Article

Founding and Funding a Life Sciences Company: An Overview

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ABSTRACT

Founding and funding a company demands that the founding team and their advisors identify and articulate the myriad of challenges and risks that they will face in pursuit of their vision. These factors have implications regarding the technology, market, and team in addition to the regulatory and reimbursement challenges. This article provides the perspective of senior industry investors and legal counsel, and covers the vast array of decisions that form and guide the organization along the pathway to the market, e. g. corporate form, governance, financing, exit.

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INTRODUCTION

More than a million companies are created every year in the United States, but most of them fail due to a lack of a clear vision or a stable plan of development. In the life sciences field, the inception of an idea usually arises from a medical professional or scientist who discovers a new form of diagnosis, treatment, or a way to meet a need in the market currently not being addressed. This is the impetus that leads to a journey to form a business and seek funding.

These first-time entrepreneurs may bring with them years of knowledge and expertise in medicine and science, but many have received no guidance on how convert their visions into a viable business entity. Establishing a solid foundation from the start is key to reducing the risk to oneself and one's investors, and, even more importantly, to increasing the payout when the company reaches an exit. A poorly planned and ill-provisioned journey only increases the probability of failure. Entrepreneurs must learn to not only understand the technology, but also the complexity of the market and the competitive landscape. And of course, being able to attract capital to reduce technology, market and team risk incrementally.

For medical professionals or scientists who have made valuable discoveries they want to share with the world, the steps to entrepreneurial success may seem straightforward: form a company, approach investors to raise the necessary capital to bring their idea to market, create a proof of concept, and then sell their companies and reap the rewards for their innovation, hard work, and perseverance. But there are common pitfalls that many aspiring entrepreneurs encounter that prevent their new ventures from reaching their full potential.

For this reason, it is important that founders understand the importance of defining success and creating a targeted roadmap on how to attain it. A comprehensive strategic plan should be incorporated in the initial documents created when forming a company. This is not a task that most entrepreneurs are equipped to perform themselves; finding experienced advisors is a necessary component of a successful business venture.

Setting up a company properly requires more than simply filing the articles of incorporation and writing bylaws. There is also a myriad of other documentation that is needed, such as investor agreements, employment agreements, and IP agreements. If this documentation is not set up properly, it can have long-reaching effects on the company's valuation, funding, and an eventual exit. Employing or contracting with a knowledgeable corporate lawyer is essential.

Additionally, founders must seek adequate funding and then apply it to product development to ensure that their innovation can produce the desired outcomes. They must then rise to the challenge of determining the readiness of the current market to accept their offering. Only after all of these steps are completed effectively and thoroughly can their product make a difference in the lives

of users. The ultimate goal for life sciences entrepreneurs is to discover a pathway that will convert their brilliant ideas into functioning business models, which will produce a significant a return on investment.

FORMING A COMPANY

Before entrepreneurs can acquire the funds necessary to bring their innovation to market, they must create a value proposition for investors. It is helpful to start by demonstrating the value that their concept will bring to the end-user. An end-user should not be confused with the customer, though they can on occasion be the same. An end-user is a user, and a customer is someone who pays. These are not always the same person, especially where technology is concerned in healthcare. Determining end-user value will result in the ultimate worth of any company. And value is a key component of the company "story" that investors need to know when deciding whether or not to invest.

This story must be complete and convincing, so that when it is told, investors see a well-thought-out plan for bringing the idea to market and creating value that will attract acquisition. In that plan, investors need to see that the founders have identified risks associated with the technology, product development, and customer acceptance, and that they have sensible strategies for minimizing these challenges. For the life sciences field, investors will chiefly be concerned with how sound the science is behind the technology. Peer review is vital. Savvy investors analyze and assess every aspect of the data presented, and anything without clear and quantifiable results poses risks, which lowers the chances of investment.

For the sake of ensuring credibility, estimates of market size, timeline to market entry, pace of acceptance, and scale of reimbursement must also be provided in this stage. Investors will require every little detail about this new company. Its corporate structure, equity distribution, financing terms, and employee compensation must be understandable, appropriate, and consistent with typical arrangements.

New entrepreneurs must ask themselves what the ideal and appropriate legal form for their company should be. A corporation is often the default choice due to its well-understood capital and operational structure. However, an LLC, or limited liability company, may present tax structure advantages for some. The management structures of LLCs and corporations have many elements in common, but they use different terminology. For instance, most corporations have a "Board of Directors," while LLCs instead have a "Board of Managers."

It is possible for the LLC's management structure to be more flexible, less formal. For instance, owners may also be officers who are involved in the day-to-day running of the company. Corporations have a more formal management structure where directors oversee major business decisions and officers are responsible for the day-to-day operation of the business. If a corporation is chosen, subsequent choices must be made regarding its qualities.

