

Should I found a spin-off?

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Taking the plunge into entrepreneurship is always a leap of faith. On the one hand, developing a new medical product is risky. On the other hand, not implementing scientific discoveries is tragic for patients and society. The choice is yours. Nobody can tell you if your project will succeed. While there are some general principles and best practices, there is no guarantee. Before you decide to give it all you've got or throw in the towel, ask yourself some uncomfortable questions.

Is a spin-off your best option?

A spin-off company is not the only path forward. Licensing may be a promising, reliable and straightforward way to help your discovery reach the market. This will relieve you of the burden of founding and funding a spin-off, negotiating with the technology transfer office (TTO), risking your money, and forgoing career options. You will be rewarded if the licensee is successful.

If your discovery is not “stand-alone” or there is a clear synergy with a company's technology, licensing may be the only way. This can be the case for a slight, yet meaningful, improvement in an existing device or for the development of a single new molecular entity in the absence of a technology platform. In this case, engage your TTO but do not rely on them exclusively to find a licensee. You are in the best position to identify that partner and you need to be proactive: a passive display of your project on an “academic technology on offer” website will likely not garner much interest. In summary, licensing should be considered in all cases, and not just a last resort when a spin-off has failed to launch.



Even if you are convinced that your project may be better off licensed to industry, you will repeatedly hear that your technology is too “early-stage” – a polite way of calling it immature. Investors, however “early” they claim to be, will say the same thing. This may be frustrating to hear after years, sometimes decades, of working on the technology. In this case,

and in all cases where a stand-alone project is promising (e.g. where you have a platform technology and a first clinical lead), the spin-off may indeed be your best path to success.

That said, if your science is solid and you are not cut out to be an entrepreneur, you could approach early-stage investors with “Entrepreneur in Residence” programs (which may have different names). They provide funding and a team (at least a CEO) to develop promising projects. You may be able to participate as a scientific advisor or, depending on the setup, as a member of the team.

Box 1: Is going “non-profit” an option or a delusion?

You may be struggling to find a sufficient potentially addressable market. Or patent your discovery. Or find funding for your PoC. But the unmet medical need is substantial and you are convinced that your product and your development plan make sense. You may consider taking the non-profit route, likely with the help of patient advocates.

Before you raise the hopes of patients, consider that your product will need to be sustainable when on the market. While you may find funds for early non-profit development, market entry and patient access are becoming limiting steps even for commercial projects, with tragic consequences for patients. A solid plan all the way to patient access is indispensable. You owe this to both patients (who will likely help you raise funds) and donors (who want to invest in projects that will result in a sustainable benefit to patients).

Is the timing right?

Confidence in your science is the basis, but it is not sufficient to take your leap. In general, we would advise that you spin off only if and when the following points are true:

1. You are convinced of your science and your (in vivo) proof-of-concept

Your science is solid. Ideally, the backbone of your discovery has been accepted in a high-ranked journal (after protecting IP), adding external validation. You have proof-of-concept (PoC) experiments (e.g. animal models, human samples) that convince you that your product works or has a credible chance of working (the need to convince others will arise soon but you have to be convinced first).

2. Your IP situation is favorable

You have filed patent applications (or rather the TTO has filed them in your name) and the first feedback is

encouraging both on patentability and freedom to operate (e.g. European Search Report (ESR), feedback from IP lawyer, Institute of Intellectual Property search, freedom to operate search). Discussions with your TTO are likely to lead to a licensing agreement.

3. Your addressable market has credible potential

There is a reasonable addressable market for your product in the targeted indication, now or expected in the future. And your product addresses a high unmet (medical) need.

4. You have identified your hands-on champion

You have identified a project leader who is or will be dedicated to this project 100%. This person may be you (you have or are about to quit your current job) or you have hired someone (and you can pay this person an adequate salary). This person will advance the project at a fast enough pace to receive funding. They may or may not be the future CEO, CSO, or COO. They have to be fully dedicated and engaged though.

The absence of any of these four points should raise a red flag and cause you to pause and address these issues before you move further. Anything else that may be keeping you up at night (regulatory issues, CMC, etc.) may be less of a reason to worry, as these issues can be addressed with proper advise and operations.

Box 2: Lack of funding: cause or symptom?

Many would say that funding is a critical step and even a go - no go criterion: while needed, it is not a decision criterion. Rather, it is a facilitator and sometime revelatory. Think twice if you cannot get money you “should” be getting: is the problem your project or the way you communicate? Is your data not as convincing as you think? Is the project still too immature?

On the other hand, do not go ahead with founding a spin-off merely because you have funding (and by all means do not “buy yourself a job” via the spin-off).

Disclaimer

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