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Tapping into foundations

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Charitable foundations are increasingly looking to help promising drugs reach the market. Often the advice and networking opportunities they provide are as valuable as the funding.

Not-for-profit organizations come in all shapes and sizes, from disease-focused patient advocacy groups to large trusts that draw on the interest from large endowments to make grants. They are an important source of funding for basic medical science but lately a number have started offering funding that is open to startup biotech companies. The types of support vary, but what follows will illustrate how not-for-profits plug gaps in drug discovery and how best to approach them for funding.

Finding your way

The Leukemia & Lymphoma Society in White Plains, New York, a voluntary health agency supported by donations, is one of the most recent not-for-profits to open its funds to biotech companies. Like many medical not-for-profit funders, it focuses on a particular disease area, in this case blood cancer. Last year, its expenditure on basic research was $60 million—a figure it expects to grow by $5 million next year. In addition to this, it has recently adopted a program to speed up the translation of findings into treatments. The Therapy Acceleration Program (TAP) takes off in July this year and its annual budget is expected to grow from $4 million in its first year to $35 million by 2011.

TAP will identify treatments that are being overlooked by commercial investors, then try to bring them closer to commercialization. "We might do this by funding a company directly, or we could encourage the company to get the potential therapy into the hands of one of our academic investigators. We won't fund straight up startups," says Louis DeGennaro, senior vice president of research at The Leukemia & Lymphoma Society. Projects involving companies with a little experience under their belts will be business alliances and each one will be crafted individually. It is anticipated that the average TAP project will garner $300,000–$500,000 but there is no set funding cap.

The Leukemia & Lymphoma Society also hopes TAP will open up the bottlenecks in phase 1 clinical trials. It intends to fund oncology nurses and data managers at a number of US clinics in return for priority for blood cancer trials. "Once we get those clinics established they'll be open to all comers—anyone who's got a validated target and good preclinical data on a particular compound, and needs a phase 1 trial done, whether it comes out of our own academic investment or out of a biotechnology company," DeGennaro says.

TAP is just one example of a project at a not-for-profit organization that extends a hand to the biotech industry. Others exist—although finding them is a challenge. For a business with a product of innovation addressing a specific disease, the best way to start looking is to simply browse the internet for foundations and charitable trusts in that disease area. A comprehensive list of medical charities in the UK can be browsed on the website of the Association for Medical Research Charities (http://www.amrc.org.uk/). In the US, web-based searches on sites like Foundation Center (http://www.foundationcenter.org) may throw up suitable organizations (see Box 1). The amount of funding on offer will vary, from $100,000 to over $1 million per year.

Businesses searching for suitable charities will soon realize that although a handful of organizations like The Leukemia & Lymphoma Society support fully-fledged programs that specifically target translation of biotech innovations (see Table 1), the majority do not. This should not stop businesses from approaching charities with ideas for projects or collaboration, however. Charitable organizations make for fairly flexible funders—particularly those with research budgets in the millions of dollars

rather than the tens or the hundreds of millions. Their goal is to provide support to their charitable mission and if supporting a private enterprise does this, so be it.

A case in point is the Parkinson's Disease Society in London, which spent £3.4 ($6.7) million on research in 2006. As a rule it funds research only in the country's National Health Service labs or universities. However, Kieran Breen, the director of R&D, says that because more universities and National Health Service trusts move towards commercializing products and treatments, the society may well make exceptions for biotech startups on a case-by-case basis. "We have not yet been approached by one of these but that's not to say that we wouldn't fund them," he says.

A wider net

Not all charitable funds target specific diseases. Giants like the Wellcome Trust in London and the Gates Foundation in Seattle focus on medical research across a wide spectrum. As with most not-for-profit organizations their particular aim is to plug gaps where commercial funders will not go.

The Wellcome Trust recently launched a 'seeding drug discovery scheme' that supports drug development in areas of unmet medical need. The scheme is open to companies located in the UK or Ireland, provided they are in an early stage of development. Most awards will be in the range of £1 ($1.9) million to £3 ($5.9) million and run for two to three years, supporting 10–20 staff. It also has a translation award for technology development that is open to small spin-outs.

"We cover every area of translational research, including diagnostics, medical devices, drugs, vaccines and enabling technologies. So we have this broad net that is designed around: if you have a really good idea, bring it forward," says Ted Bianco, director of technology transfer at the Wellcome Trust.