C-CORP VS. S-CORP

The two categories of corporations are C-corps and S-corps. Most life sciences corporations are registered as C-corps because the founders intend to bring on multiple investors (often including institutional investors) and then exit through a merger and acquisition or IPO. S-corps present their own range of benefits. Like an LLC, an S-corp's P&L flows through to the individual owners. Typically, however, most life science companies will set up one C-corp or LLC to hold everything. It is also prudent to consider where this new company will be formed, as each state has different laws regarding incorporation. Every company will be different. A corporate lawyer can advise as to which legal structure is best for each individual company as well as the best location for incorporation.

In the case of a corporation, it is vital to understand the management roles within a Board of Directors. The board has the fiduciary duty to oversee the company on behalf of the shareholders. In addition, the board acts through the management team, especially the CEO. The shareholders' role is to elect the directors. They are dependent on the board/management to produce a positive return on investment. They vote on fundamental changes such as financing and exit opportunities, but they are not involved in day-to-day operations, except informally.

The board and the CEO work together to govern the company, with the CEO being the go-between that translates the board's policies into the daily operations of the company. Good oversight by the board means that it should not be simply either the CEO's cheering section or her firing squad. The board-management relationship is influenced by how well the CEO communicates information, both good and bad, and adheres to the policies of the board.

FINANCING

After employing the help of a lawyer who is well versed in start-up creation, the well-thought-out corporate

structure devised by a company's founders will provide a solid foundation for the story they will tell investors when the time comes to seek funding. Financing is about more than money—it's about building relationships in a way that will not inhibit a company from moving onto the next stage and beyond.

There are two sources of funding early in the life of a company: debt in the form of convertible notes and equity, also called "seed money" or "Series A funding." A convertible note is issued to an investor in exchange for a loan that will be repayable in cash at a future date, along with interest at a set rate, which is referred to as the coupon rate. Unlike other debt instruments, convertible notes also give the investor the right—or the obligation—to convert the principal and interest into shares of stock. Any conversion terms will be spelled out in the note.

Investors are partial to convertible notes because their repayment may be secured by the company's assets. However, because the notes do not convey ownership in the company when they are issued but may convert into an equity interest reflecting the (hopefully higher) valuation of the company at the time of that future equity offering, the conversion may not convey all of the equity interest these investors would have received if they had made an equity investment at the outset. Also, investors holding notes often do not have a voting interest in the company or other ability to participate in company decisions. The conversion feature of these notes is often triggered by an equity financing, which means the company can force investors to convert at that time.

Investors who provide equity funding in the form of seed or Series A money typically get a portion of the business in return for their investments. This usually means that they have voting rights and certain other rights and protections, which may include the right to nominate someone to serve on the board or to participate in future equity offerings ahead of new investors. The details of each of these funding forms must be documented in purchase agreements, shareholders' agreements, investor rights agreements, and other documents.

Where ownership is concerned, the main forms for entrepreneurs to familiarize themselves with include preferred stock and common stock. Preferred stock combines features of debt, in that it may pay dividends, and equity, and in that it has the potential to appreciate in value. Equity investors with preferred stock have a prior claim on company distributions. And, any dividend for preferred shares generally must be paid out before dividends to common shareholders. The details of each class of preferred stock the corporation may issue are spelled out in the Certificate of Incorporation: the document filed with a state government to create a corporation.

In addition to the classes of stock, the Certificate of Incorporation also defines the issue price of each share in each series of funding.

VALUATION

No matter how a company may be financed, investors are looking for a return on the money that they lend or contribute. They need to know the current value of the company to estimate what their return may be or how much of the company their investment will buy them. It is important for founders to assign a reasonable value to their company at each funding stage so that it will be attractive to investors, and so that they have the funds they need to make it to each successive development and funding milestone on the way to exit.

If a company is not valued properly, or if its funding cycles are not consistent with development needs, later funding rounds may become "down rounds" where a lower valuation causes dilution in value for shareholders and may trigger anti-dilution rights that, in effect, give certain shareholders more shares to offset this apparent loss of value. Until a company's stock is publicly traded, investors need to evaluate the company's assets and any revenue stream to estimate its current value and the potential return on their investment. This can be especially challenging when the company is just starting out, as it often has no assets, other than its IP, and has no revenue.

A pre-money valuation is the current value of the company before it conducts an investment round. A pre-money valuation at the pre-revenue stage, or even before the company has its product or service ready for release, will be based on a variety of other factors. One such measure may be comparable businesses. An assessment of the revenue and market value of established, more mature companies that have a similar focus and operational approach can serve as a gauge of the current pre-money value.

This pre-money valuation may be a figure proposed by a potential investor. The valuation amount would then be used as a basis for how much ownership they expect in exchange for their investment. That ownership interest will be the percentage of the company's post-money valuation (which is the sum of the pre-money valuation, the amount raised through the financing and any amount attributable to notes converting in the financing) represented by their investment. The leadership of the company may reject pre-money valuations proposed by others until they reach an amount that matches the aspirations of the company. This is when it pays to have done proper research into risks, estimates of market size, and other parts of the "story" proposed to investors. A solid

understanding of a company's value is essential in order to negotiate with potential investors on these terms.

