

Entrepreneurial outreach

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Starting and sustaining a business in the life sciences is not for the faint of heart. And in an increasingly complex business environment, biotech entrepreneurs should look for complementary partners and new business opportunities to effectively build their companies.

In 2004, the Larta Institute in Los Angeles was selected by the National Institutes of Health (NIH; Bethesda, Maryland) to run its Commercialization Assistance Program (CAP), which is designed to introduce companies receiving Small Business Innovation Research (SBIR) grants to the realities of the marketplace. These companies are educated on the need to find partners, raise money and navigate a complex web of interactions necessary to ensure success. Companies in the CAP—all small businesses—are drawn from multiple sectors: from biotech to specialty pharma and from diagnostics and devices to healthcare solutions.

In my time as CEO of Larta, I have had the opportunity to work with more than 400 entrepreneurs under the CAP program over the past 4 years. And if there is one key take-home message from this experience, it is that although the road to success and sustainability, especially in the life sciences, is a long and unpredictable one, the increasing ease of finding partners can make the trip easier than it used to be.

Entrepreneurs: nature or nurture?

Entrepreneurs are often celebrated—and sometimes isolated—for possessing qualities that set them apart from the communal experience: single-mindedness, persistence, aloneness. But it is clear that entrepreneurs also have a capacity for optimism even in the presence of contrary evidence.

Larta Institute, which I founded in 1993, cut its teeth on the notion that entrepreneurship is an acquired discipline: in other words, it can be taught. Through working with thousands of scientist-entrepreneurs emerging from universities and labs, the Larta team has decided that

entrepreneurship, far from being a lonely endeavor, is a highly social one that requires interacting far outside the entrepreneur's circle. Furthermore, we also understand that the step-by-step approach to building a business must be tempered to suit the dynamic environment in which those businesses are being built.

Good advice for entrepreneurs sounds like this: supplement your know-how with 'know-who'. An invention may succeed, but it succeeds only to the extent that it brings others into its fold to shape and form the details—and sometimes even the outlines—of the original inspiration.

The role of CAP

In the NIH-CAP (**Box 1**), there have been some remarkable examples of entrepreneurs who have aligned the joy of research with the expansion of their companies' prospects into the world beyond. One of the companies we are currently assisting in the 2007–2008 CAP is Molecular Design International (MDI) in Memphis, Tennessee. Its business model is discovering small-molecule therapies and out-licensing them to larger companies for development and commercialization. That approach allows MDI to create innovative treatments for various conditions in a cost-effective manner while also benefiting from commercialization through milestone and royalty-bearing agreements. The company has drug candidates in the pipeline for obesity, diabetes and wound healing, and in the past it has out-licensed products to Johnson & Johnson, of New Brunswick, New Jersey; Eli Lilly in Indianapolis; and GlaxoSmithKline in London.

As an entrepreneur, your first obligation is to understand the structure of the life sciences industry. If you are going to be part of it, you need to know what makes your industry tick. Beyond having a general understanding of the

industry, it's important to know who is doing what, how they are doing it and how well they are doing it in your sector. Another responsibility is to know the life cycle of products and services provided by that industry. How a product begins its journey in the market, what current solution it displaces, who uses it, what are the risks of its being displaced in turn, how that might happen—these are all questions and considerations that allow you to anticipate issues and build them into your strategy and your business model. Becoming knowledgeable about these issues will allow you to plan your entrance better, but it will also allow you to articulate this strategy to potential investors and help you align your objectives with those of potential partners.

In the CAP, the Larta team explores these issues in the Commercialization Training Workshop (CTW), which launches the ten-month CAP in October each year. We start with the CTW in order to align the entrepreneurs with the realities of their industry sector. Through interactive panels comprising past CAP entrepreneurs, fireside chats with industry figures and panel sessions on various topics of general interest (regardless of sector), we tease out the issues facing businesses, because these issues matter so much to the orientation of the entrepreneur. The intention is for them to make the transition from working on a 'project' to working on an 'enterprise'. Vivo Biosciences, of Birmingham, Alabama, a past CAP company, had an SBIR grant (**Box 2**) to develop their preclinical assay. In the course of the program, Vivo began to focus on testing drug candidates for the platform while developing a pitch for the commercial market. A venture capital firm associated with the program showed some interest in the assay's prospects and invested; thus, the firm went from a project to an enterprise in a few short months.

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Exploit today's economy, pharma's troubles

Inevitably, in any sector of the industry, you will see concentrations along the chain: large companies, often aggregators and integrators, with mass consumer businesses, entrenched positions, strong internal inertia and long cycles from innovation to product. These large companies are also marked by sales channels that are highly developed, mostly 'vertically integrated' (meaning that they are associated with specific sets of products) and embedded in the front line of medicine: physicians and consumers. In addition, they have long histories, both positive and negative, with regulatory and reimbursement regimes. For a small company, this landscape looks daunting.

But think again. With patent expirations, competition from generics, dwindling pipelines, long development cycles and spectacular late-stage failures, there is growing recognition from the pharma industry that innovations created outside a company may prove to be as important as those created internally. One large company that exemplifies this approach is Procter & Gamble (P&G) in Cincinnati; its pharma division has declared 'open innovation' as its preferred path. The company has partnered with Larta Institute through CAP to look at innovations being proposed by emerging companies. The association is recent, so I can't yet gauge how successful it will be, but it should be noted that P&G has considerable interest in emerging

innovation in its core areas of women's health and musculoskeletal conditions, and in other areas such as incontinence and fibromyalgia. CAP companies seeking alliances with the likes of P&G should know the large pharma's areas of interest and be ready to provide a solution to a specific problem and to provide clinical data. In the past two years, early-stage companies in CAP are seeing greater interest from larger companies in the pharma and device areas.

What this means for an entrepreneur is that today, more than ever before, there are increasing opportunities for partnering with big companies. And these larger firms can provide vital experience in preclinical testing, navigating the regulatory process, inserting new products into a pipeline, liaising with payors and distributing the product to the market.

But before partnering, you must get your ducks in a row. A competitive analysis of your space is vital, because in order to be responsive to the new global 'connectedness,' you must understand what others are doing. In achieving this, however, many entrepreneurs fall into a fatal trap of their own making: they inevitably describe their companies or innovations with such specificity that it becomes easy for them to dismiss competition as not being important because 'they don't do what we do.' You will need to assess competition in the global marketplace in terms of entities that are in the same area of interest even if they don't have your approach. Also, indirect competition is guaranteed: what

the marketplace is doing, the current state of the art and just the inertia built up in the market are all competition for your great new innovation. In other words, the marketplace is not going to beat a path to your door; it deals with what it has, and the current solutions have probably developed traction, are certainly more entrenched than you are and have been adopted by users. Be flexible, adaptive, aware and generous about the competitive landscape—your instinctive dismissiveness may really just be defensiveness, and that is the one sure way to turn off a potential partner (or an investor, for that matter).

Global presence, right from the start

Today, the Internet serves as the principal competitive research tool; its global reach and speed ensures that it reflects developments in the entire world more thoroughly than any other tool. Many programs and information feeds on the Internet can be customized to your needs. Researchandmarkets.com is an excellent source and programmer of biotech-related feeds. Also, competitive intelligence derived from practical case studies in areas of considerable global interest is available from Knowledge@Wharton and the Massachusetts Institute of Technology's Opencourseware, which provides information on trends and developments in the field. An Internet search will find you both of these sites.

The competitive analysis you'll need should encompass far-ranging places such as Oulu, Finland, and Mumbai, India. Going global helps create scale and reach by allowing you to partner with other nimble entrepreneurial firms and find the push-pull points for each of you—that is, determining your objectives and those of your partner (push) and finding what each of you needs (pull). One of the most important things for young companies to do is to become educated on the cultural context for the use of certain products in foreign countries. They should also gain experience interacting with local consumer and end-user culture and understand the use of certain words (especially in the branding, naming and even descriptions of products) because although they may be harmless in our culture, they could be offensive or inappropriate in another. Being culturally sensitive and also understanding the environment in other countries is part of the new complex of global skills that you must cultivate.

The fact is that there are many more options relating to partnerships and market penetration now than there were in the past. It used to be that the dream of the life science entrepreneur was to be acquired by a giant. Today, despite the increase in the cost of compliance and regulation (especially in the

Box 1 What is CAP?

The Commercialization Assistance Program (CAP) is designed to help some of the nation's most promising small life science and healthcare companies develop their commercial businesses and transition their SBIR-funded technologies into the marketplace. The ten-month program is customized to meet the needs of early-stage or advanced companies and is comprised of training and informational workshops, mentoring and consulting sessions, and public events in which companies present their technologies to the biomedical, biotechnology and healthcare investment communities, as well as to industry and professional service communities.

By the program's end, each participant has developed a 'Management Toolkit' that includes materials that are useful for implementing its commercialization plan both during and after the program ends. Although it is customized for each company's needs, the toolkit may include any of the following components:

Road show presentation: a short PowerPoint presentation to pitch the company to potential investors, strategic partners or licensees.

Business case presentation: a comprehensive, in-depth PowerPoint presentation of the company's intellectual property, technology, product or service, value proposition, customer base, financials, management team and other important features of the company.

Virtual showcase materials: a virtual online showcase that will be set up to market the business opportunities and technologies of all CAP participants.

Strategic action plan: a list of strategic tasks and milestones for the company, created at the end of the program, with a timeline looking forward for the next 18 months.

Source: Larta Institute

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pharma area), the world truly is your oyster, because nearly every country has aspirations to become a hub for the life sciences. Many have invested considerable sums in developing their infrastructure (including investment programs, regulatory regimes, incubators close to universities, wet labs and Class A facilities). Emerging life sciences entrepreneurs need to look beyond their comfort zone and search for those opportunities to collaborate with entrepreneurs from around the world in virtual arrangements, without the need to dilute their stakes.

There are also opportunities to make your expertise available to countries in which the pursuit of excellence is every bit as compelling as the traditional biotech markets. (Think Singapore, Finland, Brazil, India, mainland China and Hong Kong.) You may decide to locate or start, with the help of friendly universities and life sciences organizations, an operation that allows you to tap into some fundamentally important skills and other attributes, such as market access, that are present in those countries. What is more, many of them believe in the power of smaller companies and have fervently embraced policies to grow their small- and medium-sized enterprises. For a budding entrepreneur in the life sciences, doing market research does not involve researching possible paths to success only in the limited geography of the country in which you are located.

Time to take the plunge

Consider the following: if you were set on a path to build your business in a typical linear fashion, you would first identify the 'sweet spot' in the industry, where there is as close to a perfect fit for your business as is possible. Then you would assemble the team and build it out gradually, staying consistent with the milestones you have set, the money you can raise, the trials you can perform and the successes you can achieve.

Instead, I suggest that you should first understand the core intellectual assets you have—this will translate later into intellectual property (IP). In a time when there is continuing convergence both in the sciences and between separate life science sectors, your innovation may have an impact that is broader than you could have imagined. This is not to encourage you to embark on a path of wishful thinking, but just to ensure that you are thinking globally. Next, investigate all the potential applications that are already being developed and glean, both by intuition and by scanning such sites as freshpatent.com, what IP has been filed in this area. This will give you a good place to position yourself. By now, you should have

Box 2 Money from the government

The Small Business Innovation Research (SBIR) program helps domestic small businesses engage in research and development (R&D) that has potential for commercialization. Currently, 11 federal agencies participate in the SBIR program. Since its inception in 1982, more than \$12 billion has been awarded to various small businesses. The program is structured in three phases:

Phase 1: Here, the objective is to establish the technical merit, feasibility and potential for commercialization of the proposed R&D efforts and to determine the quality of performance of the awardee before providing further support in phase 2. The award normally does not exceed \$100,000.

Phase 2: The objective is to continue the R&D efforts initiated in phase 1. Funding is based on the results achieved in phase 1 and on the scientific and technical merit and commercial potential of the project proposed in phase 2. Only phase 1 awardees are eligible for a phase 2 award, and it usually does not exceed \$750,000.

Phase 3: The objective is for the small business to pursue, with non-SBIR funds, the commercialization objectives resulting from the phase 1 and 2 research and R&D activities.

Source: NIH Office of Extramural Research

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already sketched out a team of folks drawn from various areas of expertise (functional as well as technological). There are a number of things here to be looked at, too involved to get into in this article, but suffice it to say that your process of 'socialization' has begun.

Conclusions

So what do you do, armed with this knowledge? First, you need to be relatively clear on answering certain questions that every entrepreneur needs to consider: what do you intend to produce? How do you intend to market it? Do you think you can go it alone, based on the information you have gathered about the industry? The answer to that last question is increasingly 'no', unless you have a product that is highly disruptive and distinct from anything the current incumbents are familiar with or is outside their interest area. Whatever the answer, though, you will have to understand and focus on your IP, on the implications of your innovation on both regulatory and reimbursement issues, on a realistic evaluation of your markets and on your exit options (what is the 'end game' for your company?).

Think through the implications of your answers. If, as I am wont to suggest, you should consider partnerships (remember the exhortation to socialize your invention to others so that you can get it out to the world), find answers for the following questions: what can partners do for you, apart from having deep pockets (which they are loathe to reach into)? What can you do for them that they cannot achieve themselves? What is the current state of the art that frames current practice in your chosen sector? How would you change that game? Do you fit into a potential partner's 'sweet spot'? What is that company currently doing in those areas? What

initiatives does it have internally? What products has it launched? What are the known results? Is your product or service merely an add-on, easily achieved by them internally, or is this truly a new product?

When you approach a potential partner, develop a pitch that is oriented to its business, and have a scientific presentation available as well (the company will do a full-court technical diligence once the business case is better established). Attempt to find an internal champion for your proposition, keeping an eye out for personnel turnover. Know also that you are not likely to be a significant priority among the numerous internal and external issues the company faces, so establish clear milestones and timelines and revisit them often with the nominated team.

The fact is that the disruption of standard supply and value chains by the new 'connectedness' has created multiple paths to the market for emerging life sciences entrepreneurs. We are discovering this in the CAP itself. The normal process of building a business for the purpose of being a stand-alone company, and struggling through a mature and difficult marketplace, is no longer the only path to success. The new realities allow companies to choose multiple paths for multiple purposes—licensing, forming partnerships, marketing, selling—depending on the breadth of their innovation and on leveraging ('arbitraging') the differences now clearly visible in many parts of the world. Considering your innovation as less narrow (even though it drives many market pundits, investors and others crazy because 'focus' is the name of the game), but choosing to extend it out in many ways, and choosing to do only one thing yourself, is a more responsive strategy for the age in which we live. 