6.3 Funding Approaches

INTRODUCTION

In 2007, US venture capitalists invested $3.9 billion in 365 medical device start-up deals.[1] *By 2013, venture activity had declined to $2.1 billion across 308 deals,*[2] *with only 49 of these investments directed to companies receiving first-time funding.*[3] *Against this backdrop, getting a new medical device start-up funded is, in many ways, harder than ever before. The US-based venture investors who fueled the industry for decades are increasingly looking to other sectors for less risky investment opportunities, shorter times to exit, and more successful initial public offering (IPO) activity. Meanwhile, capital requirements for medical technology companies continue to grow, driven in part by prolonged regulatory timelines and complex, unpredictable reimbursement processes. In short, the medtech funding landscape is in the midst a historic shift, where "business as usual" has been significantly disrupted and new opportunities are just beginning to take shape. Successful innovators will take advantage of the evolving sources of funding that emerge as the US healthcare industry undergoes restructuring and global markets and businesses continue to expand.*

OBJECTIVES

- Learn about different types of funding, the stage at which they might be most appropriate, and how they are likely to affect the company and its investors at exit.
- Understand the wide range of sources available to innovators in the new medtech funding environment, and when they might be most appropriate to get involved.
- Appreciate the criteria used by different investors to evaluate a business opportunity.
- Recognize that funding is not an event, but the beginning of a longer relationship with the funding sources that can add strategic value to a venture.

In rare circumstances, medical technology companies can get to market without the involvement of institutional investors. However, in most cases, innovators will require this type of support. A growing number of different funding sources can be leveraged to finance a medtech start-up, and innovators are getting increasingly creative about the sources they tap and the combination of investors they target. When choosing among funding sources, the innovators' focus should be on identifying the best fit between the project's capital needs and the goals of the potential investors. Selecting the right investors is particularly important because the innovators enter into a working relationship with these firms, organizations, and/or individuals that can span multiple years. Accordingly, everyone will be more satisfied if their true financial objectives, timelines, and management styles are aligned.

This chapter explores different types of funding and when they are most relevant to a company, the various sources of funds innovators can consider, and how these sources compare in terms of their advantages and disadvantages. Additionally, it describes the

funding process and what innovators might expect when entering into a funding agreement. The chapter's emphasis is on funding sources for companies that can achieve sufficient clinical and/or commercial progress to be acquired, or ultimately generate the cash flows necessary to become self-sustaining entities. If the need addressed by a new solution does not support a stand-alone company, different funding options are presented in 6.4 Alternate Pathways.


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FUNDING FUNDAMENTALS

Many innovators find the process of raising funds for a new company frustrating and stressful. Similarly, they are often perplexed about why investors fail to grasp the potential of their ideas and decline to fund them. Mir Imran, a seasoned device entrepreneur who has experienced the funding process from the perspective of the innovator and the investor at different times during his career, summarized the situation this way:[4]

> *I used to really ponder why these venture capitalists didn't invest in all my companies and give me big checks. I finally got the answer when I started writing checks. When you put on the investor hat, you ask a different set of questions. You're looking at risk – how to measure and gauge risk. So I have sympathy for both sides.*

In the **medtech** industry, the costs (and related risks) of forming a new venture can be particularly high due, in large part, to the clinical, regulatory, and **reimbursement** requirements associated with commercializing new products in the field. A survey of more than 200 medical device companies found that the average company expenditure from **concept** just through regulatory approval was $94 million for technologies on **FDA's PMA** pathway and $31 million for those seeking **510(k)** clearance.[5] A sample of assorted medtech companies and their funding requirements to **exit** are shown in Table 6.3.1. Given these substantial capital requirements, funding in the industry was dominated by venture capital (VC) investors who could provide these sizable sums. However, the VC sector as a whole, was hard-hit by the 2008 financial crisis. In the resulting fallout, venture firms began shifting their investments away from start-ups to later-stage, less risky companies.[6]

Medical device companies were impacted by this shift to a greater degree than companies in other industries because it corresponded with other changes that combined to make many medtech investments less attractive. In particular, investors were discouraged by longer regulatory review times, greater clinical requirements, increasing unpredictability surrounding reimbursement, and the implementation of the 2.3 percent medical device excise tax that took effect in the US 2012.[7] As a result, medical device VC investment declined by more than 40 percent from its peak in 2007 to the end of 2013.[8] Generally, more money flowed into software and, within the life sciences sector, into biotechnology.[9]

In response, the vast majority of medical device start-ups have had a harder time raising money than in years past. On one hand, some observers fear that the current funding environment may be stifling medtech innovation. On the other, aspiring companies have become more rigorous and resourceful in planning to get to market, and a wide range of non-VC funding sources have become more active in the medtech field.[10]

While the downturn in VC funding is almost certainly cyclical, the recent funding trends in medical devices highlight several important points about financing an idea. First, innovators are well served to recognize that the capital requirements of developing and commercializing a medical technology are sufficiently large that they are likely to have to seek institutional funding of some sort – very few device companies are able to get to market by **bootstrapping** alone. Second, deciding on a funding strategy should involve a broad exploration of the financing landscape to determine which type of

Table 6.3.1 Device start-up funding requirements vary widely, but are not insignificant (compiled from Preqin, unless otherwise cited).

Acquisitions				
Company	**First funding date**	**Total known funding (millions)**	**Exit date**	**Total known value of exits (millions)**
Acclarent	June 2004	$103.5	January 2010	$785
Ardian	February 2005	$64.1[11]	January 2011	$800
BarRx	June 2006	$42.8	February 2012	$325
CoreValve	June 2004	$63	February 2009	$700
Lutonix	July 2007	$35	December 2011	$225
Minnow Medical (now Vessix Vascular)	October 2010	$27.2	November 2012	$425

IPOs				
Company	**First funding date**	**Total known funding (millions)**	**Exit date**	**IPO market cap (millions)**
Foundation Medicine	April 2010	$89.5	September 2013	$394.2[12]
GI Dynamics	July 2003	$113.6	August 2011	$304[13]
LDR	September 2006	$48.7	October 2013	$339.8[14]
Stentys	January 2007	$22.2	October 2010	$121[15]
Tandem Diabetes Care	June 2008	$158.79	November 2013	$287.7[16]

funding, at what stage of the company's development, and what funding source provide a good match. And, third, in order to raise money from external investors, innovators must be able to tell a compelling story for how those investors will recoup what they put into the business. Importantly, not all sources of funding demand a financial return – but all have specific requirements for what they expect to get out of a deal. By directly taking these requirements into account early in developing an approach to funding, innovators will significantly increase their chances of success.

Topics related to these three important points, along with a series of others, are covered in the sections that follow. The chapter begins with types of funding, stages/uses of funding, and exit scenarios to provide innovators with a context for then evaluating the full range of funding sources available to them and targeting the one (s) that provide the best strategic fit.

Types of funding

For all practical purposes, equity is the most widely available type of funding for early-stage device start-ups. However, under certain circumstances, innovators can also explore debt and grants.

Equity

Equity refers to a share of ownership in the business received by an investor in exchange for money. This is the most common way that external entities invest in medtech start-ups. The primary advantages of **equity funding** are that equity contributions generally do not have to be paid back (even if the company goes

bankrupt), the company's assets do not have to be used as collateral, and no monthly payments are due. On the other hand, equity investments require the innovators to relinquish some ownership of the business and the investors may assert their ownership rights by seeking input into how the business should be run. The company also may be expected to share its profits with its equity investors through the payment of **dividends** (profits can be shared as dividends or reinvested in the business as retained earnings).

Equity investments take two primary forms: **common** and **preferred stock**. Both common and preferred shareholders own a portion of the company, but they are granted different rights in exchange for their investments. Both types of stock give shareholders **voting rights**. However, preferred stock provides shareholders with additional rights, which may include a liquidation preference (meaning that preferred stockholders are paid before common stockholders if a company is sold or its assets are liquidated), or preemptive rights (the option to keep a proportionate ownership of the company by buying additional shares when new shares of stock are issued as they would be in a subsequent financing). Holders of preferred stock are also often given priority over the common shareholders in the payment of dividends when and if declared by the board of directors. Based on the rights associated with preferred stock, it is considered less risky and generally favored by institutional investors, such as VCs and corporations. Individuals as well as founders and early employees, on the other hand, are more often issued common stock. Founders will likely own common stock, while key employees may be allocated stock options for common stock or in rare cases preferred stock as part of an incentive program.

Debt

Debt refers to money that is borrowed by a business. Debt must be paid back by borrowers (usually in monthly payments of principal and interest over a fixed period of time, similar to a mortgage). It is generally obtained from individuals, banks, or other traditional lenders. As noted, debt is primarily available in later stages of the start-up, once the company is generating revenue and has tradable assets that can be used as collateral. Given this later-stage orientation, innovators should keep in mind the effect of debt on other investors in the company. Debt lenders always have the first claim on the company's assets, followed by preferred shareholders and then common shareholders. What this means is that, if the company is sold, the proceeds will first be used to pay any outstanding loans and then distributed to the shareholders according to the rights corresponding to the specific type of shares they hold.

The main advantages of **debt funding** for later-stage companies are that the innovators usually do not have to turn over any ownership in the company or future profits to the lender, the lender does not exercise control over the business, and interest on loans can usually be deducted on the company's taxes. On the other hand, debt financing requires that a company have an adequate cash flow to make loan payments. Loans to start-ups are generally considered risky, carry relatively high interest rates, and may require a co-signer or guarantor. They also may specify that the company's assets be used as collateral (which means they can potentially be seized if the company fails to make its payments). Too much debt can also negatively affect a company's credit rating and impair its ability to raise money in the future. The types of loans most frequently used by start-ups are summarized in Table 6.3.2.

In certain conditions, companies may benefit from using a modest amount of term debt to extend their cash and delay their next round of equity financing.[17] However, from a practical perspective, debt financing only should be considered when the company's prospects appear promising.

Grants

Grants involve funds that do not have to be repaid by the company. They are disbursed to a team or company by a government entity, corporation, foundation, or other grant-making organization to support a particular project. Grants traditionally have been a primary type of funding sought by medtech innovators working in areas without significant commercial potential. Rather than seeking a financial return on the funds that they provide, grant makers instead require recipients to achieve some

Table 6.3.2 Innovators may decide to consider different types of loans, depending on their circumstances.

Loan type	Description	Key considerations
Bridge loan	• A **bridge loan** is the most common form of interim debt financing available to innovators and companies. • Typically used to span a period of time (e.g., before additional financing can be obtained, before the company closes a pending M&A transaction, or until the company achieves positive cash flows). • Amounts can range from $100,000 to several million dollars.	• Commonly extended to companies by existing **angel** or venture capital investors. • Usually can be arranged relatively quickly (with limited documentation), but often commands higher interest rates than conventional debt. • Principal and accrued interest may often be converted into equity at the lender's option, usually at a discount to current price/share. • Points, fees and other costs of obtaining the loan must be amortized over a short period of time. • The term is often short (commonly less than two years) and lenders often require relatively rapid repayment of principal if conversion does not occur.
Venture debt	• **Venture debt** is debt financing available to companies that have at least one professional investor as a significant equity-holder in the company. • Can serve a similar purpose of a bridge loan, but is also used to fund equipment purchases. • Loans typically range from $1 million to $15 million, with the debt maturing in 2 to 4 years. • Sometimes interest-only payments can be made for a pre-defined period.	• Specialized banks and non-bank lenders extend venture debt to companies that do not have positive cash flows or other significant collateral (although they are still likely to place a lien on what assets do exist, including IP). • Lenders can request operating covenants which specify minimum cash balances. • The lenders are compensated for the higher risk of default through a mix of high interest rates and **warrants**, which give them the right to purchase a number of shares of the company's stock at a price per share paid by other investors.
Royalty-backed loans	• With **royalty-backed loans**, the lender extends a loan to the company in exchange for a royalty on the company's product sales. • Lenders will sometimes combine their loan with making an equity investment. • Loans range from $5 million to 10 million.	• Because the lender's source of repayment is based on the success of the product, these loans are usually only available once the company can clearly demonstrate the product's sales potential. • The royalty becomes a cost of selling the product which requires that the product have adequate gross margin to allow payment of the royalty and still remain an economically attractive business opportunity.

other measureable form of "impact" that is aligned with the priorities and interests of the grant-making institution. However, as the number and type of grants and grant makers has proliferated, grants are becoming a viable early-stage funding alternative for more and more medtech companies.

In addition to the fact that grants do not have to be repaid, many innovators like that grant-making organizations often provide other forms of support, such as relevant expertise and resources, connections to other innovators, and increased visibility and credibility for the project among certain audiences. However, grant

funding is inflexible from a timing perspective, which means that innovators must work to fixed funding cycles rather than thinking about when funding would be optimal for the project. Innovators also may face stringent restrictions on how grant money can be spent, and this money may come with oversight and reporting requirements that are burdensome to a start-up company.