Once the pre-money valuation is determined and a company undergoes the first round of funding, the investments from both converting notes (if any) and new equity are added to this pre-money valuation to arrive at the "post-money" valuation.

Life sciences companies are generally valued using industry standards. Below is a partial view of a typical small molecule Therapeutic Valuation Metrics. It was calculated by downloading venture funding data of like companies and plotting their accomplishments by funding round. In this example, we explore the Seed and Series A activities that should be accomplished with each round. In our example, for the startup to raise its Series A and attain a pre-money valuation of $8 million, they should have accomplished the milestone identified in the Seed Phase. This type of analysis and process would continue with each subsequent round until they exit the company through a liquidity event such as an IPO or merger and acquisition. During each phase, there is a pre-money valuation, a capital raise that is provided by investors, and then a post money valuation. See Figure 1.

It is in this circumstance that down rounds can occur. For instance, if between the seed round and 1st round, the valuation of a company jumped, it would indicate that value has been added through development efforts. However, if the valuation of the company had been set too high in the seed round and not enough additional value was created through the first phase of development, it would lose value between rounds, resulting in the existing shareholders' equity being diluted and losing value. Another issue when setting fundraising goals is the timing of each offering. Companies must anticipate when they will need new injections of funding to move their technology through the development cycle so that they don't end up in a trough between financings, which can delay development.

Capitalization changes with subsequent rounds of funding; as the company grows and develops its assets, the valuation of the company grows, creating a bigger "pie" for all stockholders to share in. Assuming the company's value is greater when later rounds of funding are collected, the value of its shares is higher. Earlier investors may end up owning a smaller piece of the company, but that piece has grown in value.

REACHING AN EXIT

All of this planning and financing moves a company's founders and investors toward their eventual goal—the launch of a product and the realization of a return on their effort. A liquidation event, or exit, occurs when the shareholders' stock is purchased through a sale to or merger with an acquirer. When that event occurs, the Certificate of Incorporation spell out the distribution of the proceeds among the stockholders. The certificate will set out the "liquidation preference" assigned to each class of stock. This preference, if included, determines the order and how much of the proceeds of the liquidation event the stockholders holding a certain class of stock will receive; importantly, it also resolves what will happen if the proceeds are less than the amounts invested by the stockholders. In this case, the holders of series C preferred stock receive 100% of their original investment

Pharmaceutical Valuations by Round

Data-set: 2011 Venture Source

Seed - in millions		
Pre-Money	Capital Raise	Post-Money
2.8	1.0 +/- 0.6	3.8 +/- 1.6

---------------------- 11 months +/- 3 ------------------------|

Fundable Milstones: Research & target Identification

- Identify clinical candidate
- Disease pathology mapped
- Biomarker program started
- Assay development started
- Pharmacology & target engagement
  - Prognostic biomarker
  - Response

Series A - in millions		
Pre-Money	Capital Raise	Post-Money
8.0	6.7 +/- 3.4	14.7 +/- 4

|--------------------- 17.3 months +/- 3.4 -------------------|

Fundable Milstones: Target pharmacology & biomarket dev'l

- Qualification: companion diagnostoc & surrogate endpoints
- Lead identification & candidate
- Define regulatory pathway & I.P. pyramid
- Clinical trial planning

Figure 1

before any distribution is made to any other stockholder. So, if the amount of the aggregate series C investment exceeds the sale price of the company, only the series C stockholders will participate in that distribution.

If the purchase price for the company exceeds the liquidation preferences of all classes of preferred stock, then the excess will be distributed to preferred stock and common stockholders on an “as converted to common” basis. Sometimes the Articles of Incorporation may set a cap on the portion of the purchase price payable to a class of preferred stock, and that cap may be a multiple of the aggregate investment for that class.

It can be helpful to imagine the liquidation process like a waterfall with several pools each being as deep as the liquidation preference of the class of stock it represents. Each series of investors must have their liquidation preference satisfied in full before the next series begins to see a payout. So, in this illustration, series C, B and A preferred stockholders must receive all of their liquidation preferences before the holders of common would receive any payout. A participation cap on the payout to classes of preferred stock would result in very different returns based on whether the exit value is higher or lower.

The participation cap can leave more for common stock holders at higher exit and leave less for common stock holders at lower exit; also, it is a disincentive for preferred stock holders with a participation cap to seek higher exit values after their capped liquidation preference amounts have been paid in full.

With all of this taken into consideration, first-time entrepreneurs interested in starting a life sciences company have a number of choices to make regarding its legal structure. Their journey to commercialization and product launch will be aided if they have protected both themselves and their investors. And once their product is on the market, it then has to stand up to the standards of the buyer. Regardless of how innovative a technology is that drives a life sciences company, if it doesn’t meet a need and rise above the other products on the market, it doesn’t stand a chance.

While this remains just an overview of the life of a startup company, the journey from startup to exit—let alone from idea to putting a product in a user’s hands—can take decades. Only those who take the time and consideration to build their company responsibly will see their efforts come to a successful fruition.