

MAXIMIZING INWARD INVESTMENT

Capital Efficiency
For Early-Stage
Life Sciences Companies



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Capital Efficiency for Early-Stage Life Sciences Companies

This publication focuses on the Life Sciences sector and pertains to attracting and using investor proceeds generally found in Seed to Series A / B funded companies. While companies in this universe are already incorporated, have a business plan and an investor slide deck, this guide can serve as a blueprint for operating executives that may have less familiarity with efficient methods of growing companies.

The GeneCoda® team initially brainstormed topics that we felt would interest entrepreneurs within this framework. Using these topics, we set out to broadly address what, why, when, and how questions associated with these by interviewing several experts with experience in these fields.

Topics:



1. Human capital.
2. Facilities.
3. Intellectual Property.
4. Product Development and Milestones.
5. Supply Chain.
6. Customers and Markets.

It is a given that the "build-or-buy" dilemma for company management applies to an entire range of human capital decisions. Whether it is operating positions (e.g., marketing, sales) or support positions (legal, finance, HR), timely decisions by management are critically important to potential investors of whatever stripe. This is also true when it comes to rent-or-buy facilities decisions.

Building a highly regarded, well-connected board of directors and a scientific advisory board as early as possible in the company's life cycle are crucial steps in attracting and jump-starting inward investment.

Active and continuous network building and outreach to influencers and KOL's, directly or indirectly via referrals in your company's space, can pay big dividends over time. These plans include early and intense grooming over the short and long-term of potential capital raise targets.

Company executives must be intimately familiar with many sources of capital as well as possible in-kind contributors. In addition, grant funding should always be top-of-mind for earlier-stage companies. Finally, earlier-stage companies should be well versed in how venture capital works.



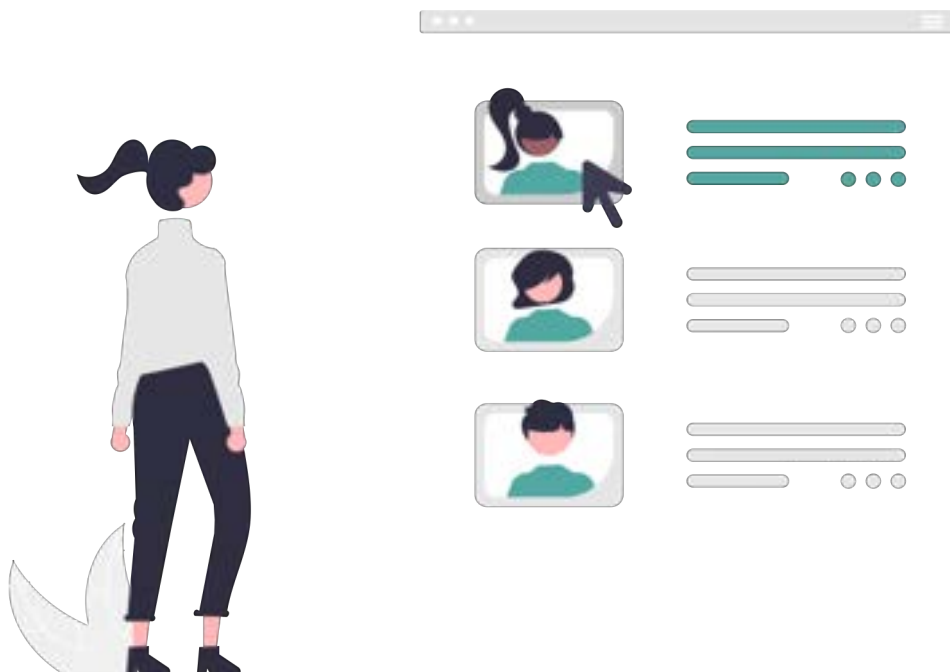
Topic I: Human Capital

Frequently, an early-stage company in the Life Sciences sector is formed through academic research that is licensed from university technology transfer offices . Early-stage activities can include articles of incorporation, patent filings, writing business plans, experiment planning, and design, grant applications, and the establishment of consulting and partnership arrangements. Companies also begin to consider advisory boards at these stages.