To receive a grant, teams usually must prepare and submit a grant application, carefully following the guidelines and deadlines set forth by the grant-making organization. Many programs are highly competitive, so there is always uncertainty about whether an award will be made.

Stages/uses of funding

During the earliest stages of its existence, a company's perceived worth is low because there is a great deal of risk and the team has not yet proven itself. This means that the cost of raising money is expensive – a large percentage of ownership in the company will be given up for relatively small amounts of money. As the company accomplishes its major milestones (see 6.1 Operating Plan and Financial Model), it is able to raise increasing amounts of money to support hiring, manufacturing, marketing, sales and distribution, and other **value**-building activities. As progressively more milestones are met, resulting in lower risk for the investor, funding becomes less expensive to the start-up.[18]

As a company moves through the stages of its development, it will likely seek different forms of investment based on the manner in which the funds will be used (as outlined below and summarized in Figure 6.3.1).

- **Seed funding** – Once a team has defined a compelling need, generated concept(s) to address it, developed a **prototype**, and performed a basic proof of concept, it can consider raising **seed funding**. Seed funding typically comes in increments of $10,000–$100,000. It is used to fuel project progress and help the team reach a stage where more substantial investment can be attracted. Innovators can use equity, grants, or even personal debt as a form of seed funding, but they should seek the type of funding with the most reasonable terms possible since the risk to the innovators and investors at this stage is extremely high.

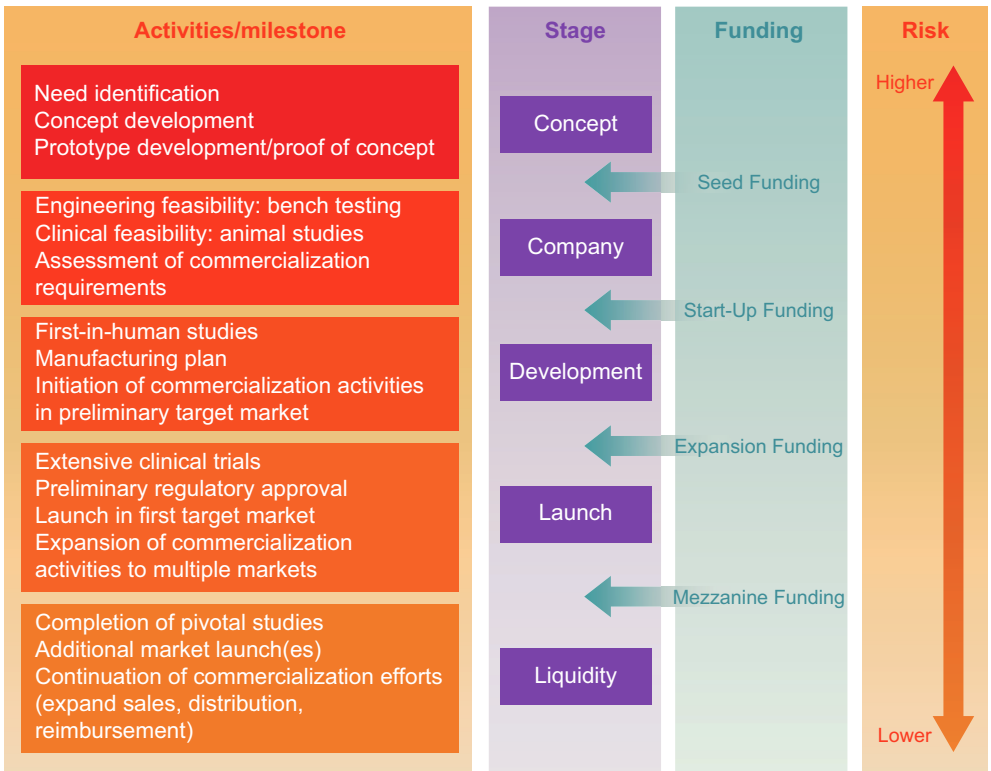

FIGURE 6.3.1
Funding at different stages of the company's evolution and the general activities in the biodesign innovation process to which they correspond (adapted from Leslie Bottorff, "Funding a Medical Device Start-Up," Medical Device & Diagnostic Industry magazine; reprinted with permission).

- **Start-up funding** – Common milestones that lead to **start-up funding** are related to product development and engineering feasibility, animal testing, and early consideration of issues related to commercialization (regulatory, reimbursement, etc.). This type of funding often comes in increments of $1–$10 million, with each round designated with a letter (e.g., Series A, Series B . . .).
- **Expansion funding** – Companies may be able to attract **expansion funding** after they initiate human studies, launch pilot trials, and begin pursuing regulatory/reimbursement and other commercial activities to prepare for an initial launch in a preliminary target market. Expansion funding is then used to accelerate and expand the project's current activities to get the product to market. It is not uncommon for medtech companies to require tens of millions in expansion funding.
- **Mezzanine funding** – At this stage, the company has retired its most significant risks but may not yet be generating sufficient revenue to fuel its growth and be self-sustaining. **Mezzanine funding** is usually available once the product is approved and has been launched. It is used to build distribution channels, fund sales and marketing campaigns, and expand/develop product lines. Commonly, this type of capital is raised in preparation for an **IPO** to ensure the company can demonstrate a strong balance sheet to prospective public investors. Mezzanine financing is sometimes provided by later-stage investors such as VCs, but often comes from private equity firms that specialize in this type of financing (sometimes referred to as "crossover" investors).

Exit scenarios

As explained in 6.2 Strategy Integration and Communication, early-stage investments in any medtech company are **illiquid** – the investors cannot easily sell their ownership stake. But eventually, most investors will want to make their investment liquid to allow them to realize a return. By far, the most common way this occurs in the medtech industry is for the company and/or its technology to be acquired by a corporation. Alternatively, the company can enter the public markets through an IPO. For perspective, 30 device companies were acquired in 2013 while only four went public.[19] Another option is for a company to enter into a **licensing** agreement as a means of generating revenue and providing a payback to investors, although meaningful licensing deals are becoming increasingly rare. (More information about licensing is provided in 6.4 Alternate Pathways.)

Acquisition

While estimates vary, **acquisitions** in the medical device field account for roughly 80–90 percent of device company exits each year.[20] The sale of a company is usually driven by the strategic fit between the assets or technology of the acquiree and the strategy of the acquirer. Acquisitions can be an attractive exit strategy to investors because they receive either cash and/or a tradable stock that can be acted on immediately, while also avoiding much of the volatility and risk that can be associated with an IPO. They can also provide investors with a reasonable way to exit a troubled company.[21]

An acquisition occurs **outright** when the acquiring company takes full and complete ownership of the business for a single payment at the time of purchase – a point in time also known as the point of "change of control." The primary advantage of this approach is that it can provide a clean break for the founders and current management team, who may be replaced. The major disadvantage is that an outright acquisition typically results in **valuations** at the low end of the typical range because the acquirer assumes the entire risk of future performance. Also, founders and current management team lose the ability to influence future performance and often exit after brief transition periods are completed.

A **structured acquisition** is a variation on an outright purchase, which can allow the selling shareholders to participate in the possible upside based on success realized after the change of control occurs. It normally involves the buyer agreeing to make an initial payment followed by additional **earn-outs** triggered by specified milestones. The founders and employees of the start-up usually continue to be involved under the aegis of the acquiring company to help it meet the defined milestones. They are rewarded when those milestones are achieved and additional payments are distributed to

shareholders. One benefit of this approach is that it can be used to resolve differences in perceived value between sellers and buyers by "sharing" future risk and return, often resulting in greater value realization for the founders. Additionally, the founders, as participants, retain some influence on the business through the transition. On the other hand, there may be less certainty regarding the level of value ultimately realized (as it may depend on how much the acquirer invests in developing and promoting the product), the payout milestones may not be under the founder's direct control, and the founders may need to remain with the company, allowing themselves to be directed by the acquiring organization.

Another form that an acquisition can take is an **option to purchase**. This occurs when a buyer receives a future right to purchase a company at a specified price, at a specified time, or following the completion of specified milestones. At the time of exercise, option agreements enable the buyer to use either an outright purchase or a structured purchase using a combination of upfront payments and earn-outs. Although the option holder often participates in governance through representation on the board of directors, there is no actual change of control until the option is exercised. This allows the management team to continue building the business (see the Nanostim case example in chapter 6.4). For the innovator, the biggest downside challenge of entering into an option agreement is making sure that the start-up will be financially strong enough to survive if, for any reason, the acquirer should decide not to exercise the option at the end of the option period.

In general, acquirers target two different types of companies for purchase. First, they will sometimes seek out start-up companies developing new technologies with "blockbuster" potential in large, undeveloped markets. In this scenario, they are seeking revenue potential in excess of $1 billion per year, supported by a novel technology, a strong IP position, and robust **clinical trial** data. Second, it is far more common for corporations to purchase more mature companies that fit well with their current businesses and have the potential to add immediate revenues (ranging from $500 million to $1 billion) and profits to the corporation's product portfolio. With these deals, the focus is on proof of a sustainable business model, a strong, profitable sales ramp, and a promising product pipeline. More information about acquisitions is provided in 6.4 Alternate Pathways.

Initial public offering

An IPO refers to the first sale of a company's common shares to public (versus private) investors. The main purpose of an IPO is to raise capital for the company. It also provides private investors with a potential exit strategy because they can then trade their shares in the public market. However, the original investors typically face restrictions on when they can sell their shares after the company goes public, with some having to keep their shares for several years before they can start divesting them. IPOs also impose heavy regulatory compliance and reporting requirements on the business (e.g., the Sarbanes–Oxley Act of 2002 in the US), which is one reason the frequency of IPOs by start-ups has decreased. The rash of IPOs in the late 1990s and early 2000s also died down following various economic corrections, with many of the medical device companies that went public during this period failing to deliver on their high valuations. In late 2006 and for some time in 2007, medtech IPOs appeared to be on the upswing, but that trend was relatively short lived. The "window" for IPOs was all but closed for device companies by 2008.[22,23] In contrast, biotechnology companies are experiencing an IPO boom, with 33 public offerings in 2013 alone.[24]

Sources of funding

Company funding can come from a number of different sources. Common funding sources applicable to the medtech industry are described in the sections that follow and then summarized in Figure 6.3.4.

Bootstrapping

Bootstrapping refers to financing a small venture without the use of equity investments, grants, or loans taken by the company. In many cases, innovators use their own savings, personal loans, a second mortgage, or credit card debt to bootstrap a company. For products without clinical or regulatory restrictions, they may also be able to fund preliminary development through small

customer advances.[25] Early-stage student teams sometimes enter business plan competitions sponsored by universities, where top prizes can be as much as $100,000. Some universities have also developed internal seed fund programs for faculty and student projects. Bootstrapping can be an effective way to get a project started, but it has obvious limits in terms of how far it can take a team on the path to market.

Friends and family

Friends and family investors refer to members of the innovators' personal networks with adequate means to make an investment in the project. Aside from grant funding, this is one of the least expensive forms of financing since friends and family are usually more flexible than professional investors in terms of their timeline and expected level of return.

Despite their strong personal relationships with friends and family investors, innovators are advised to treat the members of this group as professional investors. Friends and family should be provided with the company's business plan or **pitch** and an investment contract should be put into place.[26] These investors can be given equity in the company at a set price. Or the investment can be made as **convertible debt**. This means the friends and family loan the money, but it can be converted into equity, sometimes at a discount, when the company secures its first round of professional financing.[27]

Getting friends and family on board demonstrates to other potential investors that the innovators believe in the idea and that other people are willing to trust them with their money.[28] The primary disadvantage is that these investors may not understand the level of inherent risk involved in the opportunity. Also, they are not usually able to participate in subsequent rounds of funding, and they often do not have skills, expertise, or connections that can help the company grow.

Incubators

Business **incubators** are for-profit or non-profit entities organized to assist innovators in establishing a new venture and/or accelerating its progress. They accomplish this by providing start-ups with a combination of infrastructure and resources, expertise and connections, and some amount of initial funding. In some incubator models, funding is provided outright, while in others it is provided indirectly through the provision of services and support.

The amount and type of funding offered by incubators varies widely by organization. At one end of the spectrum, non-profit incubators like StartX provide up to $100,000 in indirect funding from its partners, as well as free office space and legal services. It also offers needs-based stipends for innovator living expenses.[29] Rock Health provides direct capital in the form of an elective $100,000 convertible note or grants ranging from $10,000 to $20,000, in addition to hands-on mentoring and support.[30] Neither organization requires an equity position in its portfolio companies. At the other end of the spectrum, for-profit incubators such as ExploraMed, The Foundry, The Innovation Factory, or Coridea explicitly seek to nurture companies in which they can take a strong equity position and provide substantial support over an extended period of time.

