

Where the bodies lie

Oded Ben-Joseph

Some suggestions for avoiding common mistakes made in life sciences startups.

As members of a life sciences advisory and investment banking group, my partners and I have often noted that life sciences companies fall victim to the same mistakes and misconceptions, repeated again and again. These failures mostly hinge upon company management misunderstanding the fundamentals of market dynamics and failing to appreciate the importance of the exit—the sole event where company investors receive a return on their investment, either through an initial public offering (IPO) or a company sale. Unfortunately, the biotech industry's track record on exits is disappointing. According to the National Venture Capital Association (Washington, DC), between 2005 and 2014, only one in five US biotech and medical device companies achieved liquidity after six years. And from my perspective over the past 20 years, that low success rate does not appear to be improving.

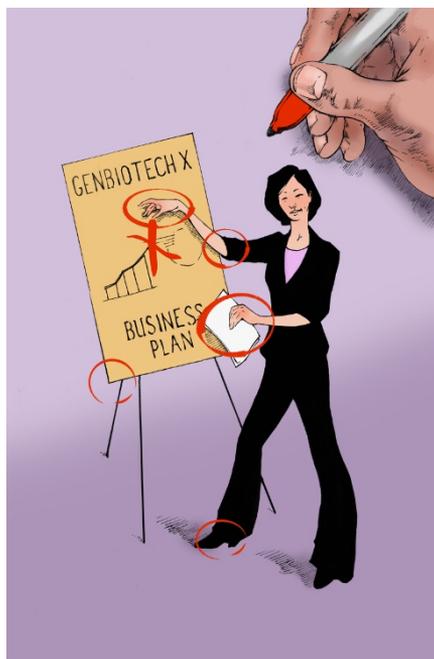
In the following article I share my perspective on common pitfalls for life sciences entrepreneurs. Going forward, I hope that these insights will help life sciences management teams increase their chances of success.

1. Believing good technology is enough

By far, the most common weakness we observe in the life sciences companies we advise is the belief that good technologies will be easily funded and ultimately adopted by the market. Although a substantial scientific or technological development provides the foundation of all life sciences companies, it is only a starting point and thus not predictive of a company's success.

Regardless of how elegant or innovative the technology, a company most likely will be constrained and influenced by internal factors, such as board and management strength, clinical development, and regulatory path, as well as

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external forces such as access to capital markets, competitive position, reimbursement policies, and sector dynamics, to name a few.

Entrepreneurs and CEOs should thus understand the risk profile within the context of benchmark companies in their sector; that is, it is not about science, it's about achieving liquidity. Often in our initial meetings with company management, we find ourselves repeatedly informing them that investors are seldom enticed by great technology or by a large market. Rather, investors act when they believe that their investment will generate a significant return.

Prudent management always knows the relationship between invested capital and exit values based on real market data. It is wise to provide a realistic point of view in presentations and pitch meetings, including a slide about the buyer universe and competition to provide a market context for the technology. In addition,

a slide on comparable exits in the past three to five years will go a long way in communicating a mature understanding of the potential size of your own exit.

For example, let's say a cardiovascular company is planning to develop a left atrial appendage closure device to treat arterial fibrillation in patients with high risk of thrombosis. Management estimates that \$80 million will need to be deployed through commercialization, including achieving US Food and Drug Administration (FDA) clearance and CE marking. An analysis of the structural heart segment reveals several potential buyers and that acquisition transactions from the past few years averaged ~\$200 million. This suggests a multiple of 2.5 × return on investment, which may not suffice to justify the risk for investors. As such, a savvy CEO may attempt to increase the multiple by running the company in a far more capital-efficient manner, thus reducing the amount of needed capital; to transact with a strategic partner earlier, before costly FDA clearance; or to identify strategic acquisition drivers specific to one or two of the players in the segment, thereby commanding an additional premium.

Most management teams we encounter have a highly developed ability to process and interpret data in an impartial scientific manner. This skill should be extended beyond science and into the market.

