HOW TO START AND GROW

A LIFE SCIENCES COMPANY

Practical Advice for Start-up Companies & Incubators



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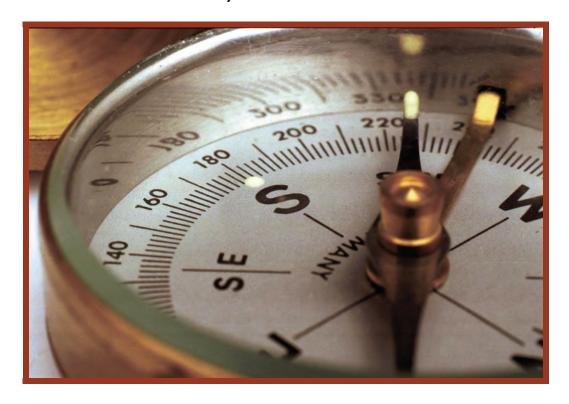
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INTRODUCTION FROM THE CO-CHAIRS OF THE BALLARD SPAHR LIFE SCIENCES/TECHNOLOGY GROUP



INTRODUCTION

From Brian D. Doerner and Douglas M. Fox, Practice Leaders of the Life Sciences and Technology Group at Ballard Spahr LLP

We at Ballard Spahr have been working for decades with entrepreneurs to start and grow technology-based companies. Over the years, we have seen it all. Terrific successes and devastating failures. We have seen life sciences companies brought to their knees by terrible setbacks, and then regroup and overcome those setbacks. We have also met, time and again, entrepreneurs and companies that have made common mistakes. Most of these mistakes can be fixed, but too often at a cost measured in both cash and the distraction of management from the task of building value.

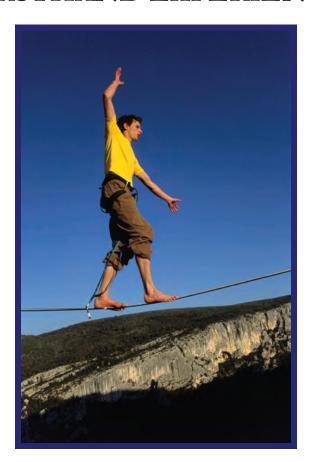
Among the new founders and CEOs of these companies, there is a universal thirst for knowledge and good advice about *how to*.

This book is meant to quench that thirst, at least in part.

It draws on the knowledge and experience of others who work with these entrepreneurs, including CEOs who have started companies, accountants, venture capital and angel investors focused on these companies, and company directors and an SBIR/STTR grant specialist. It covers the life sciences start-up company from formation to financing to exit. The book also pulls together the knowledge and experience of the Ballard attorneys who have worked with entrepreneurs over the years (including those who managed to get it right and those who learned the hard way).

We hope this book serves as a useful guide to all aspects of starting a life sciences company. More than that, we hope it inspires you to forge ahead, turning your great ideas into tangible results.

LIFE AS AN ENTREPRENEUR: FIRSTHAND EXPERIENCE



CONTRIBUTORS

WORDS OF WISDOM FROM THE TRENCHES

PERSONAL NOTES OF WISDOM AND ADVICE TO NEW CEOS FROM CEOS WHO HAVE BEEN THERE AND DONE THAT

CHRISTOPHER CASHMAN is co-founder of Protez Pharmaceuticals Inc. and most recently served as Director, President and CEO. He has 30 years of experience in the pharmaceutical industry including of prior roles as President and CEO, Message Pharmaceuticals, and as Vice President, Sales and

Marketing, for both Pfizer and SmithKline Beecham. Mr. Cashman currently serves on the Board of Directors of the Science Center, Noble Biomaterials and as non-executive chairman of JDP Therapeutics and MBF Therapeutics.

JANE HOLMES HOLLINGSWORTH co-founded Nupathe Inc. in 2005 and has been its Chief Executive Officer since January 2005. Ms. Hollingsworth founded Auxilium Pharmaceuticals Inc. and served as its Executive Vice President, Secretary and General Counsel from July 1999 to October 2004. From 1994 to 1998, she served as Vice President, Secretary and General Counsel at IBAH Inc. (now Omnicare Clinical

Research, Inc.), a publicly traded contract research company. Prior to 1994, she served as the Chairman of the Board at NuPathe, Inc. She has been a Director at University City Science Center since June 2010. She serves as a Director at the Pennsylvania Biotechnology Association.

LARRY D. RIGBY is a founder of Larada Sciences (Chairman and CEO) and Vice Chairman and Founder of ZARS Pharma, both spinouts from the University of Utah. He was CEO of ZARS Pharma from its inception in 1996 to January 2006. Prior to that, he founded three successful biomedical companies. Mr. Rigby started his medical career with Sorenson Research Co., where he was Vice President of Sales and Marketing, and played a major role in leading the company from \$1 million to \$60 million in revenues over a period of six years. Abbott Laboratories acquired Sorenson in 1980, and is known today as Abbott Critical Care. He was founder and CEO of

Cardio Pulmonics, a developer of advanced artificial lung and non-thrombogenic coating technologies, which went public in 1992 and later merged with Innerdyne and then again with Tyco. His second venture was Alton Dean Medical, where he was Chairman, CEO and founder. Mr. Rigby was President of MicroJect, a developer of a leading technology for intravenous drug delivery, which he founded in 1993. Mr. Rigby is also a founder and former Director of Iasis Medical and current Chairman of VisualShare, Inc., a University of Utah spinout. He is also a published novelist.

WARREN COOPER is CEO of Prism Pharmaceuticals, a specialty pharmaceutical company focused in acute care cardiovascular medicine, which was established in 2004. He was the first employee of Prism, which has received two FDA approvals in its brief history and is poised to commercialize its first product. Mr. Cooper is a U.K.-trained physician with over 30 years in the global pharmaceutical industry. With a background in cardiology and cardiac surgery, he spent 12 years with Merck, initially as a U.K. clinical research physician, then as head of European and Worldwide Clinical Research Operations for Merck Research Laboratories across all therapeutic areas.

Moving to AstraMerck (now AstraZeneca PLC), he led that company's cardiovascular business division, a role with full business life cycle leadership from in-licensing through development to P&L responsibility for sales and marketing. Mr. Cooper then founded a health care consulting practice, Coalescence Inc., which he led for five years prior to joining Prism. Mr. Cooper is a member of the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom, the American Association of Pharmaceutical Physicians and the American and International Societies of Hypertension, and serves on the Board of Directors for Nutrition 21.

RICHARD F. POPS serves as Chairman, President and Chief Executive Officer of Alkermes. He assumed the role of Chairman of the Board in April 2007 and previously served as Chief Executive Officer of Alkermes from February 1991 through April 2007.

Under his leadership, Alkermes has grown from a privately held company with 25 employees to a publicly traded pharmaceutical company with more than 500 employees and two commercial products. Mr. Pops currently serves on the Board of Directors of:

Alkermes, Inc.; Neurocrine Biosciences, Inc.; Acceleron Pharma, Inc.; Epizyme; the Biotechnology Industry Organization (BIO); the Pharmaceutical

Research and Manufacturers of America (PhRMA) and the Harvard Medical School Board of Fellows.

RICHARD E. CARUSO, Ph.D., is the founder and current Chairman of Integra LifeSciences Corp., a publicly held company. He is also founder of The Provco Group, a group or amalgamation of business or activity, which organizes and provides funding for a variety of entrepreneurs and complex business activities. Dr. Caruso is a former principal of LFC Financial Corp. in Radnor, PA, and a founding shareholder of Interactive Investor International, once publicly traded on NASDAQ and the London Stock

Exchange (acquired by an Australian insurance group of Advanced Voting Solutions, Inc.) and of First Sterling Bank, which is now part of Bank of America. Dr. Caruso also founded Tenly Enterprises, which acquired and operated Rustler Steak Houses before its sale to Sizzlers. Dr. Caruso has more than 35 years of experience in entrepreneurial and finance type ventures and is the author of "Mentoring in the Business Environment."

WORDS OF WISDOM FROM THE TRENCHES

PERSONAL NOTES OF WISDOM AND ADVICE TO NEW CEOs FROM CEOs WHO HAVE BEEN THERE AND DONE THAT

By Chris Cashman, Director, President and CEO of Protez Pharmaceuticals, Inc.

In the foundation of any new business venture is a set of clear business, financial and operational objectives backed up by precise planning detailing the human and capital resource requirements to build value. Using a biotech start-up example, careful thought needs to be given "day one" to your intellectual property strategy, target patients, payers, competitor benchmarks, clinical/regulatory strategy, financing strategy, value proposition and potential buyers.

The list above may seem premature or overkill to new entrepreneurs in the start-up phase. However they will quickly discover a well-thought-out road map is handy in their fund-raising efforts as it aligns the enterprise/project milestones (value inflection points) with the use of investment capital (a requirement of angels and venture capitalists). Operationally it becomes a very useful tool to better anticipate and prepare for the future development requirements and to be in a position to take advantage of a timely exit.

In my experience, the biggest "trip wires" in the start-up and building of a start-up biotech company are the following:

- Underestimating the technical difficulty of discovery/development projects, which results in time delays and increased cash burn
- Recruiting high-quality, right-minded people suited to a biotech environment
- Underestimating or miscalculating regulatory requirements
- Underestimating the time and effort required to raise capital and in general not raising enough money
- Underestimating the time and effort required to attract a buyer

Biotech start-up, and in general drug discovery/development, exhilarating, is an challenging experience. Persistence and requirements perseverance are absolute of entrepreneurship. Rewards are high both in the journey and the opportunity to make a positive impact on the lives of mankind.

By Jane Hollingsworth, Chief Executive Officer of NuPathe, Inc.

- You are in the problem-solving business: expect problems and be good at solving them. If you do this well, with minimal panic and drama, you have a much better chance of succeeding.
- Test your business plan and product plans with those who have been in the early stage world before, as investors or entrepreneurs.
- Urgency matters a lot. Have it every single day and instill it in your people.
- Details matter a lot, too. Inattention to the little things may kill you.
- Leave behind your ego and concern about living the good life; enjoy the process, the challenge, the fun, and even the doubt that you may face at every turn from skeptics and believers alike.
- For every dollar you spend, you need to make at least three back, so spend it wisely.
- Have a core group of employees inside the company who have the track record of success and expertise needed to do what you are trying to do.
- Consultants, such as CROs, will be very expensive in time, money and maybe results if they are not carefully managed internally by knowledgeable people.
- Never be afraid to keep pushing to find the answer, regardless of timing or events on the horizon; it is better to know a negative answer than to suffer from a fear of failure or, even worse, to inject that fear into your team.
- Regardless of whether the company succeeds, you will grow, learn an incredible amount and make yourself better and more valuable by going through the process.
- It is a fantastic feeling to create something positive and special out of nothing something special for patients, employees and investors. That is why we do it.

By Larry Rigby, Chairman and CEO of Larada Life Sciences

THE EMOTIONAL SIDE OF THE START-UP

In the early morning, when my mind is swinging lightly between consciousness and sleep, it is precisely then that the tormentor, my affliction, arrives: *fear*. In those few minutes each day, this ghost, this gray monster, tries its best – while I am still in my sleep, battling still with my start-up's problems, but moving without volition into the wakeful reality – to destroy the optimism that I inherently enjoy, a quality that in the first place has nudged me to found yet another start-up. Fear of total financial disaster. Fear of technical non-feasibility. Fear of the unknown competitor, scooping our work. Fear of patent applications being denied. FDA clearances delayed or denied. Fear, Fear, Fear.

THE THREAT OF FEAR These minutes each day (or have they been hours?) pose my greatest threat. (Are we not our own greatest threats ultimately?) And if I were ever to linger longer in that horrifying swamp of fear, hesitating, perhaps, before popping into my awaiting cheerful wakefulness (or is it merely a denial of fear?) perhaps I could, even within those short minutes, receive my defeat. I have thought it possible that I would lie in bed longer, encouraging the ghost to convince me of my ultimate future failure. GIIIIVE UPPP!!! It would moan. **GIIIVE** UPPPP NOOOWWW!!! WHYYY WASTE ITTTT?? NOWWW!!! GIIIVVE IIIIT UUUP! And I would lie longer. Under the covers. Soon to be totally paralyzed, rendered helpless to act. Disarmed. Toothless. Spineless. A failure as we all knew I would become.

OPTIMISM But this I have never permitted to happen. I have resisted lingering and giving the specter even one hint of an opening, one crack of light through which to enter. This quality, if ever I could characterize it as a quality of an entrepreneur, is probably the one that has saved me and propelled me away from fear toward my perennial optimism, my strong point.

ADVICE #1: Resist the paralyzing effects of fear. Be the optimist that entrepreneurship requires.

All the problems with a start-up stem from fear.

ADVICE #2: FINANCING STRATEGY AS BALM: A sound financing strategy helps overcome fear. Hope is not a strategy. Get a firm grip on: (a) what your company is worth today; (b) how much money you need to move from point A to milestone B; (c) the definition of B; (d) the definition of new investors when you reach B; and (e) what your likely exit will be. If you know (a) to (e), your fear will be tolerable; you can keep it at bay.

Naysayers have a way of inflicting entrepreneurs, infecting them with doubt, which axiomatically turns into fear. Do not ignore the naysayers. Listen to them. Give them credence. But in the end, pose the question: Do they know more about this business, this market, than I?

THE NAYSAYERS Even on my seventh start-up (all health care), there were naysayers. (Have they not examined my track record?) Naysayers have a way of inflicting entrepreneurs, infecting them with doubt, which, you guessed it, turns into fear. Do not ignore the naysayers. Listen to them. Give them credence. But in the end, pose the question: Do they know more about this business, this market, than I? Get the answer quickly. If the answer is yes, then face up and give up, too, at least on this project. If no – ignore them and prove them wrong, a great source of personal satisfaction.

THE SPOUSE The start-up person often possesses a delusion of spousal support: "My spouse loves me. My spouse will go through ups and downs, thick or thin with me." While spouses have been known to think like the entrepreneur, the existence of such is rare. This means that the spouse must be brought into the overall calculus very early and with great care and explicitness. Fear plays a major role here. Is the house on the line? Will we have to eat into retirement capital? Will I have to go to work?

ADVICE #3: Make sure the spouse understands the business plan and where things are most likely to go wrong, and, if they do go wrong, what that could mean to the spouse in gradations of

severity. Paint a realistic picture, but don't make it so graphic that you scare that person off the deal. Minimize the fear without lying.

THE FOUNDERS Minimize the number of founders. Founders must understand that their founders' stock compensates for future work – NOT PAST WORK. Discuss such questions: Who is the ultimate boss? How many hours of work per week are expected? How and when to take vacation? Who does the speaking in front of investors? What will be expected when the going gets tough? Definition of the continuum of expected sacrifices? Overt, uninhibited expression

of fear (except among the founders alone) is VERBOTEN. These are almost all emotional issues.

THE ESTABLISHMENT OF A CULTURE

Members of your start-up work for money, opportunity, growth, recognition and fulfillment. These reasons are all charged with emotion that you, the start-up king, must understand. Every member needs emotional support from the CEO. In the start-up she leads, she inspires, she wipes away the tears, she kicks butt, and gives pats on the back. This becomes the culture within which members, including you, thrive. Nurture it.

All the problems with a start-up stem from fear.

By Warren Cooper, CEO of Prism Pharmaceuticals

THE IMPORTANCE OF FOCUS

Focus: We all know what it means, right? That's an easy concept! Though if you look at a dictionary definition of focus, you'll see that it's a word that has many similar but distinctly different interpretations, all of which we can readily agree with. So which interpretations of focus should be most valuable to a new CEO of a new enterprise, particularly one with constrained and valuable resources?

1. Focus is a noun as in "a center of interest or activity." What is the focus of the company? Defining this at a strategic level is imperative; some call it a mission statement but I have tended to see these as often too broad and abstract to give real focus at a practical level. It doesn't matter what you call it, but your statement of focus needs to be as brief and succinct as possible so as to leave no room for ambiguity in its interpretation by all relevant stakeholders - management, employees, investors, board members, and customers in their broadest sense. That statement of strategic focus must be a touchstone for everyone; as ideas and opportunities arise and they constantly will - it's easy to ask the question "Does this align with our focus?" If the answer is yes, then pursue the situation. But I have found using a statement of focus to be most useful to get everyone to quickly agree that this new opportunity is not in

- alignment and then they comfortably let it go. So a statement of focus describes not just what you are going to do, but by reverse definition, it says what you are not interested in either. Use it both ways!
- Focus can also be a verb as in "to concentrate attention or energy." This focus is helpful to keep the activities of your company tightly aligned toward the intended outcomes. It's always helpful to critically challenge why a particular task or tactical program is needed. Focus is achieved through encouraging the use of the question "Why are we doing this?" Is this task really needed to support the While many higher-level goal? companies and start-ups are populated with experienced folk from larger companies, that transition often brings considerable baggage. Bigger companies tend not to ask these questions rigorously and routinely because the activities are so embedded in the culture, structure and political framework of that organization. When did you last hear a manager ask, "Why does my function exist?" More often than not, you will find that a suggested project, tactic or approach is rooted in the traditions of an industry - we always did these at "XYZ!" It will be cathartic, energizing and aligning to ask whether that same approach has relevance and value in your environment. Not only will this focusing be resource-efficient, you may also find that it lowers risk and liability, particularly if your enterprise is at or approaching commercial

activities. This is your chance to establish a discipline for your company to be really frugal with your resources so that only the activities that truly expect to bring value to the business are adopted and at the appropriate scale. Focusing as part of the culture of your

company depersonalizes challenges and discussion. Never be afraid to ask why you are doing a particular activity and never accept the answer "Because that's just the way it's always done." Keep asking "Why?" until you are satisfied!

By Richard F. Pops, Chairman, President and CEO of Alkermes

THE RIGHT STUFF FOR BIOTECH LEADERS

Building and leading an emerging biotech company is a thrilling, yet challenging, mission. To many outside our industry, the inherent development risk and huge capital requirements associated with the discovery, development and ultimate approval of a new drug create reactions that range from awe to disbelief to true pity. Reflecting on those people who are successful leaders and pioneers in biotech, I found there are some important common elements. I would like to highlight two personal leadership traits that I feel are particularly important: passion and pragmatism.

Translating new science into medicines that make a difference for patients is a process that requires remarkable innovation. Passion - and the drive and tenacity that it engenders - is the fuel that pushes teams over the winding and bumpy road that is the hallmark of innovative drug commercialization. A11 ambitious biotech programs experience setbacks, from unanticipated clinical results to unexpected FDA responses. Successful leaders of biotech companies learn from these challenges, overcoming the setbacks and continuing to push their teams forward by providing the long-term perspective and vision that can be forgotten in the midst of here-andnow events. There is no doubt that the role of a biotech CEO requires resiliency. In the face of

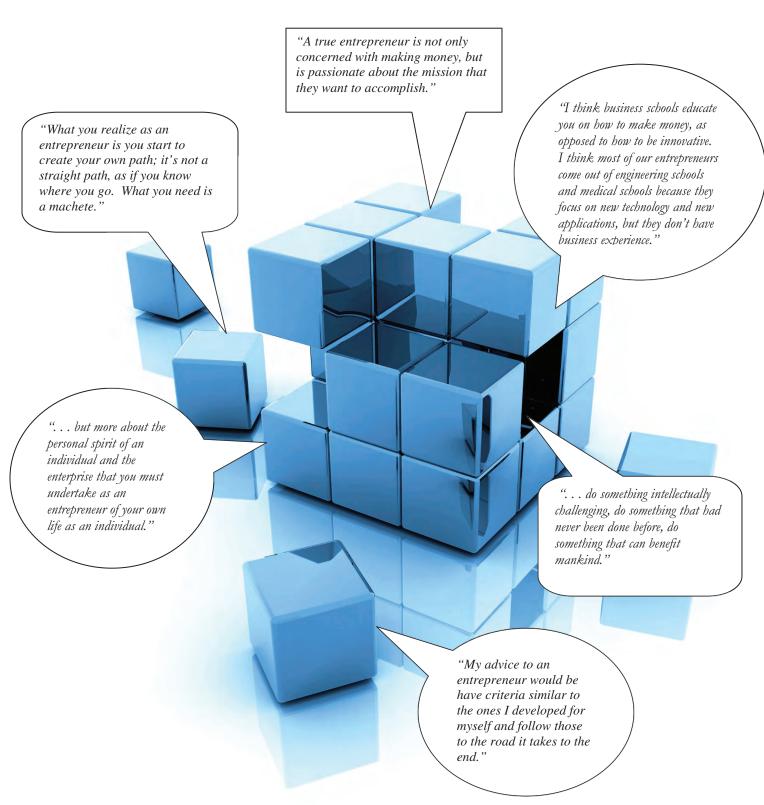
challenges, you must rely on your passionate strength to keep moving forward.

While passion is clearly needed – and frankly it is often abundant in many early stage ventures - it must be strategically balanced with pragmatism. For example, you cannot rely on passion to implement a cost-effective clinical trial program or make the strategic decisions on which lead drug candidates to pursue. As a pragmatic leader, you must both ensure that your company's important programs are thoroughly managed and - of paramount importance - that your company's balance sheet is strong enough to "weather serious storms." Indeed, the capital needed can be so significant and the probability of setbacks so real that a prudent biotech leader is always strategically evaluating how and when to raise additional capital, no matter how much money the company has on its balance sheet.

The biotech industry has and will continue to deliver amazing new therapies to patients in need; it represents one of the most vital wellsprings of innovation in developed countries like the United States. The next wave of great biotech companies will likely be led by people who demonstrate the passion and pragmatism that characterize so many of today's successful biotech entrepreneurs. Being a biotech CEO is no doubt difficult at times and requires perseverance. But when you speak with a patient whose life your company's drug has forever improved, trust me, it is all absolutely worth it.

SELECTED QUOTES

From Richard E. Caruso, Ph.D., Chairman, Integra LifeSciences Corp.



III.

FORMATION: GETTING STARTED



CONTRIBUTORS

TEAM MEMBERS - WHO IS REALLY IMPORTANT?

FREDRICK J. FRITZ is CEO, President and Director of NeuroDx, an early stage commercial medical device company focused on the neurosurgery market. NeuroDx launched ShuntCheck, the first noninvasive device for evaluating the shunt function of hydrocephalus patients, in late 2008. Mr. Fritz also founded companies that developed the world's first

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SELECTION OF AN ENTITY

DOUGLAS M. FOX is a partner in the Business and Finance and Intellectual Property Departments of Ballard Spahr LLP and Co-Chair of the Life Sciences/Technology Group. He is resident in the Baltimore office. He practices corporate, securities and technology law, with an emphasis on representing businesses and institutions in the life sciences industry.

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SETTING UP ACCOUNTING AND FINANCIAL SYSTEMS

ROBERT FESNAK is the Managing Partner of Fesnak and Associates, LLP. He has more than 20 years of experience in audit, accounting, tax, valuation and financial consulting for many public and middle market companies and has assisted clients in the registration of various debt and equity securities with the Securities and Exchange Commission. Mr. Fesnak, concentrates on the life sciences, manufacturing, hightech, service, real estate, wholesale, health care, leasing and broker-dealer industries. Mr. Fesnak has been quoted in business magazines and has authored articles on business valuations.

JAMES CARUSO is a partner overseeing the Financial Management Outsourcing & Advisory Services and the Mergers & Acquisitions practices at Fesnak and Associates, LLP. Mr. Caruso has 20 years

of diverse experience in financial management, M&A, operations, information technology, auditing and consulting. Since joining Fesnak and Associates, he has led the delivery of outsourced financial management services to numerous organizations, while serving as acting CFO to help several emerging-growth companies get to the next level. Mr. Caruso has also led financial due diligence for 20 acquisitions over the past two years. Before holding his current position, Mr. Caruso was EVP/CFO of a private equity-backed middle-market company, where he was brought on to help facilitate a turnaround, reorganization and ultimate sale of the business. His functional expertise includes financial and operational analysis, M&A, budgeting and forecasting, strategic planning, business process analysis optimization, turnarounds and change management.

ASSEMBLING THE RIGHT BOARD OF DIRECTORS AND SCIENTIFIC ADVISORY BOARD

JENNIFER L. MILLER is a partner in the Business and Finance Department of Ballard Spahr LLP and Co-Chair of the Life Sciences/Technology Group. Ms. Miller, resident in the Philadelphia office, works with start-up, emerging, and public companies, and those that invest in them. Her focus encompasses securities, corporate financing (public and private), strategic alliances, pharmaceutical and biotechnology licensing, technology transfer, mergers and acquisitions, general corporate law, and corporate governance.

AMY UNDERWOOD is a former associate at Ballard Spahr LLP, where she concentrated on corporate financings, pharmaceutical and biotechnology licensing, technology transfer, mergers and acquisitions, general corporate law, and health law. While in private practice, she utilized her background in biology and experience in the biotechnology and pharmaceutical sectors to advise large pharmaceutical companies as well as start-up and emerging companies. Ms. Underwood is now associate general counsel at a generic pharmaceutical company.

DR. PHILIP R. JOHNSON serves as Chief Scientific Officer, Executive Vice President, and Director of the Stokes Research Institute at the Children's Hospital of Philadelphia. He also holds the Edmond F. Notebaert Chair in Pediatric Research and is a Professor in the Department of Pediatrics at the University of Pennsylvania School of Medicine. In his role as Chief Scientific Officer, Dr. Johnson oversees the research enterprise at Children's Hospital that supports over 1,600 faculty and staff engaged in a wide array of basic, clinical and translational research activities with an annual budget in excess of \$250 million. Dr. Johnson received his undergraduate and medical degrees from the University of North Carolina

at Chapel Hill, followed by a pediatric residency and infectious diseases training at Vanderbilt University. After fellowship training, he worked at the NIH and Columbus Children's Hospital for 20 years before assuming his current positions in Philadelphia in 2005. In addition to his administrative duties, Dr. Johnson also directs his own research laboratory, which over the last decade has focused on gene transfer technology for use in vaccine antigen delivery. Dr. Johnson has been a board member of both public and private companies and has served as an advisory board member. Dr. Johnson has extensive experience working with entrepreneurs and as a board member of many start-up companies.

COMMON TYPES OF EQUITY-BASED COMPENSATION

MARY J. MULLANY is a partner in the Business and Finance Department of Ballard Spahr LLP and resident in the Philadelphia office. Much of her work with pharmaceutical, biotechnology and life sciences

companies focuses on mergers and acquisitions, securities offerings and other corporate financing, and on licensing agreements, including collaborations and joint ventures.

AGREEMENTS WITH EMPLOYEES AND CONSULTANTS

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ALLOCATING EQUITY

BRADLEY B. BERTOCH serves as President and a member of the Board of Trustees of the Wayne Brown Institute (WBI). He is a nationally recognized leader in equity-backed business development, capital formation and technology commercialization and entrepreneurship. Under his direction, WBI has established close relationships with numerous venture capital firms and developed over 50 programs to match entrepreneurs with investors: Arizona Venture Capital Conference, Los Angeles Technology Venture Forum, Texas Venture Capital Conference, Illinois Venture Capital Conference and Investors Choice Venture Capital Conferences (Utah, Hawaii, New York, Alabama, Central Coast California). Mr. Bertoch also developed the Cooperative Venturing Educational Process, the Cooperative Venturing Network® and has promoted the development and deployment of the

Venture Ready® Report - all models in technology commercialization. Currently, he is a member of Olympus Angels, Park City Angel Network, managing member of the WBI Angels, and is Vice Chairman of the Salt Lake County Revolving Loan Fund (a venture debt fund), and Board member of Mountainlands Revolving Loan Fund. Mr. Bertoch has more than 30 years of experience in economic development, focusing homegrown, high-technology development, including research park and incubator development; strategic planning consulting for SRI International and the BluePrint Team; and assistance in the validation of the New Venture Template, a set of analytical tools designed to improve new venture formation.

TEAM MEMBERS - WHO IS REALLY IMPORTANT?

By Fredrick J. Fritz, CEO, President and Director of NeuroDx

THE LIFE SCIENCES START-UP TEAM

Success in life sciences requires sound strategy and solid execution on a number of fronts — technical, clinical, regulatory, reimbursement, commercial, financial, intellectual property, etc. Eventually, life sciences companies build teams with expertise in all of these areas. But where and how does a start-up begin?

Start by determining what needs to be accomplished over the next one to two years. For early stage start-ups, this will usually focus on technical, clinical and regulatory milestones – proving that the technology works. Use this assessment to identify team needs – what expertise and experience does the current team possess (often the "team" is the founder) and what does it need to reach those 12-to 24-month goals? This assessment will identify critical hiring needs or dictate use of consultation or outsource vendors.

Determine if each position requires a full-time vs. a part-time hire. For example, start-ups need expert regulatory advice, but usually only require part-time consulting help. But plan conservatively – technical developments nearly always run into obstacles and require more time and effort than initially projected.

The full-time core team will go through a great deal together – terrific successes, terrible failures, long hours, heavy pressures. Bring together people with different (and therefore complementary) skills but who, deep down, are kindred spirits ("Possessing a burning desire to change the world" is a great spirit for a start-up team to share) and have good chemistry with one another.

Think "Scientific Semper Fi."

Complete the technical team with scientific advisers. These will be high-level experts who can provide occasional but critically important input and guidance. They are often university colleagues or scientific collaborators, but they can also be world-class experts in areas critical to your project. They might be working at major corporations (some companies allow their scientists to advise small companies); they might be recent retirees; they might be academics. You

can usually compensate them with equity. More important, you will reward them with bragging rights. "I helped NewCo get started" or "I helped develop NewTherapyTech" is the real motivator for many of these experts.

Administrative build-out is a task that must begin early on. But in the current financing environment, a lean, capital-efficient approach is mandatory. Hire a part-time CFO to set up the financial system and create the financial projection model. Retain a corporate lawyer with experience in life sciences start-ups to set up the corporate structure. Retain an intellectual property attorney to help guide the development of your patent protection. And hire a reimbursement consultant to ensure that your product design, clinical and regulatory strategies will support reimbursement.

Use these professionals sparingly. They will want to, and can, contribute broadly to your mission – but keep it lean.

Build a roster of medical/clinical advisers. These will be key opinion leaders and future customers for your technology. They will help guide your development - so that you create what they really need. You can organize a formal Medical Advisory Board or use a looser, more ad hoc approach. If you need a lot of their time, you will need to compensate these advisers. If they will not take part in future clinical studies, they can be compensated with equity. If they will participate in studies, conflict-of-interest concerns will rule out equity - they must be paid in cash. Many clinicians require no compensation because the modest fees they can get from a start-up are more trouble than they are worth. If you are sensitive to their time constraints, you can build a strong network of clinicians who will provide input and guidance - because your work can help their patients.

If you plan to commercialize your technology, there are two reasons to go slow on building out a commercial organization.

First, market launches are often delayed. The technology needs a tweak, FDA clearance is delayed, etc. Early investments in a commercial organization raise the company's burn rate prematurely and create a frustrated sales-

marketing team chomping at the bit to hit the market.

Second, the initial commercial strategy is seldom spot on. Early market experience provides valuable learning – often along the lines of this isn't working; we need to change direction. If you have invested heavily in a commercial team geared toward the wrong strategy, changing direction will be costly and time-consuming.

This is not to say that start-ups are ignoring or should ignore the commercial strategy issues that will impact product design, or clinical, or regulatory strategy.

If at all possible, the founder should play the role of commercial chief in the early days, quickly sorting out winning versus losing elements of the market strategy. Once the correct commercial path is clear, the commercial organizational investment can begin in earnest.

Complete your team by building your Board of Directors. A typical start-up board will have five members – including the CEO, two or three investors and one or two outside, independent directors. As you begin to recruit your independent director(s), ensure that your board will have deep experience in raising venture funding, structuring business development deals, commercializing life sciences technologies and successfully exiting opportunities. Their expertise will help shape your company's long-term path to success. (See the article "Assembling the Right Board of Directors and Scientific Advisory Board" in Section III of this book.)

SELECTION OF AN ENTITY

Considerations for Selecting an Entity and Summary of Main Documents for Each Entity

By Douglas M. Fox, Co-Chair, Life Sciences/Technology Group, Partner, Ballard Spahr LLP; Sandra Wintner, Associate, Ballard Spahr LLP, and Christopher A. Jones, Associate, Ballard Spahr LLP

INTRODUCTION

Choosing the proper type of entity is one of the first legal decisions you will make when pursuing a new business opportunity. Of the forms of entity available, most start-up companies are best served by organization as either a corporation or a limited liability company and, less frequently, by a limited partnership. This article gives a basic overview of the formation and maintenance, liability protection, governance, and tax consequences of each form, including a comparison of C Corp to LLC. We close with a discussion of the impact that state law has on your entity.

CORPORATIONS

Formation and Maintenance

Corporations are the form of entity that has been in use for the longest time, and consequently has the best-developed body of law regarding the rights and obligations of various parties, including the corporation itself. If a company plans to go public, a corporation is usually the best choice. However, corporations also are a less flexible form and can be harder to maintain properly.

A corporation is formed under state law by filing the Articles of Incorporation (also known as the Certificate of Incorporation) with the secretary of state of the chosen jurisdiction. Certain states also require advertisement of the formation. After filing the articles, the incorporators hold an organizational meeting to appoint the directors and adopt bylaws. The directors then hold their own organizational meeting to appoint the officers of the corporation, select a registered agent, establish a minute book and other corporate records, and take care of other organizational If, however, the initial Board of Directors is named in the articles, then the organizational meeting of incorporators is not necessary and the first meeting will be that of the named directors.

Corporations must maintain a registered agent in the state of formation. Depending on state law, corporations must also make annual filings with the state and may be liable for state franchise taxes. Corporations must additionally hold meetings of the stockholders and directors, usually at least annually.

Liability Protection

Generally, the stockholders of a corporation are not liable for the corporation's debts and obligations. The only money the stockholders have directly at risk is what they pay for their shares. However, under a legal doctrine known as piercing the veil, a court may refuse to recognize a corporation as a separate legal entity and make the stockholders liable for the corporation's debts. In determining whether to pierce the veil, courts examine whether the corporation was adequately capitalized, whether the formalities of corporate governance were observed, and whether the stockholders' actions with regard to the public treated the corporation as a separate entity. While piercing the veil is unusual, it is nevertheless important for start-up companies to make sure that corporate funds are not commingled with the stockholders' personal funds, to deal in the name of the corporation with third parties instead of as a person making a business deal on his own, and to take care of corporate formalities like minute authorizing resolutions, and proper shareholder and board meetings.

As compared to stockholders, the directors (and, perhaps to a lesser extent, the officers) of a corporation are at significantly greater risk for being sued in their capacity as such, but most state corporation laws either protect directors and officers from liability or provide them with indemnification, unless there is a showing of bad faith, active or deliberate dishonesty or receipt of an improper personal benefit. Nevertheless, most corporations that can afford to do so maintain directors and officers liability insurance to protect their officers and directors from claims filed against them. This insurance is typically purchased by the corporation rather than by each director and officer individually and should cover the cost of defense of the suit or claim.

Governance

Corporations are governed by three different groups: the officers, who are responsible for day-to-day management of the corporation and implementation of strategy and business plans; the directors, who appoint, guide and supervise the officers and must approve important transactions of the corporation; and the stockholders, who are the equity owners of the corporation and who elect the directors.

The rights and obligations of these three groups are governed by the corporations statute in the state of formation, the articles of incorporation, and the bylaws. Because the law on governance of corporations is better developed than the law on governance of limited partnerships and limited liability companies, some business owners feel more comfortable using the corporate form.

State law dictates the minimum number of the corporation's directors and officers, and whether one person can hold all the officer positions. Typically a corporation has at a minimum a president, secretary and treasurer as its officers, but other officer positions can be created if desired. A very simple corporation may have a single individual as the sole shareholder, sole director, and sole officer. Despite this overlap, the individual would still have to follow the corporate formalities and make sure appropriate documentation is maintained and is reflective of his actions in each specific role. It is also generally helpful to have at least two officers, so that one can certify the other's signature.

In addition to the explicit duties set forth in the bylaws, directors and officers also owe fiduciary or similar duties to the corporation. This means that directors and officers must act in good faith, in the best interest of the corporation, and use reasonable care in performing their duties. Some courts have also recently held that majority stockholders owe these duties to the minority stockholders.

With regard to stockholders, the state law, articles and bylaws usually are most concerned with when and how stockholders elect directors and approve certain fundamental corporation actions (such as mergers). Stockholders typically act at shareholder meetings called in accordance with the bylaws and applicable law, but can usually also act by signing a written consent rather than holding a formal meeting. The stockholders may also choose to create and set forth additional rights and

obligations, such as voting arrangements and restrictions on the transfer of shares, by adopting a stockholders' agreement.

Federal Taxation

Corporations can be taxed either as a "C" corporation, in which case tax is imposed at the entity level on income earned and then again on the stockholders in respect of distributions made to them, or as an "S" corporation, which is taxed as a pass-through entity in which tax is imposed only at the shareholder level. For example, if a C corporation has \$100 of earnings, the corporation will pay tax on that amount, and then if it pays a dividend to its stockholders, the stockholders will also pay tax on the amount of the dividends. In contrast, in an "S" corporation, the stockholders will be treated as receiving the \$100 of income and will pay tax on it - but they will be obligated to pay that tax regardless of whether the \$100 is actually distributed to them. As a consequence, "S" corporations typically make distributions to their stockholders to allow them to pay their tax liabilities.

Qualifying and maintaining "S" corporation status require special attention. A corporation must file a form with the IRS to elect to be an "S" corporation. Timing constraints apply to the making of an "S" election, so when forming an "S" corporation, it is important that the "S" election be made promptly. A corporation can be an "S" corporation only if it has fewer than 100 stockholders, all of whom are individuals who are U.S. citizens, and the "S" corporation can have only one class of stock. These restrictions mandate the use of a stockholders' agreement or buy-sell agreement to ensure that "S" corporation status is maintained.

LIMITED PARTNERSHIP

Formation and Maintenance

Limited partnerships are a newer form of entity and offer more flexibility in their governance than corporations. A limited partnership is formed by filing the Articles of Limited Partnership (or Certificate of Limited Partnership) with the secretary of state of the chosen jurisdiction. The articles are a very simple document essentially setting forth the name and registered office of the partnership. Although it is technically not necessary for formation of the partnership, it is most desirable for the partners to adopt an

Agreement of Limited Partnership setting forth the rights and obligations of the partners and the partnership.

Liability Protection

Limited partners of a limited partnership are generally not liable for the debts of the partnership, similar to stockholders of a corporation. However, unless the partnership is formed as a special kind of limited partnership typically called a limited liability limited partnership, or LLLP - the general partner of the limited partnership has full liability for the debts and obligations of the partnership. The general partner is thus usually another entity (a corporation or limited liability company) rather than an individual. Limited partners may also lose their liability protection if they have too much control over the management of the partnership and begin to act more like general partners than a limited partner. Also, some partnership agreements may require that the limited partners contribute additional capital from time to time. If that is not desired, the agreement of limited partnership should expressly disclaim any obligation on the part of the partners to contribute additional capital.

Governance

A limited partnership consists of at least one general partner and any number of limited partners. The general partner manages all aspects of the partnership, including admission of the limited partners, and is liable for any debts or other liabilities of the partnership (except in the case of an LLLP) as mentioned above. contrast, the limited partners do not have control over the entity, and are basically passive investors. Within certain fundamental parameters, the governance of a limited partnership and the respective rights and responsibilities of the general partner and the limited partners are largely defined by agreement between the parties, which is set forth in the Agreement of Limited Partnership. For example, the partnership agreement may set forth circumstances in which the limited partners can remove the general partner, restrictions on buying and selling partnership interests, and actions requiring approval of all the partners.

The general partner owes fiduciary duties to the partnership. This duty may be judged by an even stricter standard than the fiduciary duties owed to the corporation by a director or officer. However,

limited partners generally do not owe fiduciary duties to the partnership or one another.

Federal Taxation

A limited partnership is taxed as a pass-through entity, in which the tax is imposed on the partners rather than on the partnership level. Like the "S" corporation, the partners in a limited partnership will be obligated to pay tax on partnership income, regardless of whether it is actually distributed to them. As a result, limited partnership agreements typically mandate distributions to the partners in amounts sufficient to pay the anticipated tax liability.

LIMITED LIABILITY COMPANY

Formation and Maintenance

Limited liability companies (LLCs) are the newest form of business entity and the most flexible, both in terms of governance structure and for taxation purposes. A limited liability company is formed by filing the Articles of Organization (or Certificate of Organization) with the state. This is a very simple document that essentially sets forth the name and the registered office of the limited liability company. The owners may also adopt an agreement regarding the governance of the LLC, known as the operating agreement.