The Gates Foundation runs its grant making on a problem-based approach. That is, the shape of a proposed project is secondary to whether it addresses the foundation's priority areas. These are heavily slanted towards diseases that plague the developing world including HIV/AIDS, malaria and tuberculosis. The foundation regularly issues requests for proposals but the content and focus of these change with time, and so it is a good idea to keep consulting the organization's website (http://www.gatesfoundation.org/). Businesses can also approach the foundation directly with ideas, by submitting letters of inquiry. Although this may not yield results directly it might be worth the wait as Gates Foundation grants are usually ambitious and generous. For example, in December last year nearly $10 million of a Gates Foundation–funded $83.5 million malaria initiative went to the Foundation for Innovative New Diagnostics (Geneva), a not-for-profit which collaborates with leading public and private sector organizations to develop new diagnostic tests for the disease.

Funders like the Wellcome Trust and Gates Foundation also support global product development partnerships like the Medicines for Malaria Venture (MMV) and the Global Alliance for TB Drug Development (GATB). These alliances are not-for-profit organizations in themselves that offer funding suitable for biotech companies. Both MMV and GATB post requests for proposals on their websites, and offer help for potential partners to write and submit applications. GATB's most recent deal was with Dallas-based Cumbre Pharmaceuticals in September, 2006, to develop new antituberculosis agents.

These foundations actively scour the research underway in their priority areas, and are happy to hear from any company that sits on research—which might include things like drug targets, abandoned drugs—that could help them fulfill their mission. A word of advice, though, from GATB communication director Al Hinman, who says that applications must be based on strong science: "Among those who do not make it past our screening process, many simply do not have the science or compounds that have the potential to achieve our mission—offer novel modes of action, faster and easier results and so on."

If the list of not-for-profits that provide suitable funds for biotech startups appears skewed towards the US so far, it is no coincidence. Charities in Europe are on the whole less sophisticated in their approach to technology transfer and nurturing spin-outs than their overseas cousins. The Wellcome Trust and Cancer Research UK in London are two exceptions, as is France's Association Francaise contre les myopathies (Evry Cedex). Certain patient organizations such as the European Organization for Rare Diseases in Paris and the European Aids Treatment Group in Brussels may also be worth exploring. This should not discourage entrepreneurs hailing from outside the states, however, as many of the US agencies are happy to fund overseas companies.

Moral support

Charities can support bioentrepreneurs in ways other than through funding. As many of them draw upon networks of top scientists, joining forces with them will open up a treasure trove of expertise for small

businesses and also boost their standing. "The intellectual feedback that was made available with [charitable] funding has been rewarding for the company. An example is the expertise one of our funders provides on cognitive testing, which gives us assurance and confidence in the protocol design of the trial," says Jacqueline Tiong, director of corporate development at Allon Therapeutics, a Vancouver-based drug development company (see Box 2).

Another example is Cancer Research UK's well-developed technology transfer arm, Cancer Research Technology (CRT), which helps bridge the gap between academia and industry. To emerging businesses it acts as a midwife service, providing expertise to help get ideas out of the lab and into the marketplace. "Just the fact that you are linked to CRT, and therefore to Cancer Research UK, gives you a pedigree, making it easier to approach collaborators, companies or investors," says Steve Jackson, professor of biology at the University of Cambridge and CSO at KuDOS Pharmaceuticals in Cambridge, UK.

Even charities that do not put funding into biotech startups can help them with networking. The Prostate Cancer Foundation in Santa Monica, California, will not fund businesses, but it has an annual scientific retreat that brings together scientific leaders from academia, governmental agencies and the biotech sector with members of the prostate cancer research community to forge partnerships in drug discovery and development.

Tips and tricks

So how best to approach not-for-profit funders (see Box 3)? First and foremost, prospective applicants should read carefully the guidelines for funding and the mission statement of the organization (see Box 4). If in doubt, ask for clarifications. In fact, it is unlikely that small businesses will be able to work out whether their proposal has a good chance to be funded just by looking at the website. This is because the terms and conditions of charity-business alliances will invariably be individually designed. DeGennaro at The Leukemia & Lymphoma Society says, "We view these as business arrangements, not as grant funding. We'll expect some kind of return on investment, but the details of that will be unique to each arrangement."

Even the Wellcome Trust, which posts a template agreement for funding into the private sector on its website, works out the nitty gritty of deals on a case-by-case basis. Variables include how to treat intellectual property (IP) and the potential wealth created. A return on investment is expected if the project is successful. It could be in the form of repayments if the grant is made as a loan or—as many small companies choose to do owing to their sensitivity to cash-flow problems—the funder's stake may be converted into equity.

On the IP front, the key thing to remember is that the charitable funder is in it for the public good. Often, clauses will be included in the funding agreement that allows the charity to take forward IP if the company does not choose to pursue commercialization. "Our interest in IP is to ensure that promising research does not sit upon a shelf. Therefore if the research looks promising and the company chooses not to continue, then we have the right to pursue it," says Stephanie Berkowitz, research manager at the Multiple Myeloma Research Foundation in Norwalk, Connecticut. IP might also be traded for funding. One example is the GATB deal with Cumbre Pharmaceuticals described above, in which the alliance will have exclusive rights to the compounds developed as a result of the partnership for the treatment of tuberculosis and other neglected diseases. However, Cumbre will retain the rights to pursue compounds for use in other infectious disease areas.

Often, biotech companies will require the charity to take a license on its technology, says Koenraad Debackere, professor in technology and innovation management at Katholieke Universiteit Leuven in Belgium. "This will certainly prohibit any commercial use in case the license is granted to, for example, an organization in a developing country that will use the know-how for local medical needs." Normally, there is a research exemption. That is, as long as it is used for research purposes only, everyone can use the invention. However, this freedom is being questioned, notably by the pharma industry in the US, Debackere adds.

Charity funding can also be more reliable than venture capital. Since a charity's primary goal is not financial return, setbacks are tolerated and sometimes expected. "Although many professional investors have rules to ensure they don't lose their money, we take the view that if the company dies, we lose what we were interested in propagating. So we are very patient investors. If the work doesn't go well and it bombs, we expect to lose our money. That's what being an early-stage R&D funder is about," says Bianco at the Wellcome Trust.

The bottom line

Not-for-profit organizations are gap funders. They are interested in plugging holes where venture capital or public sector funding will not go—as long as doing so furthers their charitable mission. Finding the right funder is not an easy task, but it is a worthwhile one as partnering with a charity will boost a business in other ways than just the financial. Perhaps best of all, their support promotes the development of medicine in areas where the need is most dire rather than where the dollar shines the greenest.

Table 1: Selected foundations that fund drug development in private companies

Foundation	Total research	Available support for	Budget	Funding priorities
US				
Epilepsy Therapy Development Project (Reston, Virginia) http://www.epilepsytdp.org/	$3.4 million in 2005	New Therapy Grants Program	Grants are $100,000 on average, although larger grants will be considered.	Funds innovative therapies from the laboratory to the patient. Open to investigators at corporations, academics and to non-US investigators.
Juvenile Diabetes Research Foundation (New York) http://www.jdrf.org/	$140 million in 2007	Industry Discovery and Development Partnerships Programs	Up to $5 million per program.	Supports research programs in companies, publicly or privately held, focused on the discovery, development and commercialization of therapeutics for type 1 diabetes and its complications.
Leukemia and Lymphoma Society http://www.leukemia-lymphoma.org/hm_lls	$65 million in 2007	Therapy Acceleration Program (TAP)	Project anticipated in the region of $300,000 to $500,000 but there is no funding cap.	Supports private sector and academic-based projects with the goal of moving more blood cancer therapies into the development pipeline.
Michael J. Fox Foundation http://www.michaeljfox.org/	$90 million since its founding	Therapeutics Development Initiative	$4.6 million in funding to ten companies.	Open exclusively to industry researchers, the strategy is to 'de-risk' preclinical research and expand and catalyze industry investments in therapies for Parkinson disease
Multiple Myeloma Research Foundation http://www.multiplemyeloma.org/	$11 million in 2007	Leveraging existing myeloma targets to accelerate drug discovery and development (LEAD) program	$6 million over three years.	Funds biotech companies with myeloma drug development programs from preclinical validation through limited clinical studies (phase 1).
Muscular Dystrophy Association (Tucson, Arizona) http://www.mda.org/	$34.6 million in 2004	Translational Research Corporate Grant	$1 million per year for one to three years.	Funds for-profit companies engaged in preclinical or clinical therapy development for neuromuscular disease.
EU				
Association Francaise contre les myopathies http://www.afm-france.org/	€60 ($79) million in 2005	Therapy Development Program	Not available.	The 2007 call focuses on gene and cell therapies, and neuromuscular diseases.
Wellcome Trust http://www.wellcome.ac.uk	£484 ($948) million in 2005/2006	Seeding Drug Discovery Technology Transfer Initiative	Most awards will be in the range £1 ($1.9) million to £3 ($5.9) million, run for two to three years and will provide support for 10–20 full time equivalent staff.	Focuses on developing drug-like, small molecules in areas of unmet medical need. Funding will be project-based and seek to develop an optimized lead compound or preclinical drug candidate, rectify deficiencies in a promising compound or chemical series, or research the use of existing compounds.
Alzheimer's Drug Discovery Foundation http://www.aging-institute.org/	$4.5 million in 16 biotech companies worldwide. Cofounded two companies.			

Box 1: Where to go for more information

The web is a good place to go for information. The following websites have databases that might be useful in identifying foundations that fund drug development.

- Community of Science Funding Opportunities (http://fundingopps.cos.com/). Database of funding information, including private foundations, updated daily. Subscription required.
- Council on Foundations (http://www.cof.org/). Membership organization of over 2,000 grant-making foundations worldwide. Provides legal services, networking opportunities and leadership expertise to members and the public.
- Foundation Center (http://foundationcenter.org/). Maintains a comprehensive database of US grant makers and their grants, provides links to private foundations, corporate foundations, community foundations and public charities.
- Foundation Finder (http://lnp.fdncenter.org/finder.html). Searchable database on the web of 50,000 US foundations, corporate grant makers and public charities.
- Fundsnet (http://www.fundsnetservices.com). Searchable database of funders categorized by subject areas.
- Grantsmart.org (http://www.grantsmart.org/). Contains over 600,000 US Internal Revenue Service (IRS) filings of over 100,000 private foundations and charitable trusts.
- GuideStar (http://www.guidestar.org/). Searchable database of 600,000 foundations based on IRS filings. Includes assets, liabilities, expenditures, revenues.
- Charity Navigator (http://www.charitynavigator.org/). Evaluates financial health of charities to guide donors.
- Association for Medical Research Charities (http://www.amrc.org.uk/). Membership organization of 111 health and medical charities in the UK, develops best practices, provides information, guidance and improves public dialogue, lobbies the government.

Box 2: Case study

Allon Therapeutics, a clinical stage company developing drugs that protect against neurodegenerative conditions, recently received funding from The Michael J. Fox Foundation for Parkinson's Research in New York to evaluate the effectiveness of its neuroprotective drug AL-108 in preclinical models of Parkinson disease. If successful, it will be in a position to begin a phase 2 clinical trial to evaluate the drug's effectiveness in patients. So far, it does not know the exact amount of funding it will receive other than that ten companies will be sharing a total pot of $4.5 million. In the past it has also received sponsorship from the Treatment Units for Research of Neurocognition in Schizophrenia (TURNS, Washington, DC) and the Institute for the Study of Aging Biotechnology Founder Program, which is affiliated with the Alzheimer's Drug Discovery Foundation (New York, NY).

“The grants provided Allon with the opportunity to advance our research and clinical programs into another major market where there is a large unmet medical need while not diluting the shareholder value. For these charitable organizations to select and fund research and clinical trial on a product from our pipeline is a significant validation of the company technology,” says Jacqueline Tiong, Allon's director of corporate development.

Tiong advises bioentrepreneurs, “When applying for charitable grant, it is important to provide the due diligence team at the funding agency with all the information necessary for them to evaluate the technology. If it is possible, try to identify a champion in the funding agency and a project coordinator and provide them with regular updates on the application progress. It is crucial to respond immediately to any request the agency asks for and provide any additional information if necessary.”

Box 3: Tips for applying for charitable funding

- Carefully read through the guidelines for applications. Then read them again. Look at the organization's mission statement. Is your proposal really in line with its aims? This is the first thing assessors will look at.
- Make sure that you express clearly in the application how your project fits in with the charity's mission statement. Do not forget to emphasize the public-good outcomes of your proposal.
- Do not be afraid to point out any profit-making possibilities. Charities may have a commitment to public good, but they are also always on the outlook for ways to swell their coffers.
- Avoid technical jargon and acronyms—some of the reviewers may well be nonscientists. At the very least provide a synopsis for the project and expected outcomes in layman's terms.
- If you fail, always try again.

Box 4: Dos and Don'ts

Do look into charitable funders if your product is

- at too early a stage or too risky for commercial backers,
- disease-specific (especially if it's a rare or neglected disease) or
- has demonstrable public-good potential.

Don't approach a charity if

- you are unwilling to deal with IP in a manner that will accommodate affordability, wide access and rapid adoption.