As early-stage companies tend to be light on cash, they often prefer to remunerate employees and others based on equity arrangements or deferred compensation post initial company formation. During this stage, companies will often pair an expert-level scientist, often a founder, with a business professional, as finding a combination of these skill sets in one person is rare. Initial team sizes may range from 2 to 10 people. Companies at this stage will likely have a small core team with expert advisers or consultants performing specific tasks.

One of the challenges for earlier-stage companies is that experienced people are expensive and may not have the right mindset for the unique startup environment. However, inexperienced people do not always know what they are doing thus requiring a balancing act between a mix of experienced people with younger, hungry, and smart people willing to take a risk on a startup. Such a balance can result in faster potential growth and responsibility than they may find in a large company construct.

As companies seek external investors, they are wise to do so based on a set of milestones to be achieved through the capital raise. Once a successful capital raise takes place and external investors are involved, company expectations are heightened. At this inflection point, further internal staff might be hired, and those involved in the company's early formation might be either replaced by or supplemented with more seasoned professionals who have "been there and done that".



Companies will have internal headcount projections (org charts) defined in their overall business plans and should contemplate how they will onboard various skill sets well before the anticipated hire date. For example, searches such as a Chief Medical Officer (CMO), can take 6-12 months from start to finish. [Contact us](#) for more information about the Life Science industry's most in-demand skill sets.

Of course, hiring internal employees is not the only solution; it is usually when milestone achievement requires both a full-time effort and extended duration that this becomes the wisest choice. For example, most companies do not hire a full-time CFO or CMO until Phase 1 or Phase 2 clinical trials are imminent.

This is often due to both the expense of these hires and the fact that fractional and consulting resources can be deployed before these stages to accomplish earlier stage milestones effectively.

Getting the team matrix correct at this early stage is especially important. In his book *Good to Great*, author Jim Collins ruminates about - First Who, Then What and getting the right people on the bus. "Those who build great organizations make sure they have the right people on the bus and the right people in the key seats before they figure out where to drive the bus."

For a comprehensive overview of the University start up world, see "[Research to Revenue – A Practical Guide to University Start-Ups](#)" by Don Rose and Cam Patterson.



Topic 2: Facilities



Early-stage companies have multiple considerations concerning lease, buy or build decisions. There are several more options within the Life Sciences sector than there were just 10 or 20 years ago. Numerous incubators and shared space options have arisen in many of the major US Life Sciences corridors that can be great facilities for locating and growing nascent companies.

In most cases, it would be prudent for early-stage companies to lease space versus buy and certainly to lease space versus building. This is particularly important in today's environment where construction and materials delays and other supply chain issues can increase lead times. It is challenging enough to get equipment in a facility that is already built out and unless a company is well established, the capital outlays can be prohibitive.

For a company that is further along the maturity curve it can make sense to build out according to specifications if the company is planning to hold on to the space for a longer time frame. This is particularly the case if the company requires a GMP manufacturing facility. Be aware that it can also be a "needle in a haystack" to locate something to buy.



As a small company, getting the attention of a large manufacturer can be difficult. You can be at risk of getting bumped in line by someone who pays more. If you slip up on your timelines, you can also pay a large penalty for booking a slot of time and wind up going to the back of the line. Because of these factors, clinical trial timelines could be significantly delayed from the contract manufacturer (CDMO).

Part of the framework may also be influenced by the company's number of pipeline programs. If the company only has one program rather than a platform, it will generally make far more sense to go with the CDMO route. Other considerations can include the backgrounds and knowledge of the executive team and whether the platform has unique characteristics to where a CDMO would also have to build or modify its existing workflows or retrofit facilities to accommodate the technology. Examples of this can be found in the gene editing field.

With lead times of 12 to 18 months, it is important to start scoping facility specifications early. If your property owner is terminating or not renewing a lease and you need to find something in 30-90 days, this is rarely practical.

It can also be extremely helpful to contact a commercial realtor who is experienced in representing life sciences companies early on to determine the costs and bake these numbers into the business plan.