Liability Protection

The owners of an LLC are generally not liable for the debts and obligations of the LLC. However, the doctrine of "piercing the veil" discussed in the corporations section above is also beginning to be applied to LLCs.

Governance

The governance of a limited liability company is very flexible and is dictated by the contents of the operating agreement. The equity owners of a limited liability company are called the "members" of the company. The LLC can be managed by its members (known as a member-managed LLC), or by managers who may or may not be members (known as a manager-managed LLC). There can be any number of members and any number of managers. The LLC can be structured to operate internally much like a corporation or a limited partnership. These matters and others, such as transfer of membership interests, management duties, or changes requiring the consent of all the members, are governed by what is set forth in the operating agreement. If the LLC does not adopt

an operating agreement, it will be governed by the default rules of the statute.

Managers will generally be treated as having the same fiduciary duties as directors of a corporation. Members (except to the extent they are acting as managers) generally will not be treated as having fiduciary duties.

Federal Taxation

Although there are default rules as to the tax treatment of a limited liability company, the limited liability company can also file an election with the IRS (known as a "check the box" election) to change its treatment from the default rules. A limited liability company that has only one member is by default a disregarded entity for tax purposes, and a limited liability company with more than one member is by default a partnership (in other words, a flow-through entity) for tax purposes. However, by filing the check the box election with the IRS, the LLC can change its tax treatment within certain limits. For example, a limited liability company with two members could elect to be treated as a corporation for tax purposes.

State Law Considerations

Corporations, limited partnerships and limited liability companies are primarily creatures of state statute, and consequently state law has a big effect

on the rights and obligations of the owners and managers of the entity, no matter which form is chosen. In choosing where to organize your entity, you should thus consult knowledgeable counsel about whether a state's laws are advantageous to your company. For example, the laws of Delaware, Maryland and Nevada tend to favor the rights of the entity over the rights of the individual equity holders. Other states are more favorable to granting equity holders control over the company. Maryland, on the other hand, has statutory provisions that allow for limited liability for not only directors but also officers, and has strong management-friendly antitakeover laws.

You should also consider the impact of state tax laws when choosing where to organize. Certain states have complicated corporate income tax laws, whereas others do not. States also typically impose an annual fee or annual franchise tax for the privilege of being organized there. Once the corporation has experienced growth, these costs can be significant. However, Maryland, for example, imposes only a several-hundred-dollar annual fee and no franchise tax.

State sales taxes are also an issue for any company selling goods or services. Knowledgeable accounting or legal counsel should be consulted before formation to avoid tax traps.

COMPARISON OF "C" CORPORATION AND LLC

The biggest difference between the two types of entities is taxation, both on an ongoing basis and at the time of a fundamental change. corporations are subject to what is referred to as double taxation. If revenue comes into the business, the corporation must pay tax on such There are offsetting deductions for various expenses, but corporate level tax is due on the net income. If the corporation then makes a distribution to its stockholders through a dividend payment, that dividend is subject to capital gains tax (currently 15%). An LLC has one level of taxation - it is taxation at the ownership level. The LLC allocates all profits and losses to the individual owners and tax is paid by the owners at their individual (or corporate if any owner is a corporation) tax rate. For example, assume a corporate tax rate of 40% (federal and state), capital gains tax rate of 15% and a maximum individual tax rate of 39%, and that an entity brings in \$1.5 million in revenue with net revenue of \$1 million and pays a dividend/distribution to

its stockholders/owners of \$300,000. In a corporation, the total tax payments would be \$445,000 and the corporation would be left with \$300,000 to fund its operations. In an LLC, the total tax payment would be \$390,000 and the LLC could hold on to as much as \$610,000 to fund its operations. This difference is more pronounced in a sale transaction – the corporate structure, in essence, forces the entity into a merger structure because the tax aspects of an asset-based sale make it prohibitively expensive.

Some venture capital investors must avoid unrelated business taxable income (UBTI) because their tax-exempt investors must avoid the flow-through UBTI that could be generated by an LLC. Therefore, some venture capital funds will not invest in an LLC.

(See the attached chart for factors that may impact the choice of entity. In addition, other articles in this book dealing with financing issues provide input on investor preferences and transaction terms that may influence the decision.)

Element	"C" corporation	LLC
Limited liability for owners	Yes	Yes
Limited liability for officers/directors	Yes	Yes
Transferability of interests in entity	Yes, but can be restricted	Yes, but can be restricted
Annual elections of directors and	Required	Not required unless agreed to by
officers		contract
Follow formal structure	Yes. Must have board, designated	Do not have to, but can. LLCs can
	officers, hold meetings, hold annual	be governed like a partnership or like
	elections, etc.	a corporation – the choice is up to the
		owners
Documentation	Certificate of Incorporation, bylaws,	Certificate of Formation and
	stockholders' agreement, if applicable.	operating agreement. The operating
	These tend to be highly structured	agreement sets forth the rights and
	documents, very routine.	obligations of the owners, managers
		(including board if desired) and
		officers (if have them). Is flexible, but
		needs to reflect the business
		relationship of the parties. Can have
2111		other documents, too
Publicly available information	Certificate of Incorporation, which	Certificate of Formation – that it is
	includes number of shares, rights and	formed and whether it is manager-
	preferences of stock	managed
Classes of equity interests	Yes, can have voting and non-voting	Yes, can have all sorts of different
	common or preferred stock	interests, including voting and non-
		voting interests, interests with some
		sort of preferred return, profits
		interests only, etc. Allows for more
		flexibility in getting different
Voting vishts	Must have at least and reating -1	Payments to different constituents At least one member needs to have
Voting rights	Must have at least one voting class.	
	Statutory voting rights given to other classes.	voting rights. Statutory voting rights,
	Classes.	but more limited than corporate
		statutory rights

Element	"C" corporation	LLC
Owner as employee	Yes	As a practical matter, no. A single individual member of an LLC cannot be treated as an owner (i.e., partner) for one purpose (distributions) and as an employee for others (withholding, payment of SS tax, etc.). In a multimember LLC, the LLC can give guaranteed payments (like salary) to some owners as compared to others, but that owner may be considered self-employed and then would need to pay taxes accordingly. Good tax advice is strongly advised
Equity incentives to employees, consultants, etc.	Yes – stock options, restricted stock awards, performance-based awards. Tax implications depend upon type of award.	Yes – profits interests ¹ , options, performance-based awards, restricted awards, outright equity awards. You can do everything within an LLC that you can do in a corporation for equity awards – you just need to be careful to understand the tax implications
Right to bind entity	Officers have general authority to bind the company by signing agreements – subject to oversight of the board.	Depends upon structure and operating agreement. Very flexible
Ability to have employees, consultants, agents	Yes	Yes
Ability to go public	Yes	Could, but very rare. Instead companies have routinely converted to a C corporation right before the IPO
NOLs	Yes	No
Comfort of investors with structure	All are knowledgeable	Increasingly comfortable and the choice of entity for some investors. Allows for greater flexibility. VCs and institutional investors frequently require conversion before invested.
Ability to take different consideration for the same equity	Generally no, particularly with preferred stock – some flexibility with common stock	Generally yes. Can agree, as between members, to the capital contributions vs. the share of ownership interests. One of the biggest advantages of an LLC is the ability to separate the voting power from the economic interests.

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A profits interest gives the holder the right to share in the future "liquidation value" of the enterprise at some liquidation event. The value of the enterprise is determined at the time the interest is created, and the holder of the profits interest would be entitled to his or her percentage share of the accumulated value. For example, assume LLC with current value of \$10 million and two members. Provide a 1/3 profits interest to an employee. Five years later, sell the company for \$19 million. The first \$10 million would be shared between the two members and the remaining \$9 million would be paid out 1/3 each to each of the members and the holder of a profits interest.

Element	"C" corporation	LLC
Ability to treat different holders of	No	Yes – the operating agreement is a
the same class of equity differently		contract, and the rights of the various
		owners can be fully set out and can
	C 11 2	differ.
Organize tax-free	Generally yes ²	Generally yes ²
Tax-free contribution of property after formation	Generally yes	Generally yes
Can have corporate owner	Yes	Yes
Need two owners	No	No
Maximum number of owners	No	No
Pass-through of federal income tax	No	Yes
Pass-through of DE (and most/all	No if multi-owner LLC	Yes, if it's an individual single
other states) income tax		member LLC
Owner gets basis for entity's debt	No	Yes
Calendar year end required	No	Yes
Can have subsidiaries	Yes	Yes
Can be disregarded for federal income	No	Yes
tax purposes		
Employment tax	Not on dividends	Yes on allocable share of income if
		member is a service member,
		participates in LLC's trade or business
		more than 500 hours during a tax
		year, has authority to contract on
		behalf of LLC, or personally liable for
	**	debt or claims of LLC
Double tax on sale of assets	Yes	No
Can receive stock tax-free in a merger	Yes	No
Entity asset basis step up on transfer	No	Yes, with Section 754 election
by owner by sale or death	Diff. 1	D 1 : 1
Ease of conversion to other form	Difficult to go from corp. to LLC – is	Relatively easy
	a liquidation event for tax purposes so	
	any value in the company is captured	
	at the time of conversion	

In both a corporation and an LLC, the contribution of services for stock is a taxable event, particularly for an employee – it is compensation for services.

SETTING UP ACCOUNTING AND FINANCIAL SYSTEMS

By Robert Fesnak, Managing Partner, Fesnak and Associates, LLP, and James Caruso, Partner, Fesnak and Associates, LLP

INTRODUCTION

A proper accounting system is a fundamental prerequisite for good financial discipline and management control over an early stage life sciences business. Although the business will likely have a low volume of transactions during its start-up phase, things can get out of control quickly if transactions are not processed in a timely manner. Technical accounting complexities can further complicate matters, regardless of the entity's size or transaction volume. Better to start right in the beginning, rather than have a backlog of transactions to unravel later. Many companies make the mistake of thinking that they will get to it when they have a need for accurate financial statements, such as for potential investors. However, the task of catching up on the backlog and unraveling past transactions can become a large and expensive undertaking before you realize it, and can be an obstacle to getting your tax returns prepared or capitalizing on a funding opportunity that presents itself. Set it up right from the beginning. Even a business that is small in size can be big in issues.

Install an accounting software package right from the start. A relatively simple package such as QuickBooks is fine, especially for a pre-revenue company that primarily needs to track expenses. Most systems, QuickBooks included, are available in both desktop versions and online versions. The online version is a monthly subscription and facilitates remote access by your accounting firm and other users who may be working in different locations, without the expense or difficulty of setting up and maintaining a server and network.

Before attempting to set up an accounting system for your business, it is important to understand the basic fundamentals of financial reporting, for this is what the underlying accounting system must support.

FINANCIAL REPORTING

The primary canned financial statements generated by any accounting system are the income statement (also known as the statement of operations, profit and loss statement, or P&L) and The task of catching up on the backlog and unraveling past transactions can become a large and expensive undertaking before you realize it, and can be an obstacle to getting your tax returns prepared or capitalizing on a funding opportunity that presents itself.

the balance sheet (also known as the statement of financial position).

The income statement presents the revenue, expenses and profit or loss of the business over a period of time (e.g., a month, quarter or year).

The balance sheet presents assets, defined as the right to receive future benefits – for example, accounts receivable from customers – and liabilities, or amounts to be paid in the future – for example, accounts payable to suppliers. The balance sheet presents the company's financial position as of a certain point in time (e.g., monthend, quarter-end or year-end).

Accounting and financial reporting can be done on a cash basis or accrual basis. Cash basis is analogous to your personal checkbook – transactions are recorded on the basis of cash in and cash out. For example, revenue is recorded when cash is received; expenses are recorded when payments are made. In this scenario, the balance sheet will show little more than cash and equity.

Accrual basis accounting recognizes that cash does not have to change hands for a company to realize revenue and create assets, or to incur expenses and liabilities. For example, if you hire an employee at an agreed-upon salary and pay him or her every two weeks, after the first week of employment you have incurred salary expense for that employee and have a liability to pay that employee, before you actually cut the payroll check. As another example, if you contract for consulting services and the agreed-upon services are performed, you have an expense and a liability (accounts payable to the consultant) before you pay for it. Similarly, on the revenue side, you generally realize revenue and record accounts

receivable when you deliver your product or service, not when the customer pays you.

While accrual accounting is more complex and requires some knowledge of accounting principles, it is the preferred method. It recognizes that there is economic substance to transactions that is distinct from the timing of when those transactions are settled in cash. A key principle of accrual accounting is that it matches revenue with the corresponding expenses in the same period. For example, if you purchase a medical device for cash from a third-party manufacturer in January, sell it to a customer in March on 30-day payment terms, and then collect cash from the customer in April, the cash basis of accounting would record the expense in January and the revenue in April. This distorts the true economic activity of the business. In contrast, the accrual method initially records the medical device purchase as inventory (an asset on the balance sheet until it is sold), not expense. In March, a sale and accounts receivable are recorded, and also in March the cost of the medical device is expensed - matched against its corresponding sale. This provides a truer picture of the economic substance of the transactions. In addition, the recording of inventory and accounts receivable on the balance sheet in this example helps to maintain visibility for the forecasting of future earnings and cash flows.

Even in a pre-revenue life sciences company, the true economic activity is better represented through accrual accounting, because expenses will be recognized as they are incurred rather than when paid in cash. Similarly, non-cash expenses – such as equity-based compensation – would be reported in accrual-basis financial statements.

Another important reason that accrual basis accounting is recommended is that it is a fundamental part of generally accepted accounting principles (GAAP), the common language of financial reporting, and is therefore preferred (if not required) by investors and lenders.

While over the complete life of a business its cumulative accrual-basis earnings or loss will be equal to cash-basis earnings or loss, from the example above it can be seen that the results reported by the two methods can be very different in a given period. Moreover, in a particular period the accrual-basis earnings or loss can be very different from the period's net cash flow.

The foundation of any accounting system is the general ledger (G/L). The G/L is essentially a list

of accounts, each account individually representing a place to accumulate a certain category of revenue or expense – for example, salaries, office supplies, rent, etc. – or a balance sheet item – for example, cash, accounts payable, equity, etc.

Individual debits and credits are recorded in the appropriate G/L accounts. The G/L account balances "roll up" into financial statements specifically, the income statement and balance sheet. These financial statements are typically generated directly out of most common accounting software systems at the touch of a button and can be created at various levels of detail – i.e., showing every individual G/L account or at some level of aggregation. The G/L accounts, or "chart of accounts," is generally set up in a hierarchical fashion to facilitate the financial statement roll-up. A basic chart of accounts is normally included within the accounting system, but it is preferable to customize the G/L structure for the unique needs of the life sciences industry and your company.

There are two additional financial statements: the statement of cash flows and the statement of changes in equity, which would be presented for the same period of time covered by the income statement (e.g., a month, quarter or year).

The statement of cash flows is difficult to obtain directly from most accounting software systems, even some higher-end ones. Advanced report writers embedded in certain software systems can be used to create statements of cash flows; in systems that do not have these report writers, off-line spreadsheets such as Microsoft Excel often need to be used.

Under the cash basis of accounting, the income statement essentially provides cash flow information because, by definition, revenues and expenses are cash transactions only. However, under the accrual basis of accounting, the income statement reflects both cash and non-cash transactions. Therefore, the statement of cash flows provides key information about cash flow that cannot be obtained from the income statement alone. It also reconciles the accrual-basis earnings or loss on the income statement to the net increase or decrease in cash for the period.

The statement of changes in equity reconciles beginning and ending members' or stockholders' equity for the period. This includes capital transactions such as issuance of new equity, other contributions or distributions, and the impact on equity from the current period's earnings or loss. Because equity is affected by transactions that are both cash and non-cash transactions, and by P&L and non-P&L transactions, the statement of changes in equity provides important information that is not available in any of the three other financial statements. When the only change to equity is the profit or loss for the period (i.e., there are no other capital transactions), a simple equity reconciliation can be presented at the bottom of the income statement, instead of as a separate statement. Either format typically requires use of the accounting system's report writer, if available, or an off-line spreadsheet.

In addition to the "nuts and bolts" of day-to-day debits and credits, there are several areas of technical complexity that life sciences companies must deal with in order to produce accrual-basis financial statements that are in compliance with GAAP. In order to conserve cash and incentivize employees and consultants, many early stage life sciences companies provide equity in lieu of cash. Such equity-based payments, which may include stock as well as options, must be appropriately valued and reported in the financial statements. The structure of venture capital investments in life sciences companies may be complex, sometimes resulting in equity instruments that may have characteristics of debt for accounting or financial reporting purposes. Revenue recognition issues may arise, such as with NIH grants; a life sciences company's accounting practices in this regard will often come under scrutiny by grantors as well as investors.

MANAGEMENT REPORTING

While financial statements provide a common language with which to report the historical results and financial condition of a business, they do not necessarily provide all of the information that management needs to evaluate business performance, make decisions, and chart a course for the future. Management reporting is focused on providing the necessary financial and non-financial information to decision-makers at all levels of an organization.

Management reports may include both lagging and leading indicators, may cover both historical and prospective periods, and can be as frequent as weekly, daily or even real time. Unlike financial reporting, there generally are no "rules" or

prescribed forms for management reporting. While there are some commonly used standard definitions, in many cases each industry or company also uses its own terminology to define the reports or metrics it uses.

The types of management reports, their formats, and the individual metrics that are tracked vary widely from company to company. Within a business, people in different positions will require reports unique to their roles and responsibilities in the organization. At the upper management and executive levels, however, some common, basic management reports include comparison of actual results to budget and prior year, with analysis of variances according to their drivers (e.g., volume, external cost, internal cost, timing, etc.), as well as key metrics such as cash burn rate. Management reporting must also supply appropriate information to investors, who will want to company's understand how the compares to its financial projections and its progress toward milestones upon which the funding was based. For revenue-generating life sciences companies, such as medical device makers, useful management analyses might sales include days in receivables, product/customer profitability, and/or pipeline reporting (sales backlog and pending opportunities), etc.

Alignment of strategy and operations is key.

Many executive teams rely upon "dashboard" reports to aggregate all of their company's key performance indicators (KPIs). KPIs are those metrics that best measure whether organization is meeting its goals and objectives. It is critical that management select and define appropriate KPIs. This should be part of the company's strategic planning process: Strategic translated initiatives into measurable objectives, and metrics are designed to track progress toward these objectives. Alignment of strategy and operations is key: What are the critical success factors in achieving the organization's strategic objectives? How will you orient your team toward meeting these goals? How will you measure progress?

FORECASTING

While not typically thought of as part of setting up an accounting system, forecasting is one of the most important components of the financial function. A long-range financial projection is a critical component of a business plan and is a prerequisite for obtaining outside funding. But forecasting should not be thought of as a onetime exercise that is completed once funding is received; rather, it should be an ongoing discipline that is institutionalized in the company's operations. Business conditions constantly change, and so should the forecast; it should be updated at least monthly, but more frequently if necessary, especially if cash flow is tight. In addition to warning of impending cash or liquidity problems, forecasting also helps foster goal alignment among different functional areas and promotes commitment, accountability and teamwork within the organization. The forecasting process itself helps nonfinancial managers think in financial terms and learn fiscal discipline, while reconciling different perspectives and producing consensus on action plans. External constituencies such as investors and lenders will also want visibility on where the business is headed.

A forecast is produced using a financial model. Although high-end enterprise software applications may have forecasting modules, this functionality is generally not found in the more basic accounting packages that early stage companies are likely to be using. While there are software applications designed specifically for budgeting and forecasting, a spreadsheet application such as Microsoft Excel is perfectly adequate for early stage life sciences companies. The financial model should include an income statement, balance sheet and statement of cash flows, with supporting schedules for revenue, cost of sales, operating expenses, and headcount. Each of these should be presented on a monthly basis using a columnar format. A robust model will also include the KPIs that have been defined for the business; this will help validate whether the financial plan is aligned with the strategic and operating plans. It is a good idea to document all assumptions in the model, which include general economic factors, market/industry factors, regulatory factors, and plans or assumptions unique to the business. Structuring the model in a way that allows assumptions to be changed and

drives appropriate changes to the forecasted results will allow you to do scenario planning and "what if" analysis. This includes preparation of "best case" and "worst case" versions of the forecast, in addition to the "most likely" version that you use to manage the business. Use these alternative versions for contingency planning.

Accurate, timely and reliable historical financial statements and management reports are key to providing baseline data for forecasting. Each month, the forecast model should be updated with actual results for the previous month. The forecasted future months should be updated with any new information and validated against the latest actual data.

A best practice is to maintain an 18-month rolling forecast; in this way, by the middle of the fiscal year you will already have a forecast for the entire subsequent fiscal year. This practice can replace the traditional, time-consuming annual budgeting process. At an appropriate time before the start of the new fiscal year, refine and "freeze" the forecast as the "budget." This establishes the plan and financial targets for the new fiscal year, and is often used as the basis for annual operational planning, incentive compensation targets, etc. Continue to update the forecast each month as you go forward. (The budget is often referred to as the "original budget" to differentiate it from the ongoing rolling forecast.)

As part of your management reporting, actual results should be compared to both the original budget and the latest forecast. This will provide the feedback loop necessary for continuous improvement in forecast accuracy. It is also helpful to track forecast performance by keeping a record of key financial metrics such as monthly revenue, earnings and net cash flow or cash burn rate as shown in each successive version of the forecast, and ultimately reported in actual results. When a new version of the forecast has changed significantly, it is a good practice to reconcile the revenue, earnings and cash flow in the newest version of the forecast to the previous version, quantifying the impact from changes in individual assumptions such as volume, price, cost, headcount, etc. The objectives of this exercise are to validate the new forecast and enhance understanding of the evolving dynamics of the business.

STAFFING

Many entrepreneurs attempt to keep the books themselves. Setting aside the complexities of accounting and the importance of maintaining reliable historical financial statements and forecasts, entrepreneurs should ask themselves if this is the best use of their time while trying to launch and grow a business. It is best for the success of the business if the entrepreneur sticks with what he or she does best and most enjoys, while leaving accounting and finance to the experts in those fields.

Once the decision is made to seek assistance with the accounting and finance function, there are several options available, including hiring fulltimers, part-timers, and/or outsourcing. Early stage life sciences companies are increasingly turning to outsourcing in lieu of internal hires.

Start-ups, early stage and emerging-growth life sciences companies need to fulfill the same accounting and finance functions as larger companies: for example, back-office transaction processing and bookkeeping to record day-to-day transactions; financial reporting, analysis and management reporting; planning, forecasting, decision support and capital raising; etc. In a large company, these different functions are typically performed by various levels of accounting and financial professionals — e.g., bookkeepers, controllers, and CFOs. The problem is that these are not individually full-time roles in an early stage

company, and the mix of expertise required changes frequently as the company grows. For example, CFO skills are needed extensively early on when developing financial projections and raising capital, and then periodically to handle additional funding rounds and other complex financial issues, but may not be needed on a fulltime basis while the company's operations are largely limited to R&D and managing clinical Hiring one person to handle the full trials. spectrum of accounting and finance responsibilities, a "jack of all trades," rarely works. High-end talent is unlikely to be attracted to a role that includes lower-end responsibilities, and hiring someone who falls in the middle of the spectrum will result in an employee who is over qualified for some roles and under qualified for others, and whose skill level will be quickly outgrown. Hiring a full-time employee for each role is likely to be too expensive and unnecessary. Hiring parttimers for each role is impractical and difficult to manage.

It is for these reasons that outsourcing the accounting and finance function to a managed-services provider is becoming an increasingly popular alternative. It is economical, allows available funds to be allocated to appropriate skills in the right proportions, turns fixed costs into variable costs, affords greater depth and breadth in technical expertise than can be found in one person, offers access to best practices, imparts credibility to the capital markets, and provides a solution that will scale with the company.

ASSEMBLING THE RIGHT BOARD OF DIRECTORS AND SCIENTIFIC ADVISORY BOARD

Creating and Managing a Stellar Board of Directors

By Jennifer L. Miller, Co-Chair, Life Sciences/Technology Group, Ballard Spahr LLP, and Amy Underwood, former Associate, Ballard Spahr LLP

Commentary by Dr. Philip R. Johnson, Chief Scientific Officer, Executive Vice President, and Director of the Stokes Research Institute at the Children's Hospital of Philadelphia

THE ROLE OF THE BOARD

As an entrepreneur, you will learn that creating and maintaining an effective Board of Directors is one of the most important things you can do for the success of your company. The Board of Directors is a panel of advisers that the CEO and management team can turn to for advice, business experience and knowledge of the company's specific industry.

From an internal perspective, the Board of Directors oversees the direction of the company and its strategy. It is also tasked with approving significant decisions, such as hiring key personnel; compensation of senior management; and whether to enter into a significant transaction such as an acquisition. The Board of Directors will review detailed, periodic financial information and reports, and the annual budget to ensure the company is staying on its strategic path.

From an external perspective, a solid Board of Directors boosts the confidence of investors and potential investors because it illustrates that management is mature and comfortable relinquishing some control for the benefit of the company. A solid Board of Directors can also help attract the type of talent and expertise needed to move the company forward.

Entrepreneurs doing business through LLCs will face these same issues regarding the structure of oversight boards, although they may have a different title.

CREATING THE RIGHT BOARD

In forming the right Board of Directors for your company, it is essential to select members who have the right mixture of business qualifications, experience and leadership skills necessary to get your company on the right track and help it stay there. Many entrepreneurs are hesitant to form a strong board because they do not want to

relinquish control, instead opting to pad the board with friends and family. However, most successful companies form a meaningful Board of Directors early on because strong board members will:

- challenge you, but also offer up fresh ideas.
- advise you when you do not have the answers.
- bring their wealth of experience and their Rolodex of contacts. Access to contacts of such experienced and well-connected business people may help open doors for your company, to venture capital financing or other key business partners.
- provide you with access to experienced consultants, advisers and experts in your industry.
- serve as well-regarded professionals in their respective fields.

What is the ideal size of a start-up board? Generally, early stage companies are better off with a small board of at least three people. When considering the ideal composition of your start-up board, remember the importance of independent, or outside, directors. One of the board's main functions will be to oversee management, so impartiality and independence are essential. It is also important to seek out persons who are considered thought leaders in their field - they will provide prestige to your company, as well as validation. Also remember that as an early stage company, your company's needs will rapidly change, so it is likely that you will change board members as your company grows and evolves. It is important that your early stage board realizes its time may be brief. Surrounding yourself with advisers with proven track records also increases your credibility.

It shows to the outside world that you are the type of CEO who can take criticism and coaching and does not plan on imposing your sole vision on the company. Will board members challenge you and cause you to make decisions you might not initially agree with? Yes, but this also shows that you do not have tunnel vision, but are willing to take the advice and opinion of your advisers and that everyone has the company's best interest in mind.

So, you have decided to assemble the perfect board. When do you select and how do you convince big-time talent to join your squad?

Present a manageable time commitment. Many corporate heavyweights sit on a number of boards and may not be able to make a large time commitment. If you present the opportunity to sit on your board correctly, you may be able to get potential board members to meet for short intervals such as half a day on a quarterly basis. The more manageable the time commitment, the more likely you will land that potential board member.

Acknowledge that creating an effective board takes some risk. The CEO will have to give up some control in order to gain some much-needed creativity. Along with that, you gain business expertise and experience from leaders in their field, who can guide you through the tough decisions and assist in making business decisions that are in the best interest of the company.

Seek out people who have experience dealing with the growth transactions you anticipate for your company. Carefully evaluate where your company is in its development, and who are the right people to lead it to the next step. Perhaps someone on your board should have managed a company larger than yours and someone else should have specific industry experience.

MANAGING YOUR BOARD

You did your homework and sought out the right players, you presented an exciting opportunity with a manageable time commitment, and you created your all-star board. Now what? How do you use your board effectively? Remember these important tips:

A Board of Directors for an early stage company needs direction. Your board members are busy, so be sure to provide them with the appropriate materials, such as financials and projections, well in advance of any meetings. Create thoughtful agendas for board meetings, so you use your board members' time wisely and effectively. Make

sure you keep the board informed and, if there are areas where you need help, make sure you communicate this clearly. The Board of Directors is there to provide knowledge and expertise, but can do so only if members know what is going on.

No surprises. Keeping board members up to date is not a quarterly exercise. Effective CEOs have many conversations with board members, keeping them current on developments and building consensus on the direction of the company. The last thing board members want is a surprise – for something to happen or a request for approval of something they know nothing about.

Surrounding yourself with advisers with proven track records also increases your credibility.

SCIENTIFIC ADVISORY BOARD

It can be important, particularly in the life sciences start-up company world, to have a scientific advisory board in addition to your Board of Directors. A scientific advisory board is typically a group of outside advisers with experience and contacts in the company's industry, formed for the purpose of providing informal advice and assistance to the company's management team concerning strategic, business, scientific, clinical, regulatory and operating advice. It does not have the formality, role or legal and fiduciary duties of the Board of Directors. A scientific advisory board has the ability to evaluate the company's scientific and product development strategy independently from the development of the business.

COMPENSATING YOUR BOARD

Typically, board members (and scientific advisory board members) are compensated with equity for their role in an early stage company in the form of stock options or restricted stock grants. (See the article "Common Types of Equity-Based Compensation" in Section III of this book.) Remember that you will need to have all board members and scientific advisory board members sign a stockholders agreement upon issuance of any stock. There may also be tax considerations that your board members or scientific advisory board members should discuss with their accountants and/or own advisers.

INVESTORS AND THE BOARD OF DIRECTORS

Most investors (particularly venture capital investors) expect a board seat (or two!) upon investment in your company. Remember when negotiating with investors that you will be working and dealing very closely with this investor and its representative board members. Be sure to have good synergy and that you can foresee yourself working with them for the long term. Remember, too, that investor board members have both a fiduciary duty to the shareholders of your company and an allegiance to the investor. It is important for an investor board member to be someone you find trustworthy, competent and knowledgeable about your company. It is also important to understand their investment horizon and vision for the company before you accept their investment.

A VIEW FROM THE INSIDE-A BOARD MEMBER'S PERSPECTIVE

We spoke with Dr. Philip R. Johnson, Chief Scientific Officer and Executive Vice President of the Children's Hospital of Philadelphia. Dr. Johnson has been a board member of both public and private companies and has served as an advisory board member. Dr. Johnson has extensive experience working with entrepreneurs and as a board member of many start-up companies.

From Dr. Johnson's perspective, one size does not fit all when it comes to creating the right board. The composition of your board/advisers may be dependent on your own specific experience prior to and as a CEO. If you are a CEO starting a company and you have a business back-ground or extensive experience with fundraising and deal-making, you most likely want to seek out advisers who are conversant with the science. Conversely, if you are a scientist or

engineer trying to form a company, you most likely want to seek out board members who have business experience and contacts in the business world.

We asked Dr. Johnson how he decided what companies to join as a board member. Dr. Johnson indicated that in the early years of his career, he joined companies based on personal contacts. More recently, however, as Dr. Johnson has become a more experienced board member, he performs a more comprehensive evaluation of a company to determine whether he can contribute in a meaningful way. Due to time constraints and other commitments, Dr. Johnson now joins a Board of Directors only if he sees great promise in the company and a meaningful way he can contribute, in which case, it is a real win-win.

We discussed how a CEO can make the role of the board member manageable and effective for its board members. Dr. Johnson remembers many a time being showered with e-mails, presentations and information on the company right before a board meeting. Dr. Johnson would encourage entrepreneurs to not only communicate ahead of a scheduled meeting but to communicate often between meetings as well.

Dr. Johnson also warned against setting up a Board of Directors for the prestige/notoriety of the board members only and never truly utilizing the advice and expertise of such board members. Dr. Johnson recalled calling a colleague after seeing him listed as a board member on a company's website, only to find out he never actually participated on that board. Using a board as a farce like this will only make potential board members hesitant to work with you and lessen your credibility in the business world. Investors will easily see through this tactic as well. You are also neglecting a great opportunity to tap into some great resources.

COMMON TYPES OF EQUITY-BASED COMPENSATION

Use of Equity as Part of a Compensation Program

By Mary J. Mullany, Partner, Ballard Spahr LLP

One of the most common issues a start-up company faces is why, how and when to use equity as a part of its compensation program. This outline discusses these considerations from the perspective of a traditional corporation¹ and also highlights differences or considerations if the entity is formed as a limited liability company (LLC). We then describe various types of equity awards that the start-up company could make. This is not an exhaustive discussion of all of the types equity-based considerations and of company considering compensation. Α implementing an equity compensation program should work with counsel to ensure that all legal requirements are satisfied.

What things should a start-up company consider when deciding on equity-based compensation?

Corporations

As a threshold matter, a company should consider whether awarding equity compensation is compatible with its anticipated business plan and exit strategy. Equity can be a very useful incentive compensation tool for companies that anticipate a liquidity event (such as a sale of the company, an initial public offering (IPO) or another liquidity event that provides for payments/distributions based on share ownership). For privately held companies that are likely to remain privately held, traditional equity awards may be less valuable because there may be no market for the underlying equity, and no realistic short-term opportunity to monetize the equity investment. Creating a repurchase obligation on the part of the company (which can include both "put" and "call" rights2), while making the equity award

more meaningful to the employee or other recipient, could create future cash flow issues for the company.

LLCs

In addition to the considerations discussed above, for an LLC the company needs to consider whether the people to whom it provides equity awards have a sufficient knowledge base in understanding what the equity provides to them. Most important, unlike in a corporation, in an LLC an individual cannot, for tax purposes, be both an equity owner and an employee - so if an officer receives a fully vested equity award, he or she becomes an owner for tax purposes (no tax withholding by the company, no payment of the employer side of FICA and Medicare tax, etc.) This situation can be delayed to some future date (if desired) if the equity award is structured like a stock option or is subject to vesting requirements and/or forfeiture risk.

How does a company make equity awards? *Corporations*

The authority to issue securities of a corporation, or a right to acquire securities, is vested in the company's Board of Directors. Depending upon the state of incorporation, the board has the statutory right to delegate its authority to a committee or, in some cases, to management. For equity awards, such as the types identified below, we recommend that awards be made pursuant to a formal equity incentive plan that is approved by the Board of Directors rather than approving individual awards to various participants. Shareholder approval of the plan may be required by the company's governing documents or by law.

^{1.} For purposes of this outline, we assume that the start-up company is a business corporation that is not publicly traded, and that is taxed as a "C" corporation. A corporation can make a Subchapter "S" corporation election, which allows it to be taxed as a partnership, i.e., the pass-through of profits and losses, and the obligation to pay taxes, to the owners of the entity, rather than paying taxes at the corporate level. There are specific rules that relate to Subchapter "S" corporations that are beyond the scope of this outline.

^{2.} A "put" right gives the award recipient the alternative of requiring the company to repurchase the equity award. A "call" right is the right of the company to require the award recipient to sell back the equity award to the company.

It is also considered a best practice to seek shareholder approval of equity incentive plans because of corporate governance considerations, and to put the company in the best position to comply with various securities laws as it grows.

The principal terms of an equity incentive plan to consider are:

- How will it be administered?
- How many shares are available for awards under the plan?
- Who is eligible to receive awards under the plan? Just employees? Employees, consultants and non-employee directors? Others?
- Are there designated vesting criteria, both time- and performance-based, or forfeiture restrictions that will serve as the default for all awards?
- What is the impact of the following events on equity awards: termination of employment, death or disability of the award recipient, a change in control of the company?
- Does the company want to retain a repurchase obligation on all equity?

Once the equity incentive plan is approved, the administrator of the plan, be it the board, a committee or a member of management, is best advised to follow a process in determining the award recipients and the amount and terms of the awards, and to document such awards in corporate minutes and in separate written instruments between the company and the award recipients.

LLCs

LLCs can have the same flexibility as corporations in devising and implementing an equity incentive plan. Because LLCs are primarily contract-driven, the operating agreement can designate the member or governing body with the authority to make equity awards. The principal additional differences and considerations for an LLC are: (1) a separate plan is not necessarily required – the provisions related to equity awards can be included in the LLC's operating agreement; (2) the vesting, exercise or lapse of forfeiture restrictions of an award will have the impact of turning the award recipient into an owner of the business, with the tax ramifications described above; (3)

there is more flexibility to provide a pure economic interest in an LLC i.e., an equity interest with no governance or voting rights; and (4) in addition to awards similar to those described for a corporation, an LLC can make "profits interest" awards (described below).

When could/should equity awards be made?

Corporations

Many start-up companies use equity as a principal component of compensation for employees, consultants and directors, particularly in the early stages when demands on available cash are significant. Generally awards are made upon the beginning of the business relationship between the individual and the company, with periodic additional awards (e.g., annually) to certain groups, such as employees. The company must keep in mind: (1) there are limitations on the number of equity award holders the company can have before being subject to federal securities law reporting requirements; (2) there will be dilution of other investors upon the grant and/or exercise of equity awards; (3) there may be restrictions imposed by investors on the number of securities that may be subject to awards without triggering anti-dilution protections; and (4) while the purpose of the award is primarily compensatory, any equity investment must comply with the applicable federal and state securities laws.

An example of federal securities law provisions applicable to equity incentive awards is Rule 701 promulgated under the Securities Act of 1933. Rule 701 permits a company to make stock option awards to its employees, directors and officers, as well as certain consultants and advisers, without the necessity of SEC registration so long as (1) the awards are compensatory; (2) the stock options are offered pursuant to a written benefit plan or other written contract; and (3) the company provides a copy of the plan or contract to the employee or other qualified recipient of the award. If the value of the underlying stock for which stock options were granted in a rolling 12-month period exceeds \$5 million, certain financial and other disclosure obligations are imposed on the company.

LLCs

There are no substantial differences for LLCs, other than the recognition that dilution will occur

with issuance of equity awards, and generally there is not as much of a tendency toward annual awards.

Common types of equity awards

Corporations

<u>Stock Options</u> – A stock option is a right to purchase a share of the company's stock at a future time of the holder's choosing (subject to vesting requirements or other restrictions that may be imposed) at a price that is fixed at the time of grant, and that must be at least equal to the fair market value of the underlying stock at the date of the grant.

All stock options should include the following terms: grant date, the number of shares/units covered by the option, the exercise price, vesting schedule (if any) and exercise terms. A stock option plan or award agreement should also include additional terms, such as the procedure for exercising an option (including any procedures for satisfying applicable tax withholding requirements) and any additional term that the company wishes to impose on the award.

There are two types of stock options – the distinctions relate to the tax consequences:

Non-qualified stock options (NQSOs)

 This is the most common type of stock option, and can be awarded to any eligible participant. There is no tax consequence to the participant at the time of grant of the NQSO, as long as the exercise price is at least equal to the fair market value on the date of grant.

- The tax event occurs upon exercise of the NQSO and the acquisition of the underlying stock. Upon exercise of an NQSO, an option holder is treated as having received ordinary income at the time of exercise in an amount equal to the difference between the exercise price paid and the then-fair market value of the stock acquired.
- Any subsequent sale of the stock will be taxed at capital gains rates (short- or long-term depending upon how long the person holds the stock) on the profit, which is the difference between the basis in the stock and the sale price.

Incentive stock options (ISOs)

- ISOs, which may provide certain tax advantages, may be granted only by a corporation (not an LLC or partnership), may be granted only to employees (not non-employee directors or consultants) and may only be granted pursuant to a plan that has been approved by the company's shareholders.³
- No income is recognized by an employee when an ISO is granted or exercised. If the stock obtained upon exercise is held for at least one year after exercise and two years after the grant date (the "holding period"), the difference between the exercise price and the amount realized on the sale of the stock by the employee is taxable to the employee as long-term capital gain. If any part of the holding period is not met, the tax treatment is the same as for NQSOs at the time of exercise and subsequent sale.

^{3.} ISOs are subject to some additional requirements, among them, that (1) no ISO may be granted to any employee if, at the time the stock option is granted, the employee owns stock comprising more than 10% of the total combined voting power of all classes of stock of the company or subsidiaries unless, at the time such stock option is granted, the exercise price is at least 110% of the fair market value of the stock subject to the stock option, and such stock option by its terms is not exercisable after the expiration of five years from the date of the grant, and (2) the aggregate fair market value of the stock as of the date of grant with respect to which the ISO may be exercisable for the first time by any individual during any calendar year does not exceed \$100,000, with any excess over that amount treated as NQSOs.

Restricted Stock and Restricted Stock Units (RSUs) - Restricted stock is an award or sale of shares of stock that are outstanding, but subject to forfeiture restrictions. As outstanding shares, the shares can be voted, and if dividends are paid by the company, the restricted stock holder will receive dividends like the other shareholders of that class. Restricted stock may not be sold or otherwise transferred until forfeiture restrictions lapse. The forfeiture restrictions can be timebased (frequently referred to as service vesting) or performance-based (with performance goals based upon business metrics or individual performance goals). RSUs represent the right to receive the underlying stock at the time the forfeiture restrictions lapse - the shares are not actually outstanding until the restrictions lapse.