Multinational companies also run incubators with the goal of supporting inventions that may turn into future acquisitions. Some of these, such as such as Johnson & Johnson's Janssen Labs are largely domestically focused, while others explicitly target innovations coming from other geographies. For example, US-based Medtronic has backed an incubator initiative in Europe called MDStart,[31] and Japan-based Sony has launched a medical device incubator called Rainbow Medical in Israel.[32] Many governments have also seized on incubators as a way to encourage entrepreneurship. In Singapore, for instance, the government has put over $30 million towards the Incubator Development Program, which supports local incubators and accelerators in healthcare.[33]

Beyond financial support, the primary advantages of working with an incubator include access to facilities and resources that may be out of reach for a young start-up; the high-quality expertise and guidance that is available; and connections to mentors, other innovators working in the medtech space, and prospective follow-on funders. Many innovators also find it motivating to be part of an incubator community. The main disadvantages vary based on the incubator model, but innovators should consider what "strings" come attached the funding that

is provided, possible distractions created by other teams within the incubator, and the potential for micromanagement from incubator leaders.[34]

Governments

One way that governments seek to stimulate economic growth is by supporting research and development that leads to new products and services. With healthcare top-of-mind for governments around the world, innovation in medical technologies has become a high priority area for investment, which many government agencies make in the form of grants.

In the United States, two of the most prominent government grant mechanisms are the Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer (STTR) program. SBIR's mission is to support scientific excellence and technological innovation through the investment of federal research funds in critical American priorities. Through the program, small for-profit or non-profit technology companies (or individual innovators who form a company) can gain access in phases to up to $1,150,000 in early-stage R&D grant funding.[35] STTR has the same mission and funding levels, but it awards its grants to small for-profit or non-profit companies working cooperatively with researchers at universities and other research institutions. Recipients of both types of grants retain the intellectual property rights to the technologies they develop. Funding is awarded competitively, but the process is relatively **user**-friendly. Multiple federal agencies are required to make SBIR and STTR grants on an annual basis. However, each agency designates its own R&D priorities and administers its program separately (according to the same general guidelines), so innovators should identify those agencies with interests similar to their own and approach each application process separately.[36] The National Institutes for Health, for example, makes SBIR and STTR grants for biomedical or behavioral research that supports its mission to improve human health.[37]

Governments outside the US actively fund medical technology innovation, as well. Of course, these programs differ significantly in their focus and details. However, a few examples highlight the range of government grant opportunities available to entrepreneurs and small companies. For instance, the Indian government provides funding for medical device start-ups via several schemes, including the Indo-US Science and Technology Endowment Fund, which awards up to $500,000 in grant financing to US-based companies interested in India as a market for their products.[38] The Irish government is working aggressively to establish the country as a hub for medtech research, development, and manufacturing. Through its Enterprise Ireland agency, the government has established an R&D Fund and a Commercialization Fund to provide early-stage grants to medtech projects based in the country.[39] It also offers a variety of additional incentives to help attract projects, including a sophisticated tax incentive structure for both start-up companies and the investors that back them.[40] Singapore is another country where the government is working to develop a strong medtech ecosystem and is using grants funding and other incentives to draw innovators and small companies to the area.[41]

With government grants, the financial interests of the company's founders are not diluted. Being the recipient of such a grant can also be a source of credibility for a start-up. On the other hand, government grant makers expect innovators to perform diligent research (comparable to what would be required by the most demanding academic institution), competition for funds can be fierce, and the review cycles for awarding funds can be lengthy. Also, with a cap at roughly $1 million per project, the amount of funding awarded through these programs is not likely to be sufficient to meet a medtech company's complete financing needs.

Foundations

Historically, foundation funding was not considered widely applicable to medical technology companies. However, over the last decade, a shift in the focus of some foundations and the nature of the grants they provide has made this a more viable medtech funding source for some device start-ups.

In the broad category of cause-driven foundations, some grant makers are focused on a specific disease state or medical condition. For example, the St. Jude Medical Foundation funds projects linked to device therapies

with the potential to change the lives of patients suffering from cardiac conditions or chronic pain.[42] In other cases, a foundation's focus can be defined more generally (i.e., addressing poverty or disparities in global health). For instance, the Bill & Melinda Gates Foundation has an overall mission to help all people lead productive, healthy lives.[43] Within its global health division, it seeks to harness advances in science and technology to save lives in developing countries with an emphasis on vaccines, drugs, and diagnostics to prevent infectious diseases such as HIV, polio, and malaria.[44] Innovators working on projects with the potential to have a positive social impact on a particular population should research cause-driven foundations to identify those that may be in alignment with their goals.

Within the new class of cause-driven foundations that has emerged over the past several years, many will support both non-profit start-ups and those with a for-profit social entrepreneurship orientation (i.e., a commercial approach to driving social change). Additionally, while many foundations were traditionally accustomed to funding programs and services, a growing number are now becoming more open to underwriting product development of technology-based solutions. The Gates Foundation, for example, has awarded close to $1 billion in funding for new technologies through a family of grants known as the Grand Challenge program.[45]

Cause-driven foundations do not expect a financial return on the grants they make, but they do have clear expectations around results. As The Mulago Foundation, which has provided funding to medical technology companies such as Embrace, Mobile Medic, and product development company D-Rev, explained on its website: "We operate like a philanthropic venture fund with proven impact as an analog for profit, and cost-per-impact for return on investment."[46] Innovators working with such organizations must be prepared to think critically about the result their technologies will deliver and build measurement and evaluation processes into their product development and commercialization efforts. Importantly, they should also recognize that the priorities of foundation participants will not necessarily align with those of the other investors that may fund the company at later stages. This disconnect has the potential to create conflicts that may require the ongoing time and attention of the company's leaders.

Another possible funding source for medtech companies is foundations focused more generally on supporting entrepreneurship. Many of these types of programs are targeted at university-based innovators, such as VentureWell (formerly the – National Collegiate Inventors and Innovators Alliance NCIIA). This already provides seed grants to student entrepreneurs developing novel, market-based technologies through its E-Teams program.[47] The Wallace H. Coulter Foundation targets faculty members working on translational research. Given their desire to help spur new products to market, these foundations often have rigorous standards regarding progress against milestones and the realization of other measureable results. The case example on the Coulter Foundation illustrates the expectations one entrepreneurship-oriented foundation places on the university-based projects it funds.

FROM THE FIELD — THE COULTER FOUNDATION

Applying business discipline to de-risk and accelerate university-based translational research projects

Wallace Coulter, a serial inventor and entrepreneur, was passionate about using science to serve humanity.[48] His most renowned invention, the Coulter Principle for counting and sizing particles suspended in a fluid, led to revolutionary developments in industries ranging from medical diagnostics and printing to food and space exploration. The Coulter Corporation was the leader in blood cell analysis equipment and other laboratory diagnostics. During his 40-year tenure as Chairman of this private company, Coulter fostered a culture of entrepreneurship and risk taking among his employees. He routinely invested significant resources in rogue R&D

projects focused on addressing pressing health-related needs. Coulter led the organization until its sale to Beckman Instruments in 1997 (now known as Beckman Coulter, Inc.).

After Coulter's death in 1998, Sue Van started the foundation to continue his life-long pursuits and passions. Van had served as Executive Vice President, CFO, and Treasurer of the Coulter Corporation and was named by Coulter as the trustee of his estate. He had instilled in her a strong commitment to helping patients, and she was determined to sustain his dedication to supporting biomedical innovation. In particular, Van wanted to continue his interest in helping innovators take their inventions from the bench to the market where they could directly benefit patients. Fondly remembering her time working with Coulter, she said, "I wanted to make up for all of the R&D projects I tried to get him to shut down when I was CFO."[49]

Van recognized that, in the changing economic environment, early-stage funding for new technologies was difficult for innovators to obtain. Additionally, she observed that universities, which are the engines for ground-breaking basic research, often struggle to translate interesting discoveries into practical innovations. "Wallace didn't believe in research for research's sake," she said. "He wanted to support research that would save people's lives." With the goal of capitalizing on the best aspects of academia and industry, Van launched a "grand experiment" that eventually led to the formation of the Coulter Translational Research Partnerships in Biomedical Engineering.[50] "But it wasn't easy," she recalled. At the time, many universities were focused solely on basic research and reluctant to broaden their focus to applied research, which was considered the domain of industry. Moreover, biomedical engineering (BME) was the newest of the engineering disciplines. "But I trained in risk taking, so we pushed ahead," Van said. Ultimately, her effort helped validate translational research in the university setting and enhanced the value of the BME degree. It also positioned the Wallace H. Coulter Foundation as a pioneer in supporting translational research in biomedical engineering with the goal of accelerating the introduction of new technologies to improve patient care.

Elaborating on the Translational Research Partnerships, Elias Caro, the Coulter foundation's Vice President of Technology Development, explained, "The goal is to support collaborative research that addresses unmet clinical needs and leads to commercial products that generate improvements in health care." Specifically, the foundation provides what it calls "bridge funding," coupled with a rigorous project management process to drive projects to the "critical endpoint" of attracting follow-on funding from investors outside the university setting. Over time, the Coulter Foundation established these partnerships with universities across the United States (a complete listing is available online).[51]

Faculty members at participating universities can apply for Coulter funding if the project is translational in nature and multidisciplinary, with at least one principal investigator from the department of bioengineering and another from a clinical department in the school of medicine. The foundation strongly supports partnership between physicians and engineers because the clinicians bring an understanding of the need to a project, along with product ideas and a sense of urgency. The engineers, on the other hand, provide the technical expertise to transform ideas into innovative solutions and then make them a reality.[52]

Each university has a Coulter Program Director and an Oversight Committee, which consists of the bioengineering department chair, other key university representatives, a member of the Office of Technology Transfer, entrepreneurs, local venture capitalists, and industry professionals. Together, these individuals apply a rigorous stage-gate process for screening, selecting, and then managing the projects that seek Coulter Foundation funding (see Figure 6.3.2). The Coulter Process, as the approach is known, provides each academic institution with a disciplined program management approach for de-risking projects,

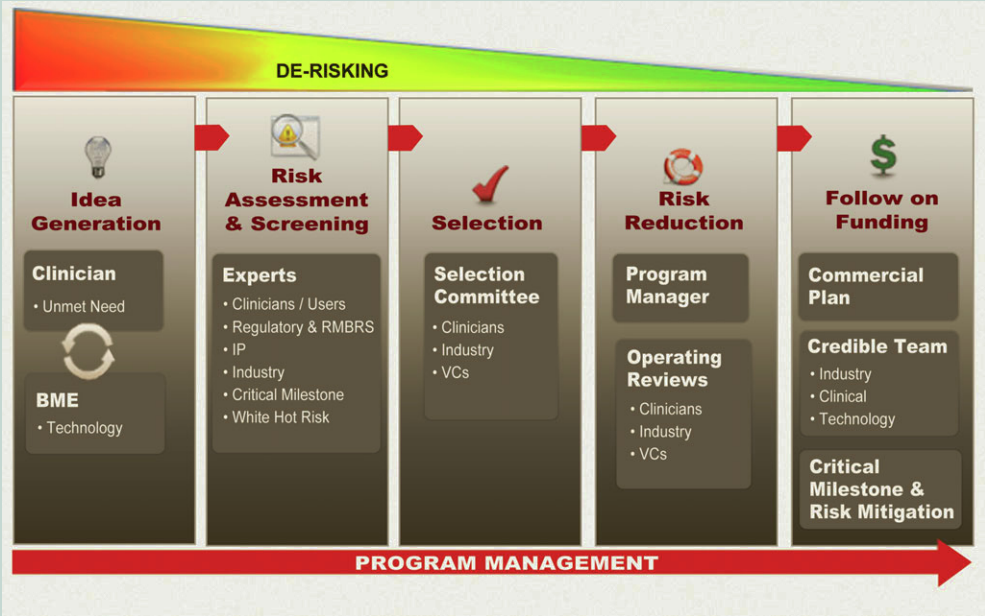

FIGURE 6.3.2
The Coulter Process for de-risking projects and bringing them to the critical endpoint of attracting follow-on funding from investors outside the university.

compressing development timelines, and keeping innovators focused on the most important activities to attract investor interest and increase the likelihood of advancing a product to market.[53]

The first step in the Coulter Process is for clinicians and engineers to work together to come up with a compelling idea. Then, when the project reaches an appropriate stage of development, they can express interest in Coulter funding. A request for proposals is issued each academic year via posters, emails, and presentations by the Coulter Program Director. At most universities, proposals are due in January. "Some universities set up boot camps to coach project teams on how to write the best proposal for Coulter funding," Caro described. Others encourage teams to meet with the Coulter Program Director before submitting a proposal. In these meetings, the Program Director evaluates whether the team is ready for Coulter funding and if the project fits the scope and focus of the award. "A lot of work must be done before the proposal," Caro acknowledged, "including answering questions like, 'What needs to be proved in order to get the next round of funding [after Coulter]?' 'What kind of clinical trials will be needed?' 'What is needed to get the technology to market and eventually to patients?' and so on."

