

Is your start-up ready to fundraise?

Make sure you are standing on four solid pillars: evidence, potential, team, and IP

By Roch Ogier and Saskia Karg

With the participation of Karim Maizar (Startup Desk, Kellerhals Carrard)

As you prepare for your first fundraising journey, take a step back, and look at your start-up through an investor's lens. You may be very proud of your product development so far, but do you have a solid base to build on from the investor's perspective? Read on to make sure you tick all of the investors' essential boxes. If your fundraising is stalling, check your four pillars and make your story more compelling. Many founders complain about early fundraising difficulties but often pitch as a one-(wo)man show or without a solid proof-of-concept.

Remember that you are selling a future product, not a technology, and that the decision to fund your spin-off is made by an investor, not an end-customer or a government. While investors may be impressed by your technology and would love to see it help patients, they will not give you money without sufficient revenue potential and a plausible route to market for your product.

Scientific evidence

Sufficient reason to believe it can work

You must have convincing data. Evidence that convinces yourself (the reason you incorporated in the first place) may be insufficient. It needs to persuade others, particularly investors and may be significantly different from what you needed to publish in peer-reviewed journals. For example, a deep mechanistic understanding may be desired for publications but of low importance to investors. Similarly, a further improvement in your methods may increase your comfort, but not that of investors.

You need to show evidence that the way your future product works will be relevant in the real world. Your product does something. This is often undebated (and was published in peer-reviewed journals or as a thesis). But will this translate into a relevant benefit for patients? Your future product should address a concrete problem considering current developments in the field you are targeting and the competition. While you often cannot access competitor products currently under development to make head-to-head comparisons, you can research what failed in your area and at which stage.

Your animal proof-of-concept for efficacy (when applicable) must be challenging and, therefore, relevant enough. Many discoveries translate poorly from animals to humans. Consequently, it is imperative to show a substantial and reproducible effect in animals in a model that is as close as possible to the real-world

human setting. Investors have seen thousands of compounds working in mice but not humans; this may be unpreventable but means that your animal data has to have a "wow" effect.

Ideally, you should show some hints or evidence that your therapy will work in humans. Nobody can predict with certainty how the effect will translate to humans, but you need to give it your best effort. Compare how similar products have shown signs of efficacy in humans, even if not in the same indication, use, or product type, and explain why you believe your product will do better. If it is a real first-in-class product, try to have meaningful data on human cells, tissues, organoids, etc.



Talk to investors and other people in your network early to gauge if they consider your data "relevant for the real world". Only very few people are likely to tell you "must do this additional experiment in this model", but the combined feedback will help you decide what steps to take. If you have the possibility, you may choose to conduct more experiments in the academic setting to have a data set to raise a more substantial round instead of the smaller round you may get with your current data. However, beware of wasting time on further experiments of academic interest that are of no relevance to investors.

Product potential

Return on investment will be significant if your product works

You must demonstrate an attractive return on investment if your product reaches the market. However high the unmet medical need, there must be a current or future credible market. A CHF 50 million market may seem substantial to you, but investors would prefer a market size of CHF 1 billion or more. Many of their investments will fail, and the ones that succeed need to bring a

considerable return on investment in order to offset failures and generate a significant return on investment for their own investors.

If the unmet need and the market size is undisputed (as for many cancers) and the route to market, even if inherently failure-prone, is relatively standard, your market analysis can be quite rudimentary. Investors will know the potential well. But sometimes, the market size (e.g. in rare diseases), the access, pricing, and reimbursement (e.g. for new cell therapies), or the route to market (e.g. health apps) are less obvious, and you need to consider them carefully. Be specific about numbers and assumptions. You can often only guess. It is fair to make assumptions, but document what you base them on (publications, websites, patient or KOL statements, your own experience, etc.) and review them when new information becomes available.

Suppose the market is small in your current indication. In that case, you must be able to argue why you will have a dominant market share, why your margin will be high, or how you can apply your technology to other areas with additional sales potential in the future. It is sad but true that a small or difficult market, be it in rare, neglected, or infectious diseases, may make it almost impossible to raise funds via the standard investor path. A limited market should make you consider early licensing or a partnership with a company that could add your innovation to an existing portfolio and consequently decrease development and marketing costs.

If you have a platform technology, many applications or indications can be considered and the market is often huge, at least in theory. But do not scare off investors by suggesting you will address too many options too early. This can show a lack of focus. The promise of value linked to platform technologies is often challenged by investors. They primarily want to see the start-up focus on a first indication and bring it closer to market before potentially wasting too much capital in other indications. For founders, this means that while platform technologies can be very promising, you should be careful in placing too much value on them in the early stages.

Team

You have the right team to make it work as planned

Everyone tells investors that they "have a great team". Of course, you are great. But do you have what it takes to inspire investors' trust? Looking at global competition, how good is your team compared to others working on similar technology, at the same level of development, and with the same ambition?

First and foremost, avoid being alone. A one-(wo)man-show is often a red flag for investors and rightly so. It is nearly impossible to run the show alone, both in terms of activities and because you cannot share decisions, failures, and successes with someone who also has skin in the game. Furthermore, if you are the only one steering the company, investors bear a great risk in case something happens to you (illness, accident, or even death). Note that a single founder with a panoply of consultants and CROs does not constitute a team. Consultants will suggest options but will not share the decisions and their consequences with you. If you are currently on your own, consider delaying incorporation or, if

you are already past that point, be ready to at least demonstrate that you have some people lined up with a clear and concrete plan to join the start-up. Saying you will recruit partners once you have money is often simply insufficient.

When looking for a partner or co-founder, most scientists will look for a "business person". Remember that an MBA and a leadership function in a large pharma company does not make someone a hands-on expert in start-ups. Some former executives join a start-up and are surprised that there is no staff to book their flight or do their expense reports. Instead, you may want to look for people who "have been there" and who will roll up their sleeves and get down into the trenches with you. They have enough skin in the game to take some risk before the company is fully funded. If a co-founder with a solid background officially joins your spin-off (even at a low percentage) before fundraising, this is a strong signal. Investors will expect this person to have done their due diligence and have evaluated the chances of success. Be ambitious in recruiting. You may underestimate the willingness of senior people to join a start-up.

Once you have a partner or team, proactively work on your relationship. Address potential conflicts. Do not allow frustration to build. Co-founder conflict is prevalent and may derail your venture. You do not have to be friends, but you have to invest in your relationship continuously. Both your sanity and your success may well depend on it. If "something is not right" within a team, an empathic investor will pick up on it, and it will damage their trust in you.

When choosing professional services to complement your team, specifically look for experience with spin-offs. For example, a law firm used to working with spin-offs will work more efficiently (e.g. negotiating with the TTO) and may facilitate access to its network of investors and other founders.

Intellectual property and freedom to operate

Competitors will not get in your way (too much)

Every investor will want to know more about your intellectual property (IP) situation and your IP strategy: which patent applications have you filed and plan to file, how likely is it that you will get your patents granted, what do the search reports say, how broad is the protection expected to be, how easily can a competitor circumvent it, or how enforceable it is. As you have no sales, customers, products, and a limited team at this stage, remember that IP is often your only somehow tangible asset. In most cases your initial IP will be licensed from your university. It is therefore imperative that you know the commercial cornerstones of the license terms (e.g. exclusivity, field/scope, royalties, sublicense fees, main due diligence items) as investors may ask questions about this before entering a formal due diligence.

Many scientists feel confident about their IP. Some investors, especially in the early rounds and before doing due diligence, are happy with you saying: "of course we have a patent". However, it is not so much about having a patent but rather about how relevant the patent is to protect your future development. For example, even a "very strong" patent covering a feature of your technology that is not essential to the future product or can be easily circumvented is not helpful. On the other hand, not having

IP yet may not represent a red flag (on the contrary) if you explain it well: there may be good strategic reasons to delay IP filing, and expert investors will understand them.

Box1: The proof is in the documentation

Inspire investors' trust by having all your company documents ready and documenting your R&D professionally. Save yourself a lot of pain by engaging a start-up lawyer specifically with experience with spin-offs, communicate openly with them, and then trust what they propose. You do not need to understand every detail of the legalese in every document, but you have to have professional documents to present to potential investors.

Now is also the time to ensure that your R&D activities are adequately documented. Documentation is essential for IP, regulatory, and due diligence processes.

You do not need to have a final version of all these documents, but neither do you want to compile them only upon investor requests, risking delays in answering them. We will discuss most of these documents in detail in upcoming articles.

Company documentation

- ✓ Articles of incorporation
- ✓ Capitalization table
- ✓ Shareholders' agreement
- ✓ Organizational rules
- ✓ Financials/cash flow statement

Round documentation

- ✓ Non-disclosure agreements (NDA), confidential disclosure agreements (CDA)
- ✓ Term sheets
- ✓ Data room

R&D documentation

- ✓ Lab books
- ✓ Quality Management System (QMS)
- ✓ Reports from contractors such as CROs, CMOs, etc.

IP documentation

- ✓ Filed IP
- ✓ International/European search report
- ✓ License agreements (e.g. with universities)

Investors will care about your invention's patentability and the patent's relevance in a competitive market situation. Be transparent about what you know (e.g. that a piece of prior art has surfaced that may be damaging or not, depending on the examiners' interpretation). Acknowledge what you do not know yet (e.g. if the academic group that just surprisingly presented a poster in your field filed any IP and could have a priority date before yours). Investors need to be able to trust you to be vigilant and proactive regarding your IP.

In addition to patentability, a lack of freedom to operate (FTO) can trip you up. As you have gone from "for research purposes only" to commercial use, you have to ensure that you do not

infringe on other people's patents. You may rely on parts, methods, or technologies patented by others to produce your product or make it work. You could need licenses from third parties whose patents you are infringing on. There is no "one size fits all" advice about how formal (e.g. from a renowned IP law firm) or comprehensive your FTO search needs to be at this stage. The granularity you need to show investors depends on your project. What every investor wants to see, though, is your awareness and vigilance regarding FTO. An FTO report done by an external expert could be helpful but will often not be requested by investors at this stage.

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