RSUs are known as "full value awards" because there is generally no exercise price or other payment associated with the "vesting" of the award. Therefore, from the perspective of other shareholders, the stock award is of full benefit to the award recipient, with no concomitant concrete benefit (like the payment of the exercise price for a stock option) to the company, and is dilutive to other investors. This is particularly true if the award is time-based – as long as the employee stays employed, the forfeiture restrictions will lapse.

The tax consequence of restricted stock or RSUs occurs upon the lapse of forfeiture restrictions, not at the time the award is made, unless an "83(b) election" is made by the holder at the time the award is made. If the holder makes an 83(b) election, income tax is due (at ordinary income rates) on an amount equal to the difference between the value of the shares or RSUs on the date of grant and the consideration paid by the holder (if any). Any subsequent increase in the value of the shares at the time of a sale is taxed at short-term or long-term capital gains rates (depending on the holding period), subject to certain exceptions. Because of this tax treatment, many initial shareholders (e.g., founders) and employees make an 83(b) election at the time the award is made, when the stock has little value. The risk the holder runs is that the shares will be forfeited - there is no refund for the tax previously paid.

If the holder does not make an 83(b) election, then upon lapse of the forfeiture restrictions the holder is deemed to acquire the shares and is

taxed, at ordinary income rates, on the difference between the fair market value at the time the restrictions lapse minus the purchase price, if any, paid at the time the award was made. Thus, the timing of the tax consequence is not within the control of the holder as it is with stock options — when the forfeiture restrictions lapse, the tax event occurs. The tax event could occur at a time when there is no ability to sell the shares (either no market for the shares, or insider-trading concerns). For this and other reasons, careful planning is needed in establishing a program that includes restricted stock and RSU awards.

Stock Appreciation Rights (SARs) – SARs, which are usually issued in conjunction with stock options, are the right to receive cash equal to the difference between the value of the shares on the date the equity award is made and the date it is exercised. This, in essence, allows the stock option holder access to cash from the company to pay the exercise price upon the exercise of a stock option.

Phantom Equity – Phantom equity awards are not equity; they are cash-based awards that vest and become payable, or lapse and are not paid, based upon whether there is an appreciation in the value of the underlying stock equal to or greater than the appreciation goal established at the time of the award. Phantom equity awards may be advantageous when the shareholders want to share the economic value of the equity without actual dilution. If a cash payment is made, the award holder will pay tax at ordinary income rates.

LLCs

Options – An LLC can award an employee, consultant or manager the right to purchase an LLC equity interest at a future time of the holder's choosing (subject to vesting requirements or other restrictions that may be imposed) at a price that is fixed on the date of grant. Until the option is exercised, the option holder is not a member/owner of the LLC. If the option holder is an employee, that status will change, as discussed above, upon exercise of the option.

Restricted LLC Interests - An LLC can award (with without LLC equity interests or consideration) that are similar to restricted stock and RSUs, i.e., the interests are not fully owned, and may not be sold or otherwise transferred, until certain restrictions lapse. The restrictions can be time-based or performance-based like restricted holder stock/RSUs. The becomes member/owner of the LLC as of the date of lapse of the forfeiture restrictions. If the holder is an employee, that status will change, as discussed above, upon the lapse of the forfeiture restrictions.

Profits Interest – A profits interest allows the LLC owners to make awards that give the recipient the right to share in the future liquidation value of the company. The enterprise value is determined at the time the profits interest is awarded. The profits interest holder will be entitled to his or her percentage share of the accumulated value at the time of a liquidation event, such as a sale of assets, sale of membership

interests or voluntary dissolution. For example, assume an LLC with a current value of \$10 million and two members, who provide an employee with a 1/3 profits interest. If the company is sold three years later for \$100 million, the initial two partners will share the first \$10 million of consideration 50/50; the remaining \$90 million will be paid 1/3 each to the members and the profits interest holder. There are tax rules related to profits interests that are complex and beyond the scope of this discussion.

Membership Interest – In an LLC, different types and classes of membership interests can be issued, and the company has more flexibility than in a corporation to treat members differently from each other. For example, one member may be able to receive a preferred return from profits before other members receive distributions; members may share in the distribution of profits based on formulas, performance criteria, etc.; and membership interests can be subject to repurchase rights.

AGREEMENTS WITH EMPLOYEES AND CONSULTANTS

By David S. Fryman, Partner, Ballard Spahr LLP, and Jocelyn K. O'Brien, Associate, Ballard Spahr LLP

AGREEMENTS WITH EMPLOYEES

After a business is formed, one of its first steps is often to hire employees. At this stage, a company should consider whether to enter into employment agreements with any of the individuals it intends to employ.

The Need for an Agreement

The first question at the start of any employment relationship should be: Does the company need a written agreement with this individual?

The principal reasons for having an employment agreement are to:

- detail equity, severance or unique or complex compensation or benefit arrangements.
- limit post-employment competition and/or impose other restrictive covenants (e.g., non-solicitation of customers and/or employees).
- protect the company's trade secrets and other intellectual property and confidential information, beyond that provided by law, and deter employees from disclosing or using that information for their own benefit.

Employment agreements detailing equity, severance or unique or complex benefit arrangements are traditionally reserved for the highest-level executives or situations in which such an agreement is needed to induce the individual to become employed organization. The company should think long and hard before binding the company to the types of often found in commitments executive employment agreements. Instead, the company should consider detailing the initial terms of employment in an offer letter, which serves to maintain the company's flexibility to change those terms of employment (which can be particularly important for a start-up).

Non-compete provisions and other types of restrictive covenants are typically found in the executive employment agreements mentioned above but can be (and often are) drafted separately in the absence of those agreements. When contemplating non-compete and non-solicitation covenants, the company needs to: ensure that they

are reasonable in time and scope; require all those (but only those) who have access to the company's highly confidential information and who are responsible for customer relationships to sign them; and require employees to execute the covenants upon commencement of employment (otherwise, additional consideration likely must be provided before the covenant will be considered enforceable).

Confidentiality and nondisclosure provisions can be included in any executive employment agreement or non-compete/non-solicitation agreement if not entered into separately. To the extent, however, that the company does not have a need for either of those types of agreements, confidentiality/nondisclosure agreements can serve a useful, deterrent purpose and protect some information not otherwise protected under law in the absence of such an agreement.

The first question at the start of any employment relationship should be: Does the company need a written agreement with this individual?

Basic Provisions of an Executive Employment Agreement

Although the terms included in an executive employment agreement will vary, the basic provisions typically found in these agreements include the following:

Position and Responsibilities. In broad terms, the agreement details the individual's duties and responsibilities and often identifies the individual or position to whom the employee will report.

Term. The agreement should specify an initial term, subject to renewal (often for shorter periods) and termination by either of the parties upon specified notice.

Compensation and Benefits. The agreement usually outlines the compensation and benefits that the employee will receive, such as:

- Base salary
- Bonus programs or opportunities

- Stock options, stock or other equity arrangements
- Health and welfare benefits (often by reference to those provided to employees by the company)
- Other fringe benefits

Termination. The agreement should describe and under what circumstances the employment relationship will end. The agreement should not restrict the company's ability or the employee's ability to terminate the employment relationship for any reason at any time. Rather, the termination provisions typically delineate how much, if any, notice must be provided and, depending on the circumstances, what if any compensation and/or benefits the individual will receive beyond that earned through termination date. The agreement may also specify that the employee will be "AT WILL," meaning that he or she has no legal right to continued employment and may be terminated at any time for any or no reason.

Severance. Executive employment agreements often provide the employee with severance upon termination, typically only in cases in which the employee is terminated "without cause" or the employee resigns for "good reason" (e.g., the employee is required to relocate or the employee's responsibility or authority is reduced significantly). Just because an employee is "AT WILL" doesn't mean that he or she cannot still be entitled to severance, if agreed to in the employment agreement.

Restrictive Covenants. As noted above, executive employment agreements can include post-employment covenants restricting employee from going to work for a competitor, soliciting customers or clients, or soliciting other employees to leave the company. enforceability of restrictive covenants varies greatly by state. Inasmuch as several states are hostile to these provisions, consideration needs to be given to the employee's work location when entering into these covenants (either in executive employment agreements or stand-alone agreements).

Confidentiality. Confidentiality and nondisclosure provisions should be included in any executive employment agreement (unless covered by a separate agreement). The company must then follow through and ensure that it takes adequate steps to truly protect and maintain that information as confidential.

Intellectual Property Rights. Related to confidentiality provisions are the more detailed intellectual property provisions. Such clauses ensure that any intellectual property created or developed by an employee while working for the company, or from information obtained while working for the company, will be the property of the company. (More information on protecting trade secrets and intellectual property rights can be found in Section IV of this book.)

Dispute Resolution. The company should consider whether it might be to its advantage to have the employee agree that any disputes under the agreement or concerning the employment relationship be submitted to some form of dispute resolution outside of court, such as binding Actions to enforce restrictive arbitration. covenants, however, should always be excepted from alternative dispute resolution provisions, so that the company can seek a court order restraining an employee or former employee from going to work for a competitor or soliciting customers or other employees in violation of the agreement's restrictive covenant provisions.

ENGAGING THE INDIVIDUAL AS AN INDEPENDENT CONTRACTOR – PROCEED WITH CAUTION

The company should proceed with caution before retaining an individual as an independent contractor, for the risks associated with misclassifying an employee as an independent contractor are considerable.

Retaining an individual as an independent contractor sometimes appears to be an attractive and low-cost alternative to employing individual. Whether the individual is independent contractor as opposed to an employee, however, is not a matter of choice but a matter of the nature of the relationship. That relationship will be scrutinized under several laws, including federal and state tax laws. unemployment compensation laws, workers' compensation laws, and a host of other employment and wage and hour laws. specific tests for determining whether the individual is an employee or an independent contractor under each of these laws are beyond the scope of this book, but they focus generally on the company's right to control the manner in

which the individual performs the job, the economic dependence of the individual on the company retaining him or her, and the intent of the parties when forming the relationship. In short, the company should proceed with caution before retaining an individual as an independent contractor, for the risks associated with misclassifying an employee as an independent contractor are considerable. These issues are often uncovered in due diligence and can be quite costly in an M&A exit transaction.

ALLOCATING EQUITY

By Bradley B. Bertoch, President and Member of the Board of Trustees of the Wayne Brown Institute.

Stock as Currency – Six myths of the use/misuse of stock.

In the go-go days of Silicon Valley (circa 2000), people talked a lot about the stock of a hot company being viewed as currency. Not only could you exchange cheap stock for money, but also services, equipment, rent, employees. It was great. Have a super idea and you could print your own money. And with some of the best law firms in venture law and most of the VC firms in the United States located there, this new Currency had credibility, real – not just perceived – value. It became a fever that eventually infected almost every tech center in the country. Ask your securities lawyer if she was allowed to take stock; if she was, you can bet she has a drawerful.

This brings us to Myth #1: If people perceive their stock has value, then it must have value.

Entrepreneurs in a start-up company will be told that their stock is cheap, and that they should trade it willingly when possible. But as soon as someone wants his or her stock for future services or services rendered, all of a sudden the stock becomes dear to the entrepreneur. His worth less (deliberately spaced) company is now extremely valuable. This leads to the entrepreneur overstating the value of his company, which can prevent the company from raising capital or attracting great talent.

Myth number #2: It's my company, it's my stock, I can give it to anyone I want!

One thing an entrepreneur needs to be careful of is whom the company gives stock to, and how it is done. When your company is first organized, it is imperative that the company allow for stock to be used to incentivize people or organizations it wants to do business with. Make sure your company anticipates that use of stock. beware! There is nothing worse than having to clean things up later. Things such as different classes of stock, buyback arrangements, vesting schedules, inconsistent valuations and promises of specified percentages screw up your cap table and your company. This, combined with Myth #3, is the biggest source of "hair on that dog." You hope no one says that about your company or deal; if so, it just might be a dead deal.

Myth #3: It's my company, it's my stock and I can give it to anyone I want at whatever value I want!

Now let's get really ugly. Have you heard of the company that has 300 shareholders, most of whom are non-accredited investors, no two of them at the same price? Disaster. The local state securities division viewed the company as basically a de facto public company, demanded investors have the right of rescission with 12% interest per annum on their investment. Did I say it used a "finder" - someone who was not a licensed broker dealer? Why is this especially important to a life sciences company? Because it takes so much money! And a longer time to mature. You run out of money, get desperate, can't pay your attorney and you stop talking to him/her, and before you know it, someone has put money in your deal who can't afford it. (For a graphic and humorous depiction of this process, rent the original version of the movie The Producers.) Remember, the road to Hell is paved with good intentions, never more so than in the financing of the life sciences startup. I wish I could say that this was an isolated example, as extreme as it is, but I've seen dozens, and hundreds with one or more of these problems.

Myth #4: Life sciences companies are just the same as every other deal.

Money. Money. And more money. Life science deals aren't some SaaS model, that with \$50,000 and an alleged monetizable model you can go into business. We're talking about real money, big money. Millions in research just to get the attention of investors or partners, millions more to get to the clinic. Even a quick and dirty 510K deal is going to run several million, and a therapeutics deal increases that by at least one order of magnitude. A SaaS deal or an iPhone app and you can have revenue in a month; life sciences deals hope for an exit in five to ten years.

What this means is that your business will evolve over time and the board, advisers and employees will change. It also means that you'll have a lot of small pieces of stock in all sorts of little hands. Usually that's OK. Hopefully, they will all be good friends and proponents of the company. However, too many shareholders for a small company can be a bad thing. Vesting is important; buyback arrangements are advised. One thing is

certain: Make sure your stock doesn't fall into enemy hands. Disgruntled shareholders with an internet connection and their own blog can be a real pain.

Myth #5: It's easier to catch flies with honey than vinegar.

This isn't really a myth, it's a truism. Trying to attract great people to your company when you have little or no money is hard. But, nothing solidifies commitment like stock. And nothing keeps commitment overtime like vesting. Life sciences companies need a scientific advisory board, a business advisory board, papers to be published, the FDA to navigate, and a big-time Board of Directors. Not to mention that the CEO needs domain and venture expertise, which can't be provided by some guy whose last job was as an accountant. (You laugh, but I've seen scores.)

Myth #6: There is nothing so unfair as treating equals equally.

Now we are going to get to truly helpful information. Let's face it, most life sciences company CEOs are technically oriented and are much more responsive to numbers than words. Keep your stock plan simple and consistent and you'll save a lot of headaches in the future.

As for compensation of advisory board members, usually there is no cash component (for start-ups), and between 0.1% and 0.25% equity with vesting on a monthly basis (no cliff) over a period of anywhere from two to four years. The length of vesting tends to be based in part on the size of the equity grant (within the range mentioned) and how active the adviser will be. A three- or four-year vesting period is still most typical for advisory board members (and some companies consider an additional equity grant in the future depending on how well the relationship is working).

Now, for the board members. Inside directors and investor directors usually get no compensation (just reimbursement for direct expenses such as travel to board meetings). The equity range for outside/independent directors is between 0.25% and 2.0%, depending on how important they are to the company and the amount of direct service they provide (vested over two to four years). Usually, there is no cash compensation (especially before the company is generating any). Obviously, there are exceptions if the person is critical or extraordinary.

Now let's talk about employees. In my experience, these ranges apply to key management-level employees:

Position	Founder?	Low Range	High Range ¹
CEO	Y	5.6%	15.2%
	N	4.2	6
СТО	Y	2.2	7.7
	N	0.7	1.6
Vice President			
Level	Y	1.3	6.7

Consultants and goods providers should be included from the get-go in the employee pool and will be a dollar-for-dollar trade (if you're lucky). Make sure you have a buyback provision.

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Numbers assume a company after the first or second round of venture funding.

IV.

INTELLECTUAL PROPERTY



CONTRIBUTORS

PROTECTING YOUR IP FROM CONCEPTION TO EXIT: "HYGIENE"

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PROTECTING YOUR IP FROM CONCEPTION TO EXIT: "HYGIENE"

By Dr. Patrick J. Kelly, Partner, Ballard Spahr LLP, and Dr. Mary Anthony Merchant, Partner, Ballard Spahr LLP

Patents are often the most valuable assets of startup companies, particularly life sciences companies. Thus, life sciences companies must ensure that the proper procedures are in place to maximize the value of these assets and that they can sell their products and services without infringing the patent rights of others. Accordingly, life sciences companies should be proactive in identifying, protecting and exploiting their patentable inventions and in avoiding the infringement of others' patent rights.

Identifying Your Patentable Inventions

Many organizations use a document to capture the details about a potentially patentable invention, generally referred to as an invention disclosure. The purpose of an invention disclosure is to record the conception and any reduction to practice of an invention, describe the invention, and provide related information to help decide if the invention is a patentable one. The invention disclosure also aids in drafting a patent application to cover the invention. An invention disclosure document should include the following information:

- Identification of persons involved with the invention, including those who came up with the idea and those working on reducing it to practice or proving the concept, and the dates when these steps took place. This may include a preliminary determination of inventorship, including the inventor's relationship to the company.
- Description of the basis of the invention, including how to make and use the invention and any improvements over current technology. In particular, how the invention is novel and not obvious in view of previous developments should be provided.
- Identification of the most pertinent "prior art" (e.g., technical papers or patents/published applications) These will help in drafting the patent application and must be provided to the U.S. Patent and Trademark Office during examination of the patent application.
- An explanation of how the invention relates to business goals – This aspect is often overlooked

- and is important in determining whether to invest in patenting the invention.
- Discussion of ways others might design around the invention to avoid a patent.
- Identification of sources of funding, collaborations and any potential obligations to others relating to the invention.

In order to capture inventing activities in real time, all life sciences companies should consider whether they need a notebook policy or some other system to document the invention process, including any critical dates. If the company's right to the invention is ever challenged, it will be necessary to have evidence to establish these dates. Any inventor-derived evidence must also be independently corroborated, such as notebook pages that are signed and dated by the inventor and a witness.

Life sciences companies should be proactive in identifying, protecting and exploiting their patentable inventions and in avoiding the infringement of others' patent rights.

Awareness of certain actions that may preclude the ability to get a patent also is needed. Keep in mind that disclosure to others can lead to a loss of novelty for inventions. An inventor has one year from the date of the first public disclosure of the invention to file a patent application in the U.S. Patent and Trademark Office. However, one can lose the ability to obtain patents in most other countries if there is a disclosure before filing. Accordingly, it is helpful to have a "gatekeeper" in the company who determines whether an invention should be the basis for a patent application before it is publicly disclosed. Disclosures that can destroy patent protection include:

- Presentations and posters
- Publications
- Public uses
- Sales and offers to sell an embodiment of the invention

 Conversations outside your company that are not covered by a nondisclosure agreement (NDA)

Protecting Patentable Inventions

Before filing for a patent application to protect inventions, certain issues need to be addressed right away, such as inventorship and ownership of any resulting patent rights.

INVENTORSHIP

In the United States, patent applications are applied for in the name of the inventors. Inventorship is determined by who conceived of the subject matter that is claimed in the patent application. Conception, under U.S. patent law, is defined as the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is to be applied in practice. Conception has two parts: (1) recognition of the ultimate result desired, and (2) development of the means to accomplish that Unless a person participates in the conception of the invention, he or she does not qualify as an inventor. For example, an individual who would be a "co-author" of the subject matter if submitted to be published by a scientific journal would not necessarily be a co-inventor of a patent application directed to the same subject matter. Because inventorship is based on the scope of patent protection sought, inventorship cannot be determined until the patent application claims are drafted. Unnamed and misnamed inventors can be fixed at any time during the term of the patent, though it is less costly to identify the correct inventors at the outset.

OWNERSHIP

Absent any agreement or obligation to assign a patentable invention, each inventor of the resulting patent would own an undivided interest in the patent. Thus, it is absolutely essential that employee and contractor agreements provide for the disclosure of all inventions relevant to the company's business or developed using company resources. Agreements must also require that the employee assign all such inventions to the company. Be aware that inventors may sometimes file patent applications on their own without advising the company, or leave the company and file patent applications based on work while done at the company. Once a patent application is filed, assignments should be prepared, executed and recorded as soon as possible to minimize the chance that the inventors are unavailable or uncooperative.

An assessment is needed to consider whether others could have an ownership stake in any issued patent. For example, a determination of any obligations to assign rights to an invention based on sponsored research agreements, collaborations, or reagents used to develop the invention should be made. It is better practice to have these relationships clarified prior to the collaborations or before inventions occur.

GOVERNMENT FUNDING IMPLICATIONS

For federal government-sponsored research, pay attention to the obligations to the government based on the sponsorship, and be aware that:

- A statement in the patent application noting the government involvement is required.
- Each disclosed invention must be reported to the government funding agency. Failure to disclose can result in the government taking patent rights.
- The government receives a non-exclusive, nontransferable, irrevocable paid-up license to practice the invention. The government, however, is unlikely to utilize this license.
- The government has march-in rights (can require the grantee/contractor to grant a license on reasonable terms to a responsible applicant).
- There is a preference that any patents based on government-funded research be licensed to U.S. companies.

INVENTION TRIAGE

Once there is a clarification of any inventorship or ownership issues, the next step is to determine if it is worth the time and expense to seek patent protection for the invention. You first need to determine what is to be protected by the patent.

- Is it a product, compound or device?
- Is it methods of making a product, compound or device?
- What are the methods of using the product, compound or device?

The patent claims should cover the product, compound or device and methods of making and using it, such that the patent can be asserted in a patent infringement suit against those that make,

use or sell the protected product, compound or device or methods of making or using the invention.

Classifying the inventions into categories based on the level of importance to the business is helpful in managing the patent portfolio. Keep in mind that while a patent may be effective protection for 20 years from the filing date, many things may change during that 20-year period, and rankings may need adjustment with time. By way of example, a patent portfolio could be grouped as follows:

- Group A Core technology vital to business, technology involved in current products and methods
- Group B Important technology technology that may be used for current or future products
- Group C Other technology not needed for business but may be licensed for use by others

These rankings can help determine where patent applications should be filed. Patent applications covering core technology (Group A) would be filed in major and growing markets such as the United States, Europe, Japan, Canada, Brazil, Russia, India and China. Patent applications covering important technology (Group B) would be filed in at least the major markets: United States, Europe and Japan. Depending on the market for the other technology (Group C), consider filing patent applications in at least the major markets for such technology. In addition to these general considerations, one should consider filing patent applications in the following locations:

- Where the product is to be sold and/or made
- Where there is a large customer base for the product
- Where the competitors are active
- Where there is an adequate judicial system to enforce any issued patents

Exploiting Your Patents

Once the patent has been obtained, a determination on how to profit from the patented product or method is needed. The primary options for profiting from your patent are:

Sell it Where the product is made and sold or the method covered by the patent is used.

Assign it Assign the patent (typically for a lump-sum payment) so that another may make and sell the product or use the method covered by the patent.

License it License the patent (typically for royalties based on net sales) so that another may make and sell the product or use the method covered by the patent.

Other options include entering into a joint venture or strategic alliance with another company to exploit the patented technology.

If the invention is to be practiced by the company, consider whether there are any regulatory approvals needed before the products can be sold or used. Such regulatory filings may result in exclusivity rights that are granted by the regulatory agency beyond what is granted by the patent laws.

Conduct a regular review of the patent estate to eliminate unnecessary patents and patent applications. For those patent applications still under examination, ask whether the patent application is likely to issue with useful claims that cover the product. This review may also lead to improvements in the criteria used to decide whether and where to file certain applications.

Avoiding Patent Infringement

One of the first questions a potential investor will ask is whether there is "freedom to operate," which means can the invention be practiced without the company being sued by others for patent infringement. For a determination of whether a freedom to operate exists, the following is needed:

- What is the product that will be sold?
- What is the process for making the product from start to finish?

Once these questions are answered, a search should be performed for issued patents and any pending patent applications that may prevent making, using or selling the product. You should also be aware of whether others are asserting any patents against any similar products.

There should be a determination of whether there are any employee issues that may prevent freely exploiting the invention. For example, an

evaluation to ensure that the technology does not rely on another company's trade secret or confidential information brought in by an employee. There should also be a check to see if employees are violating any non-competition agreements.

BEST PRACTICES FOR TRADEMARKS & TRADE SECRETS

By Jamie B. Bischoff, Partner, Ballard Spahr LLP

WHAT IS A TRADEMARK?

A trademark is any word, symbol, name or device used to identify goods or services and distinguish them from other goods and services. Trademarks can include letters, numbers, shapes, slogans, colors and even smells. Examples of trademarked names and products include Genentech's ACTIMMUNE® (a drug that stimulates the immune system), ACTIVASE® (a tissue plasminogen activator), and PULMOZYME® (a drug enzyme that selectively cleaves DNA).

Getting Started

New companies should identify any word, symbol, name or device they might wish to trademark. Effort should be taken to choose the *right* mark – a mark that is distinctive and easy to protect. The strongest, most protectable marks are those that are arbitrary or made up. These marks are not descriptive of the goods or services they represent and have no relationship to them. Suggestive marks are also strong, protectable marks that suggest, rather than describe, the goods or services. Descriptive marks that directly convey information about the goods and services represented are typically not protected as trademarks. Finally, generic marks including the common category name of the goods or services are not protected at all.

The most important aspect of getting started is staying informed about the goods and services your proposed trademark represents. Do not be too quick in clearing an already registered mark based on generalizations.

After identifying your mark, you should conduct a comprehensive search for other marks that are similar or that may cause confusion if used in commerce. A preliminary "knock out" search eliminates possible conflicting marks and assists in assessing if use of a mark would infringe on existing rights. The "knock out" search is inexpensive, can be done in-house, and will

ultimately save time and money for companies down the road.

The "knock out" search should be followed by a basic or advanced search on the Trademark Electronic Search System (TESS) and Trademark Registration Retrieval Applications System These databases contain pending, (TARR). registered and dead federal trademarks. Basic and advanced searches on TESS and TARR are free. In addition to searches within the United States, you should be aware of internationally registered trademarks, some of which may enjoy certain benefits and rights in the United States. The International Register can be searched to identify any possible conflicts. Searches can be done through the World Intellectual Organization (WIPO) website or a host of other Internet search engines. The most important aspect of getting started is staying informed about the goods and services your proposed trademark represents. Do not be too quick in clearing an already registered mark based on generalizations.

Registering a Trademark

Once you have identified a mark and cleared it, you can register the mark on the Principal Register by filing an application in the U.S. Patent and Trademark Office. The application can be based on your actual use of the mark in commerce, on your bona fide intent to use the mark in commerce, or on a foreign registration or application. The advantage of having your mark registered on the Principal Register includes the presumption that your mark is valid, you are the owner, and you have the exclusive right to use the mark on the goods and services specified in the registration. Registration reserves your rights throughout the entire United States for any eventual expansion of use and allows you to claim incontestable rights under certain conditions. You may also register your trademark internationally to preserve your rights abroad.

Rights to a mark may also be obtained through use in commerce. In this situation, rights are afforded in the geographic area where the mark is actually used. Additionally, trademark licensing is permitted so long as you maintain control over the quality of the associated goods and services sold.

Registration and use rights last as long as you continue to use your mark in commerce and you provide periodic affidavits proving your continued use. Initial proof must be given between the fifth and sixth year after the date of registration, again within the first ten years after the date of registration, and then every ten years subsequent.

Registration will be refused if the mark is too descriptive, if there is a likelihood of confusion with another mark, if it is a surname, or if it is geographically descriptive.

Infringement and Dilution

When you register a trademark, you have nationwide protection against infringers or counterfeit marks and can block importation of products that infringe on the mark. Infringement occurs when the same or a similar mark is used in a way that makes it likely that consumers or purchasers will be confused about where the product or service is coming from, or whether there is an affiliation between you and the alleged Similarity of mark, similarity of infringer. prospective purchasers, and likelihood of confusion are factors assessed for infringement. Remedies for infringement include injunctions ordering that the infringement must stop, money damages, and recalls of infringing products.

Additionally, dilution of a mark can occur. Dilution is a weakening in the ability of a "famous" mark to clearly identify and distinguish a single source. Dilution occurs in two ways: (1) blurring – when others use a famous mark on different products or services resulting in weakened significance; and (2) tarnishment – when unauthorized use of the mark places the famous mark in an objectionable light.

Many companies have trademark usage guidelines to prevent dilution and ensure the integrity and value of their trademarks. These include using the proper typeface, font and punctuation for trademarked products and names; always using ® after registered marks; and limiting use of the marks and associated logos to licensed users.

Protecting Your Mark

The most effective way of protecting your mark is by using it. Marks that are never used in commerce are considered abandoned and all rights are lost, even if registered. Always use your mark as a brand name and as an adjective rather than a noun. Take timely action against infringers, send cease-and-desist letters when appropriate, and sue when necessary. Consider a monitoring service to identify infringers both on the Internet and in the *real* world. If you wish to protect your trademark rights abroad, consult an experienced trademark attorney.

BEST PRACTICES FOR TRADE SECRETS

What is a Trade Secret?

A trade secret is anything (1) that gives you an advantage over a competitor because it is not generally known; and (2) that you have used reasonable measures to keep secret. Nearly anything can be a trade secret – customer lists and contacts; buying habits; pricing formulas; computer programs and databases; manufacturing techniques or processes; marketing or product plans; product formulas; ingredients or recipes; drawings and blueprints; instructional training methods; etc. Trade secrets can also include any failed research attempts or development processes. Trade secrets are property that can be valued, sold, licensed or used as security.

There is no national or state registration for trade secrets. Different states have different criteria for determining whether something is a trade secret, so it is important to be aware of those criteria when starting your business.

Trade secrets are trade secrets only as long as you keep them secret and they continue to give you an advantage over competitors. A trade secret is lost when it is disclosed via a publication, if someone steals it and you fail to enforce your rights against this person, or if you fail to take sufficient steps to protect it. Additionally, a trade secret can be lost through legitimate means, including: (1) independent discovery; (2) reverse engineering; or (3) observing the item or process in public.

Protection

Unfortunately, even if someone steals or discloses your trade secret without your consent, once the secret is revealed, it is no longer a trade secret. Therefore, it is very important to take appropriate measures to protect your secret.

These measures fall generally into three categories: contracts, physical measures and notices.

You should consider requiring your employees to sign confidentiality or nondisclosure and non-compete contracts. Have similar rules for contractors, consultants, licensees and any other individuals outside the company who may work with a trade secret.

Adopt physical measures such as a formal information security and protection policy to identify trade secrets, prioritize them, and institute the appropriate safeguards for each trade secret. Periodically monitor and regularly audit trade secret information flow and access. encryption, coding and tracking devices for electronic communication. Establish employee education programs that inform and train employees on the practical side of protecting trade communication. secrets during use and Management should know the company's information systems, create security passes for access to sensitive information, and ensure that employees have access only to the information they need to do their job.

To most effectively protect your trade secret, you should also provide appropriate notices. Label all

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documents or items that contain trade secret information and restrict access to and circulation of these documents. Give notice designating sensitive documents and areas as confidential. Maintain meticulous records of the investment into your trade secret to reinforce its value. Revealing a trade secret to an individual who has signed a confidentiality agreement and needs the information to do his job does not automatically result in loss of the trade secret.

Additionally, often larger biotechnology and pharmaceutical corporations have the luxury of using immense resources to obtain patents to protect their intellectual property. The patent process is expensive, and as a start-up, you may not have this advantage, especially if your focus is on one or two products that are not ready to be patented. Taking steps such as those outlined above to protect your intellectual property as trade

secrets becomes extremely important when starting your business.

Government Protection and Remedies

The federal government protects trade secrets through the Economic Espionage Act of 1996. This act makes the intentional theft, copying or receiving of trade secrets a crime punishable by heavy fines and imprisonment. The Computer Fraud Abuse Act allows you to obtain money damages to compensate for any loss or damage to your computers through unauthorized access. State protection varies but provides for both criminal and civil remedies.

If someone discloses or uses your trade secret without your consent, you may be able to (1) obtain an injunction preventing any further unauthorized use or disclosure, and order the return of the item; (2) bring an action to collect compensatory money damages; (3) collect punitive damages if the person acted willfully or maliciously; and (4) collect attorney's fees if the person acts in bad faith or maliciously.

Resources

There are several resources you can consult when you are ready to begin the trademark registration and trade secret process. The Pennsylvania Bar Institute provides general resources on trademarks and trade secrets, for a cost. Internet resources are widespread, but you must be conscious of source reliability. The U.S. Patent and Trademark Office website (http://www.uspto.gov) and the WIPO website (http://www.wipo.int) are both valuable, free online resources. Some legal treatises offer the forms necessary to apply for trademark registration, but unless you have access to a law library, these may be difficult to utilize, and there are significant nuances to trademark registration that cannot be gleaned from the We recommend that you consult an attorney for guidance.

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COMMON MISTAKES IN IP AGREEMENTS

By Jennifer L. Miller, Co-Chair, Life Sciences/Technology Group, Ballard Spahr LLP and Sandra Wintner, Associate, Ballard Spahr LLP

Early stage companies are famous for handling common contracts without counsel, and in the process making significant mistakes that can create big problems later. This chapter discusses the common mistakes we have encountered in key agreements related to owning, controlling and protecting intellectual property. In particular, this chapter reviews legal errors in:

- Assignments
- Licenses and sublicenses
- Confidentiality agreements
- Non-compete agreements

We conclude with an overview of mistakes in signing, filing and performing agreements that commonly affect small companies.

Intellectual Property Assignments

Assignments of intellectual property are usually obtained from a start-up company's founders, employees and consultants upon the organization of the company and on an ongoing basis. Assignments are key to building a company's portfolio, whether in connection with an acquisition of another entity or as a straightforward purchase of the intellectual property.

Mistake: Obtaining a license instead of an assignment

An assignment transfers ownership of the entire right, title and interest in the intellectual property from one party to the other. Assignments must be in writing and transfer all rights (not just some) of the assigning party. As a corollary of the rule that assignments must transfer all rights in the property, patent assignments may not transfer patents claim by claim or be restricted to a field of use. If a purported assignment does not meet these requirements, a court may construe it to be a license, with serious ramifications for a company's ability to exploit, control, transfer and protect the property.

Mistake: Failure to obtain assignments from all co-inventors or co-owners

A co-owner of intellectual property can sometimes act independently of the other co-owners and sometimes must act in coordination with the other co-owners, depending on the type of intellectual property at issue. For example, a one-tenth coowner of a patent can commercialize the patent freely, license the patent to others, and keep any royalties paid to it, all without the consent of the other co-owners. However, the cooperation of all the patent owners is needed to sue for infringement of the patent and to enforce confidentiality obligations. Co-ownership of patents is particularly likely to occur because a coinventor, even as to one patent claim, owns a prorata undivided interest in the entire patent. To avoid these problems, it is best for the company to become the sole assignee (and thus owner) of its intellectual property by obtaining assignments from all co-inventors or other co-owners.

Mistake: Granting clause stated in the future tense

The granting clause of an assignment must be stated in the present tense, even if the intellectual property being described has not yet been created. An assignment stated in the future tense is deemed to be a mere promise and does not actually transfer ownership of the property from one party to the other. For example:

<u>Mistake</u>	<u>Better</u>
"Employee will assign to Company"	"Employee hereby assigns to the Company all of his right, title and interest in and to all"

The company has not obtained ownership of the purportedly assigned property in the "Mistake." On the other hand, in the case of intellectual property that does not exist yet, the present assignment results in legal title being transferred automatically to the assignee upon creation of that intellectual property (see "Better" column).

Mistake: Inadequate description of what is being assigned

Most assignment agreements are intended to transfer not only the intellectual property rights, but also the corresponding technology. Patents, copyrights and trademarks are sets of legal rights granted to the owners. In contrast, processes, techniques, know-how, algorithms, software, content, data, databases, protocols, and business plans are the tangible or intangible things that are covered by the intellectual property rights. Assignees should ensure a complete transfer by obtaining the technology as well as the intellectual property rights. For example:

<u>Mistake</u>	<u>Better</u>
"intellectual property rights"	"all inventions, discoveries, data, know-how, research, procedures, designs, formulas, techniques, methods, trade secrets, developments, software and works of authorship, whether patentable or not"

Licenses and Sublicenses

After assignments, licenses and sublicenses are the most important tool for a technology company in building its portfolio and operations. A start-up company will typically license technology at the time of its organization from a university, another company, or its founders. During its life, the company will also license technology out to collaborative partners and to other companies to obtain value from unused applications. Unlike an assignment, a license does not transfer ownership. Instead, licenses grant certain specific and limited rights to use the property without being subject to an infringement claim from the owner. Licenses may be oral or written agreements, exclusive or non-exclusive, and express or implied.

Mistake: Failure to appropriately tailor definitions

The permissions to use intellectual property in license agreements depend on key definitions, such as "Field" or "Territory." These definitions must be carefully reviewed to make sure they capture the intent of the parties. Companies should consider whether:

- the definition of "Patent Rights" adequately covers the universe of what will be licensed
- the definition of "Field" properly describes the indication or use of the technology
- the definition of "Product" describes the items to be developed and commercialized
- the definition of "Territory" actually covers the proposed markets and proposed obligations can be met everywhere in the "Territory"

These definitions can be broad to grant broad authority to use the intellectual property (and thus be of greater value) or be specifically and narrowly tailored to limit the granted authority.

Mistake: Inadequate license grant

The granting clause is the heart of a license agreement, and both licensors and licensees are damaged by granting clauses that are not sufficiently explicit. For example:

<u>Mistake</u>	<u>Better</u>
"A grants to B the right to make and sell the Patents in the Field in the Territory"	"Subject to the terms and conditions of this Agreement, A hereby grants to B the exclusive (even as to A) right and license under the Patents and Intellectual Property to research, develop, make, have made, import, have imported, sell and have sold Product in the Field in the Territory."

The "Mistake" has several problems. It does not make clear that the license grant is subject to the other terms of the agreement, with the result that a licensee could argue that its license rights are perpetual, even if it breaches another part of the agreement. It is silent, and hence ambiguous, as to whether the license is exclusive or non exclusive. It also confuses the intellectual property rights with the product covered by those rights. Finally, the licensee's rights are overly limited. Our "Better" shows how these problems can be corrected.

Mistake: Obligations of licensee are unattainable

Licensees of technology are typically subject to diligence obligations that set standards and milestones for the licensees' development and commercialization of the covered products. When these diligence obligations are stated baldly, as in the "Mistake" below, the licensee risks agreeing to a bar that is set beyond its reach. Licensees should keep in mind that many circumstances beyond their control, including trial results, governmental approvals and the availability of materials, can affect their ability to develop and sell the product.

<u>Mistake</u>	<u>Better</u>		
"shall develop and	"use commercially		
sell Product in each	reasonable efforts to (a)		
country in the	begin human clinical		
Territory by the	trials within X months		
third anniversary of	of effective date, and (b)		
the effective date"	commercialize Product		
	in the Major Market		
	Countries."		

Mistake: Inadequate expiration or termination provisions

Licensees should carefully review the expiration and termination provisions of a license agreement. If a long-term license is desired, the agreement should expire on the expiration of the intellectual In the "Mistake" below, the property rights. licensee will be forced to pay royalties without having receiving any exclusivity benefit from those payments if the intellectual property rights expire before the end of the 20-year period. Rights to terminate the license agreement at will are also valuable to licensees, as this allows easy exit from license arrangements that are no longer profitable. Finally, licensees should ensure that their license rights survive any termination of the agreement for a breach by the licensor, which punishes the licensor by terminating royalty payments while allowing the licensee to retain the benefit of its bargain (continuation of the right to use the intellectual property).

<u>Mistake</u>	<u>Better</u>
"expires 20 years from the first sale of Product"	"expires upon the expiration of the last Valid Claim covering the Product." (and all licenses survive as fully paid) "Licensee can terminate at will" (and give up all license rights)

<u>Mistake</u>	<u>Better</u>	
	"License rights should survive" (not	
	terminate) for Licensor breach	

Mistake: No quality control provisions in a trademark license

Trademark rights are rooted in the concept that a trademark identifies a particular business as the source of goods or services. Consequently, when a trademark is licensed so that the particular business is no longer the direct source of those goods or services, the license agreement must include quality control provisions. The quality control provisions help ensure that the consumer receives the same quality product from the licensee as it would directly from the licensor. If a licensor does not adequately supervise the quality of the products, it may be deemed to have abandoned the mark and lose all rights to the mark.