Once submitted, the Coulter Oversight Committee carefully reviews each proposal and assesses the caliber and progress of each project. Criteria for their evaluation include scientific merit, potential healthcare impact, technical feasibility, and the potential for commercialization. Particular emphasis is placed on identifying "white hot risks" that could potentially prevent the project from attracting follow-on funding from angels, venture capitalists, or corporate investors, licensors, and/or acquirers. This involves the rigorous assessment of stakeholder and competitive dynamics, health economics, and other factors that can facilitate or impede adoption. The committee also considers how attractive the opportunity is to those who will fund it beyond the Coulter Process by looking at the most likely exit scenario(s) and potential return-on-investment calculations for the next round of external funders. Finally, the committee evaluates how the team proposes using its Coulter funding and the milestones it will focus on over the next 12 months to ensure that the project has a "laser focus" on retiring critical technical and commercial risks in preparation for graduating the idea beyond the university.

The committee invites about a third to a half of applicants to make an in-person, 20-minute presentation. At some schools, finalist proposals are also reviewed by outside

IP counsel to evaluate any associated risks. The Committee then selects 6–8 proposals to receive an award of approximately $100,000, typically over a one-year period (the money does not have to be repaid and the foundation does not take equity in the projects).

After the selection decisions are made, the focus of the Coulter Program Director and Oversight Committee shifts to providing guidance to teams to help them achieve their defined milestones and build toward the goal of attaining follow-on funding. For example, to address important technical risks, all Coulter-funded teams are advised to conduct "a killer experiment." "Technologies need proof-of-concept data to get seed funding," said Caro. Project teams must talk to domain experts and research clinical precedents to identify and design a killer experiment for their project such that the outcome either increases confidence toward further development of the product or recommends the project be abandoned. To help address commercial risks, each project is assigned an industry mentor with extensive experience in commercializing new healthcare technologies. Teams are encouraged to meet regularly with their mentors.

Importantly, Caro noted, "Projects can be killed and their funding revoked." Most often, this occurs if a project is not progressing to plan and the milestones have not been met for two consecutive quarters, or if the technology simply fails to perform as intended. However, the Oversight Committee occasionally withdraws funding from projects with dysfunctional team dynamics.

Over the life cycle of the funding term, teams prepare brief, written quarterly progress reports and present project updates to the Oversight Committee at specified points in the year. The process culminates at the end of the funding period with projects hopefully securing follow-on funding from angel, venture, or corporate investors outside the university. The Coulter Foundation does not formally engage in a "match making" process, but the Program Director, members of the Oversight Committee, and team mentors informally collaborate to introduce team members to interested parties. By the end of 2012, the Coulter Translational Research Partnerships had funded more than 250 projects. Of those, 45 had led to start-up companies that collectively raised over $840 million; 20 have formed start-ups that are seeking funding; and 29 licensed their technologies to established medtech companies. One start-up sold for $450 million in early 2013, and nine products have already received FDA approval. According to Caro, most university partners achieve a project success rate of more than 27 percent.[54]

Whether or not they pursue Coulter funding, Caro recommended to all innovators that they "begin with the end in mind," emphasizing the importance of focusing on the patient and what it will take to get the technology to market. "Many teams underestimate the importance of commercial risks that can derail a project and often focus solely on the technology. Find business mentors who can help you understand the commercial aspects of the project and help you navigate these challenges," he said. The Coulter Process, with its focus on de-risking projects via a staged approach, "is applicable to all medical technology innovation teams," Caro commented. "Some innovators say that Coulter money is 'expensive' because it comes with so many requirements, but these expectations are often exactly what makes a project successful." And each successful project honors Coulter and his commitment to translational research. As Van concluded, "We want others to see the impact of their research on patients."

Impact investors

Another emerging source of funding that may be applicable to some medtech companies is called impact investing. Impact investors are looking for both social impact and financial return on their investments (sometimes called the "double bottom line"). Specifically, they seek companies with business models that can create a financial return on the investment at (or just below)

market rates, as well as deliver measureable social impact. Many impact investors are focused on needs in global markets, such as Asia and Africa.

One pioneer in the space is Acumen Fund. Acumen raises donations from foundations and individual donors that do not expect a financial return on their money but are instead interested in driving social change and impact. Acumen then seeks to identify companies that are finding innovative ways to address core problems affecting the poor in its target geographies. These companies could be non-profit, for-profit, or hybrid organizations. After rigorous **due diligence**, Acumen invests in select projects by providing loans or taking an equity position in exchange for capital. In some circumstances, it also makes guarantees to third-party lenders to facilitate access to local sources of capital, sets up licensing or royalty agreements when assisting with the creation or registration of intellectual property (IP), or provides lab investments to fund innovative but high-risk experiments expected to generate important near-term lessons. For-profit and hybrid companies most often receive equity investments, while non-profits are given loans. Over time, Acumen expects to realize a return on its investments, for example, through the repayment of loans or exit opportunities that allow it to liquidate its equity position. As a non-profit, Acumen invests all proceeds back into the fund so that the original philanthropic dollars can be reinvested many times over.[55]

The amount of capital directed toward impact investing continues to grow, and many of these investors report that their portfolio performance is meeting or exceeding social, environmental, and financial expectations.[56] However, impact investing has been slow to expand into the medical device sector. Acumen Fund invested in a company called Circ Medtech, maker of a non-surgical device for male circumcision,[57] and Khosla Impact, another impact investment firm, backed the Embrace infant warmer.[58] But overall activity in the sector has been light. Mobile health technologies may be one way to draw more impact investor attention to medtech. Both Acumen and Khosla recently funded **mHealth** applications (Sproxil, Inc. and EyeNetra, respectively).

Innovators considering working with impact investors should carefully target appropriate firms and seek to clearly understand their expectations. While delivering results against a double bottom line is appealing to many innovators, it is often not easy to achieve.

Crowdfunding

Crowdfunding, a recent development in fund raising, allows innovators to raise capital from a large number of donors or investors over the Internet. This approach has been successfully used to fund a wide variety of projects in sectors such as technology, consumer products, and entertainment. Crowdfunding across all industries was projected to total $3 billion in 2013,[59] on its way to $93 billion globally by 2025.[60]

Crowdfunding has two main models: (1) donation-based funding, where money is raised without the expectation of financial return, though some perks or rewards may be given to donors; and (2) investment funding, where businesses can raise capital in exchange for equity in the company. Crowdfunding platforms in the medical field, like MedStartr, allow innovators to collect financial contributions from the public in exchange for rewards; for example, pre-orders of devices or services.[61] Others, such as Healthfundr, offer equity investments in health-related companies, but can only allow accredited investors (individuals with a net worth of more than $1 million or income exceeding $200,000 per year) to participate as of the time of this writing.[62]

Raising investment funding (rather than donations) is potentially the more attractive model for medtech innovators, but in the US the Securities and Exchange Commission (SEC) has been hesitant to allow non-accredited investors to get involved. New legislation, called the Jumpstart Our Business Start-Ups (JOBS) Act which was signed into law in 2012, allows start-ups to raise up to $1 million in equity-based crowdfunding from non-accredited investors[63] (although there are limits to how much individual investors can contribute). In order for this provision to take effect, the SEC was required to issue rules governing such investments. The rules were expected in 2013, but were still unavailable as of late 2014 as the agency considered the most appropriate way to loosen long-established investor protections.[64] Until

the SEC provides its ruling, non-accredited investors are unable to participate in equity crowdfunding of any type.

The story on VentureHealth.com explores the many issues associated with crowdfunding and outlines some of its benefits and risks.

FROM THE FIELD VENTUREHEALTH.COM

Crowdfunding medtech innovations

Mir Imran, a prolific entrepreneur and seasoned medtech investor, identified a gap in the fundraising landscape. He and his team observed that accredited investors who are looking to deploy capital often lack access to the most compelling biomedical innovations. In turn, promising healthcare opportunities are consistently underfunded, and innovators expend great energy raising capital for the development and commercialization of their technologies. Using his investment firm, InCube Ventures, to run some carefully controlled experiments, Imran and his team allowed a select group of accredited investors to participate in their **syndicated** investments. The response from investors was enthusiastic and the results were promising.

With the passage of the JOBS Act, they decided to initiate a detailed assessment of opportunities related to online financing from individual investors. Imran discovered plenty of online crowdfunding activity, but not many models that appealed to him. One common approach was for crowdfunding portals to post business plans or slide decks from start-up companies and invite investors to contribute funding. But, he discovered, many such websites conducted little or no due diligence on the opportunities. "They make money on the volume of companies on the platform, not the caliber of the opportunities," Imran said.[65] (Typically the portal retains 5–10 percent of the total money raised by the start-up company.) "This is a relatively unsophisticated approach," he continued. "There is no quality control, so investors are exposed to risks that they cannot adequately assess. I would advise innovators and investors to stay away from this approach."

Seeking a better solution, Imran and his team developed a crowdfunding model with much higher standards for the opportunities it presents and the investors it attracts. They founded VentureHealth as an online venture fund platform for accredited investors who want access to breakthrough opportunities in the healthcare sector (see Figure 6.3.3).[66] VentureHealth acts as an aggregator of knowledgeable, accredited investors who are invited to invest in a select group of medtech deals, with full disclosure of benefits and risks involved in the process. "This doesn't mean there is no risk involved, but we have much higher quality control." Investors gain access to disruptive innovations that have been traditionally reserved for venture investors; they invest alongside venture capitalists on similar terms; and the opportunities are rigorously vetted by the VentureHealth team, as with other venture deals.

The VentureHealth team vets investments based on its deep experience in company building. "The start-up companies' business plans go through detailed diligence process, and are selected as a VentureHealth deal offering only if they meet our criteria," Imran emphasized. For example, the team seeks major clinical breakthroughs in a large market, where reimbursement is well-established, and the innovators have devised a thoughtful clinical and regulatory strategy.

In terms of how VentureHealth makes money, "We don't take a fee from the start-up company [for listing them on the site]. Instead, we use a carried-interest model, typical of venture capital firms," Imran stated. (Carried interest refers to the share of profits paid to investors after a company has had a successful exit, which aligns the returns of the investors with the success of company.)

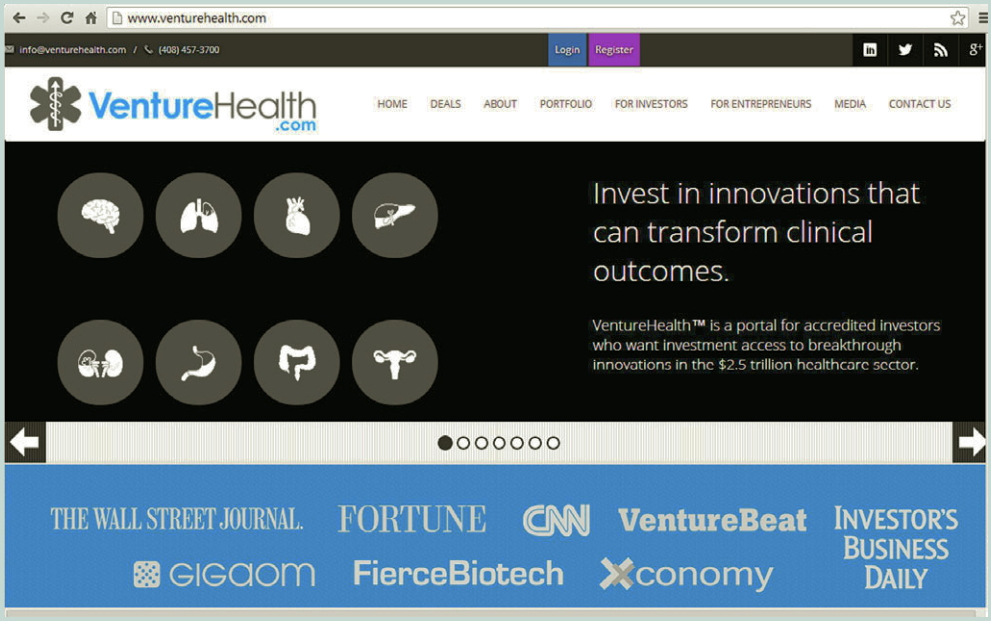

FIGURE 6.3.3
The VentureHealth portal (courtesy of VentureHealth).

VentureHealth has built a stage-diversified portfolio of companies and deals, which means that it gets involved in early-stage and later-stage investments. "With second and third round deals, investors get to liquidity sooner. This gives them confidence and encourages them to keep investing. Otherwise, long development timelines can cause fatigue in investors not used to deploying capital in healthcare," he said. Recently, VentureHealth closed a $2.6 million Series B round in approximately two weeks for Rani Therapeutics, with InCube Ventures and Google Ventures as co-investors on the deal.[67] Channel Medsystems was also able to raise its $9.7 million Series B round through a syndicate of investors led by Boston Scientific, with VentureHealth participating.[68]

As these examples demonstrate, Imran recommended that medtech innovators undertake crowdfunding as part of a financing round rather than relying on it entirely. "That way, at least the start-up company will undergo some additional diligence," he commented. Bringing in other types of investors also helps validate the valuation of the deal and ensures that innovators have access to some of the benefits offered by other funding sources, such as the connections and expertise that experienced angel and VCs provide.

