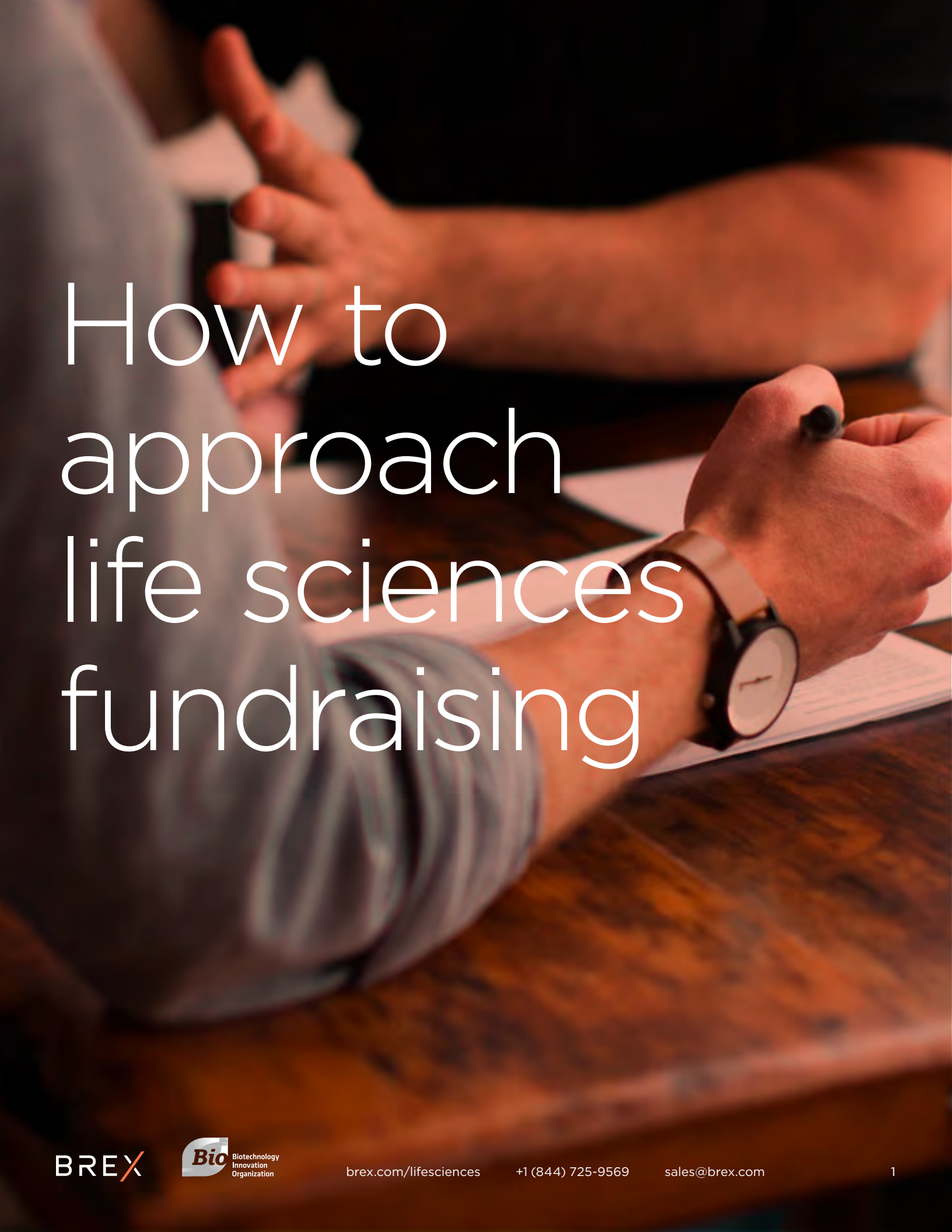
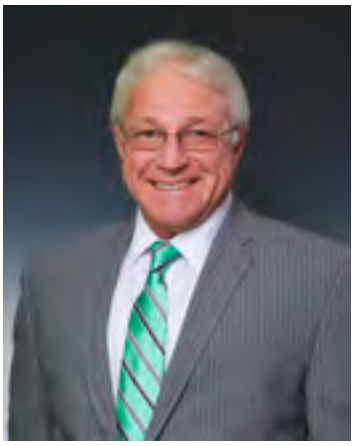


How to approach life sciences fundraising



Foreword

Without access to affordable capital and strategic resources, it's difficult for small biotechnology companies to navigate the complex world of fundraising and turn their novel concepts into approved medical products. Securing investment at all stages of the business life cycle is a priority for the vast majority of BIO's member companies and it's also a key component of our policy efforts in Washington D.C.

That's why BIO is working overtime in Washington to preserve our world-leading investment ecosystem and to incentivize innovation. BIO's strategic advocacy initiatives are focused on preserving strong intellectual property rights and efficient tech transfer, promoting a robust capital formation environment, improving patient access to transformative therapies in development, and preserving market-based pricing for drugs.

BIO's global portfolio of partnering and investor events also provide a forum to shape deals and drive collaboration. To make this process easier, I'm thrilled to introduce "How to Approach Life Sciences Fundraising."

This report is brought to you by our BIO Business Solutions® Partner, Brex. Designed with your mission in mind, the Brex corporate card for life sciences extends cash runway and streamlines your financial operations so you can spend more time on the work that really matters.

Brex created this report to help our member base navigate the fundraising landscape and outline opportunities for biotechs at various stages of development: government grants, non-government grants, incubators and accelerators, private investment, and large pharma partnerships.

I hope this report can serve as a helpful roadmap as you pursue the R&D funding that will allow your scientists to create breakthroughs that can change and save lives.