Mistake: Lack of ability to assign or sublicense

If a license agreement is silent on the subject, a licensee may not assign or sublicense its licensed rights to a third party, materially affecting a licensee's ability to use outside manufacturers, distributors and other vendors. A company should make sure each license agreement it enters into has clear provisions on when and who may assign or sublicense its rights under the agreement.

Confidentiality Agreements

Confidentiality agreements (also known as nondisclosure agreements confidential or disclosure agreements) protect against unwanted disclosures of sensitive information by obligating the party who receives that information to hold it in confidence, with certain narrow exceptions. Confidentiality agreements may be one-way, in which only one party is disclosing its confidential agreement to the other, or two-way or mutual, in which both parties are disclosing and receiving information. confidential Confidentiality agreements are used throughout the life of a life sciences or technology company in a variety of business contexts.

Mistake: Failure to prohibit nonconforming use of disclosed confidential information

A confidentiality agreement's obligation that the receiving party not disclose the received information is not always adequate to protect the disclosing party's interest, as it does not restrict the receiving party's internal use of the information. For example, a receiving party that is only subject to a nondisclosure obligation could use the confidential information to help develop a competing technology. Better protection is provided by obligating the receiving party to use the information only for a specific purpose. For example:

<u>Mistake</u>	<u>Better</u>		
"Receiving Party shall not disclose, distribute, or disseminate"	"Receiving Party shall not disclose, distribute or disseminate, or use the information for any purpose other than(the "Purpose")		

Mistake: Failure to tailor definition of "Purpose" or "Intended Use" to the real purpose

As discussed above, confidentiality agreements should define a "Purpose" or an "Intended Use" for which the receiving party may use the confidential information. However, broadly drawn definitions of "Purpose" or "Intended Use" offer little protection to the disclosing party. For example:

<u>Mistake</u>	Better (examples)
"disclose information to evaluate a potential business transaction (the 'Purpose')"	"to permit Receiving Party to evaluate a potential license from the Company to certain patent rights related to the XYZ technology" "to allow Receiving Party to understand product and manufacturing processes in order to propose and perform manufacturing services for the Company"

The "Mistake" is a problem because almost any use by the receiving party could arguably be in connection with a "potential business transaction" as none of the parties, the type of transaction, or the information is identified. In contrast, the "Better" examples restrict the receiving party's use to the specific transaction with the disclosing party.

Mistake: No end to the confidentiality term

Confidentiality agreements may explicitly provide that the receiving party's nondisclosure obligations last forever; alternatively, a perpetual obligation may be implied if the agreement has no stated term. These perpetual obligations place a high burden on the receiving party and do not acknowledge that the sensitivity of most confidential information has a limited life span. Receiving parties may appropriately request an expiration of the nondisclosure obligation after a certain time, as in the following example.

<u>Mistake</u>	<u>Better</u>		
"Receiving Party will not at any time during the term of this Agreement and thereafter disclose"	"Receiving Party will not for the term of this Agreement and for a period of 5 years thereafter disclose"		

Mistake: Failure to review definition of "Confidential Information"

Most confidentiality agreements have very long lists that define "Confidential Information." These definitions can lull disclosing parties into a false sense of security. Disclosing parties should carefully review the definition to make sure it clearly covers the information the party expects to disclose instead of relying on the apparent breadth of the definition.

Mistake: Failure to disclaim an implied license

An implied license occurs when, based on factual circumstances, a party obtains a right to do something it would normally need an express license to do. Including an express disclaimer of any implied license helps to prevent a receiving party from later claiming, based on circumstances surrounding the disclosure of confidential information, that it obtained rights to that information greater than or different from the "Purpose" or "Intended Use."

Mistake: Failure to include right to seek injunction and other equitable relief

The most common legal remedy for a breach of contract is to sue for money damages. This remedy offers little protection to a disclosing party when an unauthorized disclosure has occurred, because lawsuits take a long time to resolve and money damages for the losses to the disclosing party will be difficult to ascertain. appropriate relief is offered by the group of nonmonetary remedies known as equitable relief, and in particular, an injunction, which is an order from a court to do (or cease doing) a certain thing that can be obtained quickly. A disclosing party would typically seek an injunction ordering cessation of the unauthorized disclosures. However, a party seeking equitable relief must meet the burden of proof of certain legal elements before the court will order the requested injunction. Having a contractual right to seek an injunction and other equitable relief, although it does not guarantee that a court will grant the relief, helps to meet this burden by showing that the parties agreed on the sensitive nature of the information, the harm resulting from unauthorized disclosures, and appropriate relief.

Non-Compete Agreements

Non-compete agreements prohibit a party, usually an employee, from doing business in certain geographic or subject matter areas after his or her relationship with the company ends. These agreements help protect against employees taking valuable information or experience from the company to a competitor. However, courts disfavor non-compete agreements due to their anti-competitive and burdensome nature, leading to the problems discussed below.

Mistake: Failure to make time, geographic and industry restrictions reasonable

Non-compete agreements are enforceable only if they are limited in scope and reasonable. Courts closely scrutinize non-competes to make sure they are reasonable, and may either refuse to enforce that contract entirely or rewrite it if the court deems it unreasonable. To increase the likelihood that non-competes are honored, companies must ensure that any time, geographic and industry restrictions imposed by the agreement are fair and balanced. Non-competes that essentially block the employee from finding any employment, as in the "Mistake" that follows, will not be enforced.

<u>Mistake</u>	<u>Better</u>
"for 2 years after employment, Employee will not be connected as officer, director, stockholder, consultant or otherwise, with any business or entity anywhere in world which competes with Company"	"for [6-12] months after employment" (same or similar term to severance payments) "with any business or entity in Pennsylvania, New Jersey or Delaware that researches, develops, markets or manufactures pharmaceutical products used for therapeutic purposes" (smaller geographic area, large industry) "with any business or entity in the United States that researches, develops, markets or manufactures blood plasma protein biotherapies." (larger geographic area, small industry)

Mistake: Not tailoring to individual situation (using same agreement for all employees)

An important factor in demonstrating the reasonableness of a non-compete agreement is showing how that particular employee would harm the company. It is thus a mistake for a company to use the same terms in its non-compete agreement for each employee. Instead, the company should consider whether the employee has access to sensitive information and then determine what reasonable terms apply to that particular person. For example, a non-compete with a 12-month term may be more appropriate for a senior officer than for a junior lab technician.

Mistake: No consideration for entering into non-compete agreements

For a non-compete to be enforceable, the employee must be given some right, benefit or other inducement (known legally as "consideration") for entering into the agreement. If the individual agreeing to the non-compete is only a potential employee, the start of employment with the company is adequate consideration.

However, usually continued employment is <u>not</u> adequate consideration for an individual already working at the company, because the employee has not gained anything extra for his or her entry into the non-compete. Instead, the company must grant some additional benefit (e.g., cash, stock option) to the employee at the time the contract is signed.

Signing, Dating, and Other Practice and Performance Mistakes

A well-drafted contract is worthless to a company if the company cannot prove that the parties actually agreed and entered into the contract or it fails to take the actions required under the contract. Common mistakes we have found in diligence of start-up companies include:

- Failure to obtain agreements with all pertinent parties and to have all parties sign the agreement; in particular, failure to obtain fully signed patent assignments, confidentiality agreements, and non-compete agreements with all founders, employees and consultants.
- Failure to date signed agreements.
- Failure to attach the schedules or exhibits called for in the body of the contract; for example,

failure to attach the schedule identifying the patent to a patent assignment.

- Failure to collect and retain all executed agreements in company files.
- If required by a confidentiality agreement, failing to mark confidential information as "confidential" or summarize visual or oral disclosures in writing.
- Failure to request return of the company's disclosed confidential information or collect a certificate of destruction of confidential information in the file.
- Failure to renew or extend agreements as appropriate when the parties have a continuing relationship (for example, where parties continue to exchange confidential information over a long period of time).
- Entry into several different agreements with the same or a related party, with the result of conflicting agreements on the same subject matter.
- Failure to meet diligence or performance obligations under a license agreement.
- Failure to provide reports required by licenses and other agreements.

IP DUE DILIGENCE

When conducting due diligence in the IP area, it can be helpful to approach the project as comprising three separate phases. The first phase is the identification phase, where all of the assignor's or licensor's IP that relates to the contemplated transaction is identified. second phase is the evaluation phase. Here, the IP that has been identified as being the subject of the transaction is analyzed and an opinion is given as to its quality or value. Stated much more simply, one typically asks: "What IP is part of the deal?" And then asks: "Is that IP any good?" The last phase of IP due diligence is the identification of any third-party IP that may affect the overall value or utility of the IP in the hands of the transferee. It is not a requirement that each of the phases be conducted sequentially. One can, and should, move fluidly among the phases as information gleaned during one phase often impacts another.

IDENTIFICATION

The usual first phase to any IP due diligence is to identify all of the assignor's or licensor's IP that is related to the transaction. This should go without saying, but because this phase is so important, and yet so often done incorrectly or incompletely, it warrants reinforcement.

The goal of the identification phase is simply completeness. Ask: "Have I identified all of the assignor's or licensor's IP related to this transaction?" Patents, trademarks and copyrights are standard considerations. However, there are other types of IP that should not be overlooked. Are there any pending patent or trademark applications, patent reexaminations, reissues, oppositions, trade secrets, know-how, invention disclosures that have not yet been filed, applications in draft form, software, domain names, clinical data, agency approvals and exclusivities?

The IP that is the subject of the transaction may be specific to certain geographic locations or have worldwide scope. Thus, always ask: "Have you considered all of the relevant jurisdictions?" For every patent or trademark, as well as every application, determine whether there are foreign counterparts. This can be done by either simple,

free computer searches or fee-based computer searches. Both are recommended.

The usual first phase to any IP due diligence is to identify all of the assignor's or licensor's IP that is related to the transaction. This should go without saying, but because this phase is so important, and yet so often done incorrectly or incompletely, it warrants reinforcement.

Another goal of this phase is accuracy. Many times the charts listing the IP that are generated in this phase of due diligence become the appendices and schedules to the closing documents. So one must ask: "Has all of the relevant IP been *correctly* identified?" Every item should be identified at least by number (e.g., patent or application number), title or mark, filing date, grant date, and jurisdiction.

In some situations it can be helpful to identify IP that is not intended to be included as part of the transaction. This can include IP that the assignor or licensor would like to make clear is not for sale or license. This can also include third-party IP that may affect the value or utility of the IP to be assigned or licensed.

Tracking down the various kinds of IP that may be related to a particular transaction can be a cumbersome, and sometimes tricky, task. For example, the identification of every member of a patent family worldwide can involve searching in multiple foreign databases, successfully navigating database search terms, and deciphering various codes for distinguishing a pending application from a granted patent. But as noted, the goal of this phase is completeness and accuracy. As such, it behooves all parties to work together to ensure that this phase is properly executed. Most often it is the assignor or licensor who is in the best position to identify all of the related IP. course, the other party should also confirm and check the accuracy because, as the buyer, it is important to make sure that you get everything you bargained for. Clarity is also important, and

no one benefits if a patent is omitted or incorrectly listed. Such errors only lead to confusion and later problems.

Here are some sample questions or items for a due diligence checklist related to identifying the assignor's or licensor's IP. These questions are essentially about facts; no legal opinions are sought.

- 1. Provide a complete description of the product, the methods of making the product, and the methods of using the product.
- 2. Provide a list of all patents and patent applications worldwide, including all divisionals, continuations, continuations-in-part, reissues, reexaminations, oppositions, renewals and extensions of the foregoing that relate to any of the answers to number 1. (Even if a project relates to a select geographic territory, it is better to request worldwide information for the sake of completeness. It is best to have identified some IP and then discuss whether it is included.)
- 3. For each item in number 2, provide the patent or patent application number, date of filing, date of issuance, title, jurisdiction, expiration date, inventors, prosecution status, and confirmation that maintenance fees or annuity fees have been paid.
- 4. For each item in number 2, please provide a copy of each patent or published patent application. (Since these are readily available online, one may want to only request (or additionally request) only copies of unpublished applications. For unpublished documents, a confidentiality agreement will likely be required.)
- 5. Are you currently in the process of preparing additional patent applications to cover the technology? If so, when do you expect to file these patent applications? Please also provide a copy of any invention disclosure documents and any draft patent application for each patent application not yet filed. (Again, such unpublished information will likely require a confidentiality agreement.)

A similar list of questions should be prepared for trademarks, copyrights and domain names.

As for information about trade secrets, it must be kept secret. Thus, a confidentiality agreement should be required as a condition to viewing trade secret information. Documents that contain trade secret information can relate to the identity and source of formulations, reagents, and catalysts, standard operating procedures and process descriptions, process designs, flow charts and diagrams, and quality control specifications.

Similarly, information about Investigational New Drug Applications and New Drug Applications can be requested but must be kept confidential.

Next, one should identify all agreements that may affect IP rights. As a baseline requirement, one should request proof that title in all relevant IP properly lies with the transferring party. Typically, Notices of Assignment Recordations are provided, though copies of the actual assignment documents are preferred. Employment agreements, research, and collaboration agreements are also helpful to ensure that inventors and authors are at least obligated to assign, or at best have already assigned, their rights in all discoveries and works of authorship to the transferring party. As such, the IP clauses in such agreements and execution dates are needed – sensitive employee information can be redacted.

Also, identify agreements where IP has previously been licensed into and out of the assignor or licensor company. Are there options to take or give a license or assignment? Has any IP been securitized? Are there liens on any IP?

CONSIDER THE FOLLOWING EXAMPLE QUESTIONS:

- 6. Provide a list and copies of all documents relating to any license agreement (including sublicenses) involving the company as a party, beneficiary, successor, or assignee, including but not limited to any amendments or modifications thereto; any documents relating to the termination thereof; any rights of first refusal; and any documents submitted by one party to the other in accordance with any license agreement.
- 7. Provide a list and copies of all assignments to company of all IP, as well as confirmation of recordation.
- 8. Provide a list and copies of all security interests, liens, loans, financings or other encumbrances relating to any IP.
- 9. Provide a copy of the company's intellectual property policy and confirm that

all relevant personnel have executed agreements containing the policy.

- 10. Provide a list and copies of all confidentiality agreements, non-competition agreements, nondisclosure agreements or standstill agreements related to IP (including the ownership or assignment of same) to which company or any past or present officer, director, or employee of company is a party.
- 11. Provide a list and copies of all material transfer agreements.
- 12. Provide a list and copies of all research and collaboration agreements.

EVALUATION

Both during and after the identification phase, the quality of the IP is evaluated. Exactly how one evaluates an IP portfolio depends on the particular circumstance of the transaction. Certain issues may be deal-breakers in some contexts and of only minor importance in others. Care should thus be taken to identify the transaction goals at the outset and then focus the evaluation efforts on areas that would directly relate to these goals.

Evaluating a patent portfolio involves three separate analyses: a technical analysis, a business analysis, and a legal analysis. For trademarks, copyrights, and other forms of IP, the technical analysis is of less or no importance, but the legal and business analyses are generally the same.

A technical analysis focuses on the scientific merits of material that is usually the subject of a patent or patent application. It can, however, extend to other areas, such as FDA or EPA submissions. This analysis is generally performed by the acquiring company's scientific personnel (or hired experts or consultants) based on information gathered during the identification phase. Thus, it may be helpful in a due diligence questionnaire to first ask who are the scientific personnel available to answer questions. Upon reviewing the patents, patent applications, invention disclosures (Questions 1-5 above), one asks: "Does the product or process work?" This can be probed further by asking: "Are the results or effects reproducible?" "Are there questions about efficacy, toxicity or side effects, compliance and dosing, marketability or manufacture?" "What has not worked and why?" The answers to

such questions also relate to a patent's validity (e.g., utility and enablement).

A business analysis relates to IP valuation (e.g., the revenue stream for each patented product, the lifetime of the stream, and new products in the pipeline). This analysis is generally performed by a valuation expert who considers sales and marketing figures and projections, manufacturing/purchase agreements, expiration dates of patents and other exclusivity rights, royalty obligations, competition, etc. To this end, it is helpful to request that the assignor or licensor identify each specific feature of the product or process, as well as under which patent or patent application it is covered.

A legal analysis focuses on information that may impact the ownership, validity, enforceability and scope of an IP right. A simple first step is to confirm whether the patents or copyrights have expired and whether the maintenance fees and annuities for all patents have been paid. As to ownership, confirm that all IP has been properly assigned (i.e., there is a clear chain of title that has been properly recorded). Review the terms of assignments and licenses (Questions 6-10 above). Is the technology assignable or sub-licensable? Who has the right to sue? Are there any collaborators who may have a claim to inventorship, and thus ownership, in any patent or patent application? (Questions 10-12 above).

As to patent validity, consider whether the claims of each patent are novel, non-obvious, enabled, adequately described, and the best mode is described. The following questions in a due diligence questionnaire are directed to obtaining information relevant to a validity analysis.

- 13. Provide copies of the substantive U.S. and foreign prosecution for the patents and patent applications relating to the company's inventions, products or processes, including information disclosure statements.
- 14. For each PCT application, please provide copies of the ISR, Written Opinion, Response thereto, IPER, and art cited in the ISR and/or PCT prosecution.
- 15. Provide copies of all known art (patent and/or non-patent literature) relating to patentability with respect to the company's inventions, products or processes. Also identify those references believed to be most relevant to the patentability of the claims of

the company's patents and patent applications. (It is recommended that an additional, independent search for relevant art be conducted, at least for the highly relevant patents.)

- 16. Provide copies of any legal opinions or other analyses that the company has obtained relating to patentability or inventorship.
- 17. Provide copies of any public disclosures of the company's inventions, products or processes (e.g., articles, notes, communications, reviews and editorials submitted to trade journals, copies of poster presentations, materials presented to potential partners, etc.).
- 18. Provide documents relating to the sale or offer for sale of any of the company's products, or processes (e.g., purchase agreements).
- 19. Provide a publication list of all persons listed as inventor or applicant on any granted patent or pending patent application.
- 20. Provide a list and copies of all documents referring or relating to inventions or potential inventions that have been disclosed to the company, as well as any investigations or evaluations of those inventions or potential inventions.
- 21. Identify and provide copies of any interference, opposition, litigation, or other proceedings (actual, potential or threatened) that may affect any of the company's IP rights.

Note that a patent in the United States (and also in some foreign jurisdictions) can be held information unenforceable if material patentability is intentionally withheld from the patent office. Material information can take many forms, but typically this situation occurs when references that are cited in one application (whether U.S. or foreign) are not cited by the applicant in another co-pending application. The history documents from prosecution application (U.S. or foreign) can also be considered material in another application. Thus, while analyzing the information from Questions 13-21 from a validity perspective, also confirm that each of these items was submitted to the patent office.

Review any data presented during prosecution. Are such data reliable and statistically meaningful?

Were there any inconsistent data presented elsewhere? Were negative data omitted? Were the examples not performed as written? The answers to such questions are also relevant to patent enforceability.

Review the claims of each patent and determine whether they cover the commercial product or process. Are the claims too narrow in that they may not cover the commercial product or there second-generation process? Are developments or easy ways to design around the claims? How were the claim terms defined in the specification, and do those definitions cause problems with claim scope or policing? amendments or arguments made during prosecution that would limit a claim's scope?

For trade secrets, one should confirm that the information has been kept secret. To this end, request information about the company's secrecy policy and procedures. How does it control access to information, what types of physical security are used, does it train its employees about trade secrets, have its employees acknowledged in writing their understanding of the company's trade secret policy and confidentiality?)

IDENTIFICATION OF THIRD-PARTY IP

This phase of due diligence is often the most contentious. On the one hand, the potential assignee or licensee has a valid desire to determine whether its expectations from the transaction may be undercut by a third party's IP. On the other hand, the assignor or licensor has a valid interest in maintaining the confidentiality of any attorneyclient communications related to a third party's rights (e.g., non-infringement, freedom-to-operate, or invalidity opinions). As such, requests for attorney opinions regarding a third party's IP rights are often met with resistance. In some situations, a common legal interest may exist, which would preserve attorney-client confidentiality. However, this should never be presumed. The law on common legal interests varies by state, and this issue should be investigated thoroughly before confidential attorney opinions and advice are shared. It is best to assume that no common interest exists and to not request or share legal opinions. The due diligence questions below seek factual data about third-party rights rather than opinion.

- 22. Provide a list of all patents identified in a search related to the company's rights to make, use, sell, offer to sell or import in the United States or other jurisdictions its inventions, products or processes.
- 23. List any third party's IP, not presently licensed, that may be required to practice the company's invention, products or products.
- 24. Provide a list and copies of all documents relating to or referring to any investigation by or on behalf of company of any actual or potential violation by the company of any third party's IP.
- 25. Provide a list and copies of all documents referring or relating to any assertion (actual, proposed or threatened) by any third party of any patent, patent application, trademark, copyright, or trade secret against the company.

- 26. Provide copies of any known art relating to the invalidity or non-infringement of any third-party IP.
- 27. Provide information relating to any potential inventorship disputes.

In conclusion, it is important to realize that conducting due diligence is a dynamic process. Obtaining answers often leads to more questions. So the process is never complete. Time and cost are the factors that usually limit the scale of a due diligence project because one could spend countless hours and dollars chasing down every facet of a company's IP portfolio. One should therefore never lose sight of the objectives of the overall transaction, and let those objectives drive the due diligence efforts.

FINANCE



CONTRIBUTORS

SHOW ME THE MONEY: FINANCING OVERVIEW AND SOURCES OF CAPITAL

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HOW A COMPANY IS VALUED - THE ACCOUNTANT'S PERSPECTIVE

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W. MICHAEL WOLFE, a Director at Fesnak and Associates, LLP, has more than 30 years of experience in public accounting, management consulting and

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SBIR AND OTHER GRANTS

CHRISTOPHER LAING is Vice President, Science and Technologys for the University City Science Center in Philadelphia and provides R&D strategy support to Science Center Port business incubator companies, facilitates their access to the Philadelphia region's academic and clinical communities, and oversees the

center's QED Proof of Concept Program. He holds a Ph.D. in molecular endocrinology and completed his postdoctoral training at the University of Pennsylvania School of Medicine. Dr. Laing is a member of the Royal College of Veterinary Surgeons in the United Kingdom.

ANGEL INVESTING FROM FRIENDS TO WEALTHY PERSONS TO ANGEL GROUPS

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area of complex domestic and international business transactions in a wide variety of legal fields and industrial sectors. Mr. Rudd is Co-Chair of the International Special Interest Group, Utah Technology Council.

ELLEN EDELMAN WEBER is the Executive Director of Robin Hood Ventures, an angel group investing in early stage companies located in the Mid-Atlantic region. She is also a Managing Director at Antiphony, a strategic consulting firm, where she leads the Leadership Development practice.

craigness of Blue Skies Properties, a residential real estate investment company. Prior to starting this business, he worked for 16 years at MBNA, a Fortune 500 financial services corporation, serving as senior executive vice president from 1996 to 2005. His background includes experience in the key areas of consumer banking, including lending, customer satisfaction, collection, and quality assurance. Early in his career, he served as assistant to MBNA's Chairman and CEO, and in that role he was a junior member of the team that took the company public in its 1991 New York Stock Exchange IPO. As senior executive vice

president, he was responsible for a number of corporate including education, operations, administration, purchasing, communications, employment and personnel programs, and international expansion strategy. He also served for several years as executive director of the MBNA Foundation, responsible for all of the company's community donations, volunteer programs, employment programs for people with disabilities, scholarships, and school grants. Mr. Schroeder is a graduate of the University of Pennsylvania and recently completed a master's degree in computer and information technology at Penn's School of Engineering and Applied Sciences.

A CONVERSATION WITH VENTURE CAPITALISTS: ADVICE FOR ENTREPRENEURS

JENNIFER L. MILLER is a partner in the Business and Finance Department of Ballard Spahr LLP and Co-Chair of the Life Sciences/Technology Group. Ms. Miller, resident in the Philadelphia office, works with start-up, emerging and public companies, and those that invest in them. Her focus encompasses securities, corporate financing (public and private), strategic alliances, pharmaceutical and biotechnology licensing, technology transfer, mergers and acquisitions, general corporate law, and corporate governance.

DR. IVOR ROYSTON is a Founding Managing Partner of Forward Ventures. Dr. Royston has been involved in the biotechnology industry in San Diego from its inception in 1978 with the founding of Hybritech, Inc. (later acquired by Eli Lilly) and with the founding of Idec Pharmaceuticals in 1986 (which later merged with Biogen). He has been instrumental in the formation, financing and development of numerous successful public biotechnology companies, including: Applied Molecular Evolution (acquired by Eli Lilly); Combichem (acquired by DuPont); Corixa (acquired by GlaxoSmithKline); Genesys Therapeutics (merged with Somatix and acquired by Cell Genesys); Morphotek (acquired by Eisai); TargeGen (acquired by Sanofi-Aventis); and Triangle Pharmaceuticals (acquired by Gilead). Currently, Dr. Royston is Chairman of Ligocyte in Bozeman, MT. He also serves on the Board of Directors of HemaQuest Pharmaceuticals.

DR. BRENDA D. GAVIN is Founding Partner of Quaker BioVentures and former President of S.R. One, GlaxoSmithKline's venture capital arm, and general partner of EuclidSR Partners, an independent venture

capital fund focused on health care and information technology. During her tenure with S.R. One, Dr. Gavin was responsible for dozens of venture and strategic investments and served as a board member or active board observer for many portfolio companies. She currently serves on the boards of BioLeap, Celator Pharmaceuticals, Tengion, TetraLogic Pharmaceuticals, and Tranzyme Pharma. Her other board experience includes service on the boards of the Ben Franklin Technology Partners of Southeastern Pennsylvania, the Ben Franklin Technology Development Authority, BioAdvance, the Penn State University Research Foundation, and the International Advisory Board of the Monell Institute. She is a past board member of the National Venture Capital Association.

DR. ELAINE V. JONES is Executive Director, Venture Capital, for Pfizer Venture Investments. She is responsible for making and managing venture investments for Pfizer and currently manages the PVI investments in Aquinox Pharmaceuticals (Vancouver, British Columbia), Flexion Therapeutics (Boston, MA), Merus B.V. (Utrecht, the Netherlands), and NeuroTherapeutics Pharma (Chicago, IL). Dr. Jones is a former General Partner with the venture fund EuclidSR Partners. There, she was responsible for the fund's investments in Acurian, Fluidigm, InnaPhase and Targacept. Dr. Jones began her private equity career in 1999 at S.R. One, GlaxoSmithKline's venture fund where she managed investments including Adolor, Avantium, Nucleonics, Scynexis and Vicuron. Previously, she served as Director of Scientific Licensing for SmithKline Beecham and was a research scientist in SmithKline Beecham Pharmaceutical R&D.

INTERVIEW WITH RICHARD CARUSO

AMY UNDERWOOD is a former associate at Ballard Spahr LLP, where she concentrated on corporate financings, pharmaceutical and biotechnology licensing, technology transfer, mergers and acquisitions, general corporate law, and health law. While in private practice,

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RICHARD E. CARUSO, Ph.D., is the founder and current Chairman of Integra LifeSciences Corp., a publicly held company. He is also founder of The Provco Group, a group or amalgamation of business or activity, which organizes and provides funding for a variety of entrepreneurs and complex business activities. Dr. Caruso is a former principal of LFC Financial Corp. in Radnor, PA, and a founding shareholder of Interactive Investor International, once

publicly traded on NASDAQ and the London Stock Exchange (acquired by an Australian insurance group of Advanced Voting Solutions, Inc.) and of First Sterling Bank, which is now part of Bank of America. Dr. Caruso also founded Tenly Enterprises, which acquired and operated Rustler Steak Houses before its sale to Sizzlers. Dr. Caruso has more than 35 years of experience in entrepreneurial and finance type ventures and is the author of "Mentoring in the Business Environment."

TERM SHEET WITH EXPLANATION

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WORKING WITH VENTURE INVESTORS POST-CLOSING

BRUCE LUEHRS is a partner in Emerald Stage2 Ventures, a Pennsylvania-based early stage venture fund focused on capital-efficient information technology companies, primarily in the Technology-Enabled Services area. Previously a General Partner of

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SHOW ME THE MONEY: FINANCING OVERVIEW AND SOURCES OF CAPITAL

By Jennifer L. Miller, Co-Chair, Life Sciences/Technology Group, Ballard Spahr LLP, and Muhammad At-Tauhidi, Associate, Ballard Spahr LLP

STAGES OF FINANCING

Seed Stage – Seed stage investments are typically made at the very earliest stages of a company's growth. At this stage the company may be little more than an idea and a business plan. The company may own some intellectual property but generally does not have a finished product. Funding at this stage is generally aimed at helping the company reach an appreciable milestone, such as a working prototype, or obtaining a license or proof of concept study, in order to make the for further rounds of company suitable investment. Seed stage investments are often associated with a "friends and family" round. Sometimes seed investments may be made by quasi-governmental organizations or incubators generally locally focused organizations that provide various types of support (office space, mentorship, and sometimes cash) to start-up companies. Occasionally, the founding entrepreneurs will finance the early life of the business themselves using credit cards and personal debt.

Angel Round – An angel round refers to an investment round consisting of one or more angel investments prior to the company taking venture capital from an institutional investor. "Angels" are typically wealthy individuals willing to invest in early stage, high-risk entrepreneurial companies. The idea is generally to provide a bridge to help a seed stage company reach a point where it is ready for its first VC round. It is no surprise then that angels generally look for investment opportunities that are likely candidates for further investment by VCs.

Series A – The term "Series A" is typically used to designate the first round of institutional investment in a company. Because venture funds have a limited life, venture firms typically look for companies that can make a viable exit (typically an IPO or sale of the company) within five to seven years of the initial investment.

Series B, C, etc. – Companies that are growing rapidly or companies that have long cycle times for R&D or product development may require

additional rounds of venture investment. Not infrequently, each round of venture investment will involve a syndicate of VC firms and perhaps one or more (often high-profile) angel investors. Typically one of the venture firms will "lead the round," meaning that it will be primarily responsible for negotiating the term sheet and conducting due diligence of the company.

SOURCES OF CAPITAL

Friends and Family

"Friends and family" typically refers to seed or very early stage capital raised from the friends or family of the entrepreneur. In most cases, a "friends and family round" provides only a small amount of funding in order to allow the company to grow beyond the seed stage. According to the Kauffman Foundation, the average dollar amount raised from a friends and family round is less than \$10,000 per company. Although raising money from friends and family may be easier than dealing with professional investors, it is still critical to formalize the terms of such investments in written Raising money from many small agreements. investors also raises legal concerns relating to the issuance of securities, which may lead to greater complexity in future rounds of financing and make the company less attractive to professional investors.

Federal Grants

Companies that are working in certain fields or that are pursuing research and development of new or novel technologies may be able to access grants made available under certain government programs. In particular, the Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program administered by the U.S. Small Business Administration (SBA) Office of Technology are designed to support small, innovative high-tech companies that are engaged in research of critical technologies. (For more information on these and other programs, please see Section V "SBIR and Other Grants," in this book.)

Regional Seed Stage Organizations

Many regions rich in life sciences entrepreneurial companies have regional seed stage organizations that provide financial support to start-ups. These organizations are founded or sponsored by their state or local government, if they are not outright governmental bodies.

Examples include the Ben Franklin Technology Partners and Pennsylvania Biotechnology Green houses in Pennsylvania; the Maryland Bank Loans, Maryland; and the Utah Science and Technology Initiative (USTAR) in Utah. Start-ups should explore these organizations and other sourses of financing. They should often be approached as if they were a VC investor as competition for their dollars can be intense and can be viewed as a prerequisite to VC funding. Be sure to understand the terms of any such financial support. Frequently you may be required to pay the money back if the company leaves the geographic region covered by the organization or if a certain number of employees are not hired by the company.

Bank Loans

Start-ups with no track record and few assets are generally not ideal candidates for loans from commercial banks. The U.S. Small Business Administration (SBA) offers several programs that are intended to improve the ability of small businesses to access bank capital. However, most SBA programs require companies to be able to demonstrate positive cash flow in addition to providing collateral and/or personal guarantees. These requirements can make this type of lending unrealistic for capital-intensive high-risk/high-reward start-ups that may be months or years away from reaching positive cash flow. However, collateralized equipment loans and some other kinds of bank debt can sometimes be utilized and should be considered as a potential financing alternative.

Professional Investors – Venture Capital and Angels

High-growth or other capital-intensive start-ups typically seek professional investors such as angels or venture capitalists (VCs) once they grow beyond the seed stage. VCs are professional investors who manage funds from outside investors to invest in companies with high-growth potential. Angels are typically successful executives or former entrepreneurs who make

investments on their own behalf, generally in areas in which they are personally familiar. Like VCs, angels seek a financial return on their investments; however, some angels may accept lower returns if they have a nonfinancial interest in advancing a particular solution or technology.

Some of the differences between VC and angel investments include:

Professional management – Because VCs look at so many deals, they will quickly screen out companies that do not meet their investment criteria in terms of investment stage, market size, management experience or return on investment. In comparison, angel investments are often analyzed more informally, and angels may be willing to meet with an entrepreneur even if the company does not satisfy formal investment criteria.

Deal terms and complexity - Completing a deal with a VC can be time-consuming and expensive. Venture investments generally involve very sophisticated deal structures and will require the assistance of counsel who is well-versed in venture capital transactions. VC investments are typically in the form of convertible stock with preferential rights over the common shareholders (including the founders). VCs will also often require financial protections (such as anti-dilution provisions) and control protections (such as veto rights and control of one or more board seats). VCs also conduct extensive due diligence of the company, which will consume significant time and Because angels are often part-time resources. investors, they are often more willing to invest on friendlier terms and to use simpler deal structures (e.g., a note that is convertible to equity upon future financing or vanilla common stock).

Resources and strategic value - VCs generally have greater financial resources and may be in a better position to support the company through follow on rounds of financing. As a rule, investment rounds of \$1 million or larger are typically the domain of venture firms, while smaller investments are generally the domain of angels or angel groups. In addition, VC firms tend to be more active in seeking to add value to their investments by leveraging their networks and introducing the company to potential customers or strategic partners and helping to recruit executives. VC board members tend to have a greater breadth of experience in working with start-ups and to be able to guide the direction of

the company. Because angels are typically parttime investors, they are more likely to remain hands-off or to limit their participation to informal mentoring.

Angel Networks

One of the ways that angels have begun to professionalize their investment process is by banding together in semi-formal networks and formal groups. By combining resources, angel groups help angels achieve greater efficiency in sourcing deals, screening investments and performing due diligence. By investing together, angels in groups can spread the risk and invest larger amounts. According to the Kauffman

Foundation, angel investors participating in organized angel groups achieved an average 27% annual return, beating the returns of both early and late-stage VC investing.

For more information see (http://www.kauffman.org/uploadedFiles/angel_groups_111207.pdf)

While the first angel groups were often little more than informal clubs, many modern angel groups have become increasingly sophisticated. As angel networks grow more professional, the line between angel investors and venture capitalists has started to blur.

HOW A COMPANY IS VALUED - THE ACCOUNTANT'S PERSPECTIVE

By Robert Fesnak, Managing Partner, Fesnak and Associates, and W. Michael Wolfe, Director, Fesnak and Associates

VALUATION OF EARLY STAGE LIFE SCIENCES COMPANIES

Many people tend to categorize the biotech or life sciences industry as the pharmaceutical industry. It actually encompasses much more. The life sciences industry includes biotech, medical device, therapeutic, diagnostic and other health care related products. Each of these areas has different value drivers and other factors that could slow approvals, market adoption and thus reduce value. Both external and internal factors can have a significant impact on value. An example is a diagnostic device that lacks market adoption due to dependency on other undeveloped products or is too expensive for its target market. Understanding both the factors that enhance intellectual property (IP) value and the factors that inhibit the value is a crucial step.

THE NEED FOR EARLY STAGE LIFE SCIENCES VALUATION

In today's market, the ability to understand the value drivers of IP is critical. This understanding will impact not only the company's IP strategy but also how best to monetize the IP. There is a clear relationship between the quality of a company's IP, how well it is protected and a company's value.

IP rights provide an opportunity and potential to generate revenues and profits. Execution of an IP strategy, taking advantage of these IP rights, allows the life sciences company to monetize such assets.

Intangible asset values generally represent a significant portion of the value of a life sciences company.

The valuation of an early stage life sciences company is difficult, to say the least. Despite this difficulty in determining value, it is one of the most important issues for a life science company as it develops through its initial stages and creates shareholder value. Early stage valuations are necessary for several reasons:

 Equity ownership must be fairly allocated at each equity funding round. This requires an overall enterprise valuation as well as a valuation of the specific classes of equity such as preferred and common interests.

 Early stage companies usually grant options, restricted stock, or similar securities in order to attract and retain the best talent. The underlying enterprise value and the value of the class of security to which the incentive relates must be determined in order to value these incentives. There are both financial reporting and tax implications of such incentives.

In today's market, the ability to understand the value drivers of IP is critical.

- In order to obtain debt financing for a life sciences company, debt holders generally require warrants as a "sweetener" to offset some of the risk they are taking. The value of such warrants must be valued for financial reporting and tax purposes.
- The Financial Accounting Standards Board (FASB) has issued accounting pronouncements that require the fair value of options, warrants, restricted stock or similar securities to be recorded in the company's financial statements.
- The Internal Revenue Service has issued regulations (IRC 409A) that require companies to grant options at an exercise price equal to or greater than the underlying security value or suffer adverse tax consequences. In order to determine whether granted options meet this requirement, the fair market value of the security subject to the options must be valued.

THE UNIQUENESS OF EARLY STAGE LIFE SCIENCES COMPANY VALUATION

Life sciences company valuations differ from traditional company valuations in that life sciences companies (i) generally lack an operating and financial history, (ii) their product or market is not yet validated and (iii) value tends to be primarily in patents, trademarks, research and development,

trade secrets and other intellectual property. Generally these companies require rapid product development and growth or risk possible loss of an opportunity.

Although traditional valuation approaches are used to value life sciences companies, special techniques are required to compensate for the unique characteristics of these companies.

When evaluating methods to value life sciences companies, it is important to separate those that have developed a product and have sales (medical device; therapeutic; diagnostic; health care consumer products, etc.) from biotech, pharmaceutical and other companies still in the process of developing products.

There are various valuation methods and approaches that can be utilized to value companies with existing products and sales. These include three broad approaches: market, income and cost. There are various methods in applying each approach, and the most appropriate methods would be selected and utilized. These broad approaches are described below.

The Market Approach - Under this approach, an established company is valued by comparison to guideline M&A transactions or guideline public companies generally using an earnings metric such as EBITDA. An early stage life sciences company doesn't have any earnings and may not even have revenue to which such multiples can be applied. In some cases, there may be some market evidence of M&A activity where larger companies are buying early stage life sciences companies for their in-process research and development in order to move their own pipelines forward faster. Finding a common metric in these cases is the key to establishing a value estimate. Last, a prior round of equity funding may be the only real market evidence available and if that round is not close to the valuation date, it may be irrelevant.

In early stage life sciences companies (i.e. preclinical) where the only asset is a patent, a valuation method that can be applied is the Relief from Royalty Method. This market approach method is based on the premise that the intangible-asset owner would be willing to pay a reasonable royalty rate to license in the functionality of the subject patented product as if it did not own it. Inbound licensing royalty rates can be estimated from an analysis of marketdriven data with respect to licenses of comparative patents.

The Income Approach - Under this approach, an established company is generally valued by estimating the present value of forecasted net cash flows using an appropriate risk rate (discount rate). This methodology is referred to as the discounted cash flow (DCF) method. Net cash flows are forecasted for a period of time that can be reasonably estimated, usually five years, along with a stabilized year representing net cash flows into perpetuity after the forecast period. future cash flows are present valued using a discount rate representing the level of risk being assumed by an investor. The discount rate can be estimated by benchmarking to various risks in the public markets such as risks of investing in equity securities, industry risks and size risks. One of the components of the discount rate is the "companyspecific risk rate," a highly subjective factor that takes into account the risks particular to the subject company. Company-specific risks can include risks such as those associated with customer concentrations, supplier dependencies, key-person dependencies, erratic historical operating results and achievement of financial forecasts in excess of predicted industry growth rates. For larger established companies with less risk, the cost of equity is generally lower and may, for example, fall in the 15% to 20% range while smaller established companies that carry more risk may, for example, fall in the 20% to 25% range. An early stage company, on the other hand, has much more risk and is usually unable to reasonably forecast net cash flows as well as an established company that can rely on its historical results to predict what will happen in the future. This would require an even higher cost of equity.