"We still have more questions than answers when it comes to crowdfunding in medical devices," Imran noted. "For example, in deals with no lead investor, it can be unclear who would set the valuation and draw up **term sheets**." He acknowledged that a certain amount of experimentation and learning was still underway, but at least for now VentureHealth represented the investors on its portal and handled all interactions and negotiations with the company so that the start-up did not have to deal with hundreds of small investors.

When asked for advice for innovators considering crowdfunding as part of an overall funding strategy, Imran said, "Be careful to provide a high-quality opportunity to potential investors. It's the responsibility of the entrepreneur to ensure that less-experienced investors understand the risks and have appropriate expectations about the time and money required to get a medical technology to market." He added, "Crowd-funding is here to stay. I think it will grow into a substantial source of funding for life sciences companies. Both investors and innovators must educate themselves about how best to utilize it."

Angels

Angel investors are experienced, accredited investors who use their personal wealth to invest in start-up companies. With the downturn of the medtech sector, angels have become a much more important and prominent source of funding for device innovators. In 2012, angel investors committed more than $3 billion in funding to companies in the broad category of healthcare services/medical devices and equipment (surpassing total VC investment in the space).[69]

On the plus side, angel funding can be less expensive than VC funding. Angels have shown a willingness to take on more risk than some other investors. As a result, they have been a strong source of seed and start-up funding. More recently, these investors have begun to syndicate with VCs to participate in expansion funding. From 2011 to 2012, total angel investment in early-stage funding declined (40 to 33 percent), while their involvement in later-stage deals increased (from 15 to 29 percent).[70] One theory for this shift is the fact that angels may be gaining increased access to later-stage projects through emerging crowdfunding platforms (see the VentureHealth example).

On the downside, funding may need to be raised from several angels to meet the capital needs of a company, and managing the expectations of numerous angels can be daunting. Additionally, angels are traditionally less likely than venture capitalists to invest in multiple rounds of funding for the same company. Typical angel investments range from a few thousand dollars to $1 million. In 2012, the average deal size was just over $340,000.[71]

Corporate investment

Corporate investors have always played an important role in funding new medical technologies and providing companies with exit opportunities. However, as investors, their participation in funding start-ups has been cyclical, rising during times of venture capital shortages and falling during periods of wide capital availability. **Corporate investments** resemble venture investment, but they are usually made from venture funds set up by a sole organization (e.g., a multinational medtech corporation). Unlike private venture firms, large companies make these investments in start-ups primarily for strategic purposes and not strictly for financial returns. Fundamentally, corporate investors are looking for growth opportunities – ways to build their business base and expand their customer impact. Specifically, corporate investors hope to exploit synergies between projects in their internal portfolios and innovation occurring in the external environment.[72] The explicit hope of most corporate venture investors is that the companies they invest in may later become acquisitions capable of helping them to meet corporate growth goals.

Traditionally, corporations got involved in medtech funding during the later stages of a project. But, as Casey McGlynn, head of Wilson Sonsini Goodrich & Rosati's lifesciences practice, explained in an article, "The corporations in general have really stepped up to be major funders of new medtech companies, all the way down to the seed level. The business development people at these large medtech companies are very sophisticated people; they do their homework, they've got huge domain knowledge in their specialist area. They're a bit more targeted than the venture capitalist. I think they're under a tremendous amount of pressure to help find and fund the best new projects."[73]

In terms of their advantages, corporate investments can be less expensive to an innovator than VC funding and can bring with them unique forms of leverage (e.g., access to established sales and distribution networks and complementary technologies). The association with a major corporation can also lend credibility to a young company. Moreover, a strong, mutually beneficial relationship with a corporate investor can provide a smooth and valuable exit strategy.

That said, innovators involved in corporate relationships must recognize the compromises that may accompany this form of funding for their business. Some corporations will only invest in situations where they can attach "strings" to their money (conditions that give them a potential advantage over their competition). These strings can include distribution rights, first rights to negotiate, or even first rights of refusal, which can be triggered if and when the company receives a buyout offer from a competitor. Conflicting agendas may arise as the corporate investor looks out for the corporation's

best interests. Issues surrounding the ownership of new intellectual property (IP) that is generated, which may be beneficial to both the start-up and the corporation, can also arise. Additionally, corporate investments may be susceptible to changes in the economy and provide innovators with limited opportunities for follow-on funding. Finally, exiting from a corporate investment can become complicated if there is more than one bidder but the corporate investor has been granted first rights to an acquisition.

A variation on traditional corporate investment occurs when an independent distributor strategically invests in a medical technology that it is potentially interested in adding to the portfolio of products it represents. In addition to creating a reasonably priced funding stream, this type of investment can provide innovators with a rapid path to market once necessary regulatory approval is received. In addition, distributors can add strategic value by connecting the company to physicians and other decision makers. Distributors usually have close relationships with the potential purchasers of the technology and can leverage them to provide insights on the requirements most likely to drive adoption. However, this type of funding can sometimes lead to conflicts if the company chooses to sell the innovation through other channels (e.g., upon acquisition). Innovators considering distributors as investors should think about incorporating a buyout clause into the deal, which allows an acquirer to begin selling the product directly post acquisition. This can help avoid any conflicts and incentivizes the distributor to maximize its selling efforts since it will then participate in the upside of an acquisition through both its equity investment and the buyout calculation. See the Loma Vista Medical story later in this chapter for more information about distributors as investors.

Venture capital

Venture capitalists are professional investment managers who specialize in funding companies with the potential for high returns.[74] Venture capitalists typically raise money from institutional investors (e.g., pension-fund managers, university endowments) or other private and public entities, with those investments put into a fund. The VC firm managing the fund is referred to as the General Partner (GP) and the outside investors are called Limited Partners (LPs). In its role as the GP, the VC firm contributes to the fund (usually 1–2 percent), but the majority of the capital is provided by the LPs. Funds vary in size, but can range from $50 million to $2 billion and beyond.

Each fund has a specific investment focus (medical devices, biotech, information technology) and a time horizon for its investments (usually from three to seven years). The capital in the fund is invested in start-ups that fit the fund's profile with the expectation of reaching a "**liquidity event**" – that is, the company will be acquired or will go public – within the fund's defined investment horizon.[75] Venture capitalists receive a share of any profits realized from investments made out of the fund (approximately 20 percent). In addition, they are compensated through an annual fee, which is a percentage of the total funds raised.

At any given time, VC firms can have several funds under their management, each of which is invested in a different group of companies. Every fund represents a separate pool of capital from which the VC is expected to generate returns over the life of the fund. The normal life of the partnership that supports a given fund is 10 years and the expectation is that most investment returns will be realized during that time interval. For this reason, it is important for innovators to understand the age and investment position of the specific fund from which their investment will be drawn in order to assure themselves that the firm will have the management and financial capacity to support potential future funding requirements.

Venture capitalists are known for having "deep pockets" when it comes to qualified investments, typically investing $3 to $30 million in each of the companies they back over the lifetime of the investment. VCs also have the ability to provide multiple rounds of funding. In addition, they often collaborate with the companies they invest in such that the start-ups benefit from substantial industry experience, as well as extensive networks of contacts (including other potential investors) that can

be leveraged to assist the company. Larger financings will often result in VC investors forming syndicates, or groups of venture investors, in order to ensure that the company's future financial needs can be met from internal sources as needed.

On the downside, VC funding is expensive since innovators must be willing to give away significant equity to attract investment, and the due-diligence associated with the funding process can be time and labor intensive. VCs are active investors and will usually insist on having effective control of the company either through percentage ownership or a shareholder's agreement. VCs also have a clear objective for their involvement in a company – a strong financial return on investment – which may be based upon an exit strategy that may or may not be aligned with the company founder's long-term objectives.

Choosing the best investor for the company

When considering funding sources, it is important for innovators to be explicit about what is most important to them. For example, is it essential to find an investor who can make a long-term commitment (and potentially contribute to multiple funding rounds)? Or, is it a higher priority to find an investor that will not restrict the company's strategic options (e.g., by requiring a large ownership stake or by taking majority voting rights that would make the company dependent on the investor's direct support on critical decisions)? The amount of relevant experience and expertise required (or desired) in an investor will vary from innovator to innovator and company to company, depending on the strength of its advisor base and/or board of directors.

Another reason to carefully consider the best investor for a company is because innovators enter into a relationship with their funders. This is generally true, regardless of whether the young company is funded by incubators, impact investors, angels, VCs, corporate money, or distributors, but not necessarily if it is funded by government grants or some types of foundations. Whereas a bank would traditionally give a loan to an established business contingent on the use of its business assets as collateral, investors in a medical device start-up are handing over millions of dollars in return for a stock certificate and the innovator's promise to build a successful company. For taking on the increased risk, investors in start-ups typically anticipate higher returns, seek to exercise more control, and expect to own more of the company. Not only can the capital carry with it an expected return many times greater than a bank loan, but it may be granted on the condition that the representatives of large investors become board members of the company and have input and voting control over the company's future. For this reason, it is critical to select investors that can add value to the company and ensure that their goals are aligned with those of the company's management team.

Two other important considerations in targeting investors are what type of funding is needed, based on the stage of the company, and how much money is required. Figure 6.3.4 provides a directional representation of when different investors are most likely to get involved. It also provides approximate ranges for the amount of money each funding source typically provides.

At some point, most medtech companies will interact with either angel, VC, and/or corporate investors. Table 6.3.3 provides a general comparison of how their priorities and investment guidelines may differ when evaluating a business opportunity.

Investor due diligence

As referenced in chapter 6.2, the process investors go through to assess how an opportunity measures up to their investment criteria is called due diligence. Due diligence is an iterative exercise that requires ongoing investigation and discovery. Each round of due diligence is different, with the approach and required time varying based on the investor's specific objectives and the characteristics of the company. However, the steps outlined in Figure 6.3.5 are generally followed.[76]

Information collected via this process is continually reviewed. If negative information comes to light at any point, an investor may decide to abandon the due diligence process (and abstain from investing in the company). When dealing with VCs, this process can take from as little as four weeks in rare cases to as long as

Funding Source	Approximate Funding Range	Seed	Start-Up	Expansion	Mezzanine
Bootstrapping	$10,000–$100,000				
Friends and family	$10,000–$300,000				
Incubators	$10,000–$2,000,000				
Governments	$100,000–$1,000,000				
Foundations	$100,000–$500,000				
Impact investors	$500,000–$2,000,000				
Crowdfunding	$500,000–$1,000,000				
Angels	$100,000–$10,000,000				
Corporate investors	$1,000,000–$30,000,000				
VCs	$3,000,000–$30,000,000				

FIGURE 6.3.4

The timing and amount of money associated with each funding source can vary quite a bit, but this summary gives innovators are directional sense of what to expect.

three years. The typical range is three to nine months. Other types of investors will also conduct due diligence, but they may not devote quite as much time. However, fundraising, regardless of investor type, usually takes much longer and requires more effort than most innovators estimate.[77] Innovators should keep in mind that the typical period between financings can range from 11 months on the low end to 18 months on the high end, with approximately 15 months being relatively common. This is because investors generally like to feel they are financing at least a year or more of "runway," during which time they expect the team to achieve milestones needed to justify raising additional capital under favorable terms. The practical implication of this interval and the time required for diligence is that the innovators are almost always "in the market" actively lining up their next financing.

Milestones

Funding is typically provided to a new venture in a staged manner. As described, rather than committing too much funding up-front, investors provide financing as the business demonstrates its ability to accomplish the milestones laid out in its **operating plan**. This process enables investors to periodically update their information about the firm, monitor its progress, review its prospects, and evaluate whether to provide additional funding or abandon the project. It also enables them to exercise greater control over the direction of the company. It is important for innovators to seek funding in stages, since the attainment of significant milestones in between funding rounds may strengthen their position from a valuation and ownership standpoint during the next round of financing negotiations.

Funding milestones represent significant events in the life of a start-up and should be selected with great care. The operating milestones chosen when creating the operating plan in 6.1 Operating Plan and Financial Model can serve as the starting point for selecting funding milestones. From an investor perspective, funding milestones represent points when a sizable amount of technical, clinical, or market risk has been eliminated from the

Table 6.3.3 Different investors have investment criteria that vary in certain areas.

