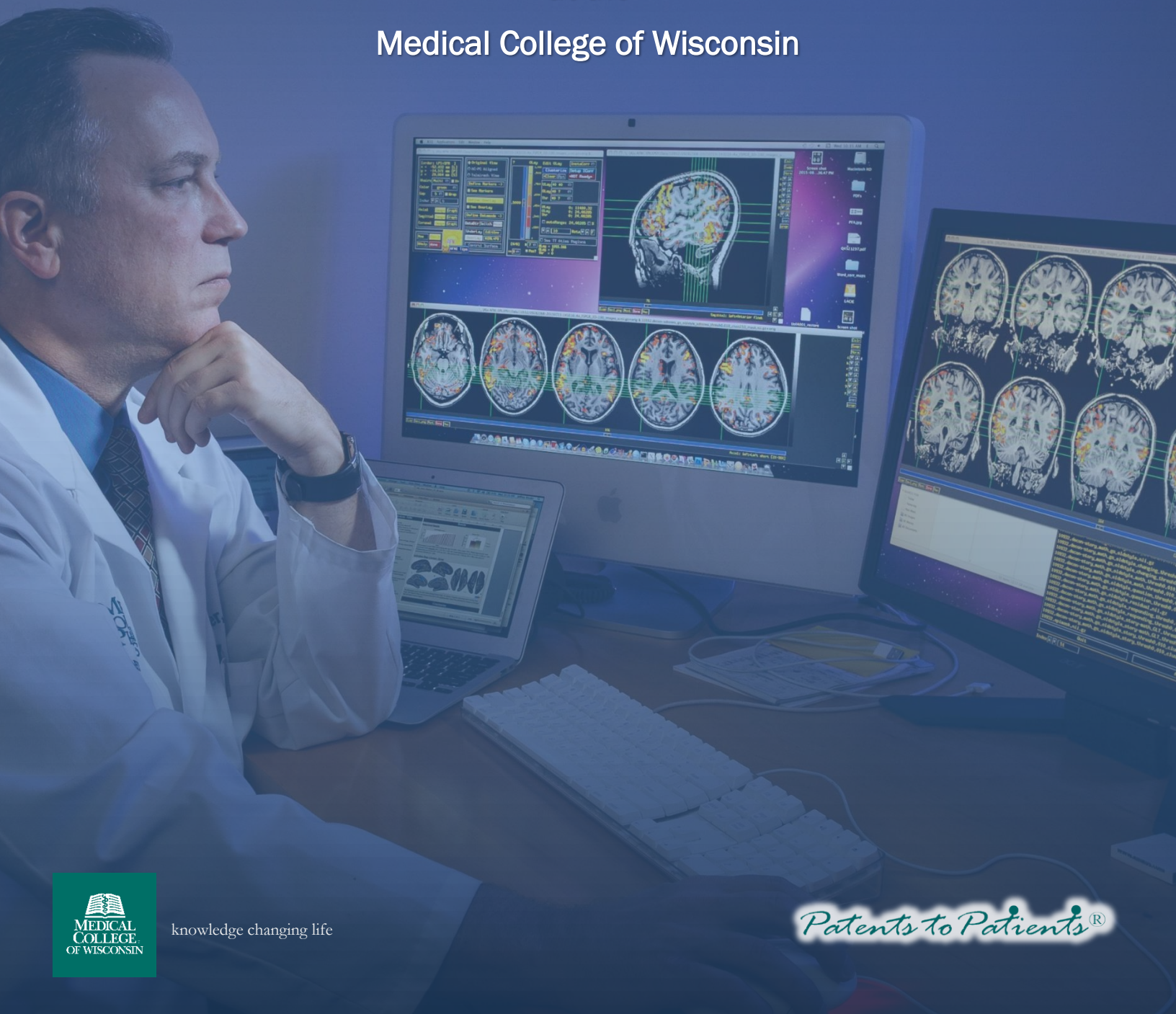


Innovator's Startup Guide

Prepared by the
Office of Technology Development
at the
Medical College of Wisconsin






**MEDICAL
COLLEGE
OF WISCONSIN**

**OFFICE OF
TECHNOLOGY
DEVELOPMENT**



Patents to Patients®



TABLE OF CONTENTS



Introduction.....	4
Technology Transfer Process.....	5
Why Start a Company?	8
Legal & Compliance Issues.....	9
Startup Funding.....	12
Key People	17
Networks & Support Organizations	20
Preparatory Considerations	22
Roles of Key MCW Offices.....	25
Am I Ready to Do This?	26
Appendix: Useful Definitions.....	27

Disclaimer: The information provided in this Guide does not, and is not intended to, constitute legal, tax or business advice, all information content and materials are for general information purposes only.

MCW encourages and is supportive of the formation of startup companies to help bring breakthrough MCW inventions to the patients and healthcare providers who need them.

This Guide is offered by MCW's Office of Technology Development as a source of important, foundational information that assists faculty, staff, trainees and students in navigating the technology development process and considering opportunities to engage in a startup.

We want to hear from you! The OTD staff looks forward to working with any MCW personnel who have an interest in learning more about these and other startup-related topics. Let us know what questions you have. We are glad to schedule a time to speak with individuals, groups, divisions or departments.