Since early stage companies do not have the benefit of this historical financial data, alternative forecasting techniques must be used. An evolving forecasting technique in the pharmaceutical industry is to "probability-adjust" or "risk-adjust" the financial forecast based on the probabilities that a particular drug will become commercialized. As each clinical trial is completed, it is more probable that the drug will be approved by the FDA and ultimately reach the marketplace to produce revenue and profitability. Techniques such as this provide a better foundation for the forecasting process. Despite improved forecasting

systems, early stage companies still carry substantial risk and thus many investors will require significant discount rates to address this risk.

Life sciences companies tend to have complex capital structures as the result of their capital-raising activities needed to fund long periods of time until products are developed and introduced into the marketplace.

In valuing a biotech company and applying a risk-adjusted forecast method, clinical-trial success rates are utilized to price the current values of biotech projects as they are being developed. We combine a traditional DCF model with these clinical-trial success rates to yield a risk-adjusted net present value (NPV) for biotech companies.

There are four main inputs in calculating risk-adjusted DCF: clinical success rates, projected costs by stage, projected revenues and the discount rate or risk. First, there are various databases and studies that provide success rates for new developments (e.g, new molecular entity (NME)) at each clinical trial stage. The stages being pre-clinical, phase I, II, III and FDA approval.

Second, the costs of performing clinical trials and animal studies can generally be estimated. They can be estimated by experienced management members and/or various outside data sources that track costs per clinical stage.

The revenues are more difficult to estimate. They can either be estimated by applying a market penetration rate and an annual cost per patient to the estimated treatable population or applying a market penetration rate to the current total market. The risk-adjusted DCF can be calculated using several market and revenue estimates. This provides a sensitivity analysis and assists in determining the appropriate estimate to be utilized.

Finally, the discount rate selected must consider that certain risks have already been factored into the risk-adjusted cash flows; however, there are other risks (market, regulatory, etc.) probably not accounted for in the risk-adjusted cash flows.

Accordingly, by applying the selected discount rate to the estimated costs by clinical-trial phase and estimated revenues, a valuation amount can be reasonably determined.

The Cost Approach - Under this approach, an established company is valued by determining the fair market value of its net assets (assets less liabilities). This approach is generally not used in situations where there is significant goodwill. Since the value of the IP and goodwill represents most of the value of a life sciences company, this Most established method is not appropriate. companies can maximize their value based on their earnings level and not their net asset value. An early stage life sciences company's value may consist primarily of its patents, other intellectual property value, and in-process research and development. A market or risk adjusted income approach is usually more appropriate for life sciences companies.

I LOCATION OF THE TRANSPORT WALLS

ALLOCATION OF ENTERPRISE VALUE TO SENIOR AND JUNIOR EQUITY INTERESTS

To this point, we have referred to the value of the overall enterprise. Life sciences companies, however, tend to have complex capital structures as the result of their capital-raising activities needed to fund long periods of time until products are developed and introduced into the marketplace.

Capital is often raised by issuing common stock, preferred stock, convertible debt, options and warrants. In certain cases, the value of one class of securities must be determined. For example, the per share value of common stock must be determined for purposes of granting options for common stock. It would be incorrect to divide the overall enterprise value by all shares outstanding to arrive at the per share value of the common stock due to the preferences of senior securities and the dilutive effect of options and warrants. Preferences of senior securities could include items such as dividend and liquidation preferences, voting rights or other control features, conversion features, participation features and redemption rights. The exercise of options and warrants could create additional shares outstanding, thus reducing the per share value of the common. Three complex yet common valuation methodologies are used to allocate value among the various classes of capital giving consideration to the preferential rights of senior securities:

The Current Value Method – Assumes senior security holders would monetize their value through their liquidation preferences and participation rights in an assumed imminent liquidity event. The remaining enterprise value would represent the common stock value.

The Option Pricing Method – Relies on financial option theory to allocate value among different classes of stock based on a future "claim" on value.

The Probability-Weighted Expected Return Method – Share value is based on the probability-weighted present value of expected outcomes such as a future liquidation event, IPO or continued operation as a private enterprise as well as the rights of each class of securities.

SUMMARY

Although traditional valuation approaches are used to value life sciences companies, special techniques are required to compensate for the unique characteristics of these companies.

Due to the long-term nature of the product commercialization cycle, and the lack of revenue and earnings metrics for guideline market comparisons, alternative approaches are necessary. Financial forecasting is difficult and risk rates are high for the application of discounted cash flow models. Probability-adjusted or risk-adjusted forecasts present a more refined analysis of expected future events and thus a more refined estimate of enterprise value. Last, capital structures are complex and consideration must be given to the preferences of senior securities and dilutive effects of options and warrants when determining the value of common stock.

SBIR AND OTHER GRANTS

Supporting Research and Development Through Federal Funding: SBIR/STTR FAQs

By Christopher Laing, Vice President of Science and Technology, University City Science Center

INTRODUCTION TO THE SBIR/STTR PROGRAM

Many federal agencies run extramural grant programs through which they provide funding (and sometimes other resources) to support research and development by nongovernment organizations. These funds are typically awarded in the form of grants (contracts, which are not considered here, are another form of government extramural funding). While small businesses are generally eligible to compete with other organizations (e.g., universities and research institutions) for many grant types, Small Business Innovation Research (SBIR) and Small Business Transfer (STTR) Technology grants exclusively awarded to small business companies, or SBC (and their collaborating sub-awardees).

SBIR and STTR are federally legislated programs, the purpose of which is to fund innovative research and development that has the potential for commercialization and public benefit. The SBIR Program was established by the Small Business Development Act of 1982, while the STTR Program was established in 1992. Congress has reauthorized SBIR three times, in 1986, 1992 and 2000. The current SBIR Program expired in September 2008, but has been extended by a series of continuing resolutions while Congress debates its reauthorization. Program features being evaluated include qualification of venture capitalbacked companies, budget allocations and award amounts, and the uncoupling of Phase I and Phase II awards.

Terms Used in this Article:

Agency: a federal agency (e.g., National Science Foundation, Department of Defense, National Institutes of Health, (Department of Health and Human Services), participating in SBIR or STTR Programs.

Component: a semiautonomous division within an agency (e.g., the National Cancer Institute, the Army). Not all components of an agency necessarily participate in both SBIR and STTR Programs, and there are often differences in the SBIR/STTR Programs of different components of the same agency.

Principal Investigator (PI): the individual who is responsible for overseeing the scientific conduct of the proposed project. In some cases, there may be more than one PI.

Small Business Concern (SBC): a small business as defined by the legislation governing SBIR and STTR.

Solicitation: the announcement of a grant opportunity, typically using a "Request for Proposals" or similar mechanism. Some agencies (e.g., Department of Defense) have very specific topic-related solicitations that are available only once or for a limited number of application periods, while others (e.g., NIH) also employ broad solicitations and solicitations that may be available for multiple application periods.

Sub-award: a component of a grant budget that is awarded to an institution (the sub-awardee) that is collaborating with the SBC receiving the grant award (e.g., if the SBC is collaborating with a university, the university would typically be a sub-awardee.)

SBIR and STTR grants are typically awarded through a competitive application process, in which small businesses submit proposals describing planned R&D projects. Awards are made to proposals that are selected through a formal review process. Agencies make awards to meritorious proposals that will typically result in a new product that aligns with one or more of the

agencies' interests, objectives or mission. SBIR and STTR grants differ from conventional equityor debt-based financing in a number of important ways:

- Awards are made to support specific R&D projects (not to grow companies).
- Because innovation is considered a highly desirable characteristic of projects being

considered for funding, SBIR and STTR grants are usually made to earlier-stage, or higher-risk projects than conventional investment financing.

• Grant awards do not result in debt or equity obligations by the recipient.

For these reasons, SBIR and STTR grants are often attractive to companies in the early stages of developing their first product (before they qualify for private investment), or to companies that are considering exploring options for follow-on products. While SBIR and STTR grants can be

highly attractive forms of funding to early stage companies, they do have limitations and drawbacks that require some consideration. Because they are project-specific, they do not provide support for many company resources; it is difficult or impossible to run and grow a company on grants alone. There are also dangers in becoming too oriented toward grant funding. While grant funding preserves a company's equity, it does dilute its R&D focus. Companies that attempt to juggle more than their share of grants rarely chart a short course to market for any one product.

SBIR/STTR Awards Have Benefits and Limitations		
Benefits	Limitations	
Equity-sparing funding: SBIR and STTR grants are awarded without an expectation of repayment and without the need to give away company equity or data rights.	Discretionary spending limitations: A detailed project budget will be required at the time of application, and deviating from this budget during implementation requires agency approval (and may not be possible). Although both direct and indirect project costs may be claimed, there are federal policies that define the types of costs that are allowed and disallowed.	
<u>Collaboration</u> : Grants often provide an avenue for establishing research collaborations with a university (or other organization). Many federal and state agencies provide assistance in identifying appropriate collaborators for small businesses.	<u>Preparation resources</u> : A competitive grant application requires a significant amount of hours to prepare. Applications should be started at least one (and preferably two) month prior to the submission date, and the most competitive applications are usually edited and reviewed by someone other than the author(s).	
Peer review: Regardless of whether they are funded, many applicants find the process of having their R&D strategies evaluated and critiqued by other experts a helpful experience. Investors may view a company that has been awarded federal funds more favorably since its R&D strategy has already been assessed by an independent third party.	<u>Peer review</u> : Applications that undergo external peer review may be read by potential competitors. Safeguards in the system include the opportunity for applicants to exclude individuals prior to review and an agreement of confidentiality by reviewers. Nevertheless, it is advisable to protect intellectual property and proprietary information prior to submitting an application.	
Interaction with federal agencies: Federal agencies provide a variety of additional resources to SBIR and STTR recipients, including informal networking opportunities and access to formal commercialization assistance programs. Some federal agencies (e.g., Department of Defense) may even act as customers following successful completion of SBIR- or STTR-funded product development.	Maintenance: SBIR and STTR grants are funded by public money, and the government takes its responsibilities for tracking the expenditure of tax revenues very seriously. SBIR and STTR recipients are required to institute an accounting and reporting system that satisfies federal auditing requirements.	

Who offers SBIR/STTR?

Federal agencies with annual extramural research budgets exceeding \$100 million are required to set aside 2.5% for SBIR Programs. Those with extramural budgets exceeding \$1 billion must set aside 0.3% for STTR Programs. Departments participating in the SBIR Program include (those asterisked also participate in the STTR Program):

Department of Agriculture

Department of Commerce (National Institute of Standards and Technology and National Oceanic and Atmospheric Administration)

*Department of Defense

Department of Education

*Department of Energy

*Department of Health and Human Services (National Institutes of Health, Federal Food and Drug Administration, Centers for Disease Control and Prevention)

Department of Homeland Security

Department of Transportation

Environmental Protection Agency

*National Aeronautics and Space Administration

*National Science Foundation

The Business Administration Small (http://www.sba.gov/aboutsba/sbaprograms/sbir/index. html) has been charged with coordinating and providing government-wide Program Policy Directives for SBIR and STTR. However, participating federal agencies are free to interpret and apply these policies in an agency-specific manner. This results in a great deal of diversity among federal agencies with respect to SBIR and STTR Programs. Differences include topic areas, dollar amounts and time of awards, solicitation dates, review processes, and many administrative components.

What are the differences between SBIR and STTR?

In most respects, the SBIR and STTR Programs are very similar. There are, however, some important differences, some of which may influence the decision to apply for one program or the other. There are also differences that probably won't (or shouldn't) influence the decision to apply for either one program or the other.

Differences that may influence the decision to select one program or the other

- Collaboration with a university partner: SBIR and STTR grants are both made to small business concerns. However, while SBIR grants permit collaboration with a university (or other) partner (typically up to 33% in Phase I or 50% in Phase II), STTR grants require that the small business be collaborating with a university partner. Current STTR rules require that the university complete at least 30% of the work and that the small business complete at least 40% of the work. If your project involves significant collaboration with a university, you should consider STTR.
- Employment status of the PI: Regardless of whether the small business is collaborating with one or more other research institutions, for an SBIR grant, the Principal Investigator (the person responsible for overseeing the scientific conduct of the project see "Eligibility," below) must be employed primarily by the small business. For an STTR grant, the Principal Investigator may either be employed by the small business or by the university partner. If the most senior scientist associated with the project is employed by your collaborating university partner, you should consider STTR.
- Differences in timing and allowable budgets: Some (not all) agencies that offer an STTR Program have different total allowable budgets and/or time limits for project completion compared with their SBIR Program. Some also have different submission dates for their STTR and SBIR Programs. Although these differences don't typically dictate the decision of SBIR vs. STTR, you should consider them when planning your strategy.

Differences that probably won't influence the decision to select one program or the other

Agency funding for SBIR vs. STTR is different: The total pool of money available in the SBIR Program is larger than that available in the STTR Program. SBIR is defined as a 2.5% "set-aside," while STTR is only a 0.3% set-aside. However, clearly the competitiveness of each program is not only influenced by the amount of funding available, but also by the number of applications received for any solicitation. This is not typically known until after the solicitation has closed. Although recent trends are sometimes used to predict the likely competitiveness of an upcoming SBIR or STTR solicitation, this method of analysis is notoriously inaccurate and varies greatly among agencies and among agency components. It is generally more appropriate to make decisions about SBIR vs. STTR on the basis of criteria such as the amount of university collaboration that the project will likely require.

Who is eligible for SBIR/STTR?

In determining eligibility for SBIR or STTR, you should consider two things: the characteristics of the applicant organization and the characteristics of the principal investigator.

Organizational eligibility

Both SBIR and STTR grants are awarded to qualifying SBCs as the primary organization, although collaborating organizations (SBCs or otherwise) can act as contractors or sub-awardees. Applicant organizations should meet the requirements outlined in 13 C.F.R. Part 121, including the following (in summary form):

- For-profit entity with a U.S. place of business
- At least 51% owned by individuals who are U.S. citizens or permanent residents in the United States (this has ramifications for foreign-owned organizations and some joint ventures)
- Fewer than 500 employees; typically not a problem!

The applicant company should occupy a physical location that it controls in order to avoid a perceived affiliation with another entity that may render the applicant ineligible for SBIR/STTR grants or awards (although access to special facilities may be exempt from this restriction).

Principal investigator eligibility

Any person with the "skills, knowledge, and resources necessary to carry out the proposed research" is eligible to apply as a principal investigator. In the case of SBIR, the principal investigator should be a full-time employee of the small business, while in the case of STTR, the principal investigator must be an employee of either the small business or the collaborating academic institution. There is no priori requirement for a principal investigator to hold a Ph.D. (or, indeed, any formal qualification). However, the reviewers of different federal agencies appear to exhibit differences in their view on this. While this is not governed by policy and is somewhat speculative, the NIH, which typically utilizes academic scientists to conduct its reviews, may favor principal investigators who hold a Ph.D., although less-experienced scientists may be viewed as capable of managing these relatively short, small-budget grants. On the other hand, agencies such as NSF and DoD, may be more accepting of principal investigators with other qualifications. Ultimately, applicants to SBIR/STTR opportunities should consider proposing the most highly qualified individual in this role.

Do I have to have a company to apply for SBIR/STTR?

Although SBIR and STTR grant awards are only made to SBCs, in many cases you do not need to have a company already formed at the time you apply for a grant (although some agencies may require it). This is because in most cases, the eligibility requirements for SBIR/STTR need only be met at the time of the grant award, not at the time of application. However, because you will still need to apply for appropriate identification numbers and register with the agency as a grant applicant, it is typically simpler to have a company registered by the time you apply for a grant. This is relatively straightforward, and does not require that the company have space, employees, or any other physical resources at the time that the application is submitted. However, it is strongly advisable that even at the time of submission, you have already planned how you will transform your company from "virtual" to "actual." This plan is important for two reasons: (1) your application needs to convince the reviewers and the agency that if you are awarded the funding, you have the capability to use it to achieve the goals you have set; (2) if you are awarded funding, you will not have much time to provide documentation demonstrating that the company meets the eligibility criteria. At a minimum, you should have identified key personnel, who will be hired in the event that the grant is awarded, and laboratory space or any special facilities that the company will be able to access in the event of an award. Letters of support may be helpful here.

What is the impact of an SBIR/STTR application and/or award on my intellectual property rights?

The federal government does not take any special position regarding the ownership of intellectual property developed using SBIR/STTR funds. SBIR/STTR applications are considered to be confidential information, and submitting an application does not constitute public disclosure.

External reviewers participating in agency peer review sessions do so under an agreement of confidentiality. Most agencies require that you indicate in your application which information is confidential or proprietary. Despite this, it is generally advisable that you take steps to protect your intellectual property prior to submitting an SBIR or STTR application. The abstract of your proposal is almost never considered confidential, and may be published by the agency in the event that the grant is awarded. should never include proprietary information in your abstract.

Although federal agencies do not take any special ownership of intellectual property associated with applications that they fund, they are often interested in understanding the status of any intellectual property involved in your application. This is because the principal metric of the SBIR and STTR programs is commercialization, and so many federal agencies may wish to understand whether the projects they are considering for funding involve intellectual property that the applicant will have the ability to commercialize. Particularly in the case of an STTR application where collaboration with a research institution is mandatory, the existence of a formal agreement between the collaborators will be required prior to the award being made. This is advisable for any type of collaboration, regardless of whether the agency requires it. Such an agreement should specify the roles and scope of responsibilities of each partner, any consideration to be paid for work completed on the project, and the ownership of intellectual property arising from such work.

What is the scope of the SBIR/STTR Program?

SBIR/STTR projects are focused on the development and commercialization of a technology (product development) and are recognized to comprise three phases. The first two phases focus on research and development and are competitively funded by the granting agency. The objective of a Phase I project, which is typically 6 to 12 months in length, and with a total budget of \$100,000-\$200,000, is to establish technical feasibility. Phase II projects may follow on from successful Phase I projects, and have a longer timescale (typically two years) and larger total budget (typically \$500,000-\$1,000,000). A

small business may obtain a Phase II grant only if it has successfully completed a Phase I-supported project. Phase II applications, like Phase I applications, are awarded competitively, and not all Phase I projects will necessarily result in a Phase II award. Phase III activities, which are usually (although not always) pursued with nonfederal funds, focus on achieving commercialization objectives arising from the R&D completed in Phases I and II.

NIH is the only agency to allow Fast-Track applications, where Phase I and Phase II applications may be submitted, evaluated and approved simultaneously. A project may be suitable for Fast-Track if there are sufficient preliminary data to support the feasibility of the project, and if there are clear, quantitative milestones outlined in the project plan.

Where do I find SBIR/STTR opportunities and how do I apply?

SBIR and STTR grant solicitations are published and closed on specific dates. The timing, frequency and inclusiveness of these opportunities vary with different agencies. For example, NIH publishes three standard solicitations per year that combine both its SBIR and STTR Programs. DoD publishes three annual solicitations for its SBIR Programs and two annually for its STTR Programs. All agencies publish research topics to which proposals must respond. However, agencies vary in the degree of specificity of these topics. NIH topics associated with its parent SBIR/STTR Programs, which account for most awards made, are broad and simply describe the interests and mission objectives of its institutes any proposal that aligns with these interests is typically eligible. NSF publishes a number of relatively broad topics and requires that applicants indicate the topic under which their application falls. DoD's solicitations involve much more specific topics that describe particular deliverables that the agency has identified as its own highpriority requirements.

Solicitations and grant topics may be viewed at the appropriate agency websites (a good portal is http://www.sbir.gov/solicitations/ and most participating agencies have their own web pages dedicated to SBIR/STTR), and many are listed on the website of grants.gov, a central government resource for searching and viewing more than 1,000 grant programs. Application instructions for

most solicitations are typically also available on these websites. Because SBIR and STTR applications are agency-specific, it is important that you obtain the appropriate application instructions for the agency to which you are applying. Almost all applications are now submitted electronically. Some agencies (e.g., DoD and NSF) still maintain their own electronic submission systems, while others share the grants.gov portal. As more agencies have been slowly migrating to the grants.gov portal as a common system, some have offered the option to either use an agency-specific system or the grants.gov system for preparing and submitting applications. Before an application is submitted, the company will be required to complete a series of registrations (both central and agency-specific). It is advisable to complete the process of registering the company one month or more prior to the submission date for the grant.

How are SBIR/STTR applications reviewed?

Agencies all review and select applications for funding using their own individual systems and criteria, and it is important to understand these when preparing the application. Most agencies start by assessing applications for administrative compliance and responsiveness to the agency or topic. Those applications that pass administrative inspection are then evaluated for merit using an agency-specific review process. Some agencies (e.g., NIH, NSF, DoE) use an external peer review process where panels of specialists are recruited to evaluate the proposals and provide guidance to the agency on the scientific and technical (and sometimes commercial) merit of a particular application. Some agencies (e.g., DoD, NIST) use an internal review process where agency employees evaluate applications on the basis of internal criteria related to the specific topic to which the application is responding.

Three general examples provide some insight into the agency-specificity of the review and award system:

National Institutes of Health: NIH uses an external review system. The review of most grants is handled on behalf of the Institutes by a single Center for Scientific Review, which convenes Scientific Review Groups (also known as Study Sections) comprising scientists with defined subject matter expertise. Some Study Sections are permanent, and some are transient; some consider only SBIR/STTR applications, and some consider other grant types as well. Each application is typically reviewed first by three reviewers, followed by discussion by the Study Section as a whole.1 While the identities of the specific reviewers for any application remain unknown to the applicant, the composition of each Study Section is published. Reviewers are asked to score five aspects of the application: innovation, significance, approach, investigator environment.

National Science Foundation: NSF also uses an external review system. Its Review Panels for SBIR/STTR typically comprise at least three technical reviewers (typically research scientists) and at least three commercial reviewers (typically people with experience in technology commercialization). All applications received by NSF are fully reviewed - NSF does not "triage" applications. Reviewers are asked to consider two general review criteria (intellectual merit and broader impacts) as well as special criteria (commercialization potential) in making a recommendation to the agency.

Department of Defense: Unlike NIH and NSF, DoD uses an internal review system. Typically three reviewers examine each application, including the author of the solicitation topic. Reviewers examine the application with respect to technical merit and innovation, the qualifications of the PI and staff, and the potential for commercial application (with reference to the needs of DoD). Unlike many other agencies, DoD Program Officers may work with the applicant company to revise aspects of a recommended proposal prior to funding.

Not all applications are discussed by the Study Section, the first order of business of which is to determine the subset of applications in any one group that are considered worthy of discussion.

It typically takes approximately three months for an application to be reviewed, and up to another three months for a funding decision to be made, although this is agency-specific. Almost all agencies provide some type of feedback to applicants in the form of a report. Agencies vary in their ability or willingness to accommodate resubmissions. For example, while NIH will allow one resubmission of an application that has been revised in light of reviewers' comments, NSF usually requires that each grant submitted by an organization be substantially different. DoD accepts applications in response to very specific topics, so the capability to accept re-submissions is usually limited by the fact that the topic may no longer be available for application in subsequent rounds of funding.

Is assistance available?

All participating agencies publish guides to applying for, and implementing, SBIR and STTR grants. These general guides are typically available on their websites, and should be read alongside the specific solicitation that may contain special instructions. In addition, there are guides to navigating the electronic submission system for each agency. (The SF424 Guide for Grants.gov, a common system shared by a number of agencies may be found at http://grants.nih.gov/grants/funding/424/index.html.)

Agency Officers (who may be program-specific or solicitation-specific) are generally listed in the

published solicitation and are ready to answer questions. Some agencies have specific guidelines for when and the how to contact Program Officers. For example, the Department of Defense actively encourages potential applicants to contact its Program Officers to discuss project strategies during a defined "communication window" prior to each submission deadline, but also defines a period of time during which Program Officers will not communicate with applicants except to answer technical submission questions (the answers to which are made public). Most agencies also provide support to their Phase I recipients to guide them in preparing for their Phase II applications, often through consultation with commercialization advisers.

Many states run programs that assist local companies to be more competitive in winning SBIR and STTR grants. These can take the form of workshops and conferences, or access to individuals or organizations with experience in SBIR and STTR submissions. One such example in Pennsylvania is the Innovation Partnership (www.innovationpartnership.net), a consortium of business support and economic development organizations (including the Science Center). Any of the Partnership's members can invite a company into its programs, including the microgrant/microvoucher programs that provide funding for engaging a service provider to assist in preparing competitive SBIR and STTR proposals.

More information about any of the information in this chapter, including invitation to the Innovation Partnership programs or the University City Science Center's grant programs, can be obtained from the author: claing@sciencecenter.org.

Disclaimer: The information presented here represents the views of the author, and does not represent any federal agency or other organization. Federal regulations and program policies are continually reviewed and revised, and the information presented here should be construed in the context of the most recent agency guidelines.

ANGEL INVESTING: FROM FRIENDS TO WEALTHY PERSONS TO ANGEL GROUPS

By P. Christian Anderson, Partner, Ballard Spahr LLP; David R. Rudd, Partner, Ballard Spahr LLP; Ellen Edelman Weber, Executive Director, Robin Hood Ventures; and Craig Schroeder, Owner and General Manager of Blue Skies Properties

What is an angel investor?

An angel investor is a high-net-worth individual who invests his or her own money directly into an early stage company in return for equity (ownership) in the company.

In addition to providing financial capital, angel investors mentor and coach their portfolio companies, and help fill in functional or skill gaps in the company. They introduce the companies to other investors and to colleagues who may be able to increase the company's value.

Most angel investors are entrepreneurs who have exited one or more businesses. They often invest in companies for reasons that go beyond monetary return. This may include staying in touch with new business developments, mentoring another generation of entrepreneurs, helping to run a company without the usual stress of day-to-day operational issues, and giving back to their communities by leveraging their skills.

Typically, angel investors invest in new, innovative companies that are highly scalable, that can quickly grow revenue and value. They primarily invest locally, so that they can stay in personal contact with their companies.

The term "angel" originally comes from Broadway, where it was used to describe wealthy individuals who provided money for theatrical productions. In one notable early angel investment, Harry Frazee, owner of the Boston Red Sox, used the proceeds from selling Babe Ruth to the Yankees (resulting in the curse of the Bambino) to finance a Broadway musical.

The Center for Venture Research estimates that angel investors invested \$19 billion in more than 55,000 start-up businesses in 2008. Many successful large companies were started with angel backing, including Google, Yahoo, Amazon, Starbucks and Facebook.

What's the difference between angel investors and venture capitalists?

Angel investors generally are investing their own money, unlike venture capitalists (VCs) who manage the pooled money of others in a professionally managed fund. Angel investments

generally take place after the initial "friends and family" investors who provide the seed funding, but before venture capital investors. VC investments tend to start at \$2 million, while angel investments are typically smaller.

What are angel groups?

In an angel group, individual investors join together to evaluate and invest in entrepreneurial ventures, and, in some cases, pool their funds to

Typically, angel investors invest in new, innovative companies that are highly scalable, that can quickly grow revenue and value. They primarily invest locally, so that they can stay in personal contact with their companies.

leverage their investments. Angel organizations come in many forms, but in general, they meet regularly, select entrepreneurs to make presentations to the group, and work together to conduct due diligence and define deal terms. For an angel investor, two main benefits of group membership are access to potential deals (deal flow) and the opportunity to discuss pros and cons of deals with other like-minded investors.

Because angel investors usually invest locally, there are many angel groups throughout the United States and in other countries. The Angel Capital Association (ACA) has 165 angel groups, which represent 7,000 accredited angel investors in North America.

According to the ACA, the average ACA member group had 42 members and invested a total of \$1.94 million in 7.3 deals per year in 2007. In the Philadelphia region, angel groups usually invest between \$250,000 and \$500,000 in a company as part of a \$1 million to \$2 million investment round.

What is angel group syndication?

Angel groups often syndicate deals, which means the groups join together to invest in a given company on the same terms. Since companies often require a greater investment than any one angel group will provide, and since angel investing requires significant research and preparation, syndication benefits both the investor and the entrepreneur.

There is usually a lead investor who defines the deal terms, but in some cases, the angel groups will work together to define the deal terms. In some cases, the start-up company will bring the different groups together, but in many cases, a lead angel investor will "syndicate" the deal to other angel groups. In the Philadelphia region, angel groups syndicate deals on a regular basis, sharing due diligence as well as terms.

What makes a company a good candidate for angel investment?

The company has a must-have product or service with a unique competitive advantage.

The company's product must identify a significant need among a large and clearly defined target market. Investors use the term "pain point" to describe the problem that the product will solve – and the company needs to relieve the customer's "pain" in a unique and compelling way. It needs to be a "must-have" rather than a "nice-to-have" product for its target market.

The company has a working prototype of its product or service, and at least one paying client.

Essentially, the product needs to be ready to go. If the product is just an idea, it is too soon for angel investors to get involved. Likewise, if the company is already a successful business looking to expand its market, it may be ready for the larger resources that venture capitalists can provide. In the case of life sciences companies, the product should be either in clinical trials or ready to begin this process.

The company has a detailed and well-thought-out business plan.

Entrepreneurs should be prepared for detailed, rigorous questioning about their business plan. Remember that most angel investors have already built and sold their own businesses, and are well

aware of the challenges and pitfalls that start-up companies face.

The company has talented managers in place.

Typically a company will have at least two key managers in place: a technical leader who understands the product's development, and a business manager who has a track record of success in running start-up companies. Other key people who are good to have, but could be added after the angel investment round, include a production manager and a marketing/sales leader. Investors also look for high-quality outside board members and advisers, who have extensive experience in the market sector and can help the growing company with advice, perspective and contacts.

The company has a way to protect its market share from competitors.

When a business is successful, competitors notice – and often try to take market share by offering a similar product. In the case of a small start-up company, there is often a very small window of opportunity before larger, better-established competitors try to move in. To be successful beyond the initial product launch, a company must establish barriers to entry, either through a patent or other intellectual property (IP) protection, or by quickly gaining a large enough share (critical mass) of the market to prevent competitors from taking over.

The company will grow very quickly.

Angel investments bear extremely high risk, and are usually subject to dilution in future investment rounds. It is an angel maxim that in a portfolio of 10 well-chosen companies, there will usually be one home run, a few singles and doubles, and the rest will eventually strike out. The problem is that even though investors can weed out many companies that lack the potential for success, it is not possible for even the best angel investors to predict which of their many promising companies will actually succeed.

Therefore, in order to get a desired return on their investment, most angel investors look only for companies that can be a home run. A good rule of thumb is that a target company should have the potential to increase in value 20 times (20X) from the initial investment to a liquidity event (buyout or IPO) five to seven years later.

Since companies are typically valued based on a multiple of their revenue or profits, an angelfunded company will be expected to increase market share, revenue and profits very quickly.

The company has already used self-funding and investments from family and friends.

In order for angel investors to make 20X on their investment, they will need to own a commensurate percentage of the company. For example, if the company anticipates being acquired for \$100 million, and the angel group has invested \$1 million, they would need to get \$20 million, or 20% of the company, at exit.

Angel capital investment thus can be expensive, and the entrepreneur should try to grow the company organically until he or she really needs the capital infusion.

The managers of the company are willing to give up some control to outside investors.

Entrepreneurs are often used to being the sole owners of their companies and making the big decisions on their own. When they finance their companies' growth with angel investments, they are also taking on new part-owners who are very focused on growth, expense control, profitability, and an eventual sale. As mentioned earlier, the primary goal of an outside investor is for the company to grow quickly and profitably so that it can be sold in five to seven years. This will require the entrepreneur to report to a professional board, and possibly even step down as CEO at some point if a more effective leader is identified. While outside investors are often able to provide substantial guidance and assistance to help companies succeed, entrepreneurs should remember that taking on outside investors means that they will no longer be making all the decisions on their own.

The company will be put up for sale in the next few years.

Angel investors receive a return on investment only when there is a liquidity event (sale of company, IPO), so they are looking for a clear exit strategy from the entrepreneur. Entrepreneurs who wish to build a business without selling it at some point should not consider angel or VC money, as the motivations will be at odds from the very beginning.

According to the Center for Venture Research at the University of New Hampshire, mergers and acquisitions represented 70% of the angel exits and IPOs 4% in 2008. Bankruptcies accounted for 26% of the exits.

How is angel investing affected by a recession?

Like most everyone, angel investors typically have less investable funds during a recession than in boom times. However, most are still actively looking for investment opportunities. Despite the reduction in available cash, early stage investing remains attractive because valuations tend to be lower and investors typically have more leverage in negotiating deal terms. Investing in high-quality start-up companies during a recession is the classic "buy low, sell high" strategy.

Because investable funds are more limited in a recession, angel investors tend to be more selective about the companies they choose for investment, and due diligence reviews tend to be more detailed and rigorous.

What do angel investors want?

There are almost as many answers to this question as there are angel investors, but in general, most angel investors want a board position and good communication. Good communication can mean anything from weekly updates to quarterly reports, depending on individual angel and stage of the company. Most are looking for a high rate of return (20X over five years), with a significant stake in the business. Many want preferred stock with rights and liquidation preferences over common stock, while some want convertible debt. In addition, some angel investors ask for the right of first refusal in the next round of financing, and specify approval rights to protect their investment, such as approving sale of stock, issuing additional stock, creating new classes of stock, and changing liquidation preferences. Many angel investors also ask for anti-dilution protection that will result in their receiving more stock should the company issue stock at a lower price than paid by the angel investors.

Deal terms

The two most basic numbers are how much money an investor is putting in and the valuation of the company. The valuation determines how much stock the investor gets. If an investor puts \$50,000 into a company at a pre-money valuation of \$1 million, then the post-money valuation is \$1.05 million. The investor receives .05/1.05, or 4.76% of the company's stock.

If the company raises more money later, the new investor will also get equity in the company from the existing shareholders. The angel investor's stake in the company would therefore be reduced. This is called dilution, and it is a normal part of the process. However, it is important that the dilution be commensurate with the added value of the company at this stage. As the adage goes, it is better to own a small piece of something worth a lot than a large piece of something worth a little.

How can an entrepreneur meet angel investors?

The best way to meet angel investors is through a referral. Private investors, attorneys, accountants, etc. are usually well-connected in their regional entrepreneurial community and can make referrals. In addition, angel investors attend venture fairs and entrepreneurial events. Before meeting with angel investors, it is important to understand their investment profiles, their portfolios, and their current appetite for investments.

What are the steps of the angel investment process?

Most angel groups go through the following steps: *Application:* The entrepreneur submits a business plan and/or an executive summary to the angel group. Many angel groups have online applications on their websites.

Screening: A screening committee reviews the applications to see if the idea would be of interest to the members. If a company meets the angel group's criteria, it invites the company to present to the membership at its regularly scheduled meeting. (Most groups meet monthly.) In some cases, the screening committee will ask the company to provide more information or to come

back when it has reached a particular milestone. In other cases, the screening committee will inform the company that the group is passing on the opportunity, and will provide some feedback about its reasons.

Presentation to Members: If the company survives screening, the management team presents to the full membership. Generally, this involves a short presentation (generally 15 to 30 minutes) followed by Q&A.

Due Diligence: If the group is interested, it will form a due diligence team to verify the entrepreneur's business plan, presentation and financial projections. A background check will generally be done, and in some cases, the team will talk to current and prospective customers, and other investors in the deal. In most cases, the team will work closely with the company throughout this process.

Term Sheet Negotiation: After successfully completing the due diligence process, the angel group will create a term sheet that defines the structure of the investment deal.

Funding: When everyone is satisfied with the terms and the due diligence, the angel group will fund the deal. At this point, board membership is defined, financial reporting requirements are established, and updates on the company's business milestones begin. In many ways, this is really only the starting point of the relationship.

INFORMATION RESOURCES:

Angel Capital Association

Center for Venture Research – University of New Hampshire National Association of Seed and Venture Funds

A CONVERSATION WITH VENTURE CAPITALISTS: ADVICE FOR ENTREPRENEURS

By Jennifer L. Miller, Co-Chair, Life Sciences/Technology Group, Ballard Spahr LLP; Dr. Ivor Royston, Founding Managing Partner of Forward Ventures; Dr. Brenda D. Gavin, Founding Partner of Quaker BioVentures; and Dr. Elaine V. Jones, Executive Director, Venture Capital for Pfizer Venture Investments

In the fall of 2010, Jennifer Miller sat down with three longtime venture capitalists. One from the East Coast, Brenda Gavin of Quaker BioVentures. One from the West Coast, Ivor Royston of Forward Ventures. And one from big pharma venture, Elaine Jones of Pfizer. Below is a condensed version of their lively conversation, which is filled with good advice and insights for entrepreneurs looking to fund their fledgling companies.

Jennifer: Let's talk first about the needs of life sciences start-ups in terms of finding investors.

Brenda: Life sciences companies require so much capital when they are starting out; they have to use venture capital and rely on VCs to fund their work and products.

Ivor: But there are exceptions. I have been amazed in San Diego that there is a start-up that has no VCs and they have already raised \$40 million from angels and high-net-worth individuals. So, I am really amazed at what can be done. Of course, that is an exception to the rule.

Brenda: I know one company that had been largely funded by angels to a fairly advanced stage. Eventually, they did close on a venture deal. They encountered issues because they had too many stockholders and because they could have used the professional help and network that a VC could bring. This led, I think personally, to their regret for not seeking VC investment sooner. The angel route can be much more problematic.

Jennifer: This is exactly the type of information start-ups need to hear. Grant money is out there right now, maybe even more so than before, but grant money doesn't get a company all the way to the finish line.

Brenda: They ought to realize that the venture capitalists bring much more than money to a company, so they should be looking for something besides money.

Ivor: That's right. This start-up that didn't take venture money has experienced people associated

with it and an entrepreneur who has been successful in the past with venture capitalists, so there is a lot more internal experience and networks than you normally see with brand new companies. The point is, most start-ups don't have the experience they need to fore go venture capital.

Brenda: It definitely helps for management to have that sort of background, experience and network.

Ivor: One of the issues for the exodus from very early stage venture capital is that there are not that many funds. I don't know about Quaker, but there are not many funds that do very early stage deals and in that situation there may not be any choice but to seek out angel money.

Brenda: Absolutely. In the very early stages, there are (in the Philadelphia area) a lot of what you would call pretty sophisticated institutional investors – economic development groups like the Ben Franklin Technology Partners and BioAdvance. They are more sophisticated and invest through convertible notes. They are very good for early, early start-ups but not for everybody.

Ivor: Yes, that's right. Out here (in California), Pfizer has a major presence in San Diego and they had talked a lot about an incubator facility for early stage technology. Is that still active?

Elaine: It is. Pfizer did not own 100 percent of these companies and instead funded for a certain amount of the development with the belief that it eventually would be an acquirer. The companies have made some progress, but not as much as hoped. Now they are at the point where their funding is exhausted, but their products did not advance enough for an acquirer to decide whether or not to buy. So, in general, I think the idea of an incubator is a good one, but incubators can be difficult models to execute upon.

Ivor: So the point of why companies should go to venture capitalists is that they should not go just for the money. None of us want to, if we are

interested in earlier stage companies, be just passive investors. We have a lot more to bring to the table than just money.

Elaine: I do think that if you are a therapeutically focused life sciences company that the angel route is extremely problematic simply because of the capital requirements. At some point you are going to have to face that control issue.

Ivor: I agree with that.

Jennifer: When is a company ready to see VCs and if they are going to look for VC funding, when do they start that process? Before they need the money?

Ivor: That's going to be different depending on the VC firm they talk with. For us at Forward Ventures, we have definitely moved to a space of investing where 12- to 18-months from clinic is our ideal investment time. We prefer a company that's already in clinical trials or about to go into clinical trials. Also, we mostly support therapeutic companies. If you are not in that space, we are not likely to be interested.

Jennifer: When is the right time for somebody to come to you, Ivor? Should they start telling you their story two years in advance of the clinic and follow up with you when it gets to the clinical stage?

Ivor: We are interested if they are on the path to get into the clinic. Within a year or so, we'd like to hear the story, absolutely.

Brenda: At Quaker, which is not evergreen, it varies a lot depending on where we are in the fund's cycle. This is something companies need to think about. They really have to be aware of the age of the fund. For example, in Quaker's Fund I, we went into a number of pre-clinical companies early in the fund life. These were companies with, say, a chemistry platform. It took quite some time to get to the compound and then to get into the clinic. We invested at a good time in the fund life. We are now investing out of Fund II and are likely to raise Quaker's Fund III in 2011. So, if you ask us today, we would probably not do a pre-clinical company at this stage of the Fund II life. It does matter where we are in the fund cycle. We try to also diversify according to the subsector. That is, we don't just do therapeutic, we also do diagnostic, devices and services.