Lesson: run a back-end analysis comparing invested capital to likely exit price based on real market data.

2. Being blinkered with an inward focus

Management must recognize and adapt to the dynamics of the sector in which it operates. Thus, it is imperative to adopt an outwardly, top-down (as opposed to technology-up), market-driven point of view from the start. This includes developing a clear path to liquidity that is closely aligned with sector dynamics or the behavior of strategic players in your specific area. Focus on strategy first, execution

later. For example, a company is developing a novel anti-inflammatory protein for the targeted treatment of acute joint pain. The potential market consists of companies in different segments: pain, biologics, and drug delivery, among others. Analysis of these segments will shed light on a buyer's behavior. Who are the players? How many are there? What kind of transactions (acquisition, merger, license, joint R&D deal) have taken place? What technology are companies looking for? What are the key value drivers for an acquisition? What do strategic buyers need to feed their pipeline? How will the technology integrate in the hands of the buyer? How can the company create an offensive value proposition for itself, spurring others in the field to acquire the technology to either improve their own technology or block competition? What company did a buyer acquire? How much did they pay for it? At what development stage did acquisitions take place? How will the company's technology complement and synergize with those potential acquirers?

Typically, a market segment will support certain valuation parameters, and most companies fall within them. Make sure you are always attuned to your industry dynamics and make it a habit to build competitive intelligence as a core competency. In biotech, transactions tend to be structured in an effort to curtail buyer's risk; for example, cash up front followed by cash payments upon completion of milestones built around clinical success or approval, and a percentage royalty for sales. Although it is possible that a company will benefit from being an outlier valuation, the probability is slim to none—and subject to pure luck.

Lesson: outline all exit multiples (either IPO or trade sale) over the next two to three years. Focus on median multiples and build a realistic plan to ensure an exit at that multiple.

3. Ignoring the critical relationship between time, capital, and milestones

When looking for investment, you should understand potential acquirers' needs and your ability to address those needs. This will go a long way in providing investors with comfort.

To this end, management should also be able to provide a clear outline of the relationship between time, capital, and milestone. We often assist CEOs in constructing a single slide graphically communicating this relationship. It could be a Gantt chart or any other graphic depiction. The slide contains a timeline, milestones, and the capital required to achieve each milestone. This allows the investor to immediately grasp the capital needs of the company all the way to a major value-inflection milestone. It would also assist the investor to understand the risk profile and how they intend to deploy

capital to de-risk the technology. Milestones refer to value-inflection or 'de-risking' milestones, not activity milestones. For example, completing data analysis of a phase 2 or pivotal trial or obtaining FDA clearance are true milestones. By contrast, hiring key personnel or building a laboratory or a manufacturing facility are not. By underestimating timelines and funding required to hit value-inflection milestones, companies routinely fall short and run out of cash. Timelines vary markedly—in particular a novel biologic drug will take years to get through clinical trials and FDA clearance.

Lesson: be able to present on one slide the critical path to de-risk your innovation, and the cost of reaching milestones.

4. Confusing invention and innovation

From a market perspective, most pre-revenue life sciences companies have only one thing to offer: innovation. All other activities—manufacturing, sales and marketing, devising a reimbursement strategy—can be conducted by strategic players more effectively and at a fraction of the cost.

The probability of competing with well-established players in the marketplace is low. It must be accepted that the life sciences are mostly a feeder industry: that is, they feed technologies to larger multinational players. In other words, most biotech companies exist to be acquired. Successful stand-alone biotech companies are rare—and getting rarer. Therefore, the focus should be on innovation, clinical development, and activities that reduce risk and enhance value for the buyer. For example, millions of dollars spent on developing a sales channel are unlikely to garner a premium from an acquirer.

So what exactly is innovation? It is easier to understand the meaning of innovation by first understanding what it is not: innovation is not merely the creation of a new product or service. Rather, life sciences innovation is the development of a product or service that solves the needs of the end users (patient, healthcare provider) and improves clinical outcomes. True innovation will change market dynamics and end-user behavior. Invention will allow change; innovation creates change. The difference in these concepts rests primarily upon the notion that innovation is not an inward-focused pursuit.