Sincerely,

Jim Greenwood
President & CEO, BIO

BREX

Bio Biotechnology Innovation Organization

Contents

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Introduction

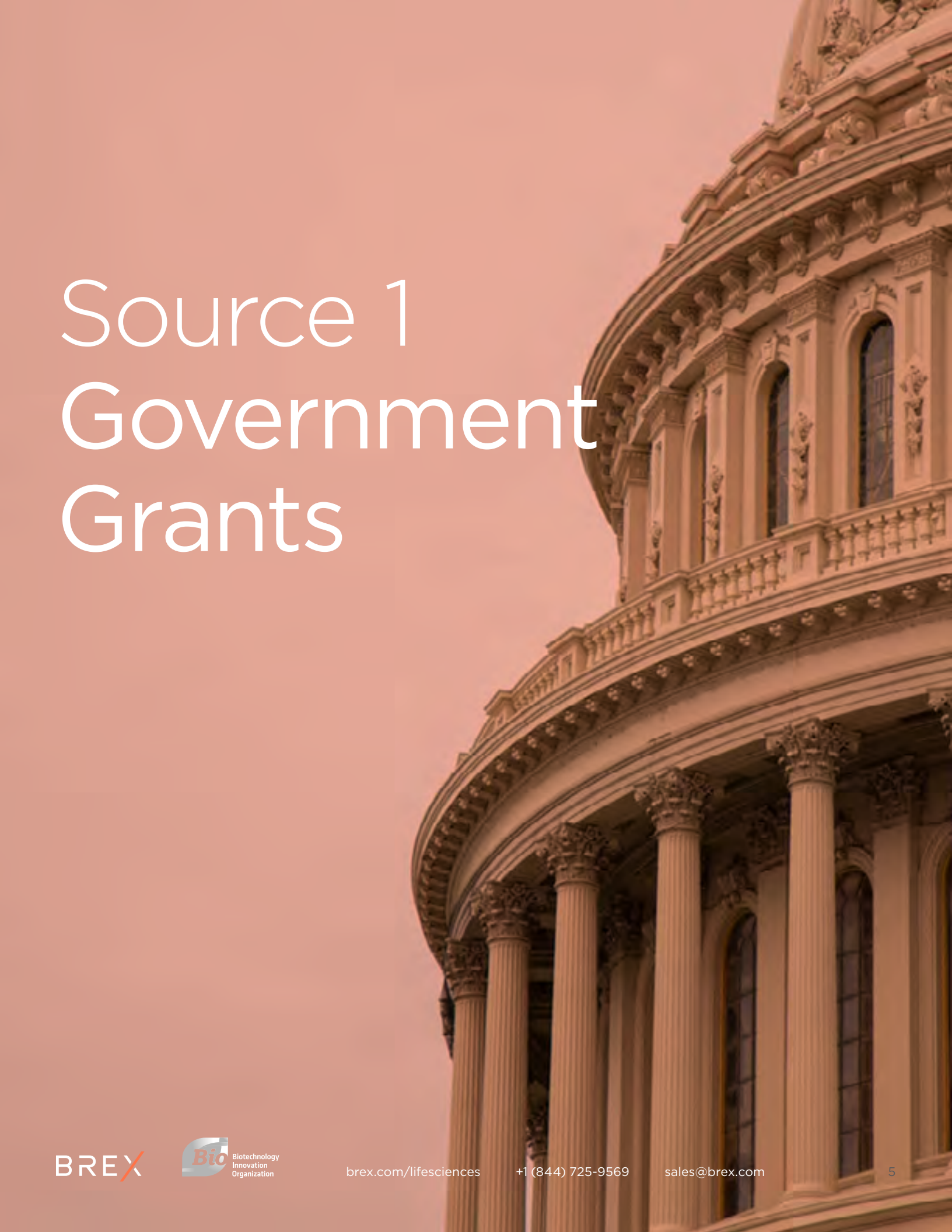
One of the biggest challenges for life sciences companies is finding sources of funding to keep their research and development moving forward. In this guide, we'll explore the different sources of funding available to biotech startups and their relative merits, and how you should best utilize that funding at each stage of your research.

In this industry, there's no single accepted pathway to fundraise for your startup. Depending on the stage of your research, you may find the pursuit of certain sources of funding to be more cost-efficient than others. For example, if you're working with just an idea, you'll want to look for different resources than if you've already finished your discovery phase and have some hard data to show to investors. It also matters how you spend your funding and at what stage in the process. If you're just getting started, your funding will probably go toward finding lab space, supplies, and instruments to help you get through discovery.

If you're going into a crowded market where multiple competitors are creating innovations to address the same therapeutic solution, you'll want to find resources that will get your product to market in the fastest, most efficient way—perhaps by recruiting experienced researchers and administrators to grow your team. You'll want to consult with law firms for advice on filing for patent protection and work with a business development consultancy to facilitate partnerships with big pharmaceutical companies.

No matter the challenge, we want to help your company examine its fundraising options.

Source 1 Government Grants



Source 1
Government Grants

Government grants are a significant source of funding for researchers looking to get their idea off the ground and as such they can be highly competitive. Depending on the agency or organization offering the grants, they have widely varying eligibility, submission, and audit requirements, as well as awards.

The first step is identifying the grants that suit the stage of research that you're currently in. If you have a well-developed hypothesis with concrete goals, you may be able to find a grant to help you reach a certain milestone. If you're confident about your direction but still want to test out a few different therapeutic candidates, there are grants to help you run a pilot or feasibility study.

Types of government grants

The biggest sources of biotech government grants are the National Institutes of Health (NIH), the Department of Defense (DoD), the National Science Foundation (NSF), the Centers for Disease Control (CDC), and the Biomedical Advanced Research and Development Authority (BARDA). Check out grants.gov for a massive list of grant opportunities and other grant-making government agencies. You can apply for grants manually during regular submission windows, or keep your eye out for Funding Opportunity Announcements (FOAs), where agencies solicit

Source 1
Government Grants

researchers to compete for a specific targeted research output.

Of these, the NIH is perhaps the largest source of funding for up-and-coming biotechs—it pours almost $1 billion each year into small life sciences companies with the mission of creating technologies that seek fundamental knowledge about nature, the behavior of living systems, and the application of that knowledge to improve human health. It offers two major federal grant programs, the Small Business Innovation Research (SBIR) grant or the Small Business Technology Transfer (STTR) grant.