Brenda: Then there are medical devices, which sometimes move more quickly in development than pharmaceuticals. With one device company, we invested at the pre-clinical stage and this company is going in for their approval soon. In a couple other cases, we have invested when companies were at the revenue stage or launch stage. When we will invest depends on the sector and the stage of the fund.

Ivor: Here is another way to look at it: Virtually all venture capital partnership agreements have a new investment period of five years, sometimes seven. With this in mind, it's easy to find out the vintage stage of an active fund and to determine where they are in the investment cycle. So I agree with Brenda that if we were in year five or six of our fund, we wouldn't do new investments. If a fund is in year four or five, any final investments are going to be at a much later stage than in year one. This is because the VC wants to be able to exit the company during the full life cycle of the fund (which is usually at 10 years), if at all possible. The life cycle is extremely important when companies are assessing which venture fund they are going to speak to about investing in their company.

Elaine: There is no list of venture capitalists that is readily available. So we often talk about having attorneys or accountants or a local group (like Pennsylvania BIO) to give companies a universe so they can begin to search. I think a website is a very good idea. It is certainly far from trivial to understand which VCs are even in your playing field.

[A directory of certain venture capitalists is included in the Appendix of this book.]

Jennifer: Elaine, do you do pre-clinical investments?

Elaine: Pfizer would in some cases, but we are really in that 12- to 18-month window before the clinic. We are not doing any seed stage investments. Probably the large differentiator that we try to put forth is that perhaps our time horizons are not quite as prescribed as the financially oriented investor. Our fund is evergreen. Our funding comes from Pfizer, not from limited partner investors. While we do need to show returns and consider internal rate of return (which is affected by time), we are not tied to five-year investment periods and 10-year fund lives.

Ivor: Right. We used to do earlier seed investments, but we didn't make money on them. So we can't fund them anymore. There are funds that invest at the earlier stages. For example, Arch, Polaris or Third Rock (which just raised another fund).

Elaine: Obviously, this type of investment has worked once or twice.

Ivor: Exactly. But when you don't have an ideal market, it is hard to make money on the early stage deals. We feel we know how to make money in this market. I believe the market environment is also very important, especially now.

Elaine: I had a company call me for financing and they didn't have their intellectual property in order. I advised them to come back when they had some patents filed and so forth. I think that is one thing that companies need to take care of before approaching investors – have their IP well in hand and have a strategy for prosecuting it.

Jennifer: I think some people are concerned that if you have a Pfizer as an investor you will look like you are a captive company. As if it might hurt your business development efforts outside of Pfizer and other companies might not want to acquire you.

Brenda: I have no patience for that thinking. I invested on that side for so long (at SR One), and we went in strictly as a venture player with no special rights. Pfizer just invested in one of our deals, with no special rights. We also were invested in the same company as Pfizer that recently exited with a sale to a big pharma other than Pfizer. I think excluding pharma venture funds is an old-fashioned way of thinking.

Elaine: I also think this gives the business development executives a lot of credit. At Pfizer, we don't look at the investor base of the company until we are pretty far along in due diligence and then it is largely just understanding invested capital and the dynamics of the investors that might impact deal price discussions. Learning that another big pharma is an investor is almost secondary to making a good investment decision and then getting a product out of the company.

Ivor: I agree with everything that has been said. I have worked with virtually all of the big companies. I have strategic corporate investors

and it works out very nicely, often with a strong wall between the VC group and the parent corporation. Now, the question really is, are these groups willing to lead investments?

Elaine: Pfizer will lead investments now, but until Barbara Dalton took over leadership of the fund, we did not.

Brenda: None of us is an IT investor, but I remember during the internet bubble that Intel and other big corporations were investing in start-up companies. Independent VCs in the IT world at that time were not really looking at these companies as real businesses, which resulted in crazy prices. The corporate investors were much more realistic in terms of pricing. To some extent, you can take some of that thinking and apply it to the life sciences world. I think sometimes the corporate investors have a much better attitude about value. That may be why they have a better return. They are more realistic.

Elaine: Almost every deal Pfizer is in now, the company wants two corporate investors.

Jennifer: It's trying to deal with that discomfort.

Elaine: I do think many of those companies believe it is just a way to achieve a Good Housekeeping seal of approval. They think that if Pfizer looks at the technology and finds it interesting enough that their corporate team made an investment, it is a kind of a plus. And they can sell it as a plus.

Brenda: Right, it adds value.

Jennifer: Let's talk about people trying to get to the venture capitalist. What is the best way to get to you, to get a meeting with you? Do you like to see companies before they really need money from you and then you can see how they develop from when you first heard their story or would you rather they not waste your time at that point and see you when they are ready?

Elaine: I would love to hear the story early, but I barely have time to hear the stories that are looking for financing.

Brenda: It's always nice to follow the companies over time. Because we are a regional fund and focused on what is available in the Mid-Atlantic, we generally know the entrepreneurs. There was a little company that had revenues at a fairly early stage that I followed for years. They were

bootstrapping and growing little bit by little bit on their own. Every now and then they would come and show me what they were doing. The problem was I didn't fully understand the technology. Once they hired a CEO who could translate, they won me over. Because I had known the company for several years, it was easy to make that leap once they got the right CEO. I'm a little different than Elaine and Ivor because of the geographical focus of my fund.

Elaine: I would love to get to know them over time. I think that is the right way to do it.

Jennifer: If they want to do that, what is the best way to get your attention or to generally get the attention of a venture capitalist?

Ivor: The referral source can be very important if it is somebody you know and trust. For instance, if it is a scientific entrepreneur at a top-flight academic institution, I am often attracted to the opportunity. If someone from Harvard, Stanford, Scripps, or Salk calls me – somebody of stature – I am going to take the call and meet with them and go over their science, but this is really early. If it is an already-formed company and I don't know anybody at the company or involved with it, it's tough to get my attention.

Brenda: It always helps if you know somebody and they refer you. Although we do log in and assign everything that comes over the transom at Quaker.

Ivor: The same for us, but it takes longer.

Jennifer: What information are you looking for in that beginning stage? A one-page summary, a five-page executive summary? What do you appreciate the most in terms of the first look?

Ivor: If you can explain to me over the phone, I am going to listen, and if it sounds interesting, I am going to ask you to send me an executive summary and I will get back to you.

Brenda: You almost never get a business plan anymore. If I did, I wouldn't read a lot of text. What I want is a really good set of PowerPoint slides. About 15 slides initially that are not too detailed. Briefly explain what you have, how far along you are, what the financing needs are, and who is managing the company. I don't want to see text. Save the detail for the meeting.

Elaine: In our case, I would say we want to see an executive summary and PowerPoint that is designated nonconfidential.

Brenda: I agree. It irritates me if material is marked "confidential" when it really isn't.

Jennifer: Let's assume that short PowerPoint or executive summary piques your interest and you agree to a meeting. What are your tips – or your pet peeves – about what people do in those meetings?

Elaine: The big mistake people make is when we give them an hour and they spend 59 minutes on the science and nothing on the deal.

Ivor: [laughter] That point is a big issue in our firm. I will always do a one-on-one meeting myself. I want to separate the science review from the partners' meeting review. If I see a deal that is heavily science-laden, I will deal with them one-on-one and I will even coach them a little bit on how much of the science should be discussed for the full partners' presentation. So, at Forward Ventures, we look at companies in two steps if it is very scientifically based. But I agree for the full partners' presentation. I have two MBAs with short attention spans, and you cannot spend a half hour on the science. I do that myself so that I can be knowledgeable about it in case my partners have questions.

Brenda: Our process is a little different. The first meeting when entrepreneurs come in is with just two or three investment professionals. If the project is of interest, that group will make a few phone calls, do a little due diligence, and do an informal market check. If there is interest, we will have them back to meet the whole group. My Quaker colleagues and I are heavy into science, but we need to understand the business proposition.

Brenda: Here is a big tip or, if you don't do this, one of my pet peeves. Be effective and say up front what's important about the investment opportunity in your first big slides. That is: Here is the post money, here is what we have raised, and here are the current investors. Here is the amount we are seeking to raise, and the milestone we are going to achieve with this money. You can do all of that in one slide. Everything after that about the company is colored by that proposition. We need to know the numbers up front.

Elaine: Let me expand on that. I think that the idea of the financing timeline – for example, you are going to raise \$20 million, it will support the company for X period of time, and achieve the

following milestone – is often missing from any presentation. That simple slide crystallizes the key drivers to the company and how they are going to create value.

Brenda: Absolutely. One thing people need to realize is that when we come in the front door, we're also looking for the back door. I want them to talk about how I am going to make money off this investment. The company often starts to talk about the market for the disease indication diabetes, heart disease, etc. - rather than increased value of my stock We need to make money to pay to our limited partners, and in order to do that we must sell our stock for a higher price than we paid for it. So, I want to know who the buyers are and since we all know that the public buyer is pretty much nonexistent these days, who are the other buyers, the strategic buyers. I want to see that they have done an analysis and identified several companies who will want their products and that they have a reason to buy the company.

Ivor: Good points. Sometimes I don't get enough information about the competitive landscape. I really want to understand that in detail.

Brenda: Here is another pet peeve: company puts up a slide that says something like: "exits over \$X billion over the last X years in this therapeutic area." And then they list the deals with the announced overall deal value. First of all, these amounts are always bio dollars - the actual return to the investors is always substantially less. I had a situation recently where a company did this in an area that I know well. The fact is this company had no appreciation for the history behind the deals they put on their slides. It was many years and many deals before the exits on their slide. My question to the company was: "Did anybody make money on these?" Since I had been an investor in some of these companies, I knew the answer. It seemed deceptive in a way – if you didn't know the space, you would have thought this was a terrific place to put your money.

Jennifer: Let's move on to the follow-up to the meeting with you. Could you comment on the difference between persistence and annoyance? What are your thoughts on what a company should do after they have had a meeting?

Brenda: If they don't call me, I guess they don't care much. I tell people to just bug me until you get an answer. I mean call me. I mean don't be annoying but be persistent. I try to return all phone calls or e-mails. My number-one priority, though, is my current portfolio companies and my LPs [the investors in my fund] and then, after that, a new deal. But that doesn't mean I don't want to be reminded.

Ivor: From my perspective, this is a very individual issue. I understand where Brenda is coming from, but I prefer that people not bug me. If I am interested in a deal, I will get back to them. If I am not that interested, I won't get back to them. I don't need entrepreneurs to bug me – I find it annoying. If the priorities that Brenda described keep me from working on a deal, then it shows me where that deal is in my priority list and interest level.

Elaine: I would say I like to be bugged. If they don't follow up at all, then I just assume they have no interest in me. So I think a call two weeks after a presentation is appropriate. Then it would be nice if we could provide some guidance about our interest level or what we are doing. I think it is incumbent on us. To be fair, it is the rare deal that I get to before somebody gets back to me. There is something in every business plan that is interesting that makes me want to do a little bit of work. I am not quite as good in the rejection part as I should be.

Jennifer: In our last few minutes, what do you think entrepreneurs should know about the process that we haven't yet discussed?

Ivor: Valuation issues. That is a very sensitive area and I deal with that up front to make sure we are in the right range before I waste any of my time. I could spend months on something only to find out that we are way off on valuation. So I deal with that early on.

Elaine: Agreed.

Jennifer: Do you find that the companies are being more flexible in this environment or are people digging in their heels?

Ivor: I think they are being very flexible. People I deal with seem to take guidance from us.

Brenda: I hear the West Coast is a bit different from the East Coast. We're regional players and I am sure Elaine and Ivor see more deals than we

do because they are not regional. Even being a regional player, we saw 600 opportunities in 2009 and we did six. A lot more than six were high quality. I think it's a buyer's market and, in my view, it always has been in the life sciences. We just have to walk away if the valuation is too far apart.

Jennifer: When there are already VC investors in a company, do the prior investors tend to be cooperative in the new deal or do they tend to make the valuation proposition tougher?

Brenda: I think we should talk about the syndicate, even though that is not exactly what you are asking. You are asking about the old syndicate's willingness to take a down round, but there are other syndicate issues as well. The syndicate is as important today as the entrepreneur. We want to know: Are they going to play ball or push for that IPO fairy tale that I don't believe exists anymore, or are they going to look for a real strategic buyer? The investors have to be aligned in their long-term strategy for the company.

Elaine: I think it depends. For example, there have been deals that I thought were interesting, but the valuation was very high and there were people on the board I know and respect well, who I know would not react favorably to the valuation that I thought was appropriate. So sometimes we just don't go any further. I would say when we decline most of the deals, the question we get is always "Why did you decline?" We are forthright: We couldn't get to your valuation. If there is no flexibility there, there is no point in pursuing the deal further.

Brenda: But, you know, make an offer. Once I looked at a deal with a VC investor that I knew well, he was a friend of mine. We thought the valuation we were willing to offer would be insulting and we started to walk away. He encouraged us to make the offer, so we did, with apologies, and we closed a deal. I think it's important to be honest.

Ivor: When there is a company with a previous syndicate, I see the fact that they are actually going out in this environment and raising money from a new source indicates that they are willing to negotiate and work out a fair market valuation with the new investors. I think that's because, in all my portfolio companies where we need

additional financing, most of the time it is an insider round done by an existing group because we know that we are not going to get the value that we want from the new investors.

Brenda: It is kind of funny. Think back – years ago when we started doing this, it would be almost embarrassing if we did an insider round. Everyone would think it was because you couldn't get an outside investor.

Ivor: Exactly.

Brenda: But the world is now the opposite. Now you don't look for outside money unless you are tapped out inside. If it is a good deal, no one wants to get diluted unless they have to.

Ivor: To take it a step further, we saw a very interesting and good opportunity with a very strong syndicate and proposed a down valuation. That syndicate turned us down and refinanced that company at our valuation. They were really looking for an external validation of a new valuation that they could take advantage of. We became a stalking horse. That's what you have to worry about in this environment.

Jennifer: Do you have any comments about the kinds of due diligence or deal issues that can kill a deal – things to avoid?

Ivor: One diligence item that is new, that wasn't there 10 years ago, is I don't do a deal unless I talk to big pharma about what they think. I go to where the expertise lies, with my contacts at Pfizer, Lilly, or Novartis or wherever the expertise lies. (That's another thing about VCs – we bring contacts with big pharma to the table.) We get an assessment of the opportunity that we are looking at from the big pharma perspective.

Brenda: That's true. Another part of diligence that is increasingly important is reimbursement. We always looked at that, but I think it's a lot harder now. For example, if somebody is developing a new antibiotic and we see that by the time it is approved, a very similar antibiotic is going to be generic, we ask what's the price going to be for the new antibiotic. We look hard at reimbursement.

Ivor: Yes. A regulatory strategy becomes increasingly important in this phase. There are certain areas that we're reluctant to go into because we don't understand the regulatory risks as well or it is too risky. For instance, in diabetes.

Elaine: I do like it all to be in one data room. It suggests that company is really prepared to facilitate our review.

Elaine: One thing I'd like to add: If the CEO says I can't talk to any of his direct reports, that's a problem. I like to talk to key staff individually.

Brenda: I agree. That would be a red flag. We all know that management is one of the most important things here. We look for good management. The inability to delegate and to trust employees will kill a deal.

Elaine: Yes.

Jennifer: Any final comments or thoughts?

Elaine: From the corporate perspective, there are a couple of things we have to have in our agreements that are really Pfizer-specific. I think it is incumbent on us to fully apprise management and other investors. Most of the time we have been able to get those inserted without too much difficulty. For example, when we need to be able to transfer stock to a subsidiary of Pfizer if that makes sense for us as a corporation without going through shareholder approval. I would say that if you are talking to a corporate venture capitalist, you might want to understand some of the details of an investment. They are not really core terms and conditions, but they are unique circumstances.

Ivor: Here is an issue that always comes up and that entrepreneurs are not always prepared for: In the old days, an entrepreneur could get common stock and then the company would go public and everything is fine. But in today's environment, companies are often acquired and it is technically a liquidation and the preferred stock has liquidation preferences. It's more important today for entrepreneurs to understand the difference between common stock and preferred stock.

Jennifer: That is a very good point. In an acquisition exit circumstance, it is almost always considered a "liquidation" under the preferred stock terms. If the purchase price will provide enough cash to pay the liquidation preference and nothing else, then the common stock holders,

management, will not receive any of the purchase price. Often in these cases, management has to wait for the earn-out or milestone payments.

Elaine: That also points to any type of debt or other arrangements where the IP or a key part of the company's technology has been pledged as security or the company has provided a negative covenant promising not to grant any security interest. Most investors will not be comfortable with that. So, it has to be dealt with to close the deal. Of course, it is much better if it does not exist.

Brenda: I think also that compensation issues are key.

Jennifer: More good advice. With more frequency, we are seeing management negotiating upfront a carveout of sorts to make sure that management will receive a certain percentage of the purchase price. This is often seen as an important motivator. The investors want to make sure management is doing their best to find and close an exit transaction.

Ivor: When companies were founded in the earlier part of this decade, people didn't worry about these things. Now they have to worry about them in the end when the exit is at hand. It is probably best for them to understand these issues at the beginning. If they go in with their eyes open, they will not be upset at the end because things didn't work out as they anticipated.

Brenda: Entrepreneurs need to look at things from an investor's perspective. We are fanatical about capital efficiency, for instance. I try to educate entrepreneurs about my motivation to make sure they understand where we are coming from and that my primary objective is to return capital to my limited partners. I think entrepreneurs need to know a bit about Venture Capital 101 – that we are always looking for that back door when we come in the front, and that we have our own set of pressures from our investors. That education is a role for us and for attorneys.

Jennifer: I totally agree. (That's the point of this book!!)

INTERVIEW WITH RICHARD CARUSO

By Amy Underwood, former Associate, Ballard Spahr LLP

We sat down with Richard Caruso, Chairman and Founder of Integra LifeSciences Corp. (Integra) to discuss his career and success as an entrepreneur. Dr. Caruso spent 20 years as a successful entrepreneurial financier before he founded Integra in 1989.

Dr. Caruso was kind enough to discuss with us his early career as an entrepreneur, key influences, how he found and kept mentors, and how he built a successful management team at Integra. In this interview, Dr. Caruso provides his perspective and some advice for fledgling entrepreneurs.

Question

Richard Caruso

"I originally thought of entrepreneurs as blind, foolhardy risk-takers, but I did not see myself that way. While I was taking risk, I thought that the risks that I was taking were appropriate for what I wanted to accomplish. It became important to me to understand entrepreneurship as more than going out in a blind way trying to do something."

Question

Caruso

How did you start your career as an entrepreneur?

The concept that I have about entrepreneurship is in many respects different than how most people think about entrepreneurship. Entrepreneurship is mostly thought of as a business venture where people take a large risk of initiating a new venture. I originally thought of entrepreneurs as blind, foolhardy risk-takers, but I did not see myself that way. While I was taking risk, I thought that the risks that I was taking were appropriate for what I wanted to accomplish. It became important to me to understand entrepreneurship as more than going out in a blind way trying to do something.

I examined the definition of entrepreneur and I realized that it stemmed from the French word "Entreprendre," meaning to undertake. I decided that I had to understand what enterprise was really being undertaken, because for me it wasn't just about a business enterprise, but more about the personal spirit of an individual and the enterprise that you must undertake as an entrepreneur of your own life as an individual.

I developed my own definition of success as to what I thought would make me feel successful and I came up with nine criteria for what would be "personal success" for me. They are: (1) do something intellectually challenging; (2) work with leading-edge technology; (3) work with people I like and respect and who respect me; (4) work on something to benefit mankind; (5) solve problems on a personal basis; (6) accomplish something important that hasn't been done before; (7) create a vision that others can understand and follow; (8) create interesting career opportunities for others; and (9) if all the above happen, then I would be rewarded by making money. The money is the reward or trophy rather than the sole objective.

Who were your main influences early on as an entrepreneur?

There were many people who I felt had this entrepreneurial spirit and helped me to identify my own entrepreneurial spirit, from my football coach to a college professor, as well as many businesspeople. A true entrepreneur is not only concerned with making money, but is passionate about the mission that they want to accomplish. That is why it is critically important when a budding entrepreneur is trying to raise money to have passion and the entrepreneurial spirit because what you are asking investors to invest in is not just what you want to accomplish, but your passion as an individual. People invested in and became a part of Integra LifeSciences because they believed in the concept and vision of the company which I was passionate about. Some of my mentors, in the early days, saw that I could help them and that they could help me, so there was really mutual respect.

Question

Caruso

Question

Caruso

Question

Caruso

In the early stages of your career, how did you find your mentors?

In our society some think that social interacting is mentoring but social interacting is not mentoring. Social interacting is connections that are arbitrary. Mentoring goes beyond social interacting in that there is a more purposeful mentoring relationship. In 1986, I started the Uncommon Individual Foundation because I wanted to find a better way of fostering mentoring relationships and to understand more about mentoring and how it occurs. We try to encourage people to not think of mentoring as circumstantial and accidental but as something that they have the ability to initiate themselves. At UIF, we have developed "open system mentoring," the concept of connecting people with more than one mentor so they can engage different people who understand that you are undertaking risk but you are also passionate about what you are doing. People then have the opportunity to encourage you or invest in your vision or work together as a team, or, as Deborah Norville says, "have mutual respect for each other."

How did you start Integra LifeSciences?

At the time I realized I was in a position to take some financial risk because I had made some money. I wanted to do something that allowed me to achieve what was success to me, not just money, but the nine criteria I developed. Even though I had no medical background, I wanted to do something in the medical field because I felt that the medical profession was an area ripe with opportunity. What was happening with regenerative medicine was very primitive and working in this area would allow me to accomplish My objectives for success.

So, I read some newspapers about how surgeons were taking body parts out of cadavers and putting them into living people. I thought if the body was able to create its parts once, why can't it re-create them when there is a problem? The medical profession said that's not possible. But one of the advantages of not having a medical background was that I thought, "I am going to ignore that." I didn't know anything about medicine, so I had to go out and get mentors to help me.

How did you reach out to the right people to compile the winning team?

There were people who I found that were also interested in this concept. However, they had licensed the technology previously. The FDA had previously expressed serious concerns and the FDA didn't think our concept would work. Companies and universities started abandoning the technology, so I went to Marion Laboratories (a university) in Kansas City to look at equipment specific to our application, and Ewing Kauffman, the founder of Marion and the Kauffman Foundation, was there and told me, "This sounds like a terrific idea, I really think you should do this." I didn't realize he was a few months from dying and he knew that, but he was still an entrepreneur, a mentor and a primary mentor for me on this venture. In the two-hour meeting I had with him, he encouraged me to continue down this path because he understood this technology, and thought that what I was trying to do made some sense. I was very impressed with Kauffman as well just from the perspective of what mentoring and encouragement is all about. Kauffman also embodied what the entrepreneurial spirit is all about, because he illustrated that if you have the entrepreneurial spirit you have it until the end of your life.

Question

Caruso

Question

Caruso

"People often think that there is an existing road that you should head down. What you realize as an entrepreneur is you start to create your own path. . . What you really need is a theoretical machete to create the path that does not exist."

Question

Caruso

'I wouldn't characterize it as luck – it's drive."

Question

Caruso

Question

Caruso

"do something intellectually challenging, do something that had never been done before, do something that can benefit mankind."

So it's part of your psyche?

It's part of your psyche, it's part of how you see things, it's part of how you understand life.

How did you persevere even when the FDA and the scientific community didn't believe in the technology?

I was passionate about what I wanted to do. I was heading down the path of wanting to accomplish something, so therefore I was looking for the people and the resources that I needed to get the job done, and that's what entrepreneurship is all about.

People often think there is (a) an existing road that you should head down. (There isn't, okay.) What you realize as an entrepreneur is that you start to create your own path, it's not a straight path, and most often you don't actually know where to go. What you really need is a theoretical machete to create the path that does not exist.

So it's focus, it's determination, it's passion, and is it also the element of luck that comes into play here?

I wouldn't characterize it as luck – it's drive. Because the reality of the situation is that no matter what the situation was, I think I would have found a path regardless, and whether it was this path that I took to get there or another path, I would have gotten there anyway. It might have taken longer, it might have been more risk, but instead of going from here to here, maybe I had to go to here then go back here and go over here and then go over there and then go over there.

How did you find people to invest in your concept?

Our investment community said I had no background in the medical field and they wouldn't invest. So, I invested my money. After a few years I got Boston Scientific to invest in our company. But you know we were always a couple months away from running out of money. That really is the big problem of entrepreneurial ventures. People have innovative ideas, and most investors won't invest in innovative ideas. And in this economy it is much harder because what they are interested in doing is making money from an investment perspective and they don't have the same criteria that an entrepreneur may have, that the money is the reward for getting something done.

So what do you suggest that entrepreneurs do these days?

Today you have to show outside investors that if they invest in the company that they can make money in a short period of time, perhaps even shorter than five years, as an example. And, by the way, federal and state programs can be difficult as well. All I can say is what I tried to do, which was to do something intellectually challenging, do something that had never been done before, do something that can benefit mankind.

Question

Caruso

Question

Caruso

Question

Caruso

How do you think the new administration is going to affect venture capital investments?

It's not just the new administration, it is the entire political system. You have two ends of the spectrum. You have very little in the middle. I think we need to focus on what is in the middle as opposed to either end of the spectrum. You know when you come right down to it, I think that is a real problem for where we are as opposed to just thinking of this administration. It's all just coming out of different environments as opposed to what is really happening in the economy.

What would you tell new entrepreneurs who come out of universities now?

One of the biggest problems we have in my judgment with entrepreneurship is our education program. I don't think that most entrepreneurs come out of business schools. I think business schools educate you on how to make money, as opposed to how to be innovative. I think most of our entrepreneurs come out of engineering schools and medical schools because they focus on new technology and new applications, but they don't have business experience. Somehow you need to combine understanding business with technology and we are not doing that in our education system.

My advice to an entrepreneur would be to have criteria similar to the ones I developed for myself and follow those to the road it takes to the end. And the reality of the situation is that you know most entrepreneurs just think because they have an idea that people are going to invest in them in some fashion or other. It doesn't work that way.

If I'm an entrepreneur starting a new venture now, should I surround myself with people who are going to help me accomplish it? Should I get a CFO? What's the initial team that I should have?

You certainly have to go through that process in order to actually start an entrepreneurial venture, but in my judgment you have to start as a dictator. People that become involved are people that sign up for my vision to start, as opposed to saying I need an advisory board to tell me what to do to start. I certainly need the advice, but whether or not I accept the advice or not is a whole other situation. Your vision and your passion.

TERM SHEET WITH EXPLANATIONS

By P. Christian Anderson, Partner, Ballard Spahr LLP, and Jennifer L. Miller, Co-Chair, Life Sciences/Technology, Ballard Spahr LLP

SHORT FORM CONFIDENTIAL TERM SHEET¹ FOR PROPOSED SERIES A PREFERRED STOCK FINANCING OF

Issuer:	[], a [] corporation ("Company") ² .
Purchaser:	[] ("Investor") ³ .
Amount of Financing:	\$4 to be provided by
Security:	Series A Convertible Preferred Stock (the " <i>Preferred Stock</i> ") ⁵ .

Typically a financing term sheet is not intended to be construed as a contract binding on either party. From the investors' perspective, they will not want to be bound in any way until all conditions precedent have been met, such as completion of due diligence and execution of a definitive purchase agreement. Often, as with this example, the term sheet is not signed by the parties

- While limited liability companies are popular business vehicles and offer great organizational flexibility to early stage companies, the corporation continues to be the most commonly used form of entity for the typical venture-backed company. Venture investors seem to be generally more comfortable with the corporate entity, and the corporation facilitates frequent changes in, and additions to, the ownership group, as well as the implementation of incentive arrangements for employees. However, limited liability companies are being used by early stage companies with increasing regularity. (See "Selection of an Entity" in Section III of this book.)
- ³ For a variety of reasons, the lead investor may want other investors to participate in the financing. The lead investor may ask for approval rights with respect to other participating investors, and the definitive agreements will be subject to approval and execution by all parties.
- ⁴ The amount of the investment is often given as a range, depending on whether the investor group has already been assembled, or if the investors want a staged pay-in, with their investments to be made in installments, if and when the Company achieves specified milestones.
- In certain circumstances, investors may wish to structure their investment as debt, with either a convertible equity feature or detachable warrants, especially where the Company valuation is not yet settled, or the investors want a preferred position in the event of a failure of the Company. Debt structures are often disfavored in early stage deals, however, as they offer little tax advantage to companies, which typically lack significant taxable income, and generally wreak havoc on an issuer's balance sheet. Also, early stage investors participating in debt deals often lose out on the upside given to the earliest equity investors.

This term sheet is intended to be illustrative of significant terms and conditions that are common in venture capital financings, but does not constitute a comprehensive or exhaustive listing of possible provisions. Each particular transaction will include terms and conditions tailored to such transaction and the parties involved, and will reflect, among other things, the agreed-upon valuation of the company involved, the particular stage of financing, the existing capital structure, the rights of existing shareholders of the company, the current investment climate, and other relevant variables. Venture capitalists typically structure their investments as purchases of shares of convertible Preferred Stock, which have preferential rights such as those referenced in this term sheet. A side benefit to the issuer from structuring a venture investment as an issuance of Preferred Stock is that it can justify a much lower price for its Common Stock (which may be allocated to employees and others having a relationship with the Company), which does not enjoy the same rights and preferences, than the value placed on the Preferred Stock to be issued in the venture capital financing. (See "Common Types of Equity-Based Compensation" in Section III of this book.)

Price:	The purchase price per share (the " <i>Original Purchase Price</i> ") shall be determined based on a fully diluted ⁶ pre-money valuation ⁷ of \$
Capitalization:	A capitalization table showing the Company's current capital structure attached as Exhibit A.
Anticipated Closing Date (the <i>"Closing"</i>)	On or about
Use of Proceeds:	Proceeds from the financing will be used for working capital and general corporate purposes. ⁸

TERMS OF PREFERRED STOCK:

Ranking: The Preferred Stock will rank senior to Common Stock, with respect to

dividends, liquidation, dissolution, voting and redemption.

Dividends: [Cumulative accruing][non-cumulative] dividends⁹ in preference to any

dividend on the Common Stock and any series of preferred stock ranking junior to the Preferred Stock at the rate of [8%]¹⁰ of the Original Purchase Price (as adjusted for stock splits, stock dividends, combinations and the like) [per annum, whether or not declared by the Board of

Directors][when and if declared by the Board of Directors].

[The preferred dividend shall be payable on a sale or liquidation of the Company or the consummation of the initial public offering of the Company's securities.]

[If a dividend is declared with respect to the Common Stock, then an equivalent dividend per share (determined on an as-if-converted basis) will

⁶ Fully diluted typically includes an option pool that is 10%-20% of the total equity to existing stockholders. Both sides should confirm that how this term will be defined is fully understood, since sometimes it only takes into account the entire option pool and sometimes only shares that have been committed for existing options.

The pre-money valuation of the Company will often be heavily negotiated and will drive many issues concerning the rights of the various parties and the structure of the investment. Investors use a variety of different methods to determine a Company's valuation and the price they will pay as they make their investment, from a discounted revenue stream approach based on business plan projections, to a more arbitrary figure based on a desire to own a predetermined percentage of the Company in return for the anticipated level of funding needed to achieve a specified milestone. (See "How a Company is Valued" in Section V of this book.)

⁸ One issue important to investors is to confirm during diligence that the Company does not have significant debt that the financing will be used to pay off, rather than go toward value-creation activities.

Generally, a dividend must be paid to the holders of Preferred Stock before any dividend is paid to the holders of Common Stock. The dividend is often cumulative, so that it accrues from year to year until paid in full, but may be noncumulative and discretionary. The nature of the dividend preference granted to investors is often a focus of negotiations. Since early stage companies are rarely in a position to pay current cash dividends, a dividend payment or accrual requirement gives leverage to the investment group, and may result in the investors being able to convert their preferred investment into a greater number of shares of Common Stock than would otherwise be the case, thereby increasing their equity position. Companies should be wary of dividends that compound, since for an investment that is in place for several years, the effect of compounding can be significant. A dividend provision may sometimes provide for issuance of additional shares or other payment-in-kind provision.

Currently, 8%-10% is market.

be declared and paid with respect to the Preferred Stock.]

Liquidation Preference:

In the event of any liquidation or winding up, the holders of Preferred Stock shall be entitled to receive, in preference to the holders of Common Stock and any series of preferred stock ranking junior to the Preferred Stock, a per share amount equal to [1X of] the Original Purchase Price (as adjusted for stock splits, stock dividends, combinations and the like) plus any accrued but unpaid dividends (the "*Liquidation Preference*"). After the payment of the Liquidation Preference to the holders of the Preferred Stock, the remaining assets shall be distributed ratably to the holders of the Common Stock and the Preferred Stock on an as-converted-to-common basis, [until the holders of Preferred Stock have received a total of _____ times the Original Purchase Price, in addition to the Liquidation Preference referenced above].¹¹

A merger, acquisition, sale of substantially all of the assets of Company in which the stockholders of Company do not own a majority of the outstanding shares of the surviving corporation, or sale or exclusive license of all or substantially all of Company's intellectual property shall be deemed to be a liquidation of Company (a "Liquidity Event").¹²

Conversion:

The holders of Preferred Stock shall have the right to convert the Preferred Stock, at any time, into shares of Common Stock. The initial conversion rate shall be 1:1, subject to adjustment as provided below. [All accrued and unpaid dividends, whether or not declared, shall be included in the conversion calculation] [or, at the holder's option, be paid in cash on conversion].¹³

Automatic Conversion:

The Preferred Stock shall be automatically converted into Common Stock, at the then-applicable conversion price in the event that the holders of at

A Liquidation Preference typically refers to the right granted to the holders of a series of Preferred Stock to receive a specified fixed amount before any assets are distributed to holders of Common Stock. A series of Preferred Stock is referred to as a "participating" preferred, if the holders will, in addition to receiving their specified preferential distribution, also participate in the distribution of any remaining amounts, along with the holders of Common Stock. Such a provision is not unusual, but the Company may argue that in a liquidation a preferred investor should be required to either retain the Preferred Stock acquired and get only the specified preferential return, or convert to Common Stock and share in all amounts available for distribution to holders of Common Stock (rather than get the benefits of both a preferred and common position). Sometimes, a series of Preferred Stock will participate in excess distributions above its preferential amount only until a specified cap is reached. Historically, the liquidation amount most typically has been tied to the original purchase price, or a multiple thereof. The amount of the liquidation preference may be adjusted depending on how long after the initial investment the liquidating event occurs. If investors ask for too much in terms of a liquidation preference, they may diminish management's incentive to work hard to achieve a liquidation opportunity. Whether a liquidation preference is 1X or 2X or more may depend on the general market conditions, the Company's particular prospects and stage of development, and the competition among potential investors for participation with the Company.

The types of transactions to be treated as a Liquidity Event may vary, and include certain transfers of voting power. By treating mergers and other transactions as Liquidity Events, the holders of Preferred Stock give themselves an enhanced opportunity to obtain liquidity for all or part of their investment (or even a multiple thereof) at a time when holders of Common Stock may not.

The provision for including cumulative dividends in the conversion calculation is a pro-investor item, as is the provision allowing dividends to be paid in cash, at the option of the holder. Note that the conversion rate is typically determined by dividing the Original Purchase Price by a conversion price that usually starts out as being equal to the Original Purchase Price, resulting in an initial 1:1 conversion rate. The anti-dilution protections referenced on the next page are implemented by changing the conversion price, resulting in a revised conversion rate. For instance, if the conversion price were to be dropped to half of the Original Purchase Price, the conversion rate would then be changed to two shares of Common Stock for every share of Preferred Stock purchased.

least a majority of the outstanding Preferred Stock consent to such conversion. In addition, the Preferred Stock shall be automatically converted into Common Stock, at the then-applicable conversion price upon the closing of a firmly underwritten public offering of shares of Common Stock of Company at a per share price not less than [400%] of the Original Purchase Price (as adjusted for stock splits, stock dividends, combinations and the like) per share and for a total offering of not less than [\$50] million¹ (before deduction of underwriters commissions and expenses) (a "Qualified IPO").14

Anti-Dilution Provisions:

The conversion price of the Preferred Stock will be subject to a broadbased weighted average adjustment to reduce dilution in the event that Company issues additional equity securities (other than in transactions as referenced below), at a purchase price less than the Preferred Stock conversion price. The conversion price will also be subject to proportional adjustment for stock splits, dividends, recapitalizations and the like.

The conversion price of the Preferred Stock will not be adjusted for the following issuances: (i) shares of Common Stock issued upon conversion of, or as a dividend or distribution on, the Preferred Stock; (ii) shares reserved as employee shares described under "Employee Pool" below and future equity incentive plans approved by Company's Board of Directors (the "Board") including at least one of the Series A Directors (as defined below); (iii) shares of Common Stock issued upon exercise of warrants or convertible securities outstanding as of the date hereof; and (iv) shares issued in connection with mergers, acquisitions, strategic transactions, equipment leasings and debt financings approved by the Board.15

A more draconian anti-dilution protection would be what is called a direct or full ratchet adjustment. This more extreme provision provides that in the event of a dilutive or down round financing, the conversion price of the Preferred Stock enjoying such right will be adjusted downward directly to the issuance price of the newly issued shares, regardless of how many shares were issued at such price. So investors having the benefit of full ratchet anti-dilution protection are treated as if they had purchased their shares at the lower price applicable to the later financing. Companies typically negotiate hard-to-avoid full ratchet anti-dilution provisions, as it can have a draconian result in the event of any dilutive financings. Even many investor groups don't like them (at least when investors other than themselves have such rights), as an investor who refuses to participate to help out a floundering portfolio Company is benefited as if it did participate in the new financings. As a result, parties dealing with a full ratchet anti-dilution provision will often consider a "pay-to-play" provision, as we have referenced elsewhere in the term sheet, which will extend the benefit of the full ratchet adjustment on the conversion of Preferred Stock previously acquired only to investors who participate in the dilutive financing that causes the adjustment. Investors are more adamant about obtaining full ratchet protection in times of questionably high corporate valuations. If they believe the Company is being unreasonable in its valuation, they may leave it to the next round investors to negotiate hard on the valuation and price, with the

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Automatic conversion serves to enable the Company to cause a simplification of the Company's capital structure, at the time of an IPO or other appropriate event. The multiple from the Original Purchase Price used for triggering an automatic conversion in the event of a Qualified IPO is often between 300% and 500%, and the size of the offering constituting a Qualified IPO varies widely, based on the amount of funds the Company may be expected to raise in an IPO, but the parties usually don't see much value in spending time negotiating either of these provisions.

A broad-based weighted average anti-dilution formula is the standard. That is, it is the most common form of protection against dilution granted to venture investors in "normal" market times. It spreads the impact of dilutive issuances over a broad base of shares (including all outstanding shares and options), and so has a more reasonable impact on the Company's other shareholders. The formula treats all shares outstanding prior to the dilutive issue as having been issued at a price equal to the conversion price of the Preferred Stock then in effect, and then lowers that conversion price as a result of a new issue to the weighted average of the purchase price of the outstanding and newly issued shares.

Redemption:

At the election of the holders of at least a majority of the Preferred Stock, Company shall redeem the outstanding Preferred Stock in three substantially equal annual installments beginning on or after the fifth anniversary of the Closing as is designated by such electing holders. Such redemptions shall be at a price per share equal to [the greater of (i)] the Original Purchase Price (as adjusted for stock splits, stock dividends, combinations and the like) plus accrued but unpaid dividends [and (ii) fair value of such shares].¹⁶

Preemptive Right/Pay-to-Play:

Holders of Preferred Stock will have the right to participate in future offerings of securities by the Company (subject to customary exceptions), on a pro-rata basis in accordance with their respective equity positions in the Company, to the extent required to protect their equity positions from dilution. The stock of any holder of Preferred Stock that does not exercise its right of first refusal or preemptive right in full with respect to future equity issuances by the Company will automatically be converted into shares of [Common Stock] [a series Preferred Stock that does not have any anti-dilution protections based on future equity offerings at a lower price].¹⁷

(...continued)

prior round investors then to be treated as if they had invested at that same price. If an investor group is insistent on a full-ratchet protection, the Company will typically try to limit it for as short a time period as possible (the idea being that if the Company's valuation doesn't drop within a reasonable period of time, the valuation set at the time of the financing is justified), or to have it lapse upon the achievement of specified goals. Alternatively, the parties might build in a "floor," so that once the conversion price drops to that amount (it might be set, for example, at the prior round financing price), the conversion rate adjustment changes to a weighted average formula.