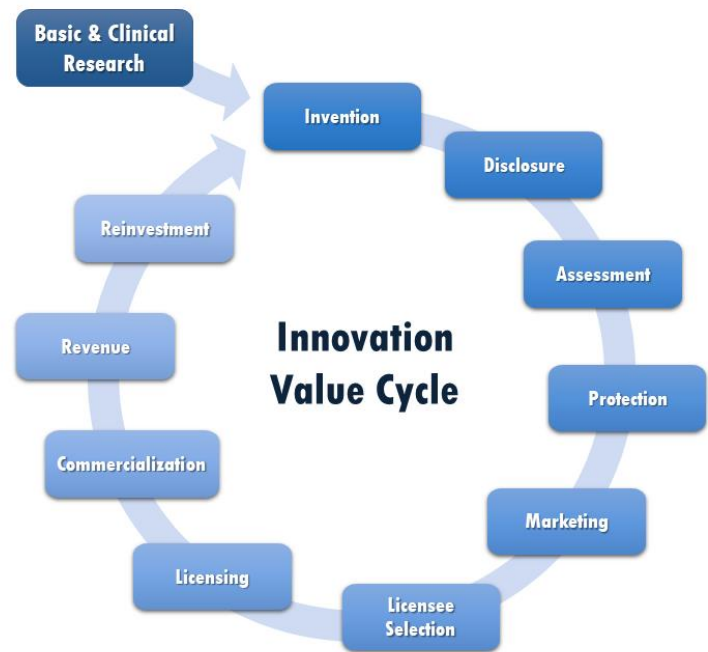


Kevin Boggs, MBA, PhD
Director
Office of Technology Development

Contact the
Office of Technology Development
anytime at
inventions@mcw.edu

TECHNOLOGY TRANSFER PROCESS

The technology transfer process can be looked upon as a cycle. Each “turn” of the cycle begins with basic science discoveries and the ability to envision those breakthroughs as new products on the market and tools to address unmet medical needs. After MCW protects and licenses to startups or existing companies the IP underlying those discoveries – which brings novel products to market – the ensuing revenue from those licenses helps support research at MCW that can restart the cycle.



Research insights lead to novel products and services

Breakthroughs generated during basic and clinical research can be the basis of new products or services that have the potential to improve healthcare outcomes.

Initial Discussions with the OTD

Researchers who believe they have made a discovery or have developed software that has the potential for development along a commercial pathway should contact the OTD via submission of a completed invention disclosure form. To ensure the broadest impact, this form should be submitted to OTD before the invention is publicly disclosed. Invention disclosure forms are available on the OTD website and can be submitted to OTD at inventions@mcw.edu.

Invention Review

OTD completes an initial review of the disclosure, which includes an evaluation of regulatory requirements, size and scope of the need and potential commercial interest.

**Find
Invention Disclosure Forms
on the OTD website**

TECHNOLOGY TRANSFER PROCESS

Intellectual Property Protection


The OTD protects patentable inventions by filing a patent application with the U.S. Patent and Trademark Office and, after careful review of international market potential, by filing applications in other countries.

Marketing

OTD, with the inventors' advice, develops marketing materials that highlight the invention's advantages and applications. OTD uses a variety of approaches to make companies in the relevant industries aware of the opportunity to license the intellectual property underlying the invention. OTD also assesses the opportunity to create a start-up at this stage.

Choice of Commercial Partner

A key responsibility of OTD is to license technologies to companies (including startups) that possess the expertise, resources and commitment to vigorously turn MCW technologies into novel products that generate revenue and enhance healthcare. To that end (and somewhat uncommon), when there is more than one potential licensee, OTD will license to the company in the best position, most committed and most able to bring the technology to the marketplace.



See
"Legal & Compliance Issues"
for more on licensing

License Negotiations

Under MCW's Patent and Copyright Policy, companies interested in licensing an MCW patent or copyright must negotiate with OTD. A license and option agreement on behalf of MCW is a contract between MCW and a company in which certain MCW rights to a technology are granted to the company in return for financial and other benefits. Start-ups generally seek an exclusive license, as they believe it is required to raise funding for the company. See Legal Issues, page 9. When MCW faculty and staff are part of a start-up company, licensing to that company can raise concerns about conflicts of commitment and interest. Thus, MCW must maintain an arms-length relationship in all its business transactions (including license negotiations). The final license agreement must fall within the range of terms and conditions of similar licenses to non-inventor-associated companies (taking into consideration the unique circumstances of each technology and transaction).

TECHNOLOGY TRANSFER PROCESS

Commercialization

As often occurs with inventions derived from basic research labs, MCW inventions almost always need further development and testing, including regulatory testing. OTD recognizes that startups working to develop cutting-edge technologies face many uncertainties. While product development milestones are a key component of all exclusive licenses, OTD will consider good-faith requests – supported by evidence of diligent efforts by the company – to modify such milestones.

Revenue

Royalties and other fees received by MCW from licensees – including cash received from liquidation of equity – are distributed to inventors and departments according to MCW's Patent and Copyright Policy (policy RS.GN.060). A portion of such revenue is retained by MCW.

Supporting Research

Further research is supported by sharing revenues generated from agreements negotiated by OTD with inventors' departments.

WHY START A COMPANY?

While everyone involved in a startup has their own reasons for pursuing such an endeavor, consider these crucial factors to guide your fundamental reasoning:

- ✓ **Intellectual Property:** Are relevant patents or other IP available to protect the company's products? Are rights to background patents available? For instance, is freedom to operate available?
- ✓ **Product Development Stage:** Is proof-of-concept data available? What are the next steps required to bring the product closer to market? How long will they take to achieve?
- ✓ **Costs vs. Financial Return:** Is the market opportunity sufficient to justify the needed upfront investment?
- ✓ **Single Product versus Product Platform:** If multiple products can be developed from the technology, there is a lower risk of failure, a greater opportunity for multiple revenue streams and a higher probability of securing the required investment.
- ✓ **Market Structure:** Is the market you have identified large enough to pursue? How many companies are competing in the market? Do a small number of them dominate the market?

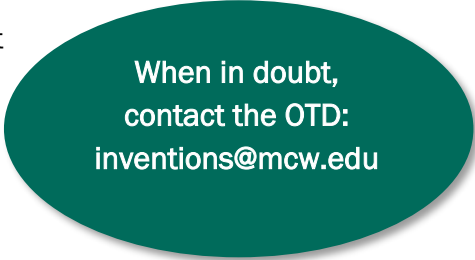


For more advice on planning, see
“Am I Ready to Do This?”

LEGAL & COMPLIANCE ISSUES

MCW Policy and Institutional Considerations

IP Ownership and Licensing: Per MCW's [Patent and Copyright Policy](#), MCW owns IP generated by its employees. For startups to access the rights to that IP, OTD negotiates patent and copyright licenses (see [Technology Transfer Process](#)). These licenses include a standard set of terms, including equity, royalties on product sales, patent cost reimbursement, and maintenance fees. Such licenses also include product development diligence milestones. These are important and help us assure that the company remains focused on taking the steps necessary to bring products based on the technology to market.



When in doubt,
contact the OTD:
inventions@mcw.edu

Institutional 'Buy-In' and Policy Compliance: Ensure MCW knows what you are doing and approves of it. You need to understand how MCW policies may impact your work in the private sector. For example, there are restrictions on how much time faculty can consult for an outside organization. OTD and other MCW offices such as Legal and Corporate Compliance can assist faculty with understanding how much time they can spend on outside endeavors and how it must be structured. You should be proactive early on and be in compliance with all relevant MCW policies. As with all aspects of IP, OTD is glad to assist and provide guidance.

Conflicts of Interest: it is important to identify and manage potential conflicts early in your innovation career. Once you engage in entrepreneurship, create a distinct separation between your MCW lab and your company's facilities. IP must not flow freely between the two, and neither should labor. Safeguards that prevent mingling are necessary and MCW may need to set up "firewalls" to manage any potential conflict of interest that could occur.

Types of Company Structures (LLC, C Corp, etc.)

The choice of the best legal structure for each startup depends on such issues as the amount and timing of funding needed and the categories of investors that will provide the initial capital. Generally, there are two options: C Corporations and Limited Liability Corporations or LLCs (see [Useful Definitions](#)).

LEGAL & COMPLIANCE ISSUES

The benefits of using the C Corporation structure increase as the amount of funding required to launch a product increases. Companies that need less capital can often take advantage of the simpler LLC structure. If the startup seeks to obtain venture capital, they will need to be established as a C Corporation. The startup also must be a C Corporation to take advantage of Section 1202 for federal capital gains exclusion. It will be important to talk to a lawyer about incorporating in Wisconsin to take advantage of certain state tax credits. Many investors prefer to incorporate in Delaware—this is because a company can be a Delaware corporation and still qualify for Wisconsin Tax Credits. This does, however, require that the company be qualified with the Wisconsin Economic Development Corporation as a Qualified New Business Venture. For support, work with your lawyer or consult with OTD.

Protecting Yourself from Liability and Tax Issues

Hiring your own attorney, and if needed, tax consultant, will help assure you that you have the protection you need.

Lawyers

Why you need one: Startups face a variety of complex legal decisions and must enter a wide array of contractual agreements. Having an attorney who is experienced in the startup and early-stage investment world is critical to keep new companies from entering agreements that may have long term harmful impact on the company, such as limiting the ability to raise funds, license IP, and enter service agreements.

When you'll need one: Need for legal counsel will vary depending on company activities. If you will engage the company in a personal consulting role in exchange for equity, OTD strongly advises you to secure personal legal advice before signing any agreements.

Where to find them: Contact OTD for a referral. While we do not endorse any specific firm, we have a list of credible law firms in the area. You will need to choose a lawyer after you evaluate their credentials, experience, and fees, as you would any professional service provider.

LEGAL & COMPLIANCE ISSUES

How much a lawyer charges: Generally, hourly fees are charged, although some firms offer flat rates for some services such as filing incorporation papers or reviewing equity agreements. Hourly rates can range from \$250-600+. Flat rates vary depending on the scope of effort required.

Before you hire an attorney: When interviewing a potential attorney, be sure to request references and ask them if they need to run a conflict check. If MCW is one of their clients, they may not be eligible to also work for your new company.



STARTUP FUNDING



Securing the initial round of funding is a huge, and often quite memorable, early event in the life of any startup. How much funding the startup needs, when it will be needed, and what the funds will be used for are fundamental questions that the startup's leadership must answer.

An important point to keep in mind is that in most cases, external funding may not be used to continue to answer basic research questions—the exception to this being SBIR/STTR grants (see page 12). Instead, external funding should be used in a focused manner to move a product along a commercialization pathway. If you need to conduct more research to better understand the role of your drug/device/software, you may not be ready to form a company.

How Much You Will Need and When

Pharmaceuticals: Whether small molecules or biologics, bringing new drugs through FDA clinical trials entails significant costs. Because startups that develop and test therapeutics through Phase 2 clinical trials can expect to be acquired by a larger pharma/biotech company, the more expensive trials are generally paid for by the larger, acquiring company.

- ✓ Preclinical cost \$2-5M
- ✓ Phase 1 trials: \$3-10M
- ✓ Phase 2 trials: \$7M-\$25M
- ✓ Phase 3: Varies widely depending on patient population, type of disease duration of trials: \$12M to well over \$500 million
- ✓ Total costs per approval of an investigational drug range between \$161M - \$2.6B. Review online articles from [Eye for Pharma](#) & [Journal of Health Economics](#) for more information.

STARTUP FUNDING

Medical device/diagnostic: Devices and diagnostics are less costly to bring to market because testing required by regulatory agencies is usually shorter and less expensive. This cost depends largely on the level and degree of testing required by the FDA and other regulatory agencies. Devices for which product failure will cause little to no safety issues are designated Class 1. In the US, Class 1 devices have very low testing costs and typically require submission of basic information such as quality control of materials and manufacturing methods. Class 2 devices are more complex, and failure may put patients at more serious risk. According to a recent study, the cost to bring Class 2 devices to market average \$24M. Finally, Class 3 devices are those that a patient's life depends on. Therefore, testing and approval costs can be between several million dollars to \$100M, depending on the complexity of the device and the duration of the clinical trials.

Software: The funding required to bring a software product to market within a healthcare application is so variable that it is best handled with a case-by-case analysis. The FDA has recently begun to approve select software as a device, in which case testing costs would be determined according to the class the software falls under.

Grants as Funding Sources

“Free” money, also known as non-dilutive funding

SBIR/STTR: Contact OTD for questions about SBIR/STTR grants that are available through the state of Wisconsin.

Center for Technology Commercialization ([CTC](#)) Programs/Funds:

- ✓ IDEA-ADVANCE [Seed Fund](#)
- ✓ [SBIR Ready](#): Building Skills, Proving Concepts
- ✓ [Micro-Grants](#)
- ✓ Pre-Submission [Review Panels](#)
- ✓ SBIR-ADVANCE [Matching Grant](#)



Equity Financing

Selling shares in the company to:...

Friends and Family

- ✓ **How it works:** If the funding needed to launch the startup and de-risk the opportunity are modest (say, less than \$100,000 total), then it may be possible to fund it through contacts in your personal network.
- ✓ **Pros:** Little need to prepare a “pitch” or to seek investors who are motivated by a potential financial return on invest.
- ✓ **Cons:** Usually only small amounts of capital are available. You will face disappointing your family and friends if they lose their investment. It’s unlikely that this investor group includes anyone with industry expertise or relevant networks that you need to grow your business.
- ✓ **Key Issues:** Maintaining a legal structure and carefully managing expectations will be important to avoiding personal conflicts and strained family relationships.

Angel Investors

- ✓ **How it works:** Because Angel Investors (see [Useful Definitions](#)) are individuals or families, their motivations, the size of the investment, and industry expertise available can vary widely. Unless they are members of a network of other Angels, they make their own investment decisions.
- ✓ **Pros:** Investment decisions can be made quickly, although not always. Many Angels will invest early in a company’s development when the highest risk exists. They may also have a longer time horizon compared to Venture Capitalists.
- ✓ **Cons:** Lower amounts of funding are generally available. The investor may have less relevant expertise and fewer industry connections.

- ✓ **Key Issues:** Carefully review each Angel investor's background and any previous investments they have made before accepting their money. If possible, talk to leaders of other companies they have invested in. Always have your attorney review any investment documents before you sign them.
- ✓ **Resources:** [Angel Capital Association](#)

Venture Capitalists

- ✓ **How it works:** VCs (see [Useful Definitions](#)) that make investments in early stage life science companies receive hundreds or thousands of unsolicited business plans and investment proposals on an annual basis. If these proposals are reviewed, it is by a junior associate. Very few of those result in a follow-up phone call from a partner who makes investment decisions. However, business plans and proposals that arrive at the firm from a trusted "gate keeper" are given more time from a senior member of the firm. Even if they pass on the opportunity, the firm will share their reasoning and feedback that can improve the odds that the plan will be funded in the future. OTD is glad to discuss accessing such gatekeepers as appropriate.



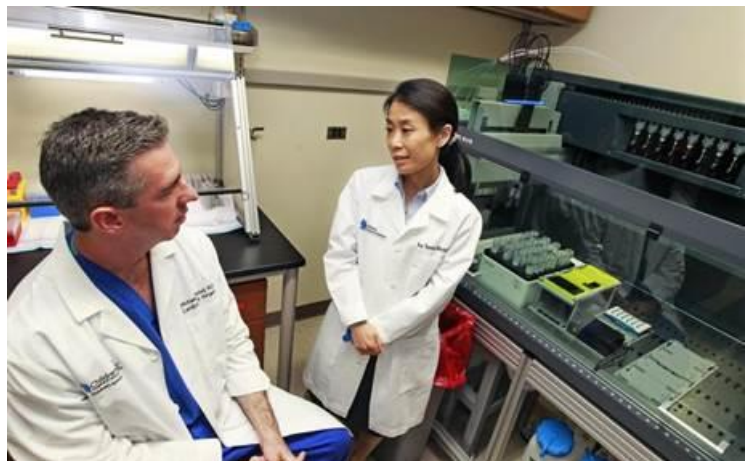
If the firm believes that the plan has significant potential and fits within its investment criteria, a senior member of the firm will take over. This involves engaging the startup team in more detailed discussions about their plan, other investors they have spoken with, due diligence and next steps. The firm may require that

the startup "syndicate the deal" by identifying other VCs to join in before any investment is made. As your CEO prepares to approach VC firms for investments, note that it is not uncommon to make several dozen pitches before finding a firm for which your opportunity is a good fit. It is also not uncommon for a VC to track progress over several years to get to know a company better before making an investment.

- ✓ **Pros:** Larger amounts of capital available. Investments from credible firms bring a level of validation, industry expertise, and connections.
- ✓ **Cons:** VCs generally invest later in a company’s development, meaning VC funding is rarely the “first money in”. Founders give up significant aspects of control, and investment decisions may take longer.
- ✓ **Key Issues:** Successfully landing a first round of VC funding requires a familiarity with a new set of jargon (e.g., “round”). Concepts and issues that significantly impact your company’s path forward with a VC are beyond the scope of this Guide. OTD is available to answer questions and, when suitable, to make introductions.
- ✓ **Resources:**
 - [National Venture Capital Association](#)
 - Several books by experienced Venture Capitalist Brad Feld, see especially “[Venture Deals, 4th Edition](#)”
 - “[Secrets of Sandhill Road](#)” by Scott Kapur is great resource for entrepreneurs

Banks

We include banks here for completeness. However, banks are very rarely, if ever, a source of early stage funds for life sciences startups.



CEO: Chief Executive Officer

Why? Having a full time CEO, or part time under some circumstances, is a key early step in the development of a company. The CEO is very important, both because they will be the one person who wakes up every morning with the sole mission of making the company successful, and because a credible CEO shows potential investors that the opportunity is real. They will also know that a professional with relevant experience will be a good steward of their investment funding.

When? As soon as it is clear that the technology works and that there is a market opportunity which will allow a CEO to raise funding, build a capable team, and develop the plan to bring products to market, potential CEO candidates should be engaged. This can start with informal discussions. OTD can assist by making introductions and doing informal background checks within our networks.

How to recruit the CEO? A credible and experienced startup CEO will have many options. They will be looking for an opportunity that excites them with a startup they believe they can add value to and have a solid chance to be successful. They also know that every early stage opportunity has a variety of risks, and that overcoming them will require working closely with the scientific founders. This means they have to have a high level of trust when interacting with those founders. If they only hear that there are no potential scientific problems, no market competition, and no IP issues, they will wonder what is



being hidden, or what they will find when they start digging into the opportunity. Better to engage in radical candor about the science and any other issues that the scientific founders are aware of. This does not mean one should bury the compelling story in negative, “what-if” scenarios, but a sense of trust is essential to carry a team through challenging times.

How to select the CEO? Criteria for considering your CEO should include their track record of successful startups and their reputation among respected VCs. A highly credible CEO is often as important—or even more important—to VCs than the technology. Be aware that the quality of company leadership is critical to VCs. In conducting their due diligence, VCs will consider if the CEO has a track record of successful startups and whether they are respected among other VCs. This is often as important or

even more important than the science to a good firm. Also, it is a common practice for VCs to insist on placing senior management in a Company which they are funding, even replacing the CEO, CSO, etc., who may have helped start the company.

What will the CEO expect? Your CEO will anticipate having a high level of autonomy to make key decisions, to report directly to the board of directors, and to have a market-comparable share of the company's equity (vested over time). The CEO should be accountable to the investors and either be the primary spokesperson for the company or appoint them. They may be positioned to defer most or all their cash compensation until the first significant round of funding has been raised.

What is the CEO's job? The CEO should raise funding, develop and execute a business plan, make hiring decisions, manage the Board, and position the company to be acquired or to go public.

Regulatory Consultants

Why? If the company's products are regulated by the FDA and similar agencies in other countries, a clear strategy to achieve regulatory clearance or approval in a timely and cost-efficient way is critical to a company's long-term success. Indeed, regulatory mistakes made early in a company's life can easily sink the company. However, most startups can't afford to hire a full-time regulatory expert and may not need one. Thus, an experienced regulatory consultant who works on a project basis is critical, even if only to advise on strategy and to review documents before they are submitted.

When? A consultant should be identified when proof of concept data is gathered, and the clear next step is to identify the regulatory path and a plan to achieve the key milestones.

How much do they cost? Like attorneys, consultants may charge in the range of \$200-400/hr. Many also offer flat fees for well-defined projects.

Where to find them? OTD can make introductions. The [Regulatory Affairs Professionals Society](#) is also a source of useful information.

Reimbursement Consultants

Why? A reimbursement consultant is beneficial for the same reasons as a regulatory consultant. Choosing the optimal reimbursement path early on is becoming an important step that can have lasting impact on the fortunes of the company. A consultant should be able to advise about strategy, tactics, likely outcomes, and the kinds of professionals you are likely to need and when. Investors will also want a clear path to reimbursement before making an investment.

When? Very preliminary discussions should occur as the product and indication are being finalized.

How much do they cost? Fees for reimbursement consultants are similar to regulatory consultants.

Where to find them? This is a more nascent profession. OTD can make introductions as can others in your network.


Chief Operating Officer/Business Development Lead

Why? While the CEO is the first and most important salesperson in the company, sales into markets with complex supply chains, long sales cycles, entrenched competitors, customers spread over a wide geographic area, and even additional regulatory issues will require careful planning and may depend on a well-structured sales force. Someone experienced with building sales plans and hiring and compensating a sales team is thus a key hire.

When? Variable, depending upon the product and the market.

How much do they cost? A Chief Operating Officer/ Business Development Lead will expect a compensation package that includes both cash (little deferred, if any) and equity.

Where to find them? The CEO and Board members should have networks that include experienced people that they trust.



For information on Lawyers, see
“Legal & Compliance Issues”

NETWORKS & SUPPORT ORGANIZATIONS

Center for Technology Commercialization



[CTC](#) can be useful in helping you find the support and resources you need to bring your innovation to market. CTC offers services and assistance with your funding acquisition efforts through the federal Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) programs.

BioForward



[BioForward](#) is the only Wisconsin organization representing over 200 biohealth member companies including biotech, biopharma, medical device, diagnostics, digital health, as well as research institutions, and service providers. It is Wisconsin's official affiliate of BIO. BioForward's programs and memberships are designed to support members through business networking events, advocacy on behalf of the industry, exclusive rebates through their select savings program, and educational and speaker programming.

Biotechnology Innovation Organization (BIO)



[BIO](#) is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

Catalyst BioConsulting



[Catalyst BioConsulting](#) (formerly PICO – Postdoc Industry Consultants) is a business consulting group comprised of highly trained scientists that provides a broad range of consulting services for the many challenges faced by startup and established firms. They offer pro-bono services geared towards the sustainable development and growth of innovative biotech and health technology companies in Wisconsin and beyond.

NETWORKS & SUPPORT ORGANIZATIONS

Gener8tor



[Gener8tor](#) is a turnkey platform for the creative economy that connects startups, entrepreneurs, artists, investors, universities and corporations. The gener8tor platform includes pre-accelerators, accelerators, corporate programming, conferences, and fellowships focused on entrepreneurs, artists and musicians.

gBETA



[gBETA](#) is a program of nationally ranked startup accelerator gener8tor. gBETA is a free, seven-week accelerator for early-stage companies with local roots. Each program is capped at five teams and requires no fees and no equity.

Wisconsin Technology Council



[WTC](#) offers a wide variety of services to Wisconsin startups, including access to the Wisconsin Innovation Network (WIN) and Investor Networks. Annual events include the Wisconsin Entrepreneur's Conference, the Wisconsin Governor's Business Plan Competition, the Early Stage Conference, and the Tech Summit.

NSF I-Corps



The National Science Foundation (NSF) created the [Innovation Corps](#) (I-Corps) Program to help accelerate the transfer of academic research into the marketplace. The [Milwaukee I-Corps Program](#) focuses on using “lean launch” methodology to help faculty-based researchers understand markets for their technologies. Since 2015, UWM, the UWM Research Foundation, MCW and other partner educational institutions have been bringing this unique program to Milwaukee.

PREPARATORY CONSIDERATIONS

What Is My Role?

Your role will evolve as the company grows and the products move along the development pathway.

Inventors are not CEOs: Your significant expertise is needed to continue the science. The tasks of a CEO would naturally put you in a conflict situation. Additionally, OTD strongly prefers to not negotiate license terms with the inventors. We are advocates for the inventors and this mixed role is best avoided. While MCW inventors are very intelligent people, there are many areas of business that few academically trained personnel have requisite expertise in.

Optimally: Inventors are well suited as Science Advisors or as head of the Scientific Advisory Board (SAB). This is the best role for researchers who want to engage with the startup. Some startups may offer a small amount of equity to SAB members. Some may also reimburse out-of-pocket costs to attend meetings or to meet with potential investors.

Potentially: An alternative role may be Acting Chief Scientific Officer. If the CEO and the early investors see the need for a higher level of engagement from the inventors than SAB membership would allow, the CSO can be a useful short-term role. Because the CSO ultimately will work with the other members of the leadership team to bring products into development in a way that will soon split off from the basic science aspects of the technology, the full time CSO will need to have more product development and testing knowledge, which often comes from industry experience.

Will I Need a Business Plan?

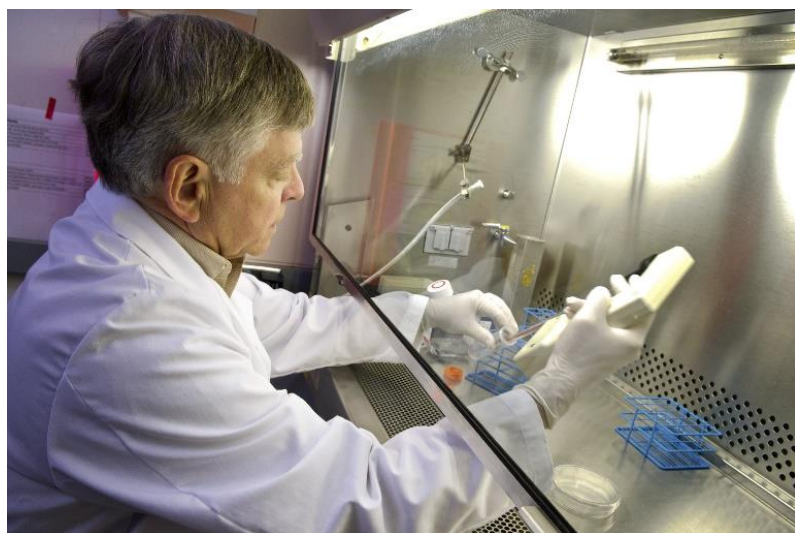


Eventually. As the company gets started, a well-reviewed slide deck will be the primary tool used to help tell its story. OTD will be glad to discuss slides and business plans. What you WILL need is a clear, focused and time-bound development plan that shows how much time and how much money are required to hit specific “Go, No-Go” decision points.

PREPARATORY CONSIDERATIONS

How Might I Benefit from Working with a Startup?

There are a variety of reasons that people choose to be involved in a startup. In some cases, the decision is purely economic: they need an income. In others, a person may believe that working for a large organization provides too little independence. If you are an MCW faculty member, these reasons are more likely to apply to others that are considering joining the effort, including post-docs and



graduate students who have recently completed their course of study.

A few of the benefits that researchers have experienced from engaging with a startup include the opportunity to bring an idea from the lab to the people who can benefit most from it. Then, of course, there is the

potential that their initial ownership stake has the potential to generate a financial return.

It is important to note that any equity you may be granted directly by the company will (1) be at the company's discretion, and (2) not be in exchange for your inventorship. Rather, it will be in exchange for your efforts to advance the company's business objectives. It will likely be vested as specific accomplishments are achieved. It is advisable to consult with your personal attorney about the terms under which such equity is granted to you.

Additional resource documents
available in "Appendix"

If MCW receives equity in exchange for an IP license and that equity is sold in the future for cash, that cash will be distributed to the inventors pursuant to the current [MCW Patent and Copyright Policy RS.GN.060](#). The policy in place at the time of such distribution is applicable.

PREPARATORY CONSIDERATIONS

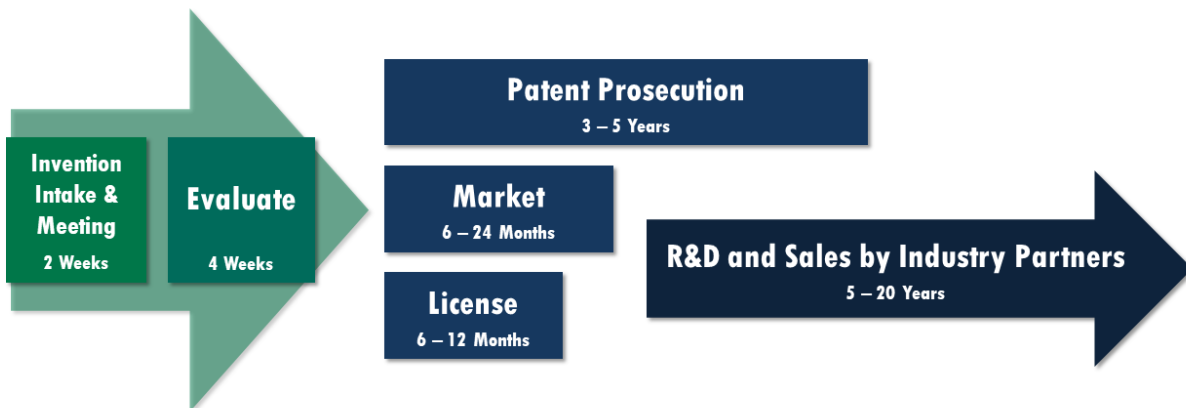
Should I Expect to Maintain Control Over the Direction of the Company?

No. Product development and testing, especially in life sciences, is very expensive. Raising the amount of money needed to bring a biotech or medical device product to market requires that the majority of the company would be owned by the investors who provide that funding. Those investors will also demand to have the right to make necessary decisions that keep the growing company on track, as well as preparing for future rounds of financing and acquisition and ensuring business development goals are met.

What Is the Estimated Timeline for Establishment, Development and Growth?

Average time frames for the various key stages of company development and growth are illustrated in the graphic below:

Technology Transfer Process



ROLES OF KEY MCW OFFICES

OTD

The mission of OTD is to support and educate MCW faculty, postdoctoral fellows, interns, students and staff. The OTD facilitates the transfer of technology generated from research and clinical practices into commercial products that benefit MCW, our community and the public. The OTD engages inventors, as well as internal and external stakeholders, to bring Patents to Patients®.



General Counsel

The Office of the General Counsel (“OGC”), is the in-house legal office for The Medical College of Wisconsin.

Grants and Contracts Office

The mission of the Grants and Contracts Office (GCO) is to support investigators and the MCW research community in submitting high quality, competitive and compliant research grants. The GCO also helps maintain commitments to our corporate and federal sponsors, ensures compliance with all applicable federal, state, local and institutional policies and regulations, and promotes best practices, policies and procedures that ensure consistency and efficiency in our interactions with sponsors, affiliates, collaborators, and investigators.

Compliance

The primary function of the Corporate Compliance program is to help ensure that the College is consistently following all federal and state regulations relating to our missions. The Division of Corporate Compliance has four offices that assist with this function: The Clinical Compliance Office, the Internal Audit Office, the Research Compliance Office, and the Risk Management Office.

AM I READY TO DO THIS?

Startups Are Hard Work

For many people, choosing to engage with a startup has an appeal that is partly derived from the splashy successes—and sometimes the failures—of startups that became legends. As with any legend, some of the stories have elements of truth while others have been stretched beyond recognition in the service of some of the stakeholders. But, common threads of any of these stories include a great team, some luck and hard work. If you work with OTD on a startup, you will have the opportunity to meet entrepreneurs who have done that hard work.

Startups Are Risky

While it depends on the type of product and the complexity of the path to market, startups generally have a 50-80% chance of failing. Starting with a strong team, seeking and heeding counsel from knowledgeable advisors, and remaining flexible in response to feedback from actual customers are three important elements that improve the odds for a fledgling company to be acquired for an attractive sum, or to gain a strategic position that will allow it to go public.

Startups Are Exhilarating!

Much like the common response to getting off of a roller coaster that one had previously been anxious about: “I want to go again!”, exiting a role in a startup often leaves people looking for the next opportunity to re-enter that world. OTD can help you find people with that experience who are willing to share their story. Other stories are at the links in the Appendix.

The OTD has helped launch over a dozen startups in the Milwaukee area and beyond!



Resources

Digital:

[How to Start a Biotech Company](#)

[Milwaukee NSF I-Corp program](#)

[National Venture Capital Association](#)

[WI Tech Council Entrepreneurs' Tool Kit](#)

[Startup Revolution](#)

[US Patent and Trademark Office](#)

[World Intellectual Property Organization](#)

[Various Cap Table Scenarios for a Hypothetical Biotech Startup](#)

[Recruiting Talent for University Startups](#)



Print:

[Books by Brad Feld](#)

[Books by Steve Blank](#)

[The Mom Test:](#)

How to talk to customers & learn if your business is a good idea when everyone is lying to you.

Useful Definitions

Angel Investors (“Angels”): Wealthy individuals who invest their personal funds in startups. When Angels first appeared as a significant source of funding in life sciences companies, many were motivated by a desire to find a treatment for a disease that had impacted their lives. In recent years, more and more Angels are investing strictly to achieve a financial return on their investment. Some Angels have formed networks, or funds, that are quite sophisticated and often invest significant levels of capital along-side VCs. Angels must be accredited investors, which means they must meet minimum income or net worth thresholds [defined by the U.S. Securities and Exchange Commission \(SEC\)](#).

C Corporation: Any corporation that is taxed separately from its owners. C corporations are governed by laws of the state they are incorporated in. Investors tend to prefer the predictability of Delaware law.

Chief Executive Officer (CEO): The most senior leader of a company. Makes key strategic decisions. Reports to the Board of Directors.

Copyright: A limited-term, government-granted intellectual property right that gives the copyright holder the right to exclude others from copying and distributing their copyrighted work. [Copyright protection](#) applies and is enforceable as soon as a creative work is applied to a fixed medium of expression—on paper or on a computer server, for instance. Copyright applies to both published and unpublished works. Relevant examples of types of works that are protected by copyright include: software code, including databases, websites, and user interface design.

Board of Directors: Investopedia defines a Board of Directors as: “A group of individuals elected to represent shareholders. A board's mandate is to establish policies for corporate management and oversight, making decisions on major company issues.” At startups, boards are generally controlled by the investors but often include the CEO, a scientific founder and an independent member. After a significant first round of investment, boards are likely to meet at least quarterly. The fiduciary duty that boards of directors and officers owe is solely to the corporation and the shareholders collectively.

Conception of an Invention: To "conceive" an invention is defined in a legal sense as the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 *Robinson On Patents* 532 (1890)). This means that all details needed to make the invention work must be available.



Embodiment of an Invention: An embodiment of an invention is a version of, or one specific way of practicing, the invention. For example, if the invention is a method to treat autoimmune diseases, a specific claim to treatment of lupus is one embodiment of the invention.

Enable an Invention: To enable an invention is to disclose sufficient details so that one of skill in the art can practice the invention.

Equity: Ownership stake in a company. One unit of equity of a corporation is a share. Ownership of LLCs is generally in units or percentages.

Food and Drug Administration: The [FDA](#) is the federal agency responsible for “protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.”

Freedom to Operate: One has freedom to operate if one does not infringe the IP rights of others while making, using, or selling a product or service. Or, that one has a license to any such IP rights that may otherwise be infringed.

Intellectual Property (IP): A government issued property right. Grants certain rights to products of the mind. Examples include patents, copyrights, and trade secrets.

License: A contract that grants the licensee certain IP rights held by the licensor. May be exclusive (licensee is the only licensee), non-exclusive (may be several licensees), exclusive field-of-use (e.g., licensee will be the only licensee allowed to use the IP in a defined application or type or market) or exclusive by territory (e.g., licensee is the only licensee in a specified country or region).

Limited Liability Company (LLC): A legal structure for a company that limits the liability of its owners but allows pass-through taxation. LLCs are not corporations and are governed based on an operating agreement, which is an agreement among the owners.

Patent: A limited-term government-granted intellectual property right that gives the owner the right to exclude others from making, using or selling products or services that infringe the claims of the patent. Patent rights are specific to each country in which they are issued, meaning a [U.S. patent](#) is not enforceable in other countries. Patent protection is available for compositions of matter such as new molecular structures, machines, articles of manufacture, methods, and processes including computer-implemented software. It is not available for naturally occurring, unmodified molecules, natural processes, and laws of nature.

Reduction to Practice of an Invention: US patent laws define the reduction to practice of an invention as the step or steps in the formation of an invention after the conception of the invention. Reduction to practice may be actual, meaning the invention is actually physically created and is found to work for its intended purpose, or constructive, meaning a patent application is filed that has a sufficient description to the extent that the invention can be physically reduced to practice.

Small Business Innovation Research & Small Business Technology Transfer Grants: [SBIR](#) & [STTR](#) grants are provided by eleven (SBIR) and five (STTR) federal agencies, including the [NIH](#). The grants are awarded via a competitive application process. While these funds are available only directly to US-owned and operated small businesses to engage in federal research and development that has potential for commercialization, a portion of such funding may be used to support work at a research institution under a sub-award.

Startup: A new company established to develop and commercialize novel technologies.

Trademark: A trademark is a brand name. A trademark or service mark includes any word, name, symbol, device, or any combination, used or intended to be used to identify and distinguish the goods/services of one seller or provider from those of others, and to indicate the source of the goods/services.

Venture Capital Firms (VCs): Specialized investment firms that raise funds from institutions and accredited investors, together called Limited Partners (LPs). VC firms invest using a clearly defined set of criteria. Investments are generally restricted to a set of industries, such as therapeutics or software, and are limited to a narrow range of company and product maturity profiles, such as pre-revenue, above \$5M/year in revenue, etc. The members of the firm who make investment decisions, individually known as a General Partner (GP), often have significant knowledge about the types of companies the firm invests in. Access to these people and their networks is of significant value to startup companies.

Acknowledgements

OTD would like to thank the following people for reviewing and/or providing critical feedback on early drafts of this Guide: William Clarke, MD, Associate Professor of Pediatrics, Harvard Medical School and Entrepreneur-in-Residence, Boston Children’s Hospital; Brian Volkman Ph.D., Professor, Department of Biochemistry, MCW and President and Co-Founder, Protein Foundry; John Neis, Executive Managing Director, Paul Weiss, Managing Director and David Arnstein, Chief Financial Officer, Venture Investors LLC, Madison WI; Jean Baker, Ph.D., Partner, Quarles & Brady, Milwaukee WI; Michael Cassidy, Emory Biomedical Catalyst, Emory University, Atlanta, GA. OTD also greatly appreciates Ms. AshLeigh Sanchez for her creative and thorough efforts to deliver our simple text in a readable, accessible and attractive presentation. Thank You, AshLeigh.

About the Guide

Parts of this Guide were inspired by the “Stanford University Office of Technology Licensing Startup Guide”. The Guide was first developed in 2020. It was designed to be a general source of information for MCW faculty, staff, and students. Any MCW policies that the Guide refers to are subject to change; official policy always takes precedent over this Guide.





Patents to Patients[®]



knowledge changing life

mcw.edu/departments/technology-development