	Angels	VCs	Corporate investors
Market size	Smaller, emerging markets	Large, established markets with $500 million or more in sales	Same as VCs but with an emphasis on markets in which they already operate; or are of strategic interest for future growth
Investment size	$100,000 to $10,000,000	$3,000,000 to $30,000,000 or more	$1,000,000 to $30,000,000
Expected return	4 to 10 times the first series of capital invested	4 to 10 times initial capital invested	May accept lower returns if investment is aligned with strategy
Capital intensity	Smaller markets with lower requirements; often look for markets untapped by VCs	Willing to enter market with intense competition if potential reward is large enough	Same as VCs
Strategic fit	More likely to be mission-driven	Seeking next blockbuster device, often regardless of specific field	Looking for opportunities that complement their existing portfolio
Investment timeline	Sometimes flexible; could be longer than 8 years	4 to 10 years; tend to prefer devices on 510(k) versus PMA regulatory pathway or early commercialization outside the US	Same as VCs but sometimes may be shorter for corporate investors
Ownership target	Small but will eventually want the start-up to seek funding from VCs or corporate investors	30 to 80 percent in early rounds, rising as high as 95 percent of company by the time of exit	Ultimately may seek to acquire technology
Board representation	Often	Almost always	Sometimes

company. Often these points will coincide with milestones in the operating plan, such as proof of concept, clinical trial initiation, regulatory approval, etc. Ultimately, the final funding milestone for investors is the exit or "liquidity" event, be it through an acquisition or an IPO. Revisit Figure 6.3.1 for sample activities/milestones that investors will expect to be completed between various stages of funding.

As each of these milestones is achieved, the company has the potential to reduce its cost of capital. As described, at the earliest stage of investment, the company's worth is lowest and the cost of raising money is highest because the business has no proven track record and thus poses significant risk for the investors. Yet, as the company begins to meet its milestones, it is able to raise increasingly large amounts of money at more competitive rates as the risks to investors decline.[78] Three of the most important hurdles for a company to overcome in demonstrating increased value include:

- **Technical feasibility** – Relies heavily on engineering, science, and clinical interactions and is accomplished when the company has proven data regarding in vitro (seed funding), animal use (some seed funding and start-up funding), and human use (start-up funding and expansion funding).

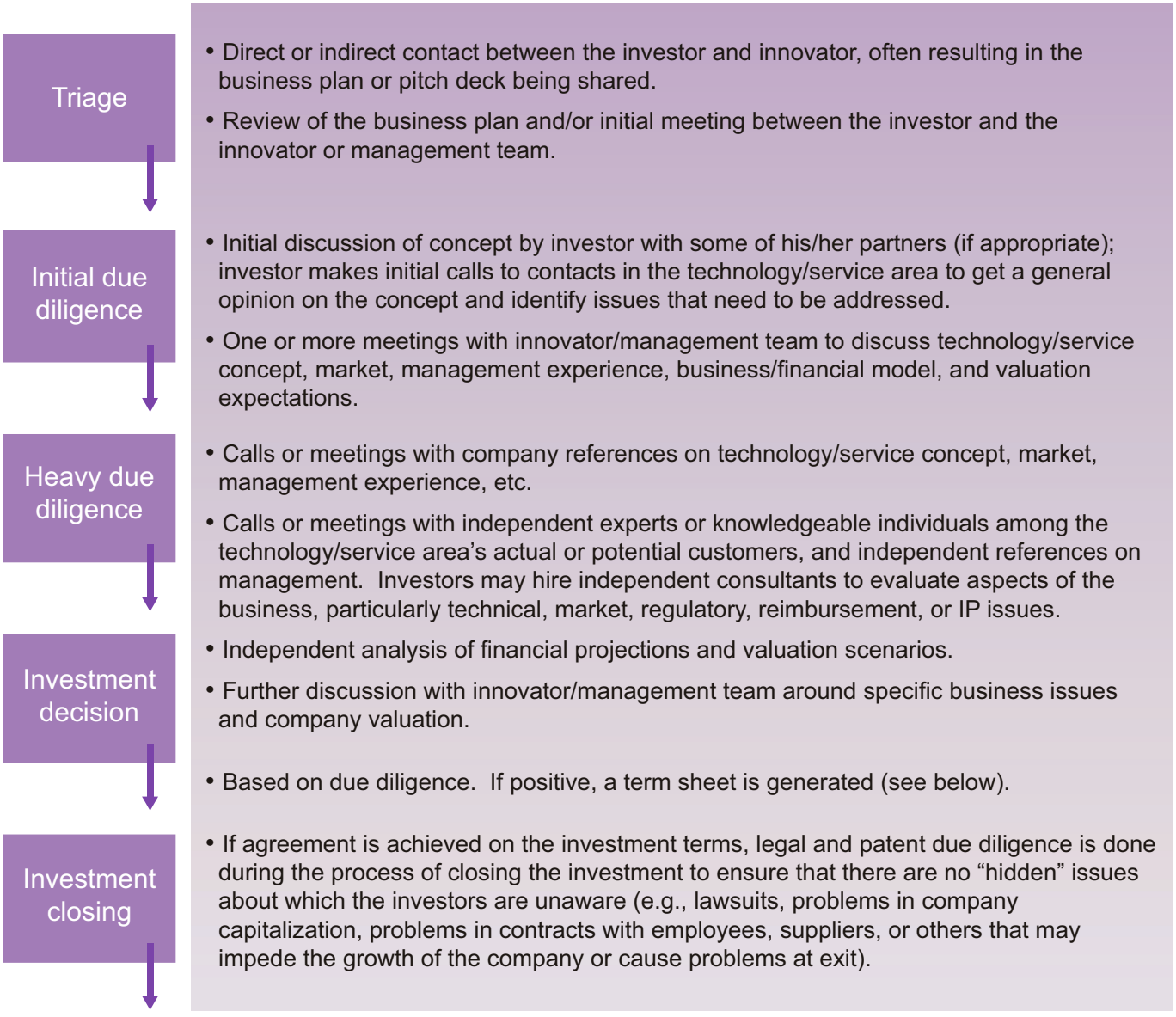

FIGURE 6.3.5

The due diligence process becomes increasingly rigorous and thorough as the innovators and investors approach an agreement (based on Ross Jaffe, "Introduction to Venture Capital"; reprinted with permission).

- **Product feasibility** – Depends primarily on R&D and clinical and regulatory expertise. Product feasibility demonstrates commercial viability and is proven through the completion of pivotal trials, regulatory approvals, support from key opinion leaders (**KOLs**), and first commercial sales (some start-up funding and expansion funding).
- **Company feasibility** – Relies on continued R&D, sales and marketing, and manufacturing to demonstrate sustainable profitability. Company feasibility can be shown through revenue and profit growth, a full product/technology pipeline with multiple generations of devices being developed, strong brand identification in the market, and defect-free quality (expansion funding, mezzanine funding, and IPO).

When deciding on funding milestones, innovators should select the ones that their target investors are

most likely to view as the most significant barriers to the success of a company. Then, as they are achieved, they will yield the greatest increase in company value. That said, it is important to stay somewhat flexible and open to adjusting the company's plans. As Aravind Swaminathan, co-founder of BioTrace Medical, Inc. explained shortly after closing a $3.4 million Series A funding round,[79] "We place a great deal of importance on constructing an ideal operational plan and seeking out an ideal set of investors. I think one lesson we learned is that it's important in this climate to remain flexible in that vision. There are multiple different potentially successful pathways a project can take and any given investor will have its own assessment of how best to handle the milestones and funding. The key is to keep the project moving forward, and flexibility will help achieve that."

Valuation, dilution, and ownership

A company's valuation, or the worth assigned to the business, is directly affected by the following factors:[80]

- The current and expected future valuations of comparable companies in the public and, when available, private marketplace: The higher the valuation of **comparables** and the more optimistic their outlook, the higher the valuation. Innovators should appreciate that active professional investors like venture capitalists develop a strong sense of the market valuation benchmarks due to their participation in multiple financings.
- The supply and demand for capital at the time of financing: Shortage of alternative investment options for investors increases the valuation. Abundance of alternative options decreases the valuation.
- Intangibles unique to a specific company, including the quality of the management team, a company's competitive advantage, and its likely pace of revenue growth and profitability: More experienced teams with proven track records can negotiate higher valuations.
- The nature and timing of an expected exit for the investor: The closer the time to exit and the higher the certainty of the exit, the higher the valuation.
- The implications of future capital raises, as well as needs to expand a company's **option pool** on the company's capital structure going forward: The more future rounds needed, the lower the valuation.

Valuation is important for any company taking on equity investors. Investors often refer to **pre-money** and **post-money valuations**. Pre-money refers to a company's value *before* it receives outside financing (or the latest round of financing), while post-money refers to its value *right after* it gets outside funds.[81] The pre-money valuation reflects the value assigned by investors to the assets the company has developed to date and the promise that the company holds. The post-money valuation is always equal to the pre-money valuation plus the capital raised.

The Working Example focused on Conor Medsystems demonstrates the concepts of pre-money and post-money valuation and introduces the concept of **dilution** to investors, founders, and employees. This particular example was chosen because it provides a rare example, with complete with data on changes in valuation as a company went through an entire funding lifecycle that included both private and public investments. It is also especially interesting because Conor Medsystems had two exits; the IPO, which because of the heady medtech market conditions at the time, generated a stunning 28.6x return on the Series A investment, followed by a second liquidity event for founders, employees, and shareholders when the company was acquired by Johnson & Johnson for $1.4 billion.[82] Moreover, the ultimate outcome of the core technology vividly underscores the inherent risk for investors in medtech development. Three months after J&J's acquisition of Conor, the device failed to meet its primary endpoint in late-stage clinical trials. As a result, J&J terminated clinical trials, halted plans to submit an application for premarket approval with the US Food and Drug Administration, and stopped selling the technology in countries in Europe, Asia, and Latin America where it was already approved.[83]

Working Example

Pre- and post-money valuation for Conor Medsystems

Conor Medsystems was founded in 1999 to develop a new generation of drug-eluting stents (DES). Over the next five years it raised more than $78 million before going public in December 2004. In February 2007, it became a wholly owned subsidiary of Johnson & Johnson. Table 6.3.4 presents the history of Conor Medsystems' funding rounds, valuations, and percentage ownership structure until the time of its IPO, as well as a summary of the returns realized by the investors.

The post-money valuation is calculated by adding the amount of funding raised to the pre-money valuation. For example, in the first round of funding on February 1, 2000, the pre-money value assigned by investors to the company based on its progress and plans to date was $2.675 million. The funds raised, $0.325 million, was then added to that amount to give the post-money valuation ($3 million), which represented the value of the company, including its assets, the promise of its plans, and the cash just raised.

Taking the example one step further helps demonstrate the effect of dilution. As more investors provide money in exchange for shares in the company, the increased number of shares outstanding reduces the percentage ownership of existing shareholders.[84] To calculate the percentage of the company owned by investors in the first round of funding, one can divide the amount of funding raised by the post-money valuation:

$$\text{Ownership} = \frac{\text{Investment in current round}}{\text{Post} - \text{money value}}$$

For example, after the completion of the first round of funding, the investors provided $0.325 million to acquire shares in Conor Medsystems. With a post-money valuation of $3 million, this means that the investors acquired approximately 11 percent of the company. The remaining percentage (89 percent) stays with the founders/management and in the employee option pool.

Table 6.3.4 Valuation for Conor Medsystems (compiled from VentureXpert and the Conor Medsystems prospectus).

Date	Funding raised (in 000s)	Pre-money valuation (in 000s)	Post-money valuation (in 000s)	Founder/ mgmt ownership	Investor ownership					
					Series A	Series B	Series C	Series D	Series E	IPO
02/01/00	$325	$2,675	$3,000	89%	11%					
11/01/00	$1,500	$8,500	$10,000	75.65%	9.35%	15%				
06/27/02	$10,200	$17,800	$28,000	48.11%	5.95%	9.54%	36.4%			
10/22/03	$28,000	$29,000	$57,000	24.88%	3.08%	4.93%	18.82%	48.28%		
08/01/04	$38,900	$111,100	$150,000	18.42%	2.28%	3.65%	13.94%	35.76%	25.93%	
12/14/04 (IPO)	$78,000	$409,000	$487,000	15.47%	1.91%	3.06%	11.71%	30.03%	21.78%	16.02%
Summary										
Initial investment					$325 K	$1.5 M	$10.2 M	$28.0 M	$38.9 M	
Terminal value				$75,339	$9,302	$14,902	$57,028	$14,624	$10,606	
ROI					28.6 x	9.93 x	5.59 x	5.22 x	2.72 x	
CAGR					110%	75%	93%	356%	630%	

Numbers may be subject to rounding errors
ROI = return on investment
CAGR = compounded annual growth rate

In each round, the same initial calculation is performed (e.g., \$1,500,000/\$10,000,000 = 15 percent in the second round) to determine the percentage of the company sold to the new investors.

However, an additional calculation is needed to compute the effect of each subsequent round of funding on the ownership percentages from previous rounds. For example, in the second round, the ownership of the original investors and founders is reduced by 15 percent (the ownership share of the new investors.) The new investors' share comes from the fraction owned by the original investors and founders. For instance, if the founders originally owned 89 percent of the company, after the new round of funding they will own 89 percent of the fraction of the company retained by the original investors and founder (which is 85 percent). So the founders' diluted share of the company is 89 percent multiplied by 85 percent, which leads to the diluted share of 75.65 percent. Similar calculations apply for investors in series A (their new ownership is 11 percent of 85 percent, which is 9.54 percent).

