

♦ Editorial

Entrepreneurship in Biotech

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Abstract

This editorial addresses the significant gap between initial scientific research discoveries and their successful commercialization in the biotech sector. Designed as a practical guide for research scientists, the manuscript outlines the critical preliminary steps required to transform an idea into a viable product or service. It highlights the vital role of customer discovery in distinguishing scientific novelty from genuine unmet market needs, and underscores the importance of securing intellectual property rights through tech transfer offices or legal options. Furthermore, it provides an overview of early corporate development, including the strategic distribution of founder's stock, the creation of a comprehensive development plan, and the structuring of diverse operational and business teams. Finally, the text explores funding strategies—balancing non-dilutive grants with dilutive venture capital—and emphasizes continuous market engagement alongside vital self-reflection on entrepreneurial readiness before launching a venture.

Introduction

There is a very large gap between a research discovery and commercialization of a product or service based on the idea. The journey to sell a product based on the discovery can sometimes take many years and requires help from many different people skilled in many different disciplines. How a research scientist can take the initial steps to begin to successfully accomplish this journey is the subject of this editorial.

At the beginning of this journey, the research scientist must first discover whether there is a need for a product or service based on their discovery and whether a commercialization

journey should be started or abandoned. If the idea seems promising, the researcher needs to worry about securing the ownership of the discovery and planning the first steps in organizing to develop the idea. How can the idea be efficiently developed and mistakes minimized? These issues are some of the ideas that will be explored and developed here.

A critical first step is for the researcher to understand whether there is a problem that his/her discovery can mitigate. Who is it that experiences the problem? Is it a company? What type of company? Is it a person? What type of person? Is it a government agency? Which agency? Is the problem big and important or small and unimportant? The researcher can spend lots of time and effort chasing an idea before validating that there is an important problem that his/her discovery can address.

Once it has been established that there is a suitable problem and, perhaps, the researcher's idea can address that problem, the next step is to discover if anyone cares about the problem and would value a solution to the problem.

Here is where a particular task called customer discovery can provide valuable information to the research scientist. Make some initial guesses as to who has a problem that the research idea can help with or fix. Make up a list of questions to ask potential customers on your list, call them up and get answers. If you don't know what kinds of questions to ask, then find someone who has some business experience and can help you. This step, customer discovery, is very important in helping you to begin to understand whether you should continue your journey to develop your idea.

Commercial Relevance

At this step you will be trying to distinguish scientific novelty from unmet need. What is the specific problem that your discovery addresses? Who experiences the problem? Is it manufacturers? Is it clinicians? Is it a patient with a disease? Do these people care?

Here are some questions to consider asking to assess commercial relevance:

- How many potential customers are there like you who experience the problem your idea can address (size of a potential market)?
- How important is the problem for you (I must-have a solution to this problem vs. it would be nice-to-have a solution to my problem)?
- Do you know of other products that address the problem (what is the status of possible competition which could be a risk for potential investors in your idea)?
- How likely would the potential customer adopt your solution (uniqueness and differentiation of your product idea)?

Assuming you are satisfied in assessing the commercial relevance of your product idea, the next step is to understand if there is any unique scientific discovery associated with your idea. If there is, it would be valuable to protect your idea. Then you should take steps to secure any intellectual property by means of patents or trademarks that address your idea.

At this time, you should be aware that there are many steps needed to successfully commercialize an idea, sometimes needed to be done in parallel, and therefore, many opportunities to make mistakes. This would be a good time to think about finding a friend to join and help you or to be introduced to someone who can help you develop your idea. This

helper should be someone with experience working at a startup or early-stage company and taking it through the stages needed to commercialize an idea into a product. A helper such as this can assist you to efficiently develop your idea and to avoid mistakes that can slow you down or sink your plan. We'll need to discuss later the issue of compensation of others who might need to assist you on the path to commercialization.

Protecting Intellectual Property

If you work at a university or government-funded laboratory where you discover your idea, the invention is probably owned by the university or government agency where you work. This is because you have used their resources for your discovery. In this case, your work location will probably have a tech transfer office where you can arrange an option, a written contract to acquire a license, exclusive or non-exclusive, to use your idea in a commercial effort.

The license is a legal agreement from the owner of an idea that permits you to develop the idea and eventually sell a resulting product or service to others. If your work location does not have a tech transfer office, you could negotiate to receive a license with an executive of your work company.

An option that you receive could require an up-front payment from you to them and future payments that could be negotiated later. You will probably need legal help to secure a proper option agreement. If your idea fits into the biotech world, then patent protection of your idea will be very important.

You might also need some money at this point to pay for the protection you are purchasing or for advice from a lawyer, so we should discuss some preliminary steps you can consider in order to obtain funds to pay for intellectual property protection and other corporate development needs.

Preparing for Preliminary Funding for Your Idea

You need to form a proper company at this point. You will require legal help for this step from a so-called corporate attorney who is experienced in legal matters associated with corporate development and is familiar with the local business laws.