Pay attention to onerous leases whose provisions are one-sided, favoring the leaseholder, and avoid too many change orders by thoughtfully planning ahead of time. It is also important that your attorney is knowledgeable about customs and terms in the specific commercial real estate market.



Topic 3: Intellectual Property (IP)



Get educated early on to fully understand what IP means to your specific business model and the importance of protecting it. Who owns it and ensures there are documents in place regarding this ownership?

What IP do you need? There are patents and trademarks but also trade secrets. You do not always need a patent, but sometimes you do, so you must understand this process. Can you maintain the technology as a trade secret, for example?

Also, there are certain requirements for patentability. Patentability questions are: is it novel, non-obvious, and useful? Generally, what companies may be doing is useful and hopefully novel because no one else is doing it. The question often becomes whether it is inventive or non-obvious. This is most often where the grey areas lie. Is it an incremental improvement over something else? The goal is to have a competitive advantage, so the patent route is not always the direction to take.

We have all heard the phrase "use it or lose it." With patents, it is disclose it **and** lose it.

With patent protection in the US, there is a 1-year grace period for disclosing technology, but in the rest of the world, there is no such grace period. Therefore, all disclosures to third parties prior to patent filing must be confidential. The patent system was built around disclosing new inventions and technologies to the public. For this disclosure, the patent owner is offered a limited monopoly on practicing the invention. If you disclose it prematurely however, you have already given it to the public and you cannot take it back. So, be careful with your disclosures!

The patent system changed about ten years ago in the US, and it is now a first-to-file system in harmonization with the rest of the world. Previously, the US operated on a first-to-invent system. In the Life Sciences, this can be a challenge as incremental developments can take place over time, so there is the question of readiness. Are you ready to file your patent in the Life Sciences? If you are, the timing of the patent filing will involve the nature of the technology and the nature of when you need to disclose it. At the same time, publication or disclosure of your invention may be important for public recognition and for inward funding purposes, so there is disclosure at this point. The same occurs with grants, so patent filings ahead of these situations are important.



It is also easier to tear down a patent than to defend one which means money spent on patent applications can be wasted. There is high value in securing patent protection, and investors and partners require it. But a crucial factor is whether the portfolio will stand up to third party challenges. IP protection facilitates a barrier to discourage other companies and gives your company lead time. But if someone wants to join the party there is a reasonable chance that they will figure out a way to do so.

Good products create value, so the best strategy is to develop products and get assets into the clinic and the market.

If your products are hugely successful in the marketplace, your company will be flush with cash to defend your patent estate or to attack other companies' potentially infringing patents.

The patent process is expensive but be careful about taking shortcuts. There are timelines that cannot be changed so you need to be strategic in the approach. For example, should our company file for a patent both within the US and outside the US? One should consider where the potential markets and partners are that could collaborate with your company outside of the US. There are often particularly good reasons to file outside the US, but this expense can be a key consideration for firms with more limited resources. In sum, think today about tomorrow.

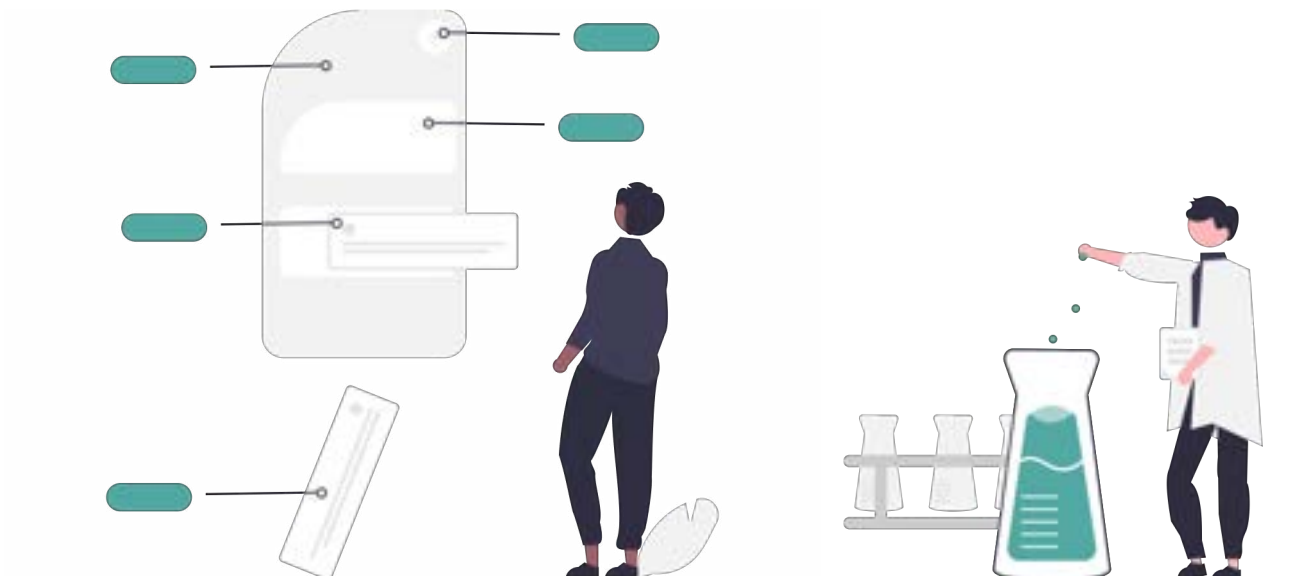


Topic 4: Product Development and Milestones



Product development and hitting major milestones are critical to a company's success in the Life Sciences industry. The industry is highly differentiated from many industries because of regulatory and quality requirements governing human (clinical) testing, GxP's, post-market surveillance, and many other government rules and regulations. For perspective, a single new drug application (NDA) can consist of over 100,000 pages so minimizing expenditures in other areas that are not needed to drive assets forward is necessary.

Development milestone disputes arise so as straightforward as it sounds, management needs to ensure that each milestone is objectively verifiable and not subjective. For example, consider a milestone for the completion of a particular study. Well, what if the study is completed but not successful? Does the milestone payment still have to be paid if the language does not specifically say "successfully completed" and how does one then define success? Being incredibly detailed and specific in the language used to define the milestone event is very important to avoid disputes that could divert focus and resources from the development work and delay future milestones.



An alternative to avoid disputes regarding development milestones is to have time-based payment milestones that are paid on certain dates (XX months after the Effective Date of the development or license agreement) rather than on development work in completing different phases. Time-based milestones can be more difficult to negotiate with the party responsible to pay the milestone (because the payor will want to pay only based on development progress), but if successful, this approach reduces the risk of milestone payment disputes.





Some scenarios can occur when two companies are collaborating on product development or perhaps a small company that is licensing an early-stage product and is still involved in some of the development. If you are the small company, you should consider a cap on how much you are willing to spend on development. Then, if you hit that cap, what happens? Do you stop and have a conversation about it? Do the future economics change? Does the other party start reimbursing you for some of those development costs?

Product development can be very unpredictable. Simply promising that you will complete these development activities without knowing what this could cost could result in you being committed to a lot more expenditure than you thought you were signing up for. This is especially true if studies must be repeated, or other development surprises arise. Many companies collaborating on product development set up a joint steering committee which is a governance body with representatives from both firms that oversees joint development efforts so that when unforeseen situations arise, they can be more effectively and quickly remediated. While a company's predisposition may be to lock other parties into contracts, management must also consider exit events.

What would make your company want to get out of this contract? Can you get out without too much pain and financial penalty? Building contractual flexibility and surrounding your company with great advisors that are knowledgeable in your specific industry is key.

If your company has a platform technology that produces multiple assets, this can enable multiple shots on goal. There is usually a dynamic tension between being more narrowly focused and building a broader product pipeline. In the case of a single asset, it is a less nuanced situation since management and investors are focused on the sole asset.

In the case of platforms, investors are concerned that management can lose focus. From an investor's perspective, they may have ten different company investments, reducing risk across the portfolio since they are not invested in a single company. In these cases, investor interests can sometimes be misaligned with management, where management would rather have backup plans B, C, and D if A does not work out. Therefore, balancing risk mitigation and portfolio management concerning the technology and resources the company has available to it becomes critical.



Topic 5: Supply Chain

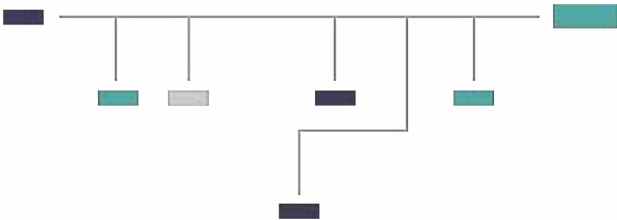


It is no surprise that challenges like COVID, spikes in demand for raw materials, economic turmoil, and war can negatively impact all companies, particularly smaller ones! Lead times as long as 14 months can be hard to plan around.

Small companies dealing with suppliers will have little leverage as bigger customers always get priority. To the extent management can have multiple suppliers of the same active pharmaceutical ingredient (API) or component, small companies should line this up and have a strategy for purchasing well in advance. In some situations, API and component suppliers will not commit to firm purchase orders or supply times and will state that they will get it to you as quickly as they can, which could be in months, not days or weeks. In a small company, someone needs to be dedicated and vigilant with respect to managing supply issues as they emerge.

Prior to 2020, companies gave minimal thought to force majeure provisions which excuse suppliers from liability for certain events (events often labelled as "acts of God" and include both natural and man-made events like fires, floods, storms, war, and labor disputes). Since March 2020, the outcome of many supply chain disputes depended on the specific wording of force majeure provisions that may have been written long before anyone had ever heard of COVID. In many cases, if the force majeure provision did not specify pandemics or epidemics, the supplier was held liable for COVID-related delays.

As a result, suppliers have since updated their force majeure provisions to define "epidemics," "pandemics," "COVID," "government shutdowns," "raw materials shortages" and "transportation delays" specifically as force majeure events, so they can avoid liability for delayed deliveries and shift that risk to their customers. While force majeure provisions are intended to relieve suppliers from liability for events that are not foreseeable and beyond their control, if they are worded too broadly, they can allow a supplier to avoid liability even for delays that the supplier could have prevented or better managed.



For example, a supplier's contract might state that COVID is a force majeure, but everyone is aware of COVID now and can plan for COVID related delays. Since we are living with it, and it is more endemic than a pandemic, the argument that COVID is still a force majeure is losing some ground. If a government shuts a supplier's plant down due to COVID, the government shutdown itself may be a force majeure, but the contract terms should not be so broad as to allow the supplier to cry "COVID" as an excuse to avoid liability for any and all delays.

Even if suppliers' contracts have broad force majeure provisions, companies should make sure that their suppliers have disaster recovery plans to deal with pandemic-related government restrictions or shutdowns, raw materials shortages, and transportation delays and that the suppliers are required to follow them.

Another supply chain issue relevant to generic medicines is that if the generic company is late in delivering products to large wholesalers and distributors, they get hit with huge "failure to supply" financial penalties

– even if the delays are caused directly by delays in their suppliers or manufacturers delivering components or products.

Suppose a generics company engages a contractor manufacturer or a component supplier that is not willing to participate in these penalties even when they deliver late. In that case, the strategy left to a generics company is to take safety stock, pre-order, and over-order what is needed so supply can be managed from inventory without getting caught short. This practice winds up in overordering, overspending, and can result in obsolete products or materials.

In summary, companies should employ multiple strategies to manage and resolve supply chain issues, including having a dedicated resource to manage orders and deliveries from redundant suppliers, negotiating force majeure and delivery terms, and keeping lines of communication with suppliers open to manage delivery timelines and delays as they occur.



Topic 6: Customers and Markets



Understanding, at least conceptually, how your product will be differentiated from what is on the market or in the pipeline is imperative. Product approval is a great milestone, but your company may fail if you do not get reimbursement or people do not use the product. Additionally, "me too" products offering only incremental benefits do not usually work out unless they are generics or biosimilars.

The two highest risks for medical technologies are reimbursement and early market development. These should be the first considerations since they are the greatest risk.

Companies in the Life Sciences have gotten much better at identifying customers, but the sales process is where many firms fail. In this regard, the SaaS / IT industry is much further ahead than the Life Sciences industry. This is often because sales cultures do not allow room for discovery first. The most common error across technology-based startup failures is premature scaling or ramping up the product development and sales effort before companies have a proven business model.



Companies selling disruptive innovation to the market should not immediately hire a VP of Sales. It is not because of the cost or expense, but rather the fact that the skill set required for early stage selling differs from growth sales. Sales at scale is an execution framework for a proven market model, so do not fall victim to premature scaling. For disruptive sales, it is a different mindset involving discovery. What is the critical concern (our technology addresses)? What is our hypothesis on how to address that issue? What is the experiment that will test this hypothesis?

Ultimately, it is not the revenue that kills a company's P&L; it is the expenses. Getting trapped in an execution mindset and doubling down to correct with new pricing, pressuring a sales team, firing leadership, and doing the same things repeatedly and expecting a different result defines insanity. Should the product be on the market? Is it addressing an unmet or poorly met need by existing market standards? If the answer to these questions is yes, the company may not have figured out a repeatable process yet. Sometimes one must slow down to speed up.



The milestone or inflection points to hiring a commercial sales team come when you have the complete sales model in place or can at least see the light at the end of the tunnel. Marketing would have flushed out who the customer is by this time. What is your target customer profile, and what are the market entry points? What is the use case and problem set you are advocating for? Then, marketing creates a lead generation engine. Do sales come through word of mouth, digital, trade shows, marketing, or a combination of these things?

Finally, if you are going to displace (or be acquired by) a major industry player, you will want to operate in stealth mode as you figure these things out. For most medical technology products that is an 18-month or longer process; in drug development it can be much longer. When you know how to solve the problem before a large rival does, you have already infected the elephant with a virus before it even knows it is sick.

GeneCoda® would like to thank the following experts for their insights and contributions to this publication.

Shawna Lemon ([Stanek Lemon Crouse + Meeks](#)); Chris Morrison ([ViaVerus](#)); Joe Nixon ([Locus Biosciences](#));

Marlene Spritzer ([Lee & Associates](#)); Jennifer Van Doren ([Morningstar Law Group](#)); Don Alexander ([GeneCoda®](#));

Barry Buzogany ([Professional Board Director](#)).



WHY WE ARE UNIQUE

At GeneCoda® we work with many Life Science firms that are looking to recruit the best new executives to their team. We understand the industry, the drivers and potential opportunities and act as an ambassador on behalf of our clients to promote their business and opportunities.

We add value to your investment team and operating companies by acting as an additional set of eyes and ears in the market for deal flow, clients and partnerships, providing you tips on hiring and other resources to assist you in successfully on boarding great talent, compensation benchmarking and white glove market reports on operating company competition, offer letter and on boarding guidance and assistance, employee guidance if a portfolio company is undergoing downsizing and partnerships and referrals to other firms and people who may serve different segments of the human capital ecosystem.

Unfortunately, the number of candidates entering the industry compared to the number of jobs available is not equal – creating a demand for talented individuals across the globe. As more companies try to find a way to pool their ideas and share resources to come up with life-changing solutions, it is clear that well informed industry investment is likely to succeed. Ultimately, the wealth of opportunities for Life Science experts is limitless, making this period incredibly exciting for employees, managers, and investors. However, it also means that recruitment experts must find innovative and exciting ways to attract new talent.

IF YOU WANT TO DISCUSS ANY ASPECT OF THIS PUBLICATION, THEN GET IN TOUCH, AND LET'S ARRANGE A CHAT!





For an initial consultation regarding your aims please do not hesitate to contact me and we can set up a no obligation conversation to ascertain your requirements.

MORE INFORMATION

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