. The innovator should have thought through the story that needs to be conveyed, and should be able to communicate it in about 20 slides. Second, he continued, "I don't get impressed by presentations that are fuzzy about things." Pitches should be specific and

contain enough detail to demonstrate that the innovators have carefully thought through their plan (rather than just preparing a sales document). "I'm always impressed when the presentation anticipates the key questions that I will ask about the specific opportunity," he said.

Innovators should build their business plans as real plans for the business, not just pitches to get funding. The realism and quality of the plan should be of as much concern to the entrepreneur as it is to the potential investors. "As an entrepreneur, you are about to invest your life, your time, your ego, and probably some of your money or your family's money in this opportunity. You should be more hardnosed with yourself than I will be with you about why this opportunity is a valuable thing for you to do and the right way for you to spend the next few years of your life," Jaffe advised.

If the pitch looks intriguing, the Versant team invites the innovators to deliver the presentation in person. This meeting lasts only about an hour, and the determination to take the next step (or not) is made fairly quickly. This decision depends on the strength of the idea, the team, and the overall pitch, as well as the **opportunity cost** of working on this project rather than something else that may be under consideration. "We're in a constant triage mode," Jaffe said. "We're evaluating dozens of opportunities at any point in time and we get together as a group within the firm to prioritize them. A lot of times, proposals come in that are potentially interesting, but they just don't make it high enough on the priority list."

The next step for promising opportunities is diligence. "During the due diligence process, I try to identify the biggest risk areas, the areas where I have the greatest concerns, and dig deep into them. Again, I try to prove to myself why I shouldn't do the deal," Jaffe stated. While addressing the same basic issues, this process is customized to each opportunity and is heavily dependent on the clinical needs being addressed, the market characteristics, type of technology under consideration, and the plans laid out by the team. Importantly, not all risks are created equal. Some can be mitigated or reduced over time, such as technical or clinical risks. While others are more difficult or problematic to potentially affect, such as market size or IP issues.

Once diligence is complete, Versant has the information it needs to make a final decision. Jaffe consults with the rest of his team to make sure that all partners are supportive. The firm then initiates negotiations on a **term sheet** for those opportunities that represent the "highest and best use of our capital at that point in time," said Jaffe.

"Raising funding really depends on how much cash is in the market, what other opportunities are available, and the credibility of the entrepreneurs and how much confidence we have in them," Jaffe summarized. "Great entrepreneurs can still raise money in this environment, but it's not as easy for the average entrepreneur." Accordingly, he advised, "Reach out to people who have built companies and get their feedback early about key challenges. And don't get defensive when they provide negative feedback – they're often shining a light on the areas where you need to look more closely and think more deeply."

Business planning and teams

Most innovators and investors alike acknowledge that it is not new technologies that create new businesses, but rather teams and people. As noted, an effective pitch can help articulate the key team and management structure behind the venture. Even more importantly, it helps the members of the founding and management teams better articulate their goals. Every individual involved in a new venture has his/her own aspirations and objectives. The exercise of building the pitch helps reconcile and potentially find synergies among those expectations. For example, some founders place significant emphasis on

ownership and control. If, in the process of developing the pitch, it becomes clear that necessary external funding will dilute management control and ownership, this discovery creates the opportunity for an open discussion about how the issue will be handled.

When it comes to team-related issues, there are several difficult questions that should be addressed as part of the business planning process to ensure that the management structure put in place lays the foundation for a successful venture:

- What will be the equity ownership of each of the founders?
- How will equity and stock options be distributed to key employees?
- What is the process through which these decisions will be made?
- What will be the responsibilities of the founders and early employees?
- What roles will the founder and early employees play as the company evolves and grows?
- Who will be the CEO (and will there be an interim CEO to be replaced by a permanent CEO)?
- What are the desired attributes of early employees?
- How and from where will important hires be recruited?

A thoughtful discussion of these questions should occur early during business planning and pitch development because it can help highlight differences in expectations. Furthermore, the answers may affect the firm's strategic directions and funding options, as well as its overall culture and performance. Do not procrastinate on addressing these issues. Although some of the topics may be difficult for the early team to discuss and resolve, no prospective investor will give a team money before they have been satisfactorily answered.

However, innovators should recognize that while there is some flexibility in how to address these questions, market forces may constrain the range of viable alternatives. Consider, for example, the question of how equity and stock options will be distributed to key employees.[13] The answer depends, to a large extent, on what other companies offer their key employees. If the current trend is to offer two percent of the company to a key senior executive, deciding to offer less may make the company's offer non-competitive. In contrast, offering more may not be considered acceptable by investors. More details on the question of equity ownership for key employees are presented in 6.3 Funding Approaches.

Business planning and intrapreneurship

Even though most people tend to think of the pitch in the context of entrepreneurship, these documents also play a critical role in intrapreneurship (entrepreneurship within the context of an established company or organization). Importantly, when **intrapreneurs** develop a pitch or executive summary to support an opportunity, they need to consider how to leverage existing resources within the firm and what complementarities exist with existing product portfolios, as described in 6.1 Operating Plan and Financial Model. They should also consider how the opportunity fits within the existing organizational structure and the extent to which it meets defined financial hurdles. Large firms, within which intrapreneurship often occurs, tend to have well-defined organizational structures that may inhibit or support important relationships with internal and external constituencies that are needed to bring an opportunity to fruition. They also have clearly defined capital budgeting processes and requirements for the return on investment (ROI) of any project that is undertaken. So, the financial model should be adapted to reflect internal processes and requirements. Factors such as these can serve as enablers or barriers to intrapreneurs as they develop a pitch.

Innovators operating within larger companies should pay particular attention to three aspects of the pitch, which take on more significance and can influence their ability to gain support. The first is the rationale for what makes the project a strategic fit with the priorities and interests of the organization. Strategic fit is commonly an issue of debate because the intrapreneurs are likely proposing a novel path with inherent risks.

The second issue is the degree of organizational autonomy required for the initiative to succeed. Intrapreneurs often cite their relationship with the core business and the potential for creating conflict as a significant barrier. Corporate innovators should be particularly careful where staffing is concerned. Here, one of the apparent strengths of a larger organization – a large, highly skilled

base of human resources – can work against effective implementation. The biodesign innovation process requires a high degree of focus, especially in the early needs finding and needs screening stages. Too frequently, the tendency of the larger company is to believe that the effort can be undertaken by part-time team members "on-loan" from their other core business assignments. Experience has shown that the presence of at least one full-time team member can significantly and positively influence outcomes. That said, large organizations should resist the temptation to make the teams larger than necessary to complete objectives of these early phases. Smaller teams of two to four people are frequently most effective.

Finally, the third factor is to develop an explicit process for characterizing and managing risk. The lower risk tolerance of an established organization can sometimes make undertaking a high-risk initiative difficult. Intrapreneurs can help address this issue by remaining focused on answering their own *key questions* (i.e., sequencing and describing the steps to be taken to reduce risk in as orderly a fashion as possible for the given project). Teams should resist the temptation to use the larger organization's greater financial resources to mitigate risk. It is somewhat counter intuitive but the biodesign innovation process has been proven to run better when resources are constrained, forcing decisions to be made on a more demanding timeline. The corporation must be able to acknowledge up-front that failure rates for intrapreneurship initiatives are generally quite high. Both successes and failures play roles in creating a culture of innovation and should be understood as part of a productive intrapreneurship process.

Online Resources

Visit www.ebiodesign.org/6.2 for more content, including:

Activities and links for "Getting Started"
- Define the purpose and audience for the pitch
- Identify the key questions
- Develop an outline
- Conduct research and compile supporting documentation
- Write the pitch, seek input, and iterate

Videos on strategy integration and communication

CREDITS

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NOTES

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4 Based, in part, on J. Skyler Fernandes, "The 'Best' Start-Up Pitch Decks & How to Present to Angels/VCs," One Match Ventures, July 6, 2013, http://www.slideshare.net/Sky7777/the-best-startup-pitch-deck-how-to-present-to-angels-v-cs (February 20, 2014).
5 Ibid.
6 "Writing an Effective Business Plan," Deloitte Touche Tohmatsu International, 1993.
7 Stanley E. Rich and David E. Gumpert, "How to Write a Winning Business Plan," *Harvard Business Review*, May 1, 1985, p. 136.
8 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.
9 Ross Jaffe, "Introduction to Venture Capital," October 6, 2004.

10 From remarks made by Rodney Perkins as part of the "From the Innovator's Workbench" speaker series hosted by Stanford's Program in Biodesign, April 14, 2003, http://biodesign.stanford.edu/bdn/networking/pastinnovators.jsp. Reprinted with permission.

11 Fernandes, op. cit.

12 Ibid.

13 "Sharing Equity in a Start-Up or Established Entrepreneurial Venture," The National Center for Employee Ownership, https://www.nceo.org/articles/equity-compensation-startup (March 10, 2014).