Inwardly focused pursuits, in which a team becomes fascinated with developing something never before seen, falls within the more academically oriented realm of invention. Although invention is a vital component of intellectual and technological progress, it does not necessarily correspond with a business venture. Consider that Thomas Edison

invented direct-current electricity, but Nikola Tesla dominated the market with alternating current, which fulfilled consumer needs. For this reason, innovation is always supported by a business enterprise. Invention will lose in the marketplace to innovation.

In life sciences, products that fall into the 'me-too' category, where they offer only improvement on, or a permutation of, an already existing technology, generally underperform in the marketplace, and the effort and capital put into development will not be rewarded by a favorable return on investment for investors. This is not innovation.

Lesson: have early conversations with key stakeholders (especially end users) as well as strategic partners about how your proprietary technology and products change the market and user behavior, and take proper actions to align your solution with users' needs.

5. Taking multiple shots on goal

Many CEOs are under the misconception that multiple 'shots on goal' will de-risk the technology and render the company more attractive to investors. In fact, we find the opposite to be true. Although a minority of investors would like to invest in a 'platform', it remains prudent to highlight a product in your presentation, while explaining that the platform itself could give rise to additional products. Pursuing multiple drug discovery and development programs is a risky and expensive endeavor and should be left to big pharma, unless there is a compelling investment rationale.

Once your company has completed a transaction around a lead product, bringing in additional cash and, most importantly, external validation for your platform, then it is time to develop other products. Of course, a platform technology can support multiple licensing deals simultaneously in different areas, but although this theoretically seems attractive, in our experience it is rarely practical in the real world.

An early-stage company should curtail risk by focusing, for example, on obtaining early human feasibility data that will serve to validate the technology and increase the probability of additional financing or corporate relationships. You should have a clear grasp of what it would take to corroborate and de-risk the central investment thesis, and what should be regarded as a 'nice to have' adjacency, not immediately essential for value creation.

Lesson: create a chart of all de-risking milestones and ensure all your profit-and-loss spend is directly tied to these specific activities.

6. Undercapitalization

You cannot build a house with a budget to build a basement, and, similarly, you cannot

build a successful company without a realistic perspective on the capital required to achieve milestones. It is a misconception that investors are sensitive to the amount of capital sought; we've heard this time and time again in our meetings with management teams. This misconception results in management teams often underestimating their budget and thereby taking the unnecessary risk of falling short of a milestone (with a consequent need for bridge financing). This is the last thing an investor wants to hear.

Biotech CEOs should be cognizant of the fact that, for investors, it is about risk management and value creation, not about conserving capital. In other words, most investors would much prefer to deploy more, rather than less, capital if the probability of hitting those milestones is increased. Also, the amount of capital required to achieve meaningful milestones should not be compromised for the purpose of achieving a better valuation or to protect your share position as founder CEO. In theory, a good venture capitalist (VC) could make an adjustment for management to avoid this problem. But, in reality, they rarely do, thereby creating a gross misalignment with management.

As advisors, we are agnostic about the amount of capital a company requires. We are much more interested in whether the amount raised would support value creation. If a company is able to communicate a clear value proposal, raising \$25 or \$35 million will be much easier than raising \$10 million.

Lesson: build a comprehensive budget and understand your cash flow needs for the next five years; review comparable companies' invested capital to ensure you are in a similar capital zone.

7. Selecting the wrong type of investor

We routinely observe mismatches between the type of investor and a company's capital needs, often resulting in unhealthy board composition. This happens when management indiscriminately approaches everyone. It is far better to learn about your potential investor. If, for example, you need \$100 million to open an exit window, avoid talking to small funds (\$50–100 million) that are unlikely to support your company over a long period. Try talking to investors who have interest in your particular area: if you are developing a new drug, there is no point in approaching a VC with a portfolio heavy on devices. You also want to identify what kind of operational knowledge and expertise they can bring to the table. Management's poor understanding of the venture capital cycle and the inability of venture firms to support the company through multiple rounds of financing are recurring challenges.