When Conor Medsystems went public, the terminal value for each investor is simply the value of their shares at the time of the exit (calculated as the number of shares multiplied by the price per share). Then, the **ROI** for each shareholder is given by:

$$\text{ROI} = \frac{\text{Terminal value}}{\text{Initial value}}$$

For example, for A round investors, the ROI is \$9,301/\$325 = 28.6. That is, the original investment made by A round investors grew 28.6 times (a return that reflects market conditions at the time, not necessarily the current funding environment).

The compound annual growth rate (**CAGR**) is the annual growth that the initial investment of each investor experienced. This is calculated using the following formula:

$$\text{CAGR} = \frac{1}{\text{Time between original investment and exit}} \ln\left(\frac{\text{Terminal value}}{\text{Initial value}}\right)$$

For the funds provided by round A investors to grow 28.6 times from February 1, 2000 to December 14, 2004, this means that the compounded annual growth rate was 110 percent. In other words, the investment grew at an annual rate with compounding of 110 percent per year.[85]

This example provides the funding requirements and valuations for Conor Medsystems, as reported after the fact. However, to derive a company's funding requirements prospectively, innovators should look to the operating plan and **financial model**. Funding requirements should be set such that the company has enough money to reach the next major milestone in the operating plan, enabling it to demonstrate risk reduction and secure the next round of funding.

Although the returns realized by the Conor Medsystems team and its investors do not provide realistic benchmarks for today's medtech environment, the example is instructive in other ways. In particular, it clearly illustrates how the company's valuation determines the ownership percentage of the innovators/founder and employees. As the company progresses and more capital is raised, the individuals should expect their ownership percentage to shrink. However, in parallel, the valuation of the company is expected to increase, which can lead to a higher total value for the owners.

In some cases, it is not uncommon for the valuation of a company to decrease between rounds of funding (a so-called "down round"). While this may be disappointing, it usually reflects a temporary setback that may be reversed in the future. Yet, start-ups are a risky investment, with some of them never generating a return on the capital and time invested. Investors are aware of these risks and seek to mitigate them in two ways: (1) by requiring high ownership stakes in the companies they fund, such that the returns on successful ventures help counterbalance investments in failed start-ups, and (2) by incorporating anti-dilution measures in a deal that prevent their equity investments from losing value (see section on "Term sheets"). Warrants are a vehicle used to protect investors from dilution. These give the investor the option to purchase additional shares of the company's stock at a prespecified price or else face the dilution of their

ownership percentage.[86] Innovators can help retain ownership in the company by carefully and proactively evaluating and managing key risks.

Strategic considerations: how much funding between rounds and at what valuation?

When thinking about the capital and time required to reach each funding milestone, innovators should consider the operating plan (validated relative to a **proxy company** or companies), plus the amount of incremental capital needed to address any deviations from the plan. Each round should include a "cushion" to address these deviations, since running out of cash between valuation points can be incredibly costly and potentially jeopardize the business. However, keep in mind that raising too much capital needlessly dilutes the ownership of the innovator and the previous investors.

Determining the value of the company at each round of funding is both an art and a science. A company can get started by doing simple modeling to develop "back of the envelope" valuations based on expected returns and potential exit valuations. Two common methods of valuing the start-up at each round are: (1) discounting terminal value; and (2) a comparables analysis. The premise behind discounting the terminal value is that investors require a certain return on their invested capital. While not a definitive valuation method, this approach represents a good exercise to understand the drivers of valuation. During earlier rounds of funding when the venture is more risky, investors expect higher returns than in later-stage rounds when risk has decreased. The critical components in determining the company value at each round are listed below:

- **Terminal value** – With the current exit strategy, what amount can investors expect the company to be worth? As an example, a start-up may determine that it could be acquired by a large medical device company for $400 million. The terminal value is often based on what comparable companies received at their exit event but can also be based on the future cash flows that the product may generate after the exit event. For instance, in the Conor example the terminal value was the IPO pre-money value of $407 million. There could be an alternative terminal value that would represent an acquisition.
- **Duration** – The time frame between the specified round and the exit event.
- **Discount rate** – The discount rate is the return that investors expect to be compensated for putting their capital at risk. Table 6.3.5 illustrates typical discount rates for different types of projects. As a rule of thumb, the discount rates may get smaller with each subsequent round of funding.
- **Calculation** – For each round of funding, discount the terminal value back by the expected duration between that round and the exit using the discount rate. The general form of this equation is:

$$\text{Post money valuation} = \frac{\text{Terminal value}}{(1 + \text{discount rate})^{\text{duration}}}$$

For example, a rough calculation for Conor's valuation on December 1, 2000 could be as follows: assume a terminal valuation of 100 million, a discount rate of 70 percent, and a duration of 5 years (time to IPO); then $100/(1 + 0.70)^5 = \$7$ million. The actual realized valuation at that point was $3 million, which implies that the investors assumed either a longer duration, a lower exit, or required a discount rate in excess of 70 percent.

In addition to using the terminal value, a comparables analysis will help a company target a realistic valuation. This analysis begins with selecting a comparable company based on at least the following criteria: stage of funding, field and application, and founders' experience. The average pre-money and post-money valuation for each round of funding and stage of that company is assessed next. The post-money valuation for the innovator's company should be based on the pre-money valuation of a comparable company, plus the estimated operating expenses to achieve the next major funding milestone from the company's financial model.

The best way to secure a favorable valuation is to have multiple interested investors with multiple deal sheets. While these analyses can help a company target a

Table 6.3.5 Common discount rates for new medtech projects.[88]

Risk level	Example	Expected return
Risk-free project	Build a new plant to make more of an existing product when there is a surge in demand	10–15 percent
Low-risk project	Make incremental improvement in existing products	15–20 percent (above corporation's goals for return to shareholder)
Low to medium-risk project	Develop next generation of existing product	20–30 percent
Medium-risk project	Develop new product using existing technology to address markets served by other products of the corporation	25–35 percent
Medium to high-risk project	Build new product using existing technology to address new markets	30–40 percent
High-risk project	Build new product using new technology to address a new market	35–45 percent
Extremely high-risk project	Build new product using new technology to address a new market when there is an unusually high level of risk associated with one or more of these factors	50–70 percent

reasonable valuation, many other factors can influence the final numbers, including the experience of the team, competitive threats, investor interest in the specific space, and macroeconomic market conditions. Online Appendix 6.3.1 provides another valuation example, using a slightly different approach for the fictitious company analyzed in 6.1 Operating Plan and Financial Model.

Sizing the option pool

Another important decision facing the founders and early investors is how much of the company's stock to reserve for key employees. Stock ownership, typically in the form of stock options, is a crucial incentive that can be used to recruit and retain valuable team members. According to analysis performed by the Silicon Valley-based law firm of Wilson, Sonsini, Goodrich & Rosati, roughly 20 percent of the company's shares should be reserved for the option pool after the first round of funding.[87] Following series A, the amount of stock options reserved for employees (as a percentage of the company's total stock) should follow the rough rules of thumb presented in Table 6.3.6.

Table 6.3.6 Maintaining competitive stock incentive program levels for essential personnel is central to a company's hiring and retention strategy (from Doug Collom, "Starting Up: Sizing the Stock Option Pool," The Entrepreneurs Report, Wilson Sonsini Goodrich & Rosati).

Employees (by position)	Post-series A preferred stock
[Founder] CEO	5–10 percent
Vice presidents	2–3 percent
CFO	1–2 percent
Director level	<0.5 percent

Term sheets

With some types of investors, the funding process culminates in a signed contract between the funder and the company. The important details of the final contract are typically worked out through a term sheet, which outlines the terms for a deal and serves as a letter of intent between the investor providing funds and the company receiving them.[89] The two most important functions of the term sheet are to summarize all of the important financial and legal terms related to a contemplated

transaction, and to quantify the value of the transaction.[90] Term sheets are commonly used by VCs, corporate investors, and syndicates of angel investors, among other investor types.

Importantly, term sheets are not legally binding documents because they are put in place before the investors complete legal and **patent** due diligence. However, both parties involved in the deal are expected to interact in good faith, preserving the essence of the agreed-upon terms until the closing of financing. Term sheets are usually prepared by the lead investor and presented to the company's CEO. The term sheet becomes an expression of the investor's interest in a company and outlines the term by which the investor is interested in investing. Following the presentation of a term sheet, a series of discussions between the company and the investor ensue, with the expectation by the investor that the company will accept the proposed terms. If a company is being courted by multiple investors, then the contents of a term sheet are potentially subject to negotiation. Once agreed to, proposing changes to the term sheet can severely undermine the working relationship between the company and the investor. As a result, any potential changes should be considered carefully and initiated only under rare circumstances.[91]

Not surprisingly, term sheets vary significantly from deal to deal – not only in substance, but in style and structure. Because the term sheets set forth all of the details surrounding a funding agreement and may have long-term implications for the business, innovators should confer with top lawyers and trusted advisors when reviewing them. There are typically anywhere from eight to 18 sections within a term sheet, several of the most important of which are outlined in Table 6.3.7. A more comprehensive overview can be found in online Appendix 6.3.2.

Managing the funding process

Whenever possible, companies should proactively manage the funding process and try to create competition among investors. During presentations to investors, anticipate their concerns and be prepared to address them in detail. Also, be prepared to talk "off script" as unanticipated questions arise. Listen carefully before providing answers, and be clear and concise in all

Table 6.3.7 These sections of a term sheets are often among those that innovators find most interesting and important (derived in part from Chapter 3 of *Term Sheets and Valuations*, by Alex Wilmerding, and used with permission. Copyright © 2006 Thomson Reuters/Aspatore).

Section	Contents
Summary of financing	This opening section summarizes the contents of the term sheet and provides an overview of the transaction being proposed. It usually includes: • The name of the investors • The name of the company • The amount of financing being offered • The number of newly issued shares • The purchase price per share • The post-financing capitalization structure (which enables the innovators to calculate the pre-money and post-money valuation). Any milestones that must be met for the release of funds will also be outlined in this section. By linking funding to milestones, investors can more closely monitor company progress and manage their downside risk.
Liquidation preference	The liquidation preference outlines the terms governing the transaction if a company is closed down. While preferred shareholders are given priority over common shareholders, the term sheet often takes this one step further by defining a multiple on the value of their initial investment that preferred and common shareholders will receive. According to these terms, the multiple promised to the preferred shareholders would be paid before any proceeds would be given to other shareholders.

Table 6.3.7 (*cont.*)

Section	Contents
Dilution	One of the single most important issues to investors, as a company grows, is how new rounds of financing will affect the value of their investment on a per share basis. Dilution clauses stipulate how conversion prices will be calculated if future rounds of financing are dilutive to preferred shareholders. If future stock is issued at a price lower than the current round, an anti-dilution clause helps ensure that preferred investors continue to hold an equal (or near equal) percentage of ownership in a company without committing more capital.[92]
Voting rights	Voting rights are included in term sheets to ensure that all shares are treated equally in the event that a shareholder vote is called. Typically, one vote per share is granted for both preferred and common stock.
Board composition	The board composition clause outlines the number of board seats and how they will be filled. Typically, companies seek to build a board with representation by both common and preferred stock holders. Investor-favorable composition would give the preferred shareholders majority control. A more neutral arrangement might give preferred shareholders (investor) and common shareholders (company management) an equal number of seats, with one additional seat granted to a mutually agreed-upon independent participant.

responses. Investors will almost certainly ask some questions for which the innovators do not have the answers. To maintain credibility, innovators should acknowledge where uncertainties and unknowns exist rather than trying to "fake" a response. No investor expects a team to have all of the answers. The importance of paying attention to what investors ask cannot be overemphasized, since it is likely that if one investor asks a question, another may be interested in the same issue. Accordingly, gathering answers to typical questions prior to each meeting is extremely beneficial.

Once innovators receive a term sheet, they may be tempted to seek other investors if the proposed deal does not meet expectations. However, even if there is no exclusivity clause in the term sheet, approaching one investor with the details from the term sheet of another is a strategy that can backfire. Especially in the relatively small and interconnected world of VC and angel financing, "shopping a deal" can potentially undermine an innovator's reputation. It is more professional and effective to do this "shopping" in advance – approaching two or three potential investors simultaneously to try to get multiple term sheets at once, and then deciding who to work with to best meet the company's financing needs and expectations.[93]

The Loma Vista Medical story illustrates how one company defined a diversified funding strategy and managed its fundraising efforts through exit.

FROM THE FIELD LOMA VISTA MEDICAL

Defining and implementing a lean funding strategy

When he became interested in building his own medtech company, Alex Tilson actively set out to find an opportunity that he could pursue using a model that would require fewer resources and less time than traditional device start-ups. His vision was to take a lean, focused approach to developing and commercializing a new technology so that he could get to market faster and would be less dependent on external funding. "The standard model had been to raise $70–$80 million and to take 8 to 10 years to get a product to market," Tilson explained, "But I had seen many problems with that

approach. I had also seen fundraising consume one-third of the executive team's time, and I did not want to do that."

Working in his garage, Tilson initially pursued an opportunity in colonoscopy. He was interested in developing a device that would make the procedure less painful and time-intensive for the patient and that also had the potential to dramatically lower facility and personnel costs for providers. Although the initial concept was sound, it was not feasible due in part to the limitations of standard medical materials. Tilson had previous experience with America's Cup sailboats and was familiar with a different class of materials typically not in the lexicon of medical device engineers – thin film flexible composites. Though it was clear that this material had the potential to be superior, it was not optimized to address the unique demands of medical device design. After endeavoring to work with a partner to develop new medical-grade composites, the company (which took the name Loma Vista Medical, LVM) decided to look inward and develop a new material in-house.

As development progressed, the team realized that the new materials opened up a wide variety of opportunities above and beyond colonoscopy. Tilson recognized that the material was not ideal for all procedures, but it was uniquely suited for applications that required exacting dimensional control and toughness. It also enabled balloons with unique shapes, and with localized feature integration. According to Tilson, "We asked ourselves, 'What are we really good at? What would we do if we thought of ourselves as a composite medical balloon company instead of a colonoscopy company?' We looked at all possible applications to find a good fit. It was clear to us that there were multiple unmet clinical needs that we could help solve."

LVM began to actively explore areas where a gap existed between the performance aspirations of an existing technology and the capabilities of available medical balloons. The team uncovered a compelling opportunity in kyphoplasty, which was used to treat painful compression fractures in the spine by inserting a balloon into the patient's vertebrae, inflating it, and filling the resulting cavity with a bone cement to stabilize the bone. "Kyphon had been stunningly successful, despite using what we saw as a balloon technology with distinct limitations," Tilson recalled. LVM produced a prototype of a kyphoplasty composite balloon and initiated discussions with Kyphon's leaders, hoping to accelerate time to market through a partnership.

Another interesting opportunity surfaced in the emerging area of transcatheter aortic valve replacement (TAVR). One of Loma Vista's board members had been a consultant to CoreValve during its early days and suggested that the company explore this area. "They had mastered the valve, but they needed a suite of enabling accessories," said Tilson. "It was clear to us that the procedure needed balloons that had better dimensional control, better puncture resistance, faster inflation deflation, and refolding. We felt that we were out in front of this need, and uniquely had the technology to deliver a solution."

Eventually, LVM held a "bake off" between the kyphoplasty and TAVR opportunities and decided to focus its efforts on TAVR. In this space, the young company found its niche, developing the TRUE Dilatation™ Balloon. The TRUE product received its **CE mark** in December 2011 and began commercial sales in Europe in early 2012. The product was cleared by the FDA via the 510(k) pathway shortly thereafter, in October 2012. In early 2013, LVM introduced the product to the US market through its new direct sales organization, which consisted of two sales reps. Six months later, C.R. Bard acquired the company.[94]

All of these activities were enabled, in large part, by LVM's funding strategy (see Figure 6.3.6). In alignment with his original goal, Tilson took a careful, measured approach to financing the company. "Many entrepreneurs think that VCs fund good ideas. They do, but they typically expect that idea to be backed up by a

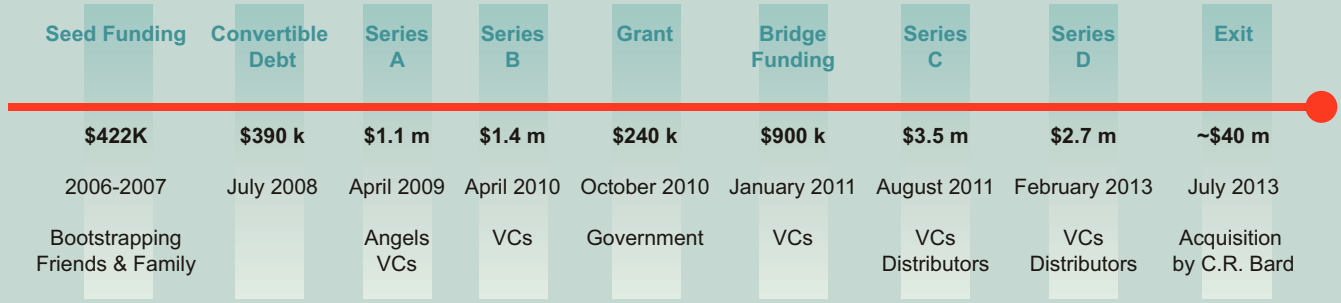

FIGURE 6.3.6
An overview of the Loma Vista Medical funding strategy, from inception to exit.

long list of milestones. As a first-time entrepreneur, I knew we shouldn't even go knocking on VC doors until we had achieved multiple real milestones," Tilson said. Accordingly, he bootstrapped the company's early development work with his own savings. He also accessed funds through friends and family. "If you're not ready to do that, then you're not ready to be an entrepreneur," he stated.

By mid-2008, Tilson had been working on the company, which was still headquartered in his garage, for almost two years. He had met with investors from De Novo Ventures several times before they finally invited him to discuss a small round of convertible debt. At this point, LVM had achieved several important milestones, including key IP filings, promising bench data, animal data for the colonoscopy system, and prototypes for the kyphoplasty balloon. Moreover, the De Novo team saw that he was persistent and committed to making the company successful. As Tilson put it, "The business plan matters, the size of the opportunity matters, the technology matters, but they are also investing heavily in people. I think that they saw that we were unusually persistent – that we would go to the ends of the earth to make something work." He was able to raise $390,000 in convertible debt in July 2008. Commenting on this type of funding, he said, "Convertible debt is very entrepreneur-friendly. It sets the value in the future and allows you to create value while you're still running. The interest rate is modest and the equity-kicker is reasonable. Importantly, it also shows that real people have put in real money, which creates a foundation that others often follow."

The next two funding rounds came in relatively rapidly succession. In early 2009, LVM had a working kyphoplasty system and positive cadaver data to support its next fundraising effort. The company raised a $1.1 million Series A in April of that year from an expanded syndicate of small VCs and angels. Over the next 12 months, the company used this money to fuel development of the balloon and also to support its increasing emphasis on TAVR. However, as LVM was getting ready to raise its Series B funding, prospects for using the kyphoplasty balloon to realize an early exit were fading. The team members recognized that they needed to go further with development and potentially prepare to commercialize their products themselves. Tilson began considering a fundraising diversification plan. Through one of his investors, he was connected with Scientific Health Development (SHD), a venture capital firm based in Dallas, Texas. The group liked LVM's approach and was the first to put money down for the B round. "One of the advantages of a smaller firm is that it can make a quick decision and then take action," Tilson stated. With this new investor leading the round, De Novo and several other investors made the decision to commit. LVM closed $1.4 million in April 2010. At that time, the company's burn rate was averaging just over $100,000 per month.

Even though much of LVM's work transferred from kyphoplasty to TAVR, the team needed to complete

significant clinical work. Additionally, the composite technology required substantial investment in new manufacturing paradigms – a use of money that sometimes causes VCs to grumble. To help fund this work, the company actively sought alternate forms of funding to help it bridge to its next major round. First, Tilson applied for and was awarded a $240,000 grant from the US government as part of the Economic Recovery Act. LVM also raised almost $1M through one of its investors. "We were lucky," Tilson said. "The investor told us, 'I'll raise almost $1 million dollars for you, commission-free, and I'll be doing it because I'm on your board and I believe in you. And *you* being successful helps *me* be successful.' So he called up other interested investors and helped us raise the bridge funding." LVM used these funds, combined with its Series B money, to advance the TAVR product (see Figure 6.3.7). In particular, the company develop the manufacturing processes and trade secrets that would allow it to scale-up manufacturing, which eventually became key to LVM's acquisition. "By committing to owning the manufacturing, we turned one of our biggest challenges into a valuable strength," Tilson noted.

The company felt ready to raise its Series C after optimizing its manufacturing approach, completing a validation study, moving the product into a design freeze, and making the company's CE mark submission. Always interested in further diversifying his investors, Tilson had been speaking with distributors. When Medtronic acquired CoreValve, it also bought out the company's distribution agreements so that it could distribute the TAVR technology through its own channels. This turn of events meant that many distributors with experience in the TAVR space had money on hand to invest in new opportunities. These distributors had developed key relationships with all of the right doctors. Additionally, they had come together to form an investor network, and they expressed interest in investing in LVM. "Suddenly, we had 30 different investors from around the world interested in the Series C round," Tilson remembered. "It was a mind-bender for us, and took some managing, but it worked. We slept well at night because we were very diversified." Loma Vista closed a $3.5 million Series C in August 2011. "Getting the distributors as investors in the company was a big break for us," he said. "It gave us credibility with the VCs because the organizations that knew transcatheter valves as well as anyone on the planet stood up and said they thought we had a good product. Also, when we did get the clearance to launch in Europe, we had an immediate commercialization pathway based on a two-year relationship with people who were ready to go sell the product." Moreover, the distributors provided an invaluable source of feedback, showing a willingness to introduce Loma Vista to key opinion leaders to assist by providing with product and adoption feedback.

FIGURE 6.3.7
The team after the device's first TAVR case. From left to right: M. Braun, A. Tilson, T. Johnson, Dr. H. Mollmann, Dr. G. Kempfert (courtesy of Alex Tilson).

The company used the Series C funding to attain its CE mark and launch commercial activities in Europe. The product was well received: Tilson estimated that, within six months of launch, LVM balloons were being used in more than half the CoreValve cases in Germany. LVM had also gained FDA clearance, was manufacturing at scale, and began making progress on a second generation product. Tilson had been actively talking with potential acquirers, but had not yet entered into any definitive discussions. At that point, he faced a decision: "We have half a million in the bank. Do we take on convertible debt? Do we take on venture debt? Do we raise half a million dollars and try to make it to an exit? Or

do we raise a big Series D while we can because TAVR is hot and we're firing on all cylinders?" Tilson said. "We were highly cognizant that, as good as things look today, the world can always change quickly." After extended board deliberations, he stated, "We decided to shoot it down the middle." Based on the strength of its commercial milestones achieved to date, Loma Vista raised a Series D in February 2013, capping total investment at $2.7 million. This round brought the company's total investment to $10.6 million raised over approximately six years.

In terms of realizing an exit, Tilson was surprised by the length and difficulty of the process. Over several years, he courted more than a dozen prospective acquirers until, just before the Series D, the company entered into serious talks with C.R. Bard. After eight months of negotiations, Bard purchased Loma Vista Medical in July 2013 for approximately $40 million.[95] Reflecting on the acquisition, Tilson remarked, "As an entrepreneur, I wanted a validated success and the investors were eager for an exit, so we were aligned in this regard. The market at the time was tough for medtech companies. We took the offer." LVM had got this far with 19 people, but would have needed to substantially ramp up to continue building the business. "We had a series of next generation products in development, we had new manufacturing paradigms that could take things to the next level, and our sales network could have been substantially expanded. We knew that we could have been worth a lot more, but the activities ahead would be a lot more expensive. There would be a lot of dilution and a lot of risk," he said. Importantly, Tilson added, "Merely existing every day carries risk. Many things are well beyond your control. Opportunities expire. People get exhausted. Sometimes a bird in the hand really is worth two – or three or four – in the bush."

When asked what advice he would offer other innovators as they consider a funding strategy, Tilson recommended his lean approach. "Scarcity breeds efficiency," he commented. "And being lean makes you hard to kill. We were never at risk of getting starved out because we had real technology that we knew that the world needed, and our burn rate was so low."

Tilson also encouraged innovators to think about fundraising as a courtship. "Every interaction matters. Investors are looking for someone they can trust and who they can work with long term." Along these lines, he pointed out that little things can make a big difference. For instance, Loma Vista instituted a policy of sending its investors regular updates about the company's progress. "We were proactive about this even though very few companies do this. Every quarter we would send out a one-page letter about what was happening at the company. And that became part of our brand. People saw us as persistent and inventive and lean, but they also saw us as unusually communicative and honest. Open communication and honesty had a big payback for us, and it made it easier to raise subsequent rounds of funding because our investors were well informed," Tilson said.

Finally, he advised innovators to be realistic about achieving an exit. More often than not, he explained, companies should be prepared to take their products into the market and generate sales before acquirers get seriously interested. This means orchestrating a real and substantive launch that "shows that you're able to ship product, earn real revenue, generate repeat orders, and handle any complaints. It means that your quality system is working, your manufacturing is reliable, and that your product is loved. And it requires creativity to figure out how to do all of this with lean funding," Tilson emphasized.

Online Resources

Visit www.ebiodesign.org/6.3 for more content, including:

- Activities and links for "Getting Started"
  - Identify comparable companies
  - Confirm funding milestones and capital needs
  - Determine a company valuation
  - Research and select investors
  - Approach investors
- Videos on funding approaches

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