The SBIR program encourages US-based small businesses to engage in research and/or R&D that has the potential for commercialization. Its sister program, STTR, is designed to facilitate cooperative R&D between small businesses and non-profit research institutions. The NIH is made up of 27 different institutes and centers (ICs), most of which have SBIR and STTR programs. Because each IC has a different focus area (the National Institute of Mental Health, for instance, or the National Heart, Lung, and Blood Institute), you'll want to apply for the SBIR or STTR with the institute that has the best fit for your research.

SBIR/STTR programs have roughly three phases: Discovery, Development, and Commercialization. Each phase requires that the potential awardee demonstrates technical merit, feasibility, and the commercial potential for the proposed R&D efforts. The awards scale with the phases: in Discovery, awards don't normally exceed $150,000 over six months, while in Development, the standard award is $1 million over two years. Though you typically have to apply for, win, and then demonstrate success in each phase in order to be eligible for the next phase, there are Fast-Track Applications that allow you to jump ahead in the process and seek larger award amounts.

Source 1
Government Grants

Grant-writing tips

Grant applications are often laborious and can be highly idiosyncratic to the agency at hand. The best applications tend to be strong in these key areas:

- **Scientific merit**. Awardee has experience with essential methodologies, clearly defined tests for feasibility, a solid experimental approach that considers potential pitfalls or alternatives, and a focused, coherent research plan.
- **Eligibility**. Awardee's research area fits in with the IC content focus, awardee's business or research consortium fits in with the small business bracket, and amount of work proposed is realistic and achievable with the award scope.
- **Commercialization potential**. This is more critical for grants that apply to later phases of research. Awardee understands the basic market for the research, has a clear commercialization scheme, and their research represents a clear innovation within the IC's field.

Source 1
Government Grants

PROS

- Helpful in getting your idea off the ground.
- Non-dilutive. You don't have to give up equity in your research.
- Prestigious grants help attract attention for more fundraising.

CONS

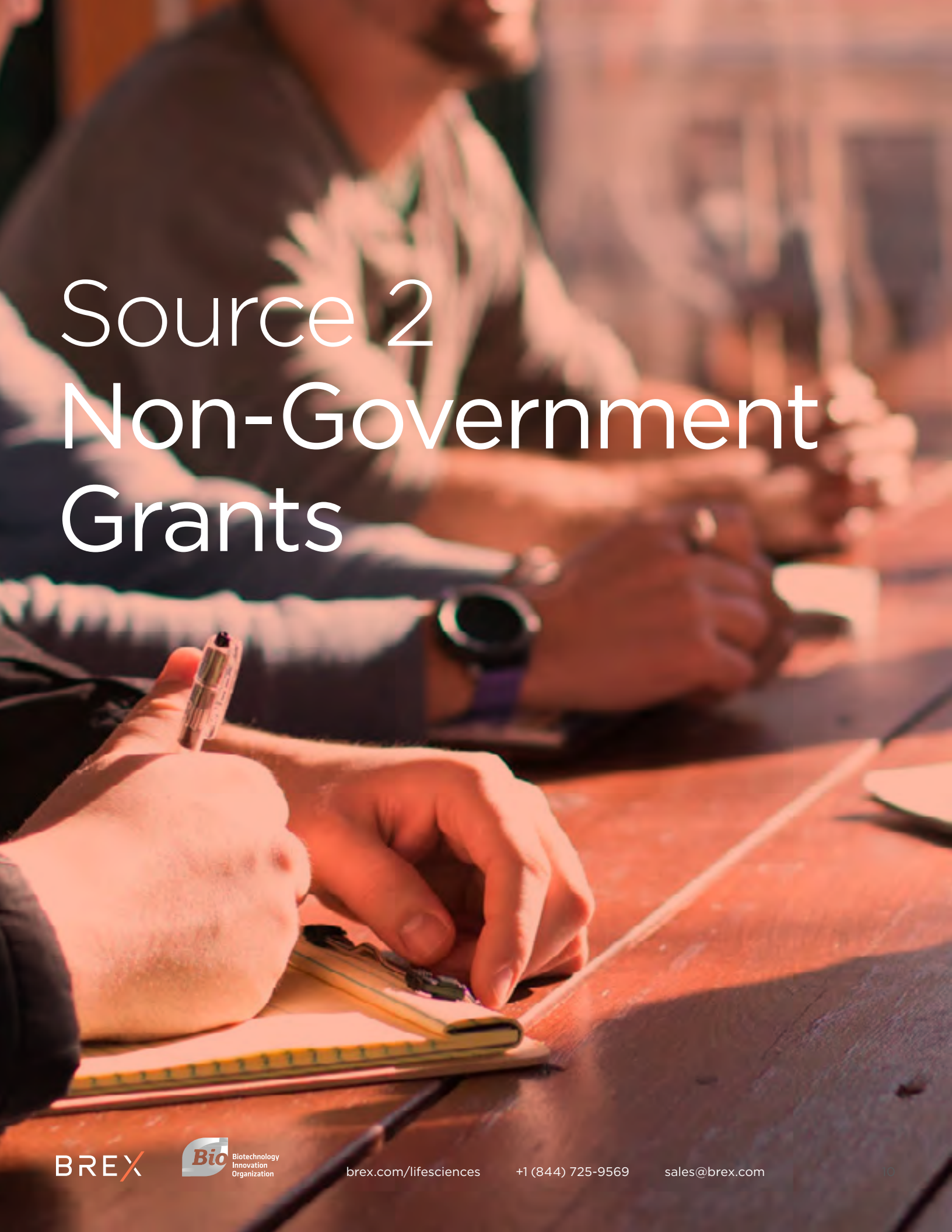
- Audits and accounting for multiple grant sources can be onerous.
- Gov't grants may have specific award conditions that require you to use the funding on certain things.
- Gov't grants are highly competitive, so you may spend a lot of time applying with a low success rate.

Key takeaways

Great funding source for startups. Generally, grants are appropriate for startups where, due to basic resource constraints or lack of hard data, it's too early to seek private investment. They can help small life sciences companies transition from having a promising idea to something that is commercially viable and of greater interest to investors.

Diversification is important. The final spending bill in 2020 raised funding for the sciences; the NIH will receive a 7% boost to funding in the upcoming fiscal year, bringing its total budget to $41.7 billion. Even so, it's still prudent to diversify your sources of funding. Grants like the SBIR/STTR are fiercely competitive. 2020 may be a good year for government funding, but the proportion of U.S. R&D supported by federal funds has been on the decline, falling from nearly 70% in 1973 to 60% in 2018. It's best to look for multiple sources of funding in case one grant falls through or you aren't approved for the next grant program phase.

Grants lend legitimacy. Grants drive the science in those early days when it's difficult to get institutional investors interested in a pre-clinical asset. But they also serve to validate your technology and put the brand of the IC behind your research. Getting a big-name government grant associated with your research will give you a leg up in raising funds later on in development, because investors trust that the government wouldn't invest in your science unless it was solid.



Source 2
Non-Government Grants

Source 2
Non Government Grants

Government grants are by no means the only source of non-dilutive funding out there. They may have a reputation for being the most competitive and prestigious, but funding from a well-known advocacy group like the American Cancer Society or a corporate foundation certainly comes with credibility and brand-recognition. They also may be comparatively looser in their auditing requirements or award conditions.

Patient advocacy groups

Also known as voluntary health agencies or nonprofit disease foundations, patient advocacy groups are composed of mission-driven individuals seeking to combat a particular disease, disability, or group of disorders. They're organized by a mix of laypeople and professionals, and they often work closely with doctors and large pharma.

Many of them fund research on their particular area, like the American Diabetes Association, the Parkinson's Disease Foundation, the American Lung Association, or the Alzheimer's Association. The National Health Council has a large membership directory of 125 national health-related organizations. If your area of research is in alignment with the advocacy group's mandate, they may offer a grant program.

Source 2
Non Government Grants

Family offices and foundations

These foundations are set up by wealthy families to support specific causes or sets of causes. They often invest in areas they believe in or to which they have a personal connection. Social impact, often in the arena of human health, is a major focus of family foundations—the Bill and Melinda Gates Foundation is a great example. Because family offices are often a vehicle by which wealth can be passed down to the family's next generation, they may also offer investment in projects that have solid potential for commercialization.

There are indications that family offices are on the rise, with a 10-fold growth in offices over the last decade. Some research puts the assets that family offices currently hold in excess of $4 trillion, so this may be a funding source to keep an eye on.

Corporate foundations

A 2018 Deloitte report shows that large life sciences corporations are increasingly pouring resources into corporate philanthropy organizations in order to improve consumer brand approval, communicate their key beliefs, inspire their stakeholders, and position themselves as constructive forces in their industry ecosystem. Major forces like pharmaceutical giants are also well-suited to understand the complex multi-year issues that

Source 2
Non Government Grants

life sciences startups face in creating new technologies and therapeutic candidates, especially in their specific areas of focus.

The Novartis Foundation, the philanthropy wing of the global healthcare company, is an instructive example. They've chosen to leverage the corporate organization's expertise in cardiovascular health and noncommunicable diseases to fuel the foundation's global health programs. As part of their effort to improve chronic health conditions like hypertension, they've funded a wide variety of organizations that, brought together, stand to make a more effective intervention.

If you're a startup with some decent initial data on your therapeutic candidate and an understanding of the industry landscape surrounding your research area, it may be fruitful to reach out to corporate foundations that are operating in similar arenas. The model of corporate philanthropy is shifting away from one-off charitable gifts toward one of targeted, strategic partnerships. If you can position your research as a valuable potential tool to help them achieve their goal, they may offer you financial backing.

Source 2
Non Government Grants

PROS

- Non-dilutive. You don't have to give up equity in your research.
- As a time investment, somewhat less risky than applying for gov't grants.
- Fewer award conditions on grants, though they still exist.
- Prestigious grants or partnerships with corporate clients help future rounds of fundraising.

CONS

- Requires you to have solid data to show that your research has promise.
- Requires knowing how to pitch to a major corporation will require business expertise.

Key takeaways

Know your industry. Get familiar with the major corporate players, philanthropy sources, and research consortiums in your area of focus. Approach the foundations and companies that have skin in your game. Keep an eye out for grant opportunities.

Tell the right story. When you approach funders, know how to frame your research as a potential tool that they can use to make better interventions. If you can show that your work represents an improvement on their current framework, they see you as another potential player to help them achieve their multidisciplinary goal.

Focus on getting through discovery. Especially when pitching to larger corporate funders or their foundations, be aware that they will want to validate your research and feel confident that it can address their needs. You'll want to focus on getting some solid initial data to show them.

Source 3
Incubators and Accelerators

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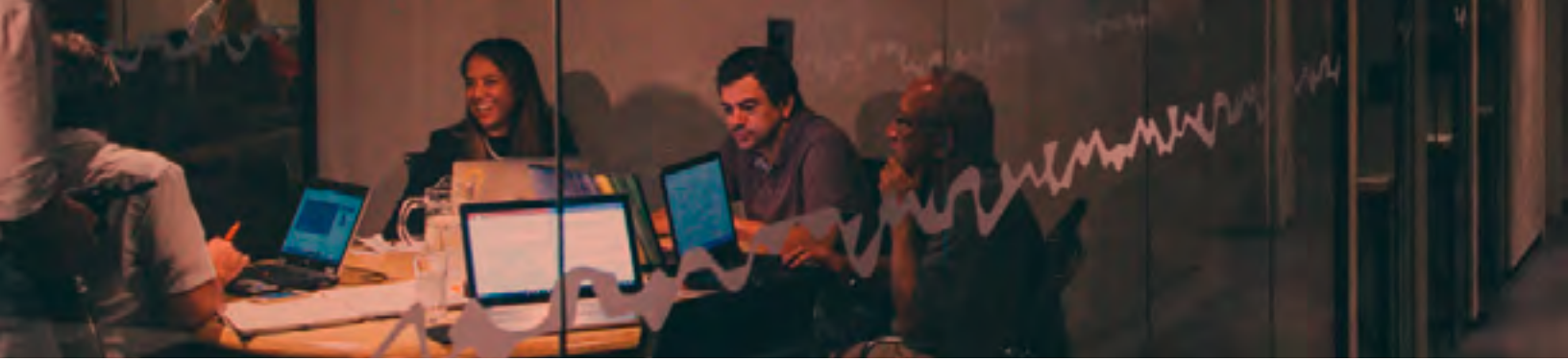


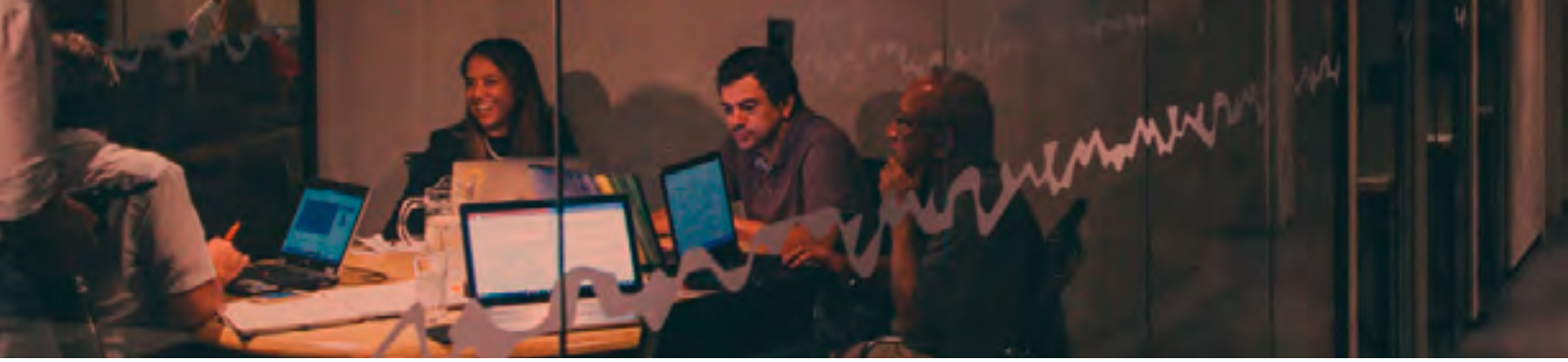
Source 3
Incubators and Accelerators

Incubators and accelerators are a major source of funding for life sciences startups. A new Silicon Valley Bank report finds that one in four life sciences startups that raised at least $4 million in 2017-2018 worked with an accelerator or incubator at some point in their lifecycle. The report found that they gave startups a significant boost by providing early stage support and sometimes a followup funding round.

It's common for new life sciences startups to seek out incubators because it helps them save money, find mentorship, and develop business acumen. They can offer fledgling research projects the breathing room they need to validate their initial theories or therapeutic candidates while they apply for grants or attract other investment. Accelerators tend to work with more advanced-stage startups that already have a minimally viable product. Some—IndieBio and Y Combinator are good examples—may even offer seed funding.

Savings

Incubators usually provide lab space, lab supplies, and access to specialized equipment—plate readers, centrifuges, HPLC systems. Some incubators have lab managers and technicians on hand to help accelerate your research. Others, like Mothership Lab, offer incorporation and legal advice, product and brand design services, and industrial design and fabrication. It all goes



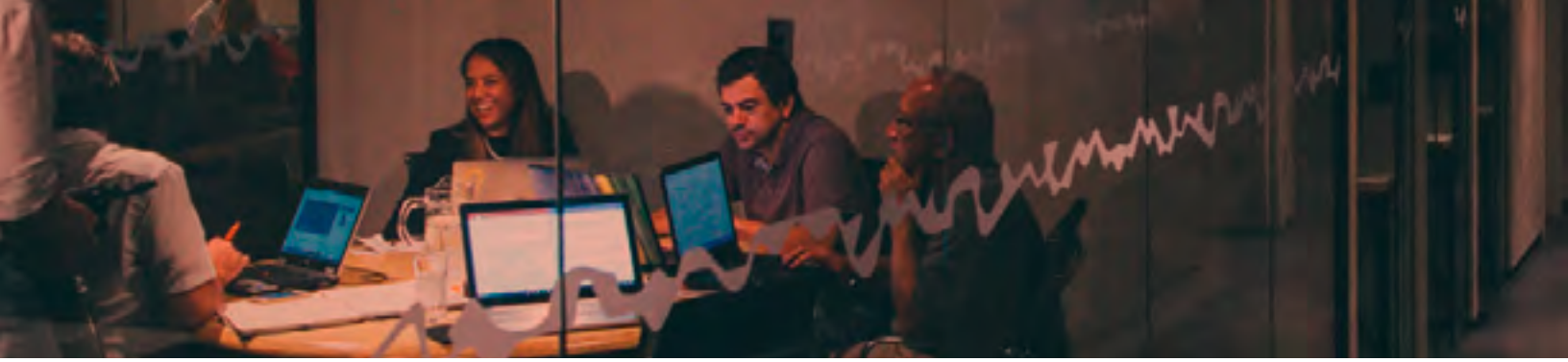
Source 3
Incubators and Accelerators

toward freeing up time for more research, more fine-tuning of technology to prepare for clinical trials or commercialization.

Administrative and research expertise

At the start, many life sciences startups face the challenge of dealing with the bureaucracy underlying biotech research. Incubators can help startups with implementing safety regulations and adopting waste disposal best practices, for example. They may also offer mentorship programs with experts in the field of life sciences research, who can give feedback on your methodology, help you see blind spots you've missed, or advise you on a commercialization scheme.

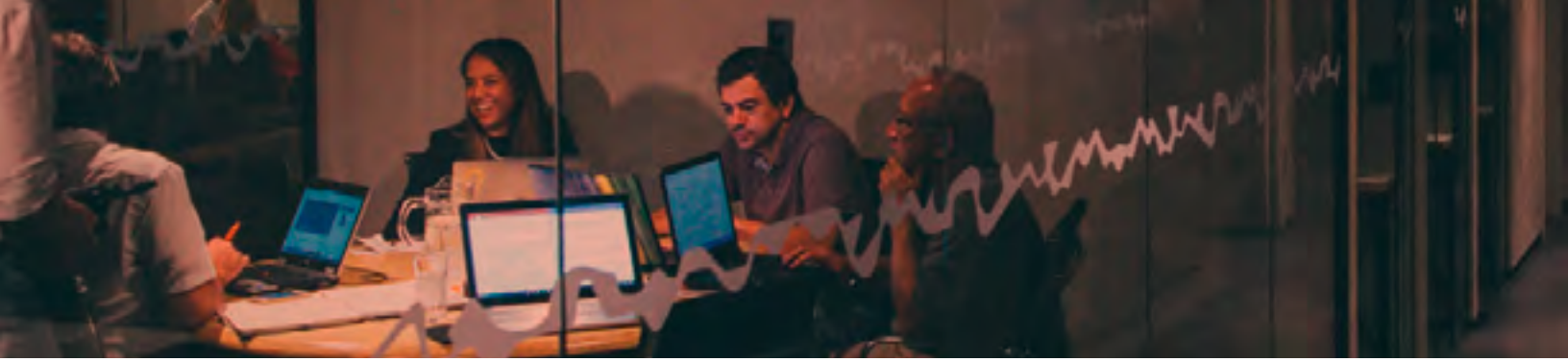
Some incubators are associated with or run by major pharmaceutical companies, which offer access to deep-seated industry knowledge. Pfizer's Centers for Therapeutic Innovation assigns a renowned researcher to each investigator and project, who helps the startup navigate and make efficient use of the company's collaborative infrastructure. CTI, like some other pharma-backed incubators, offers this aid in exchange for joint ownership of the intellectual property. JLabs, the incubator under Johnson & Johnson Innovation, provides similar support while allowing the entrepreneur to hold onto their IP.



Source 3
Incubators and Accelerators

Community and networking

Incubators can be a great source of community for early-stage investigators. Boston based LabCentral places a lot of emphasis on the importance of connecting current cohort members with alumni and other life sciences companies in associated fields, in the belief that shared experience can speed up the pace of innovation. Many incubators host speaker series where you can learn from and interact with world-class scientists in your area of research. They can also attract and connect you to investors: the incubator network QB3, for instance, has an annual summit that introduces their startup cohorts to investors and industry partners.



Source 3
Incubators and Accelerators

PROS

- You don't have to worry about finding and managing lab space or ordering lab supplies.
- Business development programming and networking opportunities.
- Reputation boost from being associated with a prestigious incubator can help with later fundraising.
- Depending on the accelerator, seed funding may be available.

CONS

- Application process is rigorous and competitive.
- For accelerators, you may need to submit a substantial business plan, including market analysis, a refined pitch and hard research data.
- Some incubators require a time commitment and adherence to a schedule.

Key takeaways

Define the help you need to get started. Incubators and accelerators offer a variety of support services for life sciences startups at various stages. Consider what your end goal is and which business areas you need most help in developing. If you're happy with your discovery data but don't feel confident about finding investment, look for an accelerator that can train you on business development and pitching to investors. If you've got an exciting idea but limited resources, look for an incubator that can help you allocate your existing funding efficiently.

Be aware of what you're trading in return. Some incubators just require a monthly or yearly membership fee in exchange for lab space, supplies, and expertise. But others—especially accelerators and corporate-affiliated incubators—may require a share in your IP or an exclusivity agreement in developing any product that comes from launch. You may want to consult with a business development expert to weigh your options.

Source 4
Private Investment

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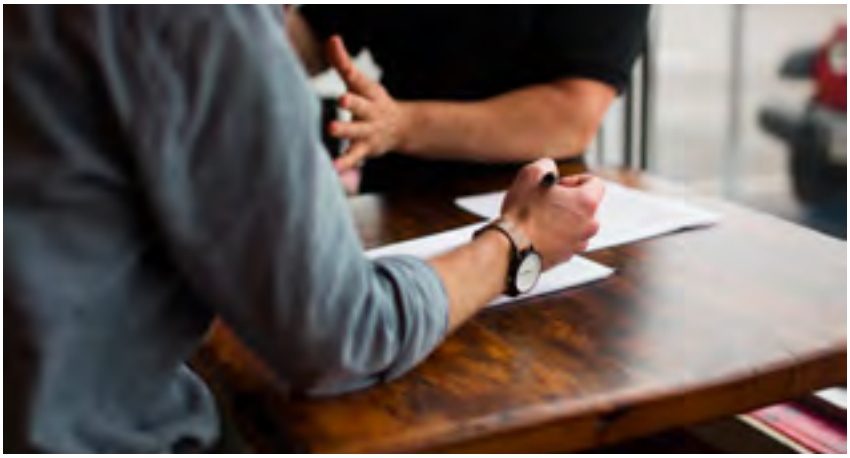
Source 4
Private investment

Many startups go after private investment because they don't have time to wait for SBIR funding or go through an incubator program. This is particularly true if you're competing with several other technologies chasing the same clinical market and your competitors have a lead on you. As you progress and become more confident in the efficacy of your end product—and as your expenses scale with the complexity of your research—it becomes important to seek private investment in addition to grant funding.



Angel investors

If you're in the early stages of your research and you're already working hard on creating a network of industry specialists, you might be able to seek private investment from a wealthy domain expert. Especially if you're trying to fundraise before you have intriguing data and you need the resources to support R&D, approaching someone who understands your space and will trust your instincts is key. If anyone's going to take a risk on a proposal that is, at this stage, little more than an idea, it's going to be someone who understands the technology or methodology upon which your hypothesis is based.

It's hard to depend on this source of capital. Having the time to prioritize networking is a luxury that most early startups don't have, particularly in life sciences. You also have to have the communication skills to convince potential angels of your

Source 4
Private investment

vision. For most early-stage startups, the best course is usually to invest in networking for its general benefits rather than solely to forge relationships with angel investors. For instance, giving and attending presentations at industry conferences is usually worthwhile for its own merits—it gets your name out there, helps you learn more about your industry, meet potential future collaborators and understand your competition. If you happen to meet a potential investor, it's icing on the cake.

If you're a later-stage startup in search of angels, the Angel Capital Association has a comprehensive directory of angel networks that may help you get started in your search. Life Sciences Angels is a network worth noting, as well. It was founded by life sciences executives and experienced angel investors and functions as a sort of angel investment/venture capital hybrid focused on funding early-stage biotech and medical device companies. You might also check out Tech Coast Angels, Keiretsu Forum, and Sandhill Angels.

Venture capital

Corporate venture capital is a massive source of funding for biotech startups. Large pharma companies like Pfizer, GlaxoSmithKline, AstraZeneca, Takeda, Novo Nordisk and others have funding arms that, alongside traditional venture capital firms, co-invest in young biotechs. There's some speculation that this represents an industry trend toward moving R&D efforts out

Source 4
Private investment

of in-house pharma labs and into venture-backed startup labs. In 2018, biotech startups raised almost $29b in seed funding, up from $19 billion in 2017.

It's not just pharma-backed corporate VCs that are active in biotech investing. Tech companies like Apple, Amazon, Microsoft, and Google have become increasingly invested in the healthcare industry. While for the most part they've focused on the consumer side, Google Ventures has funded a number of biotech companies. GV recently hired biotech industry veteran David Schenkein to co-lead its investments in life sciences, signalling increased interest in the space.

Traditional venture capital is a big player in the life sciences investing world, as well. Firms like Domain, Sofinnova, Versant, OrbiMed and 5AM Ventures have historically focused mostly on life sciences, while others spread their investments across a number of industries, such as NEA, Canaan Partners, and Kleiner Perkins.

It's much harder to secure the confidence of VC firms than it is to win a grant, but similar challenges apply. Unless you have a track record of substantial success in other companies, you'll need to have impressive data to show investors. Because the nature of life sciences means that R&D takes a lot of time, you'll want to bring as much proof as possible that your research represents a low-risk investment.

Source 4
Private investment

You should consult with a corporate development team and your attorney to help you understand your market and shape your pitch in the context of your competitors. Many of the largest law firms have a life sciences-specific practice and can be helpful in identifying the best-fit VC firm for you. Mentors associated with incubators and accelerators are often connected to venture capitalists and can make introductions for you.

Source 4
Private investment

PROS

- Source of major funding and stability in later phases of R&D, where risks and financial needs compound.
- Reputation boost from being associated with a prestigious angel investor or VC firm can help with later fundraising.

CONS

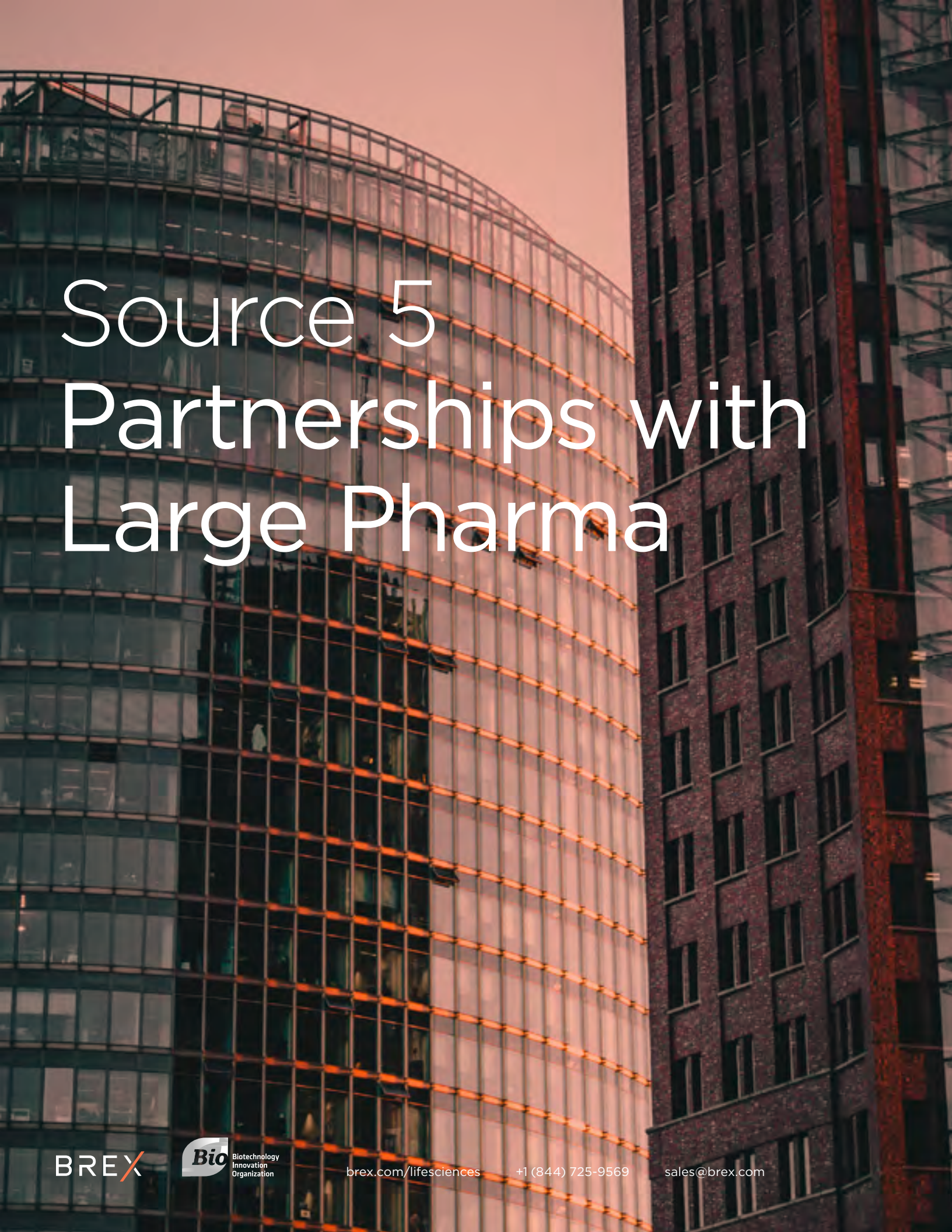
- The bar for a successful pitch is high. VCs and investors need to know they're investing in promising research with strong potential for return.
- A good pitch requires substantial investment on your part in networking and business development know-how.
- This funding is dilutive. Make sure you consult with legal counsel and work with BD teams on the valuation of your company.

Key takeaways

Have a good story. It's not enough to have good data, though that is essential. You need to shape what data you have into a story that convinces investors that your research stands to solve a critical problem for a certain clinical market or, better yet, that it represents a major innovation for the industry. This story should be backed up by solid market research, competitor analysis, and a business plan that demonstrates a clear path to profitability.

Make sure you understand what you're signing up for. Be sure to understand how much your VC expects to be involved in or have input on your process. Having funding is obviously important to move your research forward, but if you stand to lose a substantial amount of autonomy, it may be worth thinking about looking elsewhere.

Timing is important. What are you going to use this funding for? Venture capitalists will want to know what their money is going toward. But more to the point, it's important not to give away too much equity too early. Map out each important milestone between the present state and your exit. Is this round of funding essential to getting past a major milestone, such as clinical trials? You'll want to work with legal counsel and business development consultants to make sure that you're not giving away too much of your company, particularly if you'll need another large round of funding in the future.



Source 5 Partnerships with Large Pharma

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Source 5
Partnerships with Large Pharma

Partnerships between large pharmaceutical companies and small biotechs are foundational to the life sciences industry. Large pharma spends an enormous amount of capital on R&D for drug development and medical devices, depending on infusions of new ideas and innovations from biotech startups to keep their business model flexible and competitive. From 2007 to 2016, the industry invested around $1.4 trillion in R&D, or about 14% of its revenues for that period. It's also no surprise that startup biotechs often look for partnerships with established pharmaceutical companies with substantial capital in reserve. By some estimates, with prolonged and uncertain R&D process, clinical trials, and the costs baked into getting regulatory approval, it can take over $2 billion to take a new drug to market.

It's particularly common for biotechs and pharmaceutical companies to collaborate on clinical trials for drugs. Biotechs' more agile, targeted research model and pharma's ability to absorb some of the risk of development and provide rich infrastructure make these kinds of partnerships effective. And if you're a mission-driven researcher who cares first and foremost about improving human health, partnering with pharma can take all business and fundraising work off of your plate altogether.

If you pursue a partnership with a pharmaceutical company, you'll often be able to share their resources, like lab space, supplies, and desk space. In addition to helping you shepherd

Source 5
Partnerships with Large Pharma

your research through clinical trials, they typically have plenty of experience in dealing with the FDA. When it comes time to go to market, large pharma often has established relationships with contract manufacturing organizations to create and package your product. You'll also be able to leverage their in-house distribution and marketing functions. The downside, of course, is that by partnering with pharma, you're often giving up direct control over your business and/or over the IP of your product. Some biotechs may choose to license their IP out to large pharma. The pharma company will do licensing deals in exchange for an upfront lump sum and royalties—which biotechs use to fund other projects or start new research.

There are several pathways to starting a relationship with large pharma. Mid-sized biotechs will often hire a VP of Business Development to help them solicit partnerships, sometimes directly out of large pharma companies themselves. There are also a variety of business development consulting firms that focus on helping life science clients identify the best potential partners and help them negotiate contracts. The major life science conferences—the BIO International Convention, BioPharm America, and BioEurope, for example—provide systems and events for facilitating partnerships between biotechs and large pharma.

Source 5
Partnerships with Large Pharma

PROS

- You get to focus on the science. No need to worry about administration, business development, basic resourcing.
- Go-to-market is largely taken off your plate.
- Pharma has deep experience in conducting clinical trials and working with the FDA.

CONS

- Partnerships are dilutive. You're likely giving up some proportion of the rights to your IP.
- The bar for a successful pitch is high. Large pharma needs to know they're investing in promising research that will bring a product to market.
- Rigorous due diligence process. Make sure your data is meticulously detailed and ready for review by the partner.

Key takeaways

Due diligence is often a sticking point. If a pharmaceutical company is interested in partnering with or acquiring your business, be ready to provide granular data on your research thus far. Pull all your references, market research, and research data together into one data room and keep it well-organized. Some pharma partners will see disorganization as a warning sign.

Work with legal counsel on the structure of your contract. Make sure you understand what you're giving in exchange for pharma help in bringing your product to market. If you're a first-time startup biotech, pharmaceutical companies will likely have much more experience than you in structuring a partnership that works to their advantage. Think carefully about what you want to accomplish (getting through clinical trials, business development, regulatory advice) and make sure that whatever royalties or equity in your company you give up is worth the expertise you'll receive from pharma. You'll also want to consult with business development consultants and financial advisors.

Culture fit is important. Up to the point of getting a partnership with pharma, you're probably laser-focused on the search for hard empirical data to back up your idea and the most effective story for your pitch. But it's important to remember that you'll be entering a large community with substantial inertia and an established way of doing business. Before you sign any papers, make sure you and the pharma partner are aligned on company culture. Ideally, the partner should help you navigate industry complexity and respect your need for flexibility, speed, and autonomy.

Conclusion

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BENEFITS OF BREX:

- Save time, accelerate R&D
- No personal guarantee
- Rewards for life sciences

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Conclusion

Effective fundraising—at the right moment, for the right reasons—is crucial to bringing your idea to market and making an impact on human health. It's a good idea to have a couple of irons in the fire at any given moment, whether that's grant funding from multiple sources or relationships with private investors, to ensure that your runway doesn't end before your research does. And in the meantime, there are ways to make the funding you've got stretch further.

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