To manage risk, investors rarely invest in life sciences companies alone. They typically co-invest with other VCs in what's called a syndicate. Since the 2009 financial meltdown, there are fewer VCs and thus the risk of putting together a group of investors has increased. Make sure your syndicate consists of larger funds with ample 'dry powder' to support the company over the long haul. A small fund or angel group in the syndicate will not be able to commit the necessary capital and will thus be resistant to other syndicate members' investing, in an effort to avoid dilution and loss of its preference.

Lesson: review the fund cycle of potential investors and how many prior investments the fund had in your space, and ask to speak with existing portfolio companies' management as well as exited portfolio companies' management.

8. Inability to manage the board

Board dysfunction is rampant in biotech companies, because they often consist of venture firms with diverging agendas and, more often than not, directors who have little understanding of the scientific and technological challenges facing the company. In addition, few directors have operational experience and expertise in building companies. Consequently, we see time and again that boards are just as likely to drive a company to the ground as management.

A clear understanding of the various drivers and incentives at the board level is key, but most important is the simple realization that as CEO, you cannot please everybody. Difficult boards are the rule, rather than the exception. Thus, CEO requirements extend far beyond mere operational and strategic aptitude. They also require the ability to manage and navigate often opposing forces. In truth, weak management plagues biotech, and board dysfunction is prevalent. Be prepared to run into these issues.

Lesson: maintain an 'owner' frame of mind, not a 'hired CEO' frame of mind, and don't be afraid to take charge.

9. Trying to go it alone

The knowledge-intensive life sciences sector is highly complex and multidisciplinary. A life sciences company is typically at the point of convergence of various disciplines, including scientific, clinical, regulatory, financial, legal, and strategic.

Although many CEOs, particularly first-timers, may feel that it is their job to master all aspects of the company, it is unrealistic to expect such broad proficiency across all those disciplines. An effective CEO understands that his or her primary responsibilities are to craft

and communicate a viable long-term strategy and then ensure that the company is properly financed.

Management teams are wise to consult with scientific advisors, physicians, FDA experts, reimbursement specialists, industry representatives, and investment bankers, the last of which can provide invaluable early feedback on market sentiment, exit landscape, and financial parameters. Most of these functions can be outsourced, and given that is not where the company's value is, they should be outsourced. The value is in the innovation, which cannot be outsourced, as well as the execution and overall strategy.

Lesson: from the beginning, make a list of your key domain weaknesses and deficiencies, and seek out and work with the best advisors you can hire who can complement your strengths and core capabilities.

Conclusions

Companies do not operate in a vacuum and are constantly subject to evolving constraints and challenges, some of which are beyond management's control. Thus, market success comes by focusing on just that: the market.

Although management teams are typically bogged down by day-to-day operational challenges, they should nevertheless take the time to reflect on strategy. It is fundamentally important to understand the world you live in. By this, I mean that one should ask, Who lives there? Who are the dominating players (potential acquirers) already playing in your proverbial sandbox? Who are the minor players (merger potentials) looking for new strengths? All of these questions center on an outward focus for the company's leadership, and a resolution on behalf of all stakeholders to maintain a self-doubt reflection of "who thinks so beyond you and me?" Although employees, board members, and company leadership might believe they are sitting on a \$500-million company, they must find someone else with \$500 million to validate these beliefs.

The key to navigating successfully is to be aware of these driving forces, to realize they will constantly change, and to pivot and change your strategy when appropriate. The compass to guide navigation is the dual tool of a market-driven frame of mind and a clear path to liquidity. By avoiding the mistakes outlined in this article, you should have a running start and substantially increase the probability of a positive outcome to the benefit of all stakeholders.

COMPETING FINANCIAL INTERESTS

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