This company is a legal entity that will enable you to attract investors needed to help fund your idea. In exchange for investment in your idea, investors will want a way to participate financially if the commercialization is successful. This is usually done by offering stock (partial ownership) in a company that becomes owner and developer of your idea.

Why did I say that the company becomes the owner of your idea? Well, if you want to attract investors to provide funds to develop your idea, these investors will want protection against certain risks as you develop your idea. The investors can get this protection by stock ownership in your company and having your company "own" the technology.

How does ownership in your company look at this stage? First, you as an inventor receive stock when the company is started, called "Founder's stock." As the company is started, you should also decide if you need help from others with skills you need to commercialize your ideas. If there is an important person or persons who are willing and able to help you develop your idea, you can compensate them with some additional amount of Founder's stock proportional to the input help expected of them.

Awards of Founder's stock are important and, if not done well, can lead to problems among the founders. Get help from your experienced helper, the one we discussed that you should find earlier and need to trust, at this point.

Building a Development Plan

At this point, you will need to develop a business plan to move from proof-of-concept (should you attempt to commercialize your idea) to proof-of-value. Investors in your opportunity will look for this proof-of-value.

It would be very useful to write a short plan that can be shared with anyone helping you so you can get their support and feedback. Having a written version can also help you formulate your ideas into a form that can be shared with potential investors and future helpers.

Investors will need to understand what you are proposing and the benefits and risks they take when investing in your opportunity. A suggestion here is that you should try to find friends who will agree to show you some successful plans so you can see what the plans look like.

Your plan should at least contain the following sections:

- The problem your discovery addresses.
- Your solution to mitigating the problem. Is it a product or service? Who uses it and how is it used?
- Who are your key team helpers? What are their roles in your company?
- Who are your potential customers and why will they beat a path to your door?
- Any competition with similar products or products that address the problem you have identified. Your differentiation.
- Commercial expectations such as revenue or customer acquisition numbers.
- History and future expected milestones you will achieve.
- Operational plan and cost.
- Exit plan that explains how your investors make money.

Assembling a Team

You will need to assemble a team to help develop your idea and make your product development and commercialization successful. If there are technology problems to be solved, as there always are, then you will need a technology team equipped to help you.

I have found that a mixed team of technologists with different cultures, different education and training, and different ways of viewing a problem can help with addressing difficult technical problems.

You also will need someone to lead a business-oriented team to help steer your product development that turns an idea into something useful that can be sold to users.

If it is a biological product, you will need regulatory help since there are many rules and procedures that you will need to follow if your product requires FDA approval. If it is a manufactured product, you will need to decide if your company will manufacture the product or outsource construction to another company.

A new issue to consider here is tariffs, which could depend on where the product is made and where it is sold. Software products will need yet another type of team. Recently AI (artificial intelligence) has been developed into a useful tool for coding (writing instructions for software to follow), so you might want to consider adding AI expertise to your team if your product requires software development.

Securing Funding for Your Venture

You will want to consider securing non-dilutive or dilutive funding for your company. Non-dilutive funding can consist of grants to your company from governments, foundations, or non-profits that do not receive stock in your company in exchange for the grant. This will make your current and future stockholders happy since they gain or keep more ownership in your idea.

On the other hand, dilutive financing, where you exchange stock in your company for financing, can come from angel investors or venture capital firms. If you receive dilutive financing, then you will exchange stock in your company for the value of the investments you receive, and the investors then will become part-owners of your company.

Generally, you will be unsuccessful in raising finances until you can very clearly articulate your need for financing and your vision for the development of your product. This can take the form of a so-called “pitch deck,” which is a series of slides that reflect your vision and plan to commercialize your product.

Talk to Your Market

You should talk to potential customers even as your product is being developed. New discoveries might necessitate changing your product development plan. You would need to find customers willing to test your product and provide feedback to you. Some potential customers could become paying customers in the future.

I have found that sometimes, talking to customers leads to introductions that can become strategic collaborations that can help you develop better products or help with selling your products.

The End of The Beginning

So far, we have discussed the beginning steps that a researcher in a biological field can take to start to turn their idea into a product or service that can be sold to users. I have tried to focus on the most important beginning steps. There are many other considerations that could fill a book, but we will leave the discussion at this point, except to consider some important questions to ask oneself before starting the journey.

The emphasis on continuous engagement with the market is a strong and appropriate concluding theme. By synthesizing the core insights of this manuscript—from initial customer discovery and intellectual property protection to securing strategic funding and building a diverse team—it becomes clear that bridging the gap between research and commercialization

is as much about adaptable business execution as it is about scientific innovation. Cultivating this market-driven mindset ensures that groundbreaking discoveries successfully transition from the laboratory bench to real-world applications where they can truly make an impact.

The reflective questions at the end are thoughtful and encourage readers to critically assess their own readiness. Before embarking on this transformative path, every research scientist should carefully consider these fundamental questions:

Questions a Researcher Should Answer Before Starting a Company

1. Do I really want to leave my research position and become an entrepreneur?
2. Do I have obligations that would interfere with my time commitment to a company?
3. Are there any "red flags" that could kill my biotech startup early?