- Preferred Stock may be redeemable, either at the option of the Company or the investors, or mandatorily on a certain date, perhaps at some premium over the initial purchase price of the shares. A primary goal of venture investors is to ensure the eventual liquidity of their investment. Puts or redemption features provide this liquidity more directly than any other mechanism. However, a put can place a tremendous burden on growing companies, which may not have the immediate ability to refinance their capital structure in order to accommodate a put. The Company will typically resist a put, on the theory that the expected liquidity will be achieved when the Company goes public or is acquired. The investors often insist on a put to give them leverage in discussions, or force the Company to cash them out at some point (assuming funds are available), if the other liquidity options have not materialized or management has become complacent in slow progress or law reviewers. Features of a put may include payment terms (e.g., installment payments) and differing payment amounts, tied to the liquidation or market value of the shares. The consequences of the Company's inability to redeem the preferred shares following the exercise of a put is an important issue to be addressed. The investors will typically require a corresponding decrease in the conversion price of their preferred shares, a chance to control the Company's Board, or some other penalty. Redemption rights give the investors holding such rights negotiating leverage, but are seldom exercised, and can make an investment look more like debt than equity. Such rights are generally renegotiated or eliminated as new investors come on board, or the new investors will typically insist on comparable redemption rights with an adjusted effective date for all preferred holders. Our term sheet reflects a fairly standard redemption arrangement, which we see more often on East Coast deals than West Coast deals.
- This pay-to-play provision penalizes investors who do not participate pro rata in future rounds by converting their equity to Common Stock or removing their economic anti-dilution protection. Investors who have the ability/desire to fund future rounds will benefit from this provision. We are seeing pay-to-play provisions only in a minority of current deals, but more so when full ratchet anti-dilution protections are part of the transaction.

Pay-to-play provisions are intended to encourage current investors to participate in future financings. If they don't, they may forfeit various rights relating to their original investment, including rights to participate in future offerings, anti-dilution protections based on future offerings at lower prices, various voting rights (to restrict the Company from participating in certain transactions), liquidation protections, or as in our term sheet provision that would cause a conversion to Common Stock, all of the rights and protections associated with the Preferred Stock terms. In some deals, the lead investor of a syndicate might require pay-to-play provision to protect his or her future investment in the Company.

Board of Directors:

Five directors shall comprise the Board, designated as follows:

- (i) [two] designated by holders of a majority of the Preferred Stock (the "Series A Directors"):
- (ii) [two] independent designated by holders of a majority of the Common Stock; and
- (iii) Company's Chief Executive Officer.

In addition, Investor shall have the right, at its option, to have one person attend Board meetings as a nonvoting observer and to receive all information distributed to Directors.¹⁸

Protective Provisions:

For so long as shares of Preferred Stock remain outstanding, consent of the holders of [at least a majority of]19 the Preferred Stock shall be required for any action that (i) alters or changes the rights, preferences or privileges of the Preferred Stock or increases the number of authorized shares of Preferred Stock, (ii) increases or decreases the authorized number of shares of Company's capital stock, (iii) creates (by reclassification or otherwise) any new class or series of shares having rights, preferences or privileges senior to or on a parity with the Preferred Stock, (iv) results in the redemption of any shares of Common Stock or any series of preferred stock ranking junior to the Preferred Stock (other than pursuant to equity incentive agreements with employees and other service providers giving Company the right to repurchase shares at cost upon the termination of services), (v) results in any merger, other corporate reorganization, sale of control, voluntary dissolution or liquidation, sale or exclusive license of all or substantially all of Company's intellectual property, or any transaction in which all or substantially all of the assets of Company are sold, (vi) amends or waives any provision of Company's Certificate of Incorporation or Bylaws that affects the Preferred Stock adversely, (vii) changes the authorized size of Company's Board, (viii) results in the payment or declaration of any dividend on any shares of Common Stock or any series of preferred stock ranking junior to the Preferred Stock, (ix) enter any transaction that results in first priority security interest being placed on all or substantially all of Company's assets or intellectual property, or (x) sale, transfer, pledge, dispose of or license any of the intellectual property rights of Company or other Company assets, other than in the ordinary course of Company's business.20

The composition of the Board is often intensely negotiated. An investor group may ask for multiple members of the Board. Investors will sometimes provide for their Board representation to increase (even to a majority position) in the event the Company fails to meet specified milestones. The parties may provide for two equal factions on the Board representing the holders of Preferred Stock and other interests, plus an independent director acceptable to all parties. Investors unable to secure a position on the Board may ask for the right to receive information distributed to members of the Board, and to have a nonvoting observer attend Board meetings.

This is typically negotiated and depends on the cap table and on relative positions of investors if there is a syndicate of investors.

The list of transactions requiring special shareholder or Board approval will vary depending on the circumstances of the issuer. Whether an item is subject to special Board or shareholder approval will also depend on the investors' comfort (continued...)

Information Rights: So long as Investor continues to hold shares of Preferred Stock (or

Common Stock issued upon conversion thereof), Company shall deliver to the Investor monthly and quarterly unaudited financial statements, and

annual financial statements.

Registration Rights: Investor shall be entitled to two demand registration rights and unlimited

piggyback and Form S-3 registration rights on customary terms.²¹

Lock-Up Provision: Each holder of Registrable Securities will agree to not sell its shares for a

specified period (but not to exceed 180 days) following the effective date of each Company's registered public offering; provided that all officers,

directors, and other 1% stockholders are similarly bound.

Drag-Along Rights: In the event that the holders of at least 80% of the Common Stock and

Preferred Stock (voting together as a single class) approve a sale of Company or all or substantially all of Company's assets, whether by means of a merger, consolidation, sale of stock or assets, or otherwise, the other stockholders shall agree that they will consent to, vote for and raise no objections to such transaction and otherwise shall agree to sell their shares of stock in the Company in such transaction. The Company shall not issue any shares of its capital stock after the Closing without an agreement from the prospective stockholder to agree and abide by these drag-along provisions. These drag-along obligations shall terminate upon a Qualified

IPO.22

Tag-Along Rights: If any holder of Common Stock holding more than 5% of the Company's

fully diluted capital stock (a "Selling Common Stockholder") desires to sell any of its shares in one or a series of transactions, the Investors shall have the right to participate in the transaction(s) on a pro rata basis on the

same terms and conditions.²³

(...continued)

level. Keeping approval and/or veto rights in the hands of the directors may simplify the approval process, but may raise fiduciary concerns where directors vote based on what is best for the investors they represent rather than what may be best for the Company and shareholders as a whole. Also, if protective provisions are granted at a Board level, if business developments cause directors to consider resigning their fiduciary positions, the investors represented by the resigning directors would lose their ability to exercise their protective rights. Shareholders are generally (but not always) free to vote according to what they believe to be in their own best interests, rather than what may be in the best interests of the Company or shareholders as a whole.

Note that publicly registering the Company's securities is extremely expensive and time-consuming. In addition, following registration there are significant ongoing expenses related to Sarbanes-Oxley compliance accounting, legal and reporting filing fees. Accordingly, the Company will try to limit or postpone the ability of the investors to force the Company to register its shares, particularly if the registration will be an IPO.

This is typically a negotiated provision, and is not always present. The desirability of such a provision may depend on the Company's capitalization table and its number of investors.

These rights are also highly negotiated, and are sometimes indicated in the right of first refusal to purchase shares offered for sale by a founder or holder of a specified number of Company shares (and may fluctuate based on what shareholders the Company can reasonably get to cooperate in providing such right), coupled with a co-sale right to sell side-by-side on a pro rata basis with the selling shareholders, if the investors decline to purchase the shares being offered for sale by the shareholders.

EMPLOYEE MATTERS: Employee Pool:

Company will have reserved an additional unallocated [_____] shares of its Common Stock (which will result in the Company having an aggregate of approximately [10%] of its fully diluted post-Closing capital stock) reserved for issuance to directors, officers, employees, advisers, consultants and other service providers pursuant to the Company's stock option plan, or as otherwise determined by the Board (the "*Employee Pool*").

Employee Agreements:

Founders will enter into [1] year employment agreements with the Company on terms acceptable to the Investors, with [1] year non-compete arrangements and [1] year severance.²⁴

Proprietary Information and Inventions Agreement:

As a condition of Closing, each current officer, employee and consultant of Company shall have entered into a proprietary information and invention assignment agreement acceptable to Investor, which shall include acceptable non-solicitation (and for employees, non-competition) provisions, Company shall provide copies of all executed proprietary information and invention assignment agreements to Investor as part of due diligence.

Key-Man Insurance:

Company shall procure a key-man life insurance policy for [CEO] in the amount of [\$_____], naming Company as beneficiary.

Transaction Expenses

The Company and Investor will each bear its own legal and other expenses with respect to the transaction, except that if the transaction closes, the Company will pay not more than \$_____ of legal fees incurred by a single legal counsel to the Investors.²⁵

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Investors may or may not want to require employment agreements with founders or key management or scientists, or to provide for such a long severance period. Investors may want to ensure that key personnel are incentivized to remain with the Company, through stock vesting arrangements or the like, and employment agreements for needed individuals may be appropriate, but employment agreements are in some cases to be viewed as more beneficial to the employee than to the Company or the investors.

Investors often ask for the ability to have their legal fees paid out of the financing proceeds. The placement of an appropriate ceiling on such expenses is often a subject of negotiation.

WORKING WITH VENTURE INVESTOR POST-CLOSING

By Bruce Luehrs, Partner, Emerald Stage2 Ventures

Tips to the Entrepreneur on Planning for Post-Investment Board of Directors

So you've got their money; now what? You made your bargain; do you really understand what is expected of you? One thing is for sure, you now have another stakeholder to please (along with customers, creditors and employees). One essential part of your relationship with venture investors is a new or expanded board. Why not make the best of it? Here are a few basics to consider as you begin to work with your new venture board:

1. What does the contract say?

Read the documents you signed, especially the shareholder rights agreement. If you haven't read them do it now. If you have read them, do it again. The VCs not only have the right to certain actions or outcomes, they also have the obligation (to their investors, not to you) to enforce these rights if they believe it is in their best interest.

2. What experiences have your peers or advisers had?

Most of what you need to know is not made clear or even mentioned. Better late than never – it's time to ask around about surviving, managing or possibly prospering with your VCs.

3. Time to set or reaffirm your goal.

The financial targets are essential but not sufficient. Do you want to make \$5 million for yourself and call it a day? Are top-line growth and market share sufficient or are you aiming for excellence and market share? Are you looking to get past Phase III trials and sell or prepare for development three approval Are you focusing on one commercialization? product and one indication or a pipeline of products and indications? For starters, look to a company you admire. Get your CFO or trusted advisers involved. Get the entire board to agree on your goals and then get its support for the necessary resources to achieve them.

4. Make explicit your strategy and business model.

No doubt you have a forecast. Wait a month and you will want to change it. The documents say you must present a budget (not a forecast) and get it approved. Nowhere does it say you must have a strategy or a clear business model. You talked about strategy while you were out raising capital. It is time to write it down. Get some help, but get started BEFORE your first draft budget is due.

5. CEO role and responsibility to the board.

If you had all of the necessary experience and success, you probably would have funded the company by yourself with grants and a few friends and admirers – no VCs! Committing to a formal Board of Directors is a major investment. Try to be honest and open. You are not expected to have all of the answers. Basic organizational skills help a lot. Prepare for board meetings and get the logistics straight (see final comments below). Encourage communication before and after the board meeting. Involve your management team frequently – it's good for the team and it's good for you.

6. Plan in advance when developing your budget.

Expect a series of meetings before final approval of your budget. You don't have the time or the money to do everything at once, so don't expect to spend as if you can. Watch your cash balance and develop future capital raises and alternatives in the case liquidity is likely to become an issue. Make sure critical investments in people or line items such as marketing or development are not dependent on your optimistic case milestones achievement or revenue and cash flow.

7. Drive the risk assessment process.

Consider the risks in achieving your budget and development plan. Highlight concerns along with ideas to deal with them. A good old SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) is a useful technique to communicate internally/downstream as well as externally/upstream. Your board and VCs are trying to figure this stuff out on their own. You

leading the discussion does not label you as a pessimist. Have alternatives or a fully baked Plan B if revenue does not materialize as forecast.

8. Milestones, next round capital or develop and update your funding strategy.

In almost all cases you will need more money if revenue companies want to become a leader in their niche or if product technology companies want to develop products. On the downside, lower service leads to a higher burn rate - more needed. capital Life sciences product/technology development companies consume massive amounts of cash before exit or commercialization. On the upside, rapid growth usually consumes working capital - more capital needed. Over a five-year horizon, you should expect to suffer setbacks on development or have a soft year; unless you can turn on a dime, you will need more capital.

Get your board and VCs involved in planning for the next round. Worst case, you don't have to pull the trigger.

9. Exit planning – (Please don't say IPO!)

While five years sounds like a long time, it will fly by as you plan to bring a product through some phase of human testing or grow your company's revenues over 300%. Remember, you really just rented this capital. What revenue, EBITDA and valuation metrics are you using to support a value where everyone wins? How long will it take to reach your milestones? What kind of development success or market share is implied in your targets? Are you selling at a time when your growth rate is falling? Are you reaching the

critical value creation stage before you need to sell?

Keep checking to see if shareholder and board expectations are similar. Have a target. Better to be proactive in discussions than reactive. Best is to prepare 24 months in advance of when you want to sell.

10. Timing and logistics

Finally, here are a few practical suggestions to consider as you plan your board meetings.

Make sure you reserve enough time for each meeting. It typically takes two to three hours just to get your board up to speed on events and information from the last meeting. Reserve time for special topics (new marketing plans, deep dive on product development or manufacturing or pipeline, etc.) and general discussion.

Begin and end with key issues and decisions that need to be addressed. Don't hide the ball or squander time when it comes to tough discussions until too little time remains

Plan on including members of management into the meeting with presentation material over a 12month cycle – not always, not never.

One or two social events can lead to better communication and more effective meetings.

Now go create some shareholder value!

Love,

Your friendly VC board member

VI.

POSITIONING YOUR COMPANY FOR THE FUTURE



CONTRIBUTORS

DUE DILIGENCE: PRACTICAL ADVICE FOR WHAT TO EXPECT

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financings, pharmaceutical and biotechnology licensing, technology transfer, mergers and acquisitions, general corporate law, and health law. While in private practice, she utilized her background in biology and experience in the biotechnology and pharmaceutical sectors to advise large pharmaceutical companies as well as start-up and emerging companies. Ms. Underwood is now associate general counsel at a generic pharmaceutical company.

GETTING READY: PREPARING A DATA ROOM

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Biotechnology Association as well as Pennsylvania Bio. Mr. Messancello's deal-room experience ranges from small licensing deals to multibillion-dollar M&A transactions and spans all industries.

BIG PHARMA DEALS: STRATEGIC ALLIANCES, CORPORATE COLLABORATIONS, OPTIONS, CO-PROMOTIONS & ACQUISITIONS

JENNIFER L. MILLER is a partner in the Business and Finance Department of Ballard Spahr LLP and Co-Chair of the Life Sciences/Technology Group. Ms. Miller, resident in the Philadelphia office, works with start-up, emerging and public companies, and those that invest in them. Her focus encompasses securities, corporate financing (public and private), strategic alliances, pharmaceutical and biotechnology licensing, technology transfer, mergers and acquisitions, general corporate law, and corporate governance.

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STRATEGIC ALLIANCES

CHRISTOPHER P. MOLINEAUX is President of Pennsylvania Bio, where he serves as the chief advocate and spokesman for the biotechnology, device, diagnostic, pharmaceutical, research organizations and support networks that call Pennsylvania home. Mr. Molineaux oversees the strategic direction for the association, ensuring that Pennsylvania Bio continues to be the catalyst that makes Pennsylvania the top location for bioscience companies. Mr. Molineaux has 20 years of experience in the bio-pharmaceutical and health-care industries, with frontline experience in developing and executing strategies to navigate a

shifting economic and political environment. Before joining Pennsylvania Bio in September 2009, Mr. Molineaux served as worldwide vice president of pharmaceutical communication and public affairs for Johnson & Johnson. He also previously served as vice president of public affairs at the Pharmaceutical Research and Manufacturers Association (PhRMA) and at the Blue Cross and Blue Shield Association. He was a public affairs executive for both the federal Departments of Health and Human Services (HHS) and Agriculture, and on the White House staff of President George H.W. Bush.

PREPARING FOR THE M&A EXIT

JENNIFER L. MILLER is a partner in the Business and Finance Department of Ballard Spahr LLP and Co-Chair of the Life Sciences/Technology Group. Ms. Miller, resident in the Philadelphia office, works with start-up, emerging and public companies, and those that invest in them. Her focus encompasses securities, corporate financing (public and private), strategic alliances, pharmaceutical and biotechnology licensing, technology transfer, mergers and acquisitions, general corporate law, and corporate governance.

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FIVE TIPS FOR AVOIDING LITIGATION

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DUE DILIGENCE: PRACTICAL ADVICE FOR WHAT TO EXPECT

By Barbara Bagnasacco, Partner, Ballard Spahr LLP, and Amy Underwood, former Associate, Ballard Spahr LLP

Demystifying/Due Diligence

Due diligence is a somewhat technical term that describes a strategic review of a company's operational financial, business, and legal documentation prior to executing a deal. You will encounter due diligence requests when initiating a number of transactions, from dealing with venture capitalists considering investing in your company, pharmaceutical or biotech companies considering whether to acquire your company or license its technology. During due diligence, you should expect a potential investor, acquirer or partner to investigate your company to assess its desirability, value and potential risks as an investment opportunity. The potential investor (or acquirer) will confirm the accuracy of the information you provided during this process in order to better understand the company and confirm its intention to enter into a business relationship.

This process typically involves an assessment of the company's intellectual property, finances, accounting records and legal contracts, as well as a employees, of discussions review management, visits to facilities, and review of other pertinent information. By conducting due diligence, potential investors (or acquirers) are ensuring that they understand the business in which they are investing (or buying). They also unearth any risks in the deal, identify any negotiating points and, in the context of an acquisition, plan a post-deal integration. process also plays a role in the rationale for key terms of the deal.

PRACTICE TIP: Advanced planning and preparation for the questions, demands and due diligence requirements of potential investors, acquirers or partners will help you distinguish your company from the rest. Making sure that your house is in order will demonstrate your seriousness and competence, and allow you to focus on the real issues and challenges that will arise during the process.

So, what can you do to make the due diligence process run smoothly when you have potential investors, acquirers or partners evaluating your company?

- 1. Formation and Organization. Organization is key early on in the formation of your company and can help facilitate the transaction in order to avoid some serious problems that could hinder your company's development down the road. This also saves money over time.
- 2. <u>IP-Centric</u>. Typically, due diligence of a life sciences company will be IP-centric, so it is essential to have your intellectual property in order. (See articles on "IP Due Diligence" and "Protecting Your IP From Conception to Exit: 'Hygiene" in Section IV of this book.)
- 3. <u>Know Your Material Agreements</u>. Certain provisions in key agreements such as assignment, termination and non-compete provisions can hinder a deal. Life sciences companies may have licenses with universities and other third parties

that contain such provisions. Know your rights with respect to your material agreements, including sublicensing provisions in any in-license agreements and right-of-first-refusal provisions in any out-license agreements and be prepared to address such provisions during this process.

- 4. Raise Problematic Issues Early in Diligence Process. Do not leave potential problems for investors (or acquirers) to uncover on their own. If it appears that the company was not up-front with certain information, this may affect potential investors' (or acquirers') confidence and trust in your company and whether they will enter into a transaction with you. In most cases, any potential issues raised during the due diligence process should not break the deal, but will be issues that are negotiated as terms of the agreement. You can help the process along by presenting a strategy for dealing with any less-than-favorable issues early.
- 5. <u>Be Knowledgeable About the Process.</u> Demonstrating some familiarity with the process

will allow you to appear more confident and sophisticated and to respond rapidly to potential partners' questions. Generally, there are two ways a potential investor (or acquirer) will perform diligence on your company:

Staged Approach. This is the type of diligence you will most likely see in a venture capital deal.

- This approach will start with a very high-level review of the technology, key intellectual property and the finances of the company, in which the investor (or acquirer) will try to identify obvious deal-killers.
- If no significant red flags are discovered during the high-level review, the diligence review will drill down deeper on all fronts.
- An advantage of the staged approach is that it may save money as it allows the investor (or acquirer) to discontinue the diligence process early if material issues are uncovered.
- Disadvantages of the staged approach include:
- Loss of credibility if the company's "skeleton" pops up later in the process.

o Time-consuming (due to the fact that the process is not as rigorous and may not uncover all of the offbalance sheet liabilities).

On-Site Visits. This is the type of diligence you will most likely see in an M&A transaction.

- The best on-site visits are conducted by a cross-functional team of financial, operational, technical and legal personnel at once.
- Each member of the cross-functional team looks at the target company from a different perspective.
- 6. <u>Continue to Operate Your Company</u>. Due diligence is time-consuming and a distraction. Be sure that your management team continues to focus on operating the business while responding to diligence requests. Assembling the right due diligence team within the company will help you minimize interruptions to the business and give you greater control over who has access to what information.
- 7. Familiarize Yourself with the Main Areas of Inquiry. It is helpful to look at your company from the perspective of a potential investor (or acquirer) prior to an actual due diligence review by an outside third party.

Main Topics of Due Diligence	Focus of Inquiry	Results Sought
Financial	Validation of historical information; review management and systems	Provide basis for valuation and confirm underlying profit; check systems and controls; assess tax liability
Intellectual Property	Validity, duration and protection of patents; freedom to operate; ability to exclude others	Expiration; impact; cost; restrictions on use; patentability
Legal	Contractual agreements; existing or potential litigation; issue spotting; equity structure; stock issuances; environmental or controlled-substances issues; employment or benefit issues; antitrust; FCPA	Warranties and indemnities; validating existing contacts; liens and encumbrances; right of first refusal in out-licenses; preemptive rights; capitalization tables; obligations and liabilities; subsidiaries and affiliates

Main Topics of Due Diligence	Focus of Inquiry	Results Sought
Commercial (dependent on stage of development)	Competitive position and commercial prospects	Input to valuation; cost of goods; supply agreements; reimbursement
Regulatory	FDA reports, presentations, IND or other submissions; regulatory audits; other potentially applicable regulations (e.g., controlled or radioactive substances, or other environmental hazards)	Questions/concerns raised by FDA or other authorities; problems with regulatory compliance; reimbursement and pricing issues
Safety and Efficacy Issues	Toxicology findings; preclinical and clinical data results	Issues with safety of potential products; efficacy concerns
CMC Issues	Manufacturing process, data and capabilities	Formulation Issues; stability; expected shelf-life

8. <u>Alternative Strategies</u>. Also remember to prepare a Plan B or alternative strategies for partnerships and collaborations should Plan A not

be feasible. A successful company should always be thinking about and working toward potential licensing, partnering and investing opportunities.

GETTING READY: PREPARING A DATA ROOM

By Matt Mezzancello, DataSite Director, Merrill Corp.

POSITIONING YOUR COMPANY FOR THE FUTURE

It is well-known that drug development and bringing a product to market are both time consuming and expensive. Success in the lab and innovation in the marketplace can easily consume 10-plus years and more than \$1 billion. As a result, the journey demands both great science and excellent information management.

Throughout development, internal and external parties are going to collect, analyze and then make very important decisions about the data they've amassed. These decisions will determine how the project will advance and who, besides the founders, will assist in bringing the drug to market.

During a progressive drug development cycle, as more parties become involved, effective information sharing becomes critical to the point where inefficient communication will become a major obstacle to progress. Because pre-clinical and clinical data are often paper-based, replicating and shipping paper content to investigators and stakeholders can pose security and logistical concerns, not to mention become costly and time-consuming.

Another key element to winning science is the development of a sustainable business plan. Companies considering capital fund-raising or other co-development activities for their product but have little experience with the markets are advised not to go it alone. Positioning for success means starting the process early and leveraging the experience of professionals who understand exit options and know how to take advantage of existing technology for maximum efficiency, cost avoidance and risk management.

The following pages provide a more detailed discussion of the critical factors in positioning a company for success that include:

- Critical factors to look for and activities generally included in a readiness assessment
- Common assumptions and potential mistakes, and how they can negatively impact a deal's outcome

- The role that technology can play in creating an efficient, inviting and cost-effective due diligence process for all parties
- Who should be on your team and how to select the right resources
- How to position the merger of company culture and human resources for a successful transition plan yielding a productive postmerger integration

Does your management team have negotiating, collaboration and joint venture experience? What preparation work must be completed and what resources will be required?

Considerations for Start-Ups When Negotiating Licenses, Collaborations and Joint Ventures

In today's highly competitive life sciences licensing environment, innovators need better and more efficient ways to protect their interests and respond to potential opportunities.

Life sciences companies of all shapes and sizes, both public and private, are looking for solutions that will streamline workflow, enhance the due diligence process, and provide uncompromised security to protect their intellectual property and lower risk, all within the context of addressing their specific business needs.

Conducting a readiness assessment is a best practice to organize and determine the steps necessary to bring companies or products to market.

Some key practice items include:

- Assessing the right time to go to market, given the company's sales and profitability trends, combined with market developments
- Preparation and validation of financial records
- Preparation of customer and market analyses
- Review and resolution of legal, operational, management and environmental issues
- Development of a summary of marketing and sales plans, including new business pipeline

A recent case study conducted by Merrill Corp. profiled an emerging biotech company. As the company took its new drug from proof of concept to development, it sought a global pharmaceutical firm to license and co-develop, and to improve on its commercialization efforts. The company attracted multiple interested parties for out-license projects, each of which undertook detailed due diligence. As part of this process, the company shared highly confidential clinical and operational information with each potential partner.

Challenge

According to the senior director of quality assurance at the biotech company, the importance of sharing critical information with potential partners is constantly checked against keeping it secure. "As with every biotechnology company, our intellectual property is the most valuable asset we own. Protecting it is worth a lot to us because we can't be in business without it."

In the last few years, virtual data rooms (VDRs) have emerged so information can be shared in a safe and virtual environment. One of the most time- and cost-saving benefits of VDRs is the ability for viewers to quickly search through documents for specific information. Licensing professionals rely on VDR technology to save time, minimize risk and gain more control over the due diligence processes. A VDR accelerates project velocity without compromising growth opportunities.

VDR Benefits:

Streamline the due diligence process and accelerate transactions

- Present the company as an attractive potential partner
- Allow you to reach more potential licensors and licensees simultaneously
- Achieve better deal negotiations and alliance management

Due Diligence: Practical Advice for What to Expect

For starters, be prepared for a full and thorough disclosure process. Experts acknowledge that spending more time on due diligence preparation will greatly improve the outcome of success. Innovators are encouraged to organize and share more due diligence material because any perception of nondisclosure may cause partners, buyers or potential stakeholders to reconsider, withdraw support, or even increase the cost of capital or cost of financing.

The due diligence process is best managed by providing full disclosure in "as transparent and efficient a manner as possible." Letting buyers "discover" issues on their own is invariably the wrong approach; this may cause them to wonder what else they may have missed in their diligence. Unexpected turns can result in renegotiation, lower valuation or the buyer's or lender's complete withdrawal from the deal.

The early organization of due diligence materials in an online data repository well prepares a company for a range of opportunistic events, enabling total control and proper presentation of all information. By implementing a data site early in the process, the company can create a firmwide culture of preparedness, routinely updating and adding to its due diligence information repository. From an operations perspective, the gathering and sharing of information also become a strategic advantage, as an organized company will know more about itself and know it sooner.

Seek professional advice. For certain innovators or companies, it is not unusual for founders, executives or owners to self-manage the project. However, a "go-it-alone" strategy may involve unnecessary risk. With a false sense of security in their own deal-making capabilities, company executives can be blindsided by the nuances and specialization required in licensing, M&A or capital-raising transactions. When considering self-management, one should objectively analyze capabilities, resources and risk.

Invite multiple buyers to drive up valuation.

Traditionally, auctions or multipartner processes have been more difficult to achieve in a paper-based due diligence environment. Paper, by its very nature, limits multibuyer participation and the ability to effectively negotiate concurrently on several concurrent fronts. However, in a secure virtual data room, multiple buyers can all review the same electronic documents from anywhere in the world at the same time.

Accelerate due diligence review. Since prospective buyers conveniently log in to a secure Web browser, scheduled visits to physical data rooms are no longer necessary. Accordingly, the entire process occurs more quickly, and either completely eliminates or greatly reduces travel time and expense and all other related costs.

Respond rapidly to buyers' questions. Most VDRs provide discreet, community-based Q&A forums for potential buyers to ask questions and view responses. This secure environment in which sellers can quickly and efficiently share confidential information helps reduce the time-consuming process of responding to individual emails. You can easily view, group and categorize questions, as well as tailor your responses according to the level of security assigned to each group.

Identify the best buyer for the deal. VDRs provide real-time tracking information that empowers innovators and sellers to more closely assess the quality and value of invited guests. A VDR can monitor the viewing, downloading and printing activities to help sellers understand interest and thoroughness of review. Real-time tracking is an invaluable intelligence tool to identify the most interested and best potential partners.

How to Position Yourself for a Deal with Big Pharma M&A

There is a tendency for sellers who are presenting their own company to package it according to their own perspective, rather than through the eyes of the buyer. This may result in focusing on the seller's interests, rather than on the buyer's. As a result, objectivity is frequently lost and, along with it, the opportunity to realize maximum value from interested buyers. Key objectives to pursue include:

• Identify the right buyers. Sellers have a tendency to home in on one buyer or group of buyers, leaving them to overlook other potential partners and, as a result, miss opportunities to land a better deal. An objective third party, such as a health care investment banker, will have knowledge of,

and access to, a broader range of buyers. Equally important, they will also better understand how to customize the approach to each party to ensure the maximum chance of success.

- Design and sustain a competitive process. M&A deals are highly specialized transactions, characterized by distinctive nomenclature and negotiating behaviors that, unless recognized, can lower a valuation for sellers who are new to the process. Worse still is when the deal unexpectedly turns in the wrong direction and concludes without satisfaction. M&A experts have the necessary experience to read the situation and help keep the deal on track, keeping multiple parties interested by creating and levering the inherent competitiveness of the bidders.
- Drive the best valuation ensuring a successful closing. Sellers need to ask themselves if they can get the deal done quickly and achieve maximum results. If so, they need to have the experience to deal with all the intangibles that go into a successful deal in the midst of a risk-averse market.

Sellers need experienced counsel to:

- Mitigate potential future issues before they result in negative consequences.
- Avoid finding themselves in trying situations.
- Have other options ready to be able to deal quickly with the obstacles that might arise.

Failure to account for the factors mentioned above is likely to have serious and damaging consequences to a deal's outcome. To drive the best results, including the highest valuation, draw on the experience and knowledge of professional experts. Establish the right team to develop an M&A strategy and decide who best should be on the M&A team. Sellers, after assessing their management team's M&A experience, may consider the following resources:

Health care banker. A health care banking firm can provide financial advisory services on mergers and acquisitions, capital allocation and divestitures. From start to finish, these critical resources help sellers refine their strategy, identify the target audience of buyers, and execute the deal by assisting in the negotiation process. Keep in

mind that such firms vary widely in terms of services and areas of expertise. Choose a team with proven experience and an established record of success of working within the biotech industry. A group with the right skill set is likely to bring your deal to market most effectively.

Venture capital firm. A venture capitalist (also known as a VC) or an investment firm will bring managerial and technical expertise as well as capital to its investments. These firms typically comprise small teams with technology backgrounds (scientists, researchers) or those with business training and/or deep industry experience.

Leverage technology. It is recommended that you and your health care banker or your selected VC use a VDR to help you bring your deal to market faster and more efficiently. A virtual data room, or "datasite," streamlines the due diligence process by transforming the traditional paper data room into an online or "virtual" data room. By managing the process in a secure, online data room, deal makers are able to do away with most of the traditional, paper-laden processes and their intrinsic limitations.

Companies that regularly use virtual data rooms to manage their M&A activities cite many benefits for both buyers and sellers, as they provide:

- Strategic platform for asset readiness
- Reduced deal costs while supporting corporate environmental sustainability goals
- An efficient and secure platform for sharing your deal information with authorized parties
- Greater control over who has access to what information. User privileges can be assigned for viewing, printing and downloading
- Intelligence regarding user activity
- Reduced quantities of critical business documents and the elimination of producing copies of additional documents on CDs or DVDs

When using a virtual data room, clerical, staffing and other inherent costs associated with hosting a physical paper room are eliminated. A VDR's convenient Web accessibility means that travel time is either eliminated or significantly reduced – extensively diminishing the costs and carbon emissions associated with business travel.

A VDR makes it easier to respond to potential partners and share information while keeping it protected. Documents are easily uploaded into a secure, centralized online document repository, where invited parties log in to conduct due diligence in accordance with the permission levels established by the seller. Real-time reports list exactly who reviewed which documents, when and for how long. Access is unlimited for all users worldwide, including Q&A functionality, and notifications of new documents are sent to users as they are added.

Keep in mind that good organization and complete information in the VDR are critical. Cataloging each document according to an intuitive index will also greatly speed the diligence process. On the other hand, multidocument pdfs that are missing signature pages or exhibits will only slow down the process, frustrate those doing the diligence and drive up costs.

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BIG PHARMA DEALS: STRATEGIC ALLIANCES, CORPORATE COLLABORATIONS, OPTIONS, CO-PROMOTIONS & ACQUISITIONS

By Jennifer L. Miller, Co-Chair, Life Sciences/Technology Group, and Gregory L. Seltzer, Associate, Ballard Spahr LLP

With ever-increasing frequency, young companies (and their investors) are looking to large pharmaceutical companies to provide non-dilutive financing to further develop their product, provide an exit to investors, or both. Pharma," of course, includes the truly global companies (such as GSK, Merck and Pfizer) but has evolved to include medium-size and emerging pharmaceutical companies (such as Shire, Teva and Endo) as well as the big, revenue-producing biotechnology companies (such as Genentech, Amgen and Cephalon). The following discusses many of the key considerations in Big Pharma Deals, the various creative and evolving structures for such deals, and some tips about negotiating the deals. (See the article "Strategic Alliances" in Section VI of this book.)

Why do a Big Pharma Deal for the development or commercialization of your product?

- To fund or partially fund the further development of the product
- To leverage, and learn from, the expertise of the other party – whether that expertise is in development, clinical, regulatory, reimbursement, manufacturing, delivery, commercialization, or all of the above
- To gain validation for the product, the management team, and/or the company in order to attract capital or other partners for other fields or products in the pipeline
- To provide an exit to current investors, by facilitating a future sale of the company to the collaborator

What should a company look for when selecting a corporate partner in a Big Pharma Deal?

- Capabilities of the potential partner, such as the tangible/intangible assets making it possible and probable the partner will develop, manufacture and sell the product
- Whether there is an internal champion at the potential party for the project who has the desire, ability and authority to deploy resources such as personnel, capital and assets to the advancement of the product
- The strategic plan of the potential partner and how the product fits with this plan and with the partner's pipeline
- Competitive considerations for each of the potential partners, the product, and other solutions to the product's target indication
- Potential partner's public image, culture and the environment and history it brings to the relationship

PRACTICE TIP: Be sure to do your due diligence of the potential partner ... the Big Pharma will control the destiny of your product.

What are some of the structures for Big Pharma Deals?

- Straight license
- Strategic alliance or corporate collaboration
- Joint venture
- Option to obtain exclusive license or to acquire the company
- Co-promotion or co-development deals (can be a component of the above)

What should a company expect in a straight license?

- A typical license is a deal between a licensor (your life sciences company) and licensee (the Big Pharma company) in which licensor grants licensee rights to intellectual property but retains ownership.
- Typically, the deal is structured as an exclusive license to Big Pharma, in return for an upfront fee, milestone payments and royalties on product sales.
- Licensee will typically acquire total control over the licensed technology and product, including development, regulatory and sale of product.
- All other structures include some form of license as part of the overall structure. Usually when there is a straight license, there is very little interaction expected between the parties other than payment of fees once the license is in place.

What is a strategic alliance or corporate collaboration?

- A strategic alliance is a relationship between two or more companies with the intent of accomplishing mutually compatible strategic goals that could be difficult for each to accomplish alone.
- More specifically, a corporate collaboration (also referred to as corporate partnering) is a strategic alliance where the earlier stage, smaller company has a technology and product that is attractive to the Big Pharma as a future potential product for its product pipeline, and the two companies come together to further develop the product, gain approval and then commercialize it while agreeing to share the costs, risks and (hopefully) profits.
- The Pros: Validation of the company's technology; cash for development funding; access to expertise, including clinical and regulatory expertise; path to commercialization; retention of and collaborative input on future of product.
- The Cons: Essentially sell future value at current deal price; Big Pharma will make

virtually all decisions if parties do not agree (cash is king), thus it places the destiny of your product in the control of Big Pharma. It is difficult for the company to terminate the contract and relationship.

What is a joint venture?

• Essentially a joint venture is a strategic alliance or corporate collaboration where the parties form a new entity into which the two parties transfer assets (for example, the technology or product and cash) to allow for the newly formed entity (the "joint venture") to develop and commercialize the product.

PRACTICE TIP: Be sure to understand the corporate governance aspects of the new entity and the tax impact of the joint venture structure.

What is an option to obtain an exclusive license or to acquire the company?

- In this structure, the Big Pharma company is seeking to remove risk by paying a smaller amount of money to help the company reach its next (usually a critical) milestone and to obtain an exclusive right to decide to take the license or buy the whole company at a predetermined price once the milestone is met and further data are available.
- The Pros: The company receives non-dilutive funding to reach the next milestone technical validation and a potential path to exit or commercialization. If the Big Pharma does not exercise the option, the company is free to find further financing or another partner or acquirer, having increased the value of the company.
- The Cons: The company is bearing the risk that the milestone is not achieved (there is no Big Pharma already committed); if Big Pharma does not exercise the option, no matter what the outcome with regard to the milestone, the company and its product may look like "damaged goods."
- Elements of an option deal:

- o The option permits the potential licensee to view additional data prior to exercising its option.
- o The potential licensee pays a nonrefundable up-front fee.
- o The parties fully negotiate the exclusive license agreement (or purchase agreement) at the time of the first up-front payment by the potential licensee (usually the date the partners execute the option agreement).
- o Upon achieving the milestone (usually receiving positive data), the optionee decides whether to exercise its option to cause the license agreement (or purchase agreement) to become immediately effective.
- o Such license agreement (or purchase agreement) typically provides for an additional lump-sum payment, milestone payments and royalties on sales of the product.

PRACTICE TIP: Co-development deals do not need to be 50/50 and can be changed at a party's option. Negotiate for a "development holiday" where Big Pharma pays more than 50% of costs or pays for costs through a milestone, such as Phase II, which adjusts the split upward for Big Pharma. Consider a royalty on top of profit split in exchange for smaller share to help reduce risk to company.

What is a co-development, 50/50, or co-promote deal?

Co-Development

- In a co-development deal (sometimes called a 50/50 deal), all development costs are shared and profits are split. This structure began as a 50/50 split on each, but deals have been done with differing splits. This structure often comes with more equal power in governance and decision-making.
- It is often an aspect of an otherwise traditional collaboration, sometimes in the form of an option on the company's part.
- The Pros: Smaller bioscience partner has the opportunity to retain some control.
- The Cons: Sharing the cost of late-stage development through product commercialization can be a high-risk

- proposition for a small, financially strapped company.
- In this structure, the company will actively participate in the project and retain equal control over critical development decisions, including where clinical trials will be conducted, the scope of the trials, who will provide clinical supply material, and who will take the lead in interacting with the regulatory agencies.
- Equal control can lead to deadlock. It is best to negotiate upfront what will happen if the parties do not agree.

Co-Promote

- The parties agree to jointly commercialize the product upon approval. It could be a 50/50 deal with equal costs and responsibilities, could be an indication split (see below), could be detailing split between specialists and generalists or geographically. Usually it includes a joint commercialization committee that sets, coordinates and monitors the parties' promotion responsibilities.
- The company can negotiate for the right, either an up-front right and obligation or an option for same, to participate in the marketing and promotion of its drug product in the market.

PRACTICE TIP: It is critical that the company understand the costs, responsibilities and risks it is assuming in a co-promote. The company takes more risk that can result in more costs, distraction and capital/infrastructure investment for less overall return. Building a sales force and marketing team, as well as branding a product, can cost millions of dollars before any product sales revenue.

Retain co-promote rights as an option, rather than firm commitment.

If concerned about availability of cash to fund 50% of development or commercialization costs, consider building in the right to seek financing, on reasonable terms, from your partner.

• Big Pharma typically has final say on issues of commercialization.

What are the goals in drafting a Big Pharma alliance agreement?

- To create a framework that fosters a longlasting relationship with room for growth and modification
- To take advantage of synergies and accomplish mutual goals
- To create an agreement that can deal with unforeseen obstacles arising over the course of the relationship

What kinds of terms should I expect to see in Big Pharma Deals?

<u>Field and Territory Restrictions</u> <u>and Split Indication Option</u>

- Field restriction is a limitation to the rights granted under the license that carves out certain uses of the technology or product. For example, the field could be "for use in animals and not humans" or "for the treatment of pancreatic cancer." If the license grant has a field restriction as in the first example, then the licensee could not use the technology in humans, and the licensor could grant a license to another company for use of the technology or product in humans.
- Territory restriction is a limitation on where the licensee can market and sell the product.
- Split indication options are similar to a field restriction in that they will provide exclusive license right to licensee to develop and promote in one or more select indication(s) while reserving indications for the licensor or for a different licensee. Sometimes a split indication includes the following additional terms:
 - Development and commercialization costs funded by licensor
 - Development plan subject to Big Pharma approval

PRACTICE TIP: To improve a split indication arrangement provide buy-in options for licensee at Phase II and Phase III

- Licensor promotes exclusively in certain defined indication(s)
- Licensee distributes and books all sales

Milestones

- Milestones are lump-sum payments that are made by the licensee upon achievement of development milestones that are generally viewed as a value creation event. They are fairly typical in a license context and can be used to increase the value paid to the licensor if the licensee does not want to pay a higher value for the product or technology until such milestone(s) are met.
- Typical examples include both regulatory and sales milestones: completion of certain preclinical studies or filing of an IND; commencement of certain phase(s) of clinical trials; regulatory approval; first commercial sale or achievement of certain sales targets.
- On occasion one or more milestones are tied to certain critical issues specifically related to the product itself. For example, successful scale-up of the manufacturing process for a technology with sticky manufacturing issues, securing a viable delivery method for a product without a commercially viable way of delivering to the patient, or obtaining reimbursement codes for a wholly new therapy that the licensee worries will not achieve reimbursement.

Terms to Mitigate Risk

• Much of the negotiation of the document is about shifting and mitigating risk. Representations and warranties are the perfect example of shifting risk. For example, if the licensor represents that the technology being licensed does not infringe on anyone else's intellectual property, then the licensor must pay for damages of a third party complaining that the sale of products by the licensee infringes that third party's IP. Thus, the risk of infringement was shifted entirely to the licensor.

Company perspective:

• Strong "diligence" provisions designed to ensure that the Big Pharma will work diligently to develop the product to approval and maximize sales once approved. In the negative, it is mitigating the risk that Big Pharma will shelve the technology – meaning not work on developing the technology and not let others work on developing it.

- Set up joint steering committees with strong input from the company's representatives.
 This will allow the company to keep its hand in the further development, testing, approval and commercialization of its technology.
- Align consideration with sales milestone targets
- Retain control, or retain notice and approval rights, of patent prosecution and any patent litigation

Big Pharma perspective:

- Detailed and strong representations and warranties
- Earn-outs and contingent value rights. Milestone payments are one example of this
- Retain final decision and control rights with regard to steering committees and development and commercialization strategy
- Obtain sole control of patent prosecution and any patent litigation

Limitations on Rights to be Granted

- The licensor can limit the rights to be granted to Big Pharma for any number of reasons, including: disagreement on value for the entire bundle of rights; the company's desire to exploit the intellectual property for other uses or indications or in other populations; or the licensee does not have the right development or commercialization muscle in certain territories.
- Limit the field of use (see field restrictions and split indications above)
- Narrow the definition of the licensed product
- Remove improvements or second-generation products from the definitions
- Limit the territory of use (be wary of antitrust issues in the United States and in the European Union)
- Retain certain rights (clinical use, research or manufacture)

Terms That Foster Long-Lasting and Fruitful Relationships

 Regular and comprehensive reporting requirements and frequent in-person joint

- meetings; promotes transparency and personal relationships
- Clearly defined roles and functions of the parties and the joint committees
- Process for handling situations where the parties do not agree, such as mandatory discussions between the parties that escalate to upper management
- Terms that allow for changing circumstances and thus changing strategy and work plans

Termination of the Relationship

History tells us that most alliance relationships do not last. The reason for termination can be very benign and natural or can be the result of a nasty dispute. Ensure strong and tight termination provisions.

- Clear terms regarding how the relationship can be unwound are a must.
- Who can terminate and under what circumstances?
- What kind of notice and cure periods are allowed?
- What are the consequences, which can vary depending on the reason and the "guilty" party? For example, if the company (licensor) breaches the agreement, termination of the license will likely cause additional harm to Big Pharma (licensee).
- What happens to the intellectual property and data?
- What happens to improvements to the IP or new joint ventures during the relationship?

Change in Control

- Big Pharma will be concerned about future acquisitions of a company in which it contemplates entering into an exclusive license agreement. If that company is acquired, the Big Pharma could find itself dealing with a competitor. On the other hand, if the Big Pharma has a change in control, the technology could sit on the shelf.
- Consequently, change-of-control provisions are usually negotiated heavily.

When Might a Collaboration Become an Acquisition?

- The size or value of the company or the number of its shareholders may lead Big Pharma to buy rather rent.
- Cash-starved company unable to raise capital through equity offering may have to sell to Big Pharma or enter into a corporate partner licensee.
- Macroeconomic environment may drive down valuations and limit availability of investment, encouraging sale instead of license deals.
- Future Milestone Event On the eve or shortly after reaching a critical milestone, the Big Pharma licensee may want to buy the

asset outright rather than continue to pay fees on a license.

When Might a Collaboration Exclude Potential Acquirers?

- A company out-licenses or corporate partners with multiple complicates an M&A deal
- Consider the effect of a change of control on the collaboration – if Big Pharma licensee can veto a change of control
- Pay attention to specific provisions that would be unacceptable to an acquirer
- Assignment limitations or approvals

PRACTICE TIP: How to Limit a Change of Control:

- Limit to certain competitors (with a similar product; not every change of control would have negative consequences on the collaboration)
- Limit to companies of a certain size measured by sales or market cap
- Time limitation

Steps in Big Pharma Deal - At a Glance

Preparation	Engage Parties	Due Diligence	Negotiation	Execution
Internal buy in Develop financial model Identify potential partners Prepare CDA Prepare diligence materials in virtual data room or on thumb drives Prepare the confidential presentation	 Execute CDA with interested parties Deliver confidential presentation Initial discussion of terms Additional data exchange Draft term sheet 	Establish timeline for completion Provide access to virtual document room or provide thumb drives Initiate the drafting of definitive agreement Perform diligence on licensee or partner	Draft agreement Multiple face-to-face negotiations Accounting and tax review Develop the collaborative relationship now	Board of Directors presentation on deal terms and conditions Partner governance approval on deal (if needed) Establish committee members (if collaboration) Plan your first post close meeting (if collaboration)

STRATEGIC ALLIANCES

By Christopher P. Molineaux, President of Pennsylvania Bio

In the increasingly complex and highly regulated life sciences industry, a growing number of leaders are creating strategic alliances to enhance their company's growth and likelihood of success. Strategic alliances are partnerships between organizations with mutual interests through which they leverage their collective resources and/or expertise toward accomplishing a common goal. Strategic alliances come in many forms – from formal partnerships and joint ventures to informal relationships that arise when two organizations are faced with a common threat.

Alliances are formed for many reasons, including, but not limited to, technology transfer, clinical development, manufacturing and supply chain expertise, and marketing and sales. The common thread is a desire by the alliance partners to take advantage of complementary skill sets to make the sum of the organizations' competencies more

effective than if one organization were to attempt to build the competency organically from within.

Strategic alliances can be beneficial at all phases of a life sciences company lifecycle. While the needs of the organizations will change, if the alliance partners maintain their mutual objectives, the alliance will continue to strengthen over time.

Strategic Alliances at All Stages

Strategic alliances take on different meanings for life sciences companies, often defined by the current stage of a company's life cycle. The needs of companies in the seed or growth stages often are not relevant for companies at a small or large cap stage. However, there is a common denominator for life sciences companies at all stages that use strategic alliances: the need for partnerships to help advance business goals and strategies.

Possible Strategic Alliance Partners Based On Stage

Stage of Company	Need	Possible Strategic Alliance Partners
Seed Stage	Financing	Venture capital firm(s); angel investor(s); venture arms of large pharmaceutical companies
	Scientific and business guidance	Scientific experts in your field or a related field; management/business experts who can guide you as you develop your strategic plan, annual business plan and company "story"; specialty consultants and professional advisers
	Strategic connections	Trade associations that can connect you with resources and offer the benefits of group purchasing clout with suppliers and other service organizations
Growth Stage	Financing	Venture capital firm(s); institutional investors; private equity investors; business partners
	Management resources and best practices	Business partners

Stage of Company	Need	Possible Strategic Alliance Partners
	Scientific, business and regulatory guidance	Specialty consultants and professional advisers
	Talent	Business partners; local workforce investment organizations; local economic development organizations
Small- to Mid-Cap Stage	Financing	Investment bankers; institutional investors; private investors; business partners
	Talent	Business partners; executive recruiting agencies
Large-Cap Stage	Financing	Wall Street; private investors; institutional investors
	Marketing & Sales	Co-promotion partners; patient groups; trade associations

Types of Strategic Alliances

Strategic alliances are developed for myriad reasons and to address needs ranging from filling scientific and business expertise gaps to leveraging distribution, supply chain and sales & marketing resources, and influencing reimbursement or public policy decisions. Alliances are generally categorized in two areas: business alliances and advocacy alliance development.

Business Alliances

Business operation alliances can take various forms, from joint ventures to global alliances, and determining the right type of alliance is critical for your corporation's success. Before determining the type and entering into any business-based alliance, it is essential that your organization takes the necessary time to conduct due diligence into potential partners, examining all details, including successes and/or failures of past partnerships. We'll explore strategic alliance due diligence further a little later in this chapter.

Below we briefly examine the various forms of business alliances.

Joint Venture. Joint venture alliances involve two or more partners establishing an independent organization to develop and execute a strategic plan to advance a program, product or other strategic initiative. While the joint venture may carry the name of one or all of the partners, its financials are kept separate from those of the "parents," or founding partners.

Equity Alliance. Equity alliances often are formed by partner organizations that bring different, complementary capabilities to the strategic alliance. The partners agree on a percentage-based ownership structure according to the value of their respective contributions to the enterprise.

Non-Equity Alliance. Non-equity alliances may or may not involve the creation of an independent organization, but are similar to equity alliances as the partners contribute unique competencies in partnership to create a competitive advantage during the development and/or commercialization of an asset or product.

Global Alliance. A global alliance is a contractual agreement among partners – sometimes multiple partners – to take advantage of scientific expertise or geographic reach. Global alliances are most frequently seen when a smaller, geographically bound company expands into markets outside its geographic sphere, utilizing the resources of partners who share a technology or strategic interest in a therapeutic area. Global alliances can help a small company obtain international reach relatively quickly, but can become contentious if

the terms are not crystal clear, and as the smaller company expands its own capabilities.

Advocacy Alliance Development

As with business alliances, advocacy alliances can take various forms based on desired outcomes and targeted parties. Similar to business-based alliances, thorough due diligence of potential partners is crucial, examining all aspects of the organizations to determine if a successful partnership is possible.

Below we briefly examine the various forms of Advocacy Alliances.

Patient Group Alliance. Life sciences companies are in the unique position of potentially changing the course of human disease. There are numerous patient-related groups waiting for our companies to discover and deliver the next innovation for their unmet medical needs. Some are diseasespecific, such as the Arthritis Foundation or Komen Foundation for breast cancer; others are broader in scope, such as the National Organization for Rare Diseases. These patient organizations can provide funding for certain types of research and, in the longrun, can become important allies as your company reaches commercialization and is seeking commercial or government reimbursement for your product.

Physician Group Alliance. Physician-based organizations - often referred to as "Colleges" or "Academies" – are critically important allies as you develop your product. Individual, "key opinion leader" physicians can provide helpful insight into your technology, become important advocates with their colleagues for utilization of your product, and bring scientific credentials to your company presentation as you attract investors. Moreover, physician groups can help your organization better understand market and potential user issues associated with your product, to help hone the design and ensure data collection that will be helpful for practitioner adoption. In this respect, physician allies can help identify and address "blind spots" as you sharpen your product and approach to commercialization. Finally, as with patient groups, a strong alliance with the physician community in your therapeutic area can provide powerful testimonial when seeking approval for your product and, ultimately, reimbursement from commercial or government payers.

Third Party Organizations. When considering strategic alliances, it's important to examine your own company holistically and consider which organizations share your goals and principles – even if they are not focused exclusively on the life sciences. Formal and informal alliances with these organizations can prove beneficial – in fact, essential – as public policy is shaped in the legislatures or regulatory agencies that affect our industry.

EXAMPLE: The Pharmaceutical Research & Manufacturers of America (PhRMA) partnered with the Motion Picture Association of America during congressional debate over a particularly onerous piece of federal legislation related to intellectual property. Two of Washington's most powerful, but seemingly unrelated, industry organizations came together in a successful alliance to defeat the legislative threat.

Advocacy organizations have been created to protect intellectual property rights, international trade, regulatory oversight and many other issues that may not immediately appear relevant to your start-up business. But it is often said that when you find yourself needing a friend to battle dangerous legislation or regulation...it's probably too late.

Attributes of Successful Partnerships

Attorneys and business development experts can craft airtight contractual agreements between partners in a strategic alliance (see also "Big Pharma Deals" in Section VI of this book), yet alliances often fail because of "intangibles" discovered during the course of the relationship. Clearly, the partners in a strategic alliance must share goals and desired outcomes. Strong strategic alliances are formed when the partners also recognize the experience and expertise being brought to the alliance by all parties — and all parties are seen as equal partners. Most important: The partnership is internalized by the partner organizations as a strategic priority, not simply a transaction.

Other attributes essential to a successful alliance:

- Compatibility of corporate cultures of the partner organizations
- Challenging, yet realistic, objectives

- A high-caliber implementation team
- Willingness to address major issues and align behind strategy and final decisions
- Agreement on rewards and recognition

- Compatible work ethic
- Transparent and frequent communication
- Trust

REASONS FOR A LIFE SCIENCES COMPANY TO ENTER A STRATEGIC ALLIANCE

Achieve scale, scope and speed
Maximize leverage, minimize risk
Bring more minds to the project
Avoid regulatory pitfalls through the experience of others who have "been there"
Enhance product development and clinical supply
Enhance market reach

Develop relationships of mutual interest to successfully conquer future challenges

Stages of Forming an Alliance

You have identified the need for alliance partners to support components of your organization's strategic plan. Now you are prepared to reach out to potential partners to establish or formalize relationships. While establishing an alliance can turn out to be simple or complex, there are six general stages of forming and managing an alliance:

Research and due diligence on potential partners. This stage is where you initially identify potential partners before directly engaging them. research and due diligence should give you an indication of how your potential partner will perform in key areas and what additional benefit you can gain from the partnership. Is it scientific know-how you are seeking? What are the credentials and successes of the scientific leadership of the organization? Manufacturing? Distribution? What are the relevant measures of the partner organization's success? Also, what kind of reputation does it have with its existing partners and customers? While you may feel its expertise is more important than its reputation, remember, you may be judged by the company you keep. The research and due diligence stage is your opportunity to assess your potential partner's strengths and weaknesses and determine approaches to address the gaps.

Development of the alliance strategy. Strategy development is crucial to determining the

direction of the partnership and can also shed light on your partner's priorities, motives and management style. Take this stage of alliance formation to establish clear objectives as well as a game plan for technological, financial and personnel resources.

Alliance partner assessment. During this stage, each party assesses its potential partner's strengths and weaknesses and develops an approach to ensuring there is alignment once the work of the alliance begins. Transparency and candor are crucial during this stage of developing your alliance. There should be no surprises or mismanaged expectations after a thorough and honest assessment.

Contract negotiations. The contract negotiation is the time in your alliance formation to structure the alliance in ways that meet your business and strategic objectives. Define the objectives; define the responsibilities of each party; protect your intellectual property; establish the ground rules for the alliance business operations, including actions or results that would cause termination of the alliance. (See also "Big Pharma Deals" in Section VI of this book.)

It's important to note that, in addition to these and other technical elements of your contract negotiation, the discourse can also reveal a great deal about your potential partner. The discussions may be challenging, but are your partner's objectives and apparent motives still aligned with yours? Negotiations at this stage can bring the alliance closer together...or they can reveal insurmountable divisive issues.

Alliance operation. Directing and managing the operations of the alliance should align with the day-to-day operations of the party organizations. Objectives should be clear and measurable; resources of the two partner organizations should be applied as needed; senior management should provide constructive, substantive critique; and support and performance should be tracked, measured and rewarded appropriately. Possibly most important, communication between the partners should be thorough, candid and frequent.

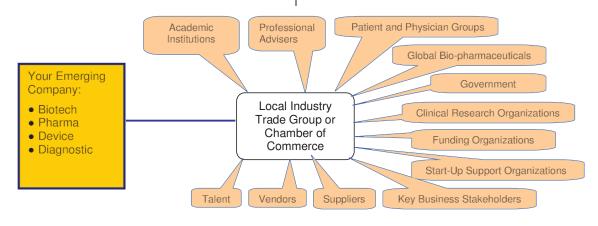
Terminating the alliance. The eventual termination of an alliance is almost inevitable. Technology and expertise change and grow over time; company strategies adapt; and, in the case of many life sciences companies, licensing and/or acquisition deals can change the control of one of the partner organizations. With truly successful alliances,

termination comes when the objectives have been met or when the expertise of the parties outgrows the need to maintain the partnership. The architects and managers of an alliance need to be prepared for its termination...and be able to recognize when the time has come to wind down operations.

<u>Utilizing Resources for Successful Outcomes</u>

As you consider the needs of your organization, recognize that there are many business-related trade groups that provide guidance and strategic connections into potential partner organizations. Life sciences trade associations, chambers of commerce, universities and other organizations in your region have the express mission of introducing you and your organization or technology to other interested stakeholders.

If you consider your company as the center of your business hub-and-spoke model, use these resources to gain access and warm introductions to meet your partnering needs.



Conclusion

For a start-up company in any industry, strategic alliances offer a way to accelerate growth by taking advantage of the experience, talent, resources and reach of other organizations. Executed properly, a strategic alliance allows all parties to grow their businesses through a network of others, while maintaining their individuality. In the complex world of a life sciences start-up, strategic alliances can provide access to scientific, clinical and regulatory expertise, allowing your business to utilize a larger number of skilled people working on the same project. This can expand your business more rapidly by bringing more creativity and solutions.

Alliances can provide manufacturing and supply chain networks and the opportunity to learn from the successes and failures of others. And alliances can provide partnerships for co-promotion activity, advocacy support and expansion into new markets.

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PREPARING FOR THE M&A EXIT

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While there are several exit strategies a company can pursue, this article focuses on mergers and acquisitions. Another potential exit strategy includes an initial public offering, but, in today's market, that is by far the minority approach.

Preparations for a company's exit strategy begin well before the company's actual exit. This article focuses first on issues that a company should be mindful of from the time it commences operations; second, on issues that the company should consider when it has decided that it is time to pursue an exit; and finally, on preliminary deal term considerations. (For the definitions of certain terms used in this article, please refer to the Glossary in Section VII of this book.)

Preparing for an Exit Before It's Time to Go

There are several things that a company does early in its life cycle that will impact its ability to sell down the line. From the very beginning of a company's life, management should ensure that all corporate documents, the capitalization table, contracts, and documents related to the company's intellectual property are complete, organized and accessible.

Companies should have standardized processes to ensure that documents are executed, collected and stored in an organized manner. (See also, "Protecting Your IP From Conception to Exit: 'Hygiene'" and "Common Mistakes In IP Agreements' in Section IV of this book and "Due Diligence: Practice Advice For What To Expect' and "Getting Ready: Preparing a Data Room" in Section VI of this book.)

Contractual Provisions

As part of their ordinary business, companies enter into contracts that have provisions that may one day have an impact on their ability to enter into an exit transaction in the future. These "problematic" provisions include change in control, anti-assignability, noncompetition, rights of first negotiations or refusal and exclusivity.

Change-in-control Provisions

Change-in-control provisions typically make a change in control either an event of default or

require the counterparty's prior written consent. In either case, the company would need to negotiate an amendment to the contract, obtain a waiver or a consent or terminate the contract prior to consummating the sale transaction. This can be time-consuming depending and, relationship between the parties, the company would likely be in a weakened negotiating position with the counterparty. In extraordinary cases, a company may need to pay a sum of money to compel consent. Change-in-control provisions could be implicated in a merger, stock sale or asset sale, as definitions of "change-in-control" are usually broadly drafted to include significant changes in the holders of the company's stock, change in the membership of the Board of Directors, and the sale of substantially all of the company's assets or the assets related to the contract.

From the very beginning of a company's life, management should ensure that all corporate documents, the capitalization table, contracts, and documents related to the company's intellectual property are organized and accessible.

In some cases, employment agreements have provisions that could impact a change in control. For example, many employment agreements contain provisions that would entitle the executive to receive additional compensation either (1) upon the change in control or (2) if he or she is terminated within some period of time before or after the change in control. These provisions can impact negotiations in several ways. potential acquirer may be unwilling to pay these bonuses, which can be fairly large. Second, if the bonus is payable upon the change in control (as opposed to only if the executive is terminated as a result of the change in control), the executive may not have an incentive to continue with the company after the merger, which can be problematic if the acquirer is hoping to keep the management team intact.

Anti-Assignability Provisions

Anti-assignability provisions typically prohibit the company from assigning the contract to a third party. As with change-in-control provisions, these clauses would require the company to negotiate an amendment, obtain a consent or waiver, or terminate the contract prior to consummating the sale transaction. These provisions are typically implicated in an asset sale, but can, depending on the language and how the transaction is structured, be implicated in a merger as well. Companies can limit the impact of an antiassignment provision by carving out assignments to any successor to the company in a change-incontrol transaction. This would still prohibit the company from assigning the contract to an unrelated third party, but not interfere with the company's ability to enter into an exit transaction. The anti-assignment clause of a collaboration agreement can effectively foreclose an exit transaction with any party other than the collaborator if care is not taken during the negotiation of the collaboration agreement.

Because time and momentum are frequently of the essence in exit transactions, a company would be well prepared by having all of its due diligence organized before investment bankers begin marketing the company for sale.

Noncompetition and Exclusivity Provisions

Noncompetition provisions generally restrict the company's ability to conduct its business in certain geographical areas or certain industries or fields. Exclusivity provisions generally restrict the company from doing business with other third parties in certain geographical areas. These restrictions can be problematic for certain buyers. First, the buyer may have agreements in place prior to acquiring the company that would violate the company's existing noncompetition or exclusivity agreements. Alternatively, the company may not be as attractive to the buyer with such restrictions in place and could result in a lower valuation of the company.

Collaboration agreements may also contain provisions that grant the company's partner a right of first refusal or right of first negotiation in certain circumstances. These provisions could be triggered if the company develops a new product or a new indication for an existing product, or even if the company desires to enter into an exit transaction. A right of first refusal or right of first negotiation could significantly hinder the company's ability to enter into an exit transaction. A third party may be unwilling to spend a significant amount of time conducting due diligence on the company and negotiating the provisions of the sale agreement if it knows the company's collaboration partner has the right of first refusal and could simply match its offer. If anything, these provisions could significantly delay the sale process.

Agreements with Investors

The agreements that the company enters into with its investors could have a significant impact on the company's ability to enter into an exit transaction. Many investors, particularly venture capital and private equity funds, will negotiate for some or all of the following rights:

- Liquidation preference. The exit transaction may constitute a liquidation event and these investors will be paid first, including accumulated dividends and the significant liquidation preferences. If the valuation is not high enough to support the full liquidation preference of its preferred stockholders, the officers, employees and even angel investors who hold common stock will not receive any consideration.
- Drag-along rights. If a large investor with drag-along rights desires to sell its shares to a third party, it could force all of the other stockholders to sell as well. This could restrict the company's ability to enter into a transaction with a third party that was not selected by the investor and can impact the timing of the transaction. If the investor wishes to sell (and thus force all of the other holders to sell) before management thinks it is the right time, valuations could be lower.
- Veto rights. An investor with veto, approval or consent rights could block a transaction.
- Super-majority voting rights. This would require a greater number of stockholders to approve a transaction than otherwise required by state law, making approval more difficult to obtain.

While it is not likely that a company can avoid giving some or all of these rights to investors as

the company raises equity through its life cycle, it should be mindful of the impact these rights could have when it decides to sell, and be sure the investment is worth giving up these rights.

Considerations at the Beginning of the Sale Process

Organizing Due Diligence and Momentum

Because time and momentum are frequently of the essence in exit transactions, a company would be well prepared by having all of its due diligence organized before investment bankers begin marketing the company for sale. Electronic data rooms provide valuable speed, control and organization. (See "Getting Ready: Preparing a Data Room" in Section VI of this book.) If an electronic data room is not a viable option, a thumb drive with diligence materials organized in folders is an inexpensive alternative. In either event, diligence should be carefully organized and readily available to be sent to interested parties upon the execution of a confidentiality agreement. The company's investment banker or law firm can provide the company with a due diligence request list that the company can use to organize its materials. (See also "Due Diligence: Practical Advice for What To Expect" in Section VI in this book.)

A typical due diligence request list will cover all information that is material to the company, including the following:

- Organizational documents
- Board and committee minutes
- Documents defining rights of stockholders, including voting, registration rights and other agreements
- Communications with stockholders
- Financing documents
- Material contracts
- Insurance
- Legal proceedings and compliance
- Licenses and permits
- Labor relations
- Intellectual property, including patent rights

- Accounting
- Real estate and environmental

Companies should organize their due diligence materials in advance for two reasons. First, when the company or the investment bankers find potentially interested buyers, the company will be able to provide the due diligence materials in an organized and prompt manner. This will help maintain the buyer's interest and the deal momentum. In fact, being unprepared, disorganized or providing incomplete due diligence can communicate a disorganized or sloppy management team (deserved or not) and starts the due diligence process on the wrong foot before the buyer even begins its review of the company. Second, by organizing and reviewing the due diligence materials prior to providing the buyer with such information, the company has an opportunity to identify any potential issues and either resolve such issues before the sale process begins or formulate responses to the buyer's questions. Third, management can stay focused on the deal rather than get bogged down in gathering documents and responding to questions.

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Engaging Investment Bankers

A key component when determining when and whether to sell the company is whether to engage an investment banker. Investment bankers can play a key role in the sale process. In particular, they will:

- help the Board of Directors develop a strategic plan and evaluate the market, timing and alternatives
- scrub the company's strategic and business plan, financial statements and projections
- market the company and identify potential acquirers, both strategic and financial
- conduct valuations of the company and make recommendations regarding appropriate valuations
- provide assistance in structuring and negotiating deal terms

- guide the company through the due diligence and deal process
- render a fairness opinion if desired or needed
- help bring the deal to closing

Management and the Board of Directors should meet with and interview several investment bankers, evaluate their skills and qualifications and adopt resolutions to formally engage the investment banker and approve the investment banker's engagement letter. The engagement letter should specifically outline the terms and scope of the engagement and keep the scope as narrow as possible. Some key deal terms to consider when negotiating the engagement letter include the length of the "tail" and the company's ability to terminate the engagement letter. The "tail" refers to the period of time following the termination or expiration of the engagement letter that, if the company enters into a transaction with certain parties that the bankers identified during the term of the engagement, the company would owe the investment banker a fee. Another key issue in drafting the engagement letter is how to calculate the consideration payable to the investment banker upon the consummation of a The letter should specify if the transaction. compensation payable to the investment banker is based solely on the amount of consideration received by the company or its stockholders or if it also includes the assumption of debt (which is more common).

In some circumstances, the board may decide to engage one investment banker to provide transaction advice and a fairness opinion. Other companies may engage a separate investment banker to provide a fairness opinion if the other investment banker has any conflicts. Occasionally, depending on the deal structure and its stockholder base, some companies may decide they do not need a fairness opinion.

When determining which investment banker to engage, the Board of Directors should consider several factors, including:

- Industry experience
- Reputation and personality whose advice does the board trust the most and who has good chemistry with the management team
- Which firm has the capacity and resources to best get the deal done

- Which firms, if any, have existing relationships with the company
- Fees
- Potential conflicts

It is very important that the investment bankers be a good fit for the company. While name and reputation are important, if the investment banker does not view the relationship as beneficial or meaningful, the company may not receive the attention it deserves.

Deal Structure Considerations

Merger versus Stock or Asset Sale

The decision of whether to structure the transaction as a merger or a stock or asset sale will depend on a number of factors. The company must weigh competing legal, tax and business considerations. For example, mergers can often be structured to be tax-free to the target company's stockholders. The structure of the transaction will impact the consents and approvals that must be obtained and the timing of closing the deal. Selecting the best structure is critical to the success of any sale.

Merger

A merger is a stock acquisition in which two companies combine into one legal entity. As with other exit structures, consideration in a merger can be for cash or stock in the surviving company or its parent company, or a contribution of both. The surviving entity assumes all assets, rights and liabilities of the extinguished entity. The merger process is governed by the laws of the states of formation of the parties. While approval of the selling company's stockholders is required, unless the company's organizational documents provide otherwise, generally only the approval of a majority of the stockholders is necessary. This is considerably less burdensome than approval of 100% of the stockholders needed in a stock sale.

The corporate laws of most states provide that dissenting stockholders to a merger can petition the court to force the buyer to pay them "fair value" for their shares. This process often adds additional time, complexity and expense to a merger. Some states also provide appraisal rights in the sale of all or substantially all of a company's assets.

Tender Offer

In a tender offer, the acquirer would make an offer directly to the stockholders of the company to acquire the stockholders' shares. Typically, the tender offer will not close unless a certain percentage of shares are tendered. A successful tender offer would give the acquirer voting control of the company and could enable the acquirer to acquire the remaining shares of the company through a "short-form" merger, which would not require stockholder approval. This structure is more frequently seen in transactions involving public companies.

Stock Sale

In a stock acquisition, the buyer acquires the company's stock directly from the selling stockholders. The buyer acquires all of the target company's assets, rights and liabilities. Following the transaction, the target company maintains its corporate existence and becomes a subsidiary of the buyer. Selling companies often prefer to structure the transaction as a sale of the stockholders' stock, as opposed to assets, because the selling company is not left with any contingent liabilities. Unless the stockholder agreement includes drag-along rights, this type of transaction requires the consent of all stockholders, which can be difficult to obtain. Negotiations can be timeconsuming if there are numerous stockholders.

Asset Sale

In an asset acquisition, the buyer acquires specific assets and liabilities of the target company as listed in the asset purchase agreement. After the deal closes, the buyer and seller maintain their separate corporate structures and the seller retains those assets and liabilities not purchased or assumed by the buyer. There are two drawbacks for the seller in an asset sale: First, the seller is left with any unknown liabilities and any liabilities not specifically assumed by the buyer. Second, a seller usually receives less favorable tax treatment when selling assets. On the other hand, buyers often prefer an asset sale to a stock sale in order to limit liability and risk as the buyer assumes only the liabilities expressly set forth in the agreement.

Asset acquisitions are typically more complicated and time-consuming than stock acquisitions because:

 assigning specific assets requires carefully listing assets and separate transfers with separate documentation

- third-party consents are often required
- some states have bulk sales laws that must be complied with

Option Structure

Recently, more companies are entering into option agreements with potential acquirers. At the time the option is executed, the potential acquirer pays the company an up-front fee that the company may use for product development. The company and the potential acquirer also negotiate certain milestones at the time the option agreement is executed. If those milestones are achieved, the potential acquirer has the option to buy the company for a predetermined amount. While this structure reduces some of the company's risk and provides it with needed capital to pursue product development plans, the company could face significant challenges in finding a viable exit strategy if the potential acquirer chooses not to exercise its option.

Consideration

Regardless of the structure, the consideration paid may be either fixed or subject to adjustment after the closing. There are two primary ways to adjust the consideration post-closing, though the variety is almost limitless. The first is a post-closing purchase-price adjustment. The second method is through an earn-out.

Post-Closing Purchase-Price Adjustments

Post-closing purchase-price adjustments (as opposed to earn-outs) are appropriate when the parties agree on the value of the target company, but due to the period of time between signing and closing, moving factors such as cash-on-hand, expenses and working capital affect that valuation. The purchase-price adjustment is intended to reflect those valuation changes.

A post-closing adjustment can be constructed in a variety of ways. Common post-closing adjustments compare working-capital or networth variances between the most recent financial statements available when the acquisition agreement was signed and the closing-date financial statements. In a transaction with a post-closing adjustment, the closing is generally scheduled for a month-end to avoid difficult cut-off accounting issues.

Within a specified time period after the closing, the buyer would deliver the closing-date financial statements to the seller, along with the buyer's initial determination of the purchase-price adjustment amount. The seller would then have a specified period of time during which to review the closing-date financial statements. The seller may accept the draft or inform the buyer of specific objections to it.

The parties may wish to identify important line items on the closing financial statements and stipulate in writing the method of valuation for those items. The items requiring attention will vary based on the formulation of the post-closing adjustment.

Earn-Outs

An earn-out provision makes a portion of the purchase price contingent upon the acquired company reaching certain milestones during a specified period after the closing. Earn-outs (as opposed to typical post-closing purchase-price adjustments) are often utilized when the parties cannot agree on the value of the company or the buyer wants to see the company's performance "prove" the value potential. Earn-outs are particularly useful when the buyer's projections for the company (for example, product development, milestones or revenue) fundamentally more pessimistic than those of the seller. An earn-out arrangement rewards the seller if its projections are accurate, while protecting the buyer from overpaying if they are not. An earnout also may be attractive to a buyer desiring to bridge a financing gap.

In situations in which the seller's management will continue to run the target after the closing, an earn-out arrangement may be used by the buyer to motivate management with performance incentives. If the earn-out used in this context, however, is characterized as compensation rather than payment for the business, there may be accounting implications to the buyer.

One difficulty with earn-outs is the calculation, standard or formula that will dictate whether the milestones have been achieved. If the milestone is achievement of a scientific or clinical trial result, then the buyer will want a subjective standard (e.g., successful proof of concept or Phase I results that indicate continuing development), when the seller will prefer a more objective standard (e.g., pre-clinical results that achieve preset minimum data points or enrollment of a preset number of subjects in a Phase I study). If the earn-out is based on earnings, then the buyers and sellers might heavily negotiate the inputs to that calculation, such as what types of revenues and expenses are included in the calculation. These issues are complicated by the fact that the sellers will no longer be managing the business after closing and will therefore lose control over the development of the product and the books and records.

FIVE TIPS FOR AVOIDING LITIGATION

Common Mistakes Made by Early Stage Companies That Can Lead to Litigation

By Robert R. Baron Jr., Partner, and Paul Lantieri, III, Partner, Ballard Spahr LLP

The last thing you or your new business needs is litigation. It is expensive, distracting, and – especially for a start-up – potentially crippling. While there is no sure way to shield your business from litigation, you can proactively avoid some of the most common pitfalls for new businesses. Here are five tips.

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ADOPT A SHAREHOLDER AGREEMENT

Even if your company consists of you, your brother and your college roommate, it is imperative that you spell out your rights, duties and expectations in a shareholder agreement. Disagreements or changes in circumstances are inevitable, but a well-crafted shareholder agreement or an operating agreement for an LLC can prevent them from devolving into contentious litigation. A shareholder agreement can govern such matters as:

- how equity is divided among shareholders
- how shareholders can acquire, transfer and sell stock, or not
- shareholders' right to vote or agreements to vote certain ways
- board makeup
- whether a percentage (60%, for example) can force the rest of the shareholders to sell the company (drag-along rights)
- how disputes among shareholders are handled
- what happens in the event of the death, incapacity, resignation, or firing of a shareholder or whether shareholders can be terminated
- how shares are valued

Thinking through scenarios that may arise down the road will strengthen your business now by ensuring that everyone shares compatible goals and visions. And should those goals and visions diverge, a clear expression of your original intent will be invaluable.

II

RESIST THE TEMPTATION TO USE "FINDERS"

Particularly when capital is scarce, it is tempting to seek help from "finders" - well-connected intermediaries who make introductions to facilitate investments. But doing so can expose issuers to substantial liability because many finders are not, but should be, registered as broker-dealers with the SEC. There is a fine and blurry line between making introductions and engaging in the broad types of activities that require registration. For example, registration may be required if the (i) solicits, negotiates or executes a transaction; (ii) gives advice about a transaction; (iii) receives compensation based on or related to the completion or size of a transaction; or (iv) handles securities or funds involved in a transaction. The SEC recently has stepped up its enforcement of the broker-dealer laws with respect to finders. While the consequences for an unregistered finder can be harsh, they can be even worse for the issuer. Among other things, use of an unregistered finder can lead to:

- private actions by investors for damages or the rescission of their investments
- the loss of an exemption from the private placement exemption from registration requirements under federal and state securities laws
- civil or criminal penalties in regulatory actions by the SEC or state authorities
- accounting issues
- trouble in obtaining legal opinions needed for future capital-raising transactions

Thus, using an unregistered finder could jeopardize the issuer's ability to raise capital at all,

now or in the future. Resist the temptation, or at least proceed with extreme caution if you are considering using a finder.

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OBTAIN ASSIGNMENTS OF INTELLECTUAL PROPERTY

Make sure your company has the value you think it has by obtaining full assignments of intellectual property from everyone who has a role in creating it - founders, employees, contractors, scientific advisers or other third parties. Potential investors will want to confirm that the company owns exclusive rights to the IP that is critical to its business. Failing to obtain proper assignments will give the people who hold rights to the IP leverage over the company that may lead to litigation, especially if those people use the IP in competition with your business. To avoid that risk, employees and contractors should sign agreements assigning the IP they create to the company. Be sure to attach exhibits the form calls for and carefully collect and store the fully executed agreements - you will need to show them to investors, collaborators, buyers and IP counsel.

This is important for copyrightable works (such as advertising materials, photos, artwork, music, software, and website content), patentable inventions as well as trade secrets and know-how. While the "work for hire" doctrine provides that copyright in materials created by an employee within the scope of his or her employment belongs to the company, the doctrine generally does not apply to nonemployees. And in the case of patents, in the absence of a written assignment, a patent typically belongs to the individual inventor, not the employer. In addition to assigning their IP rights in works and inventions, employees and contractors should agree to execute documents needed to effectuate the company's rights (such as assignment forms that must be filed with the United States Patent Office). Also consider asking your employees to reasonable non-compete agreements. Attention to these details at the outset requires little effort but can prevent major headaches in the (See also "Common Mistakes in IP Agreements" in Section IV in this book.)

IV

USE NONDISCLOSURE AGREEMENTS TO PROTECT YOUR SENSITIVE INFORMATION

You must take reasonable measures to maintain the secrecy of any information that gives you a competitive advantage (such as customer lists, data, formulas, manufacturing processes and other know-how) to receive legal protection for the information as a trade secret. And, freely discussing an unpatented invention may constitute a public disclosure that limits your time to file a patent application to one year. So, consider carefully whether any disclosure of data, knowhow, trade secrets or potentially patentable inventions is necessary, and use nondisclosure agreements (also known as "confidentiality agreements") when you must discuss them. Keep this in mind when discussing your confidential information with potential advisers, consultants, investors, suppliers and customers. An NDA should be designed specifically for a particular situation. A well-tailored NDA should, among other things:

- define the confidential information and describe the purpose of the disclosure as specifically as possible
- limit disclosure by the recipient of the information as strictly as possible
- prohibit the other party from using the information other than for the specified purpose
- have a term that is long enough to protect your business but not so long as to unreasonably burden the recipient of the information
- require the recipient to return or destroy any documents with the confidential information when the agreement ends or the documents are no longer needed

In addition, don't forget about your employees. Ensure that they also are bound to maintain the confidentiality of and not use the company's proprietary information, and remind them regularly of their obligations. These measures will protect the value of your information, reduce the likelihood of litigation, and – if you do end up in a lawsuit – provide necessary support for your position. (See Sample One-Way and Two-Way CDA in Section VII in this book.)

\mathbf{V}

SEEK LEGAL ADVICE ABOUT IMPORTANT SUPPLY AGREEMENTS

Supply agreements may seem innocuous when you sign them, but they often give rise to legal disputes when the market changes or money gets tight. It is important to understand, before you sign the agreement, your rights to terminate the agreement and what will happen if the supplier terminates the agreement. Think through how risks should be allocated and how changed circumstances could

Should either party be affect your needs. permitted to terminate the agreement without cause? How much notice must a party give before terminating the agreement? If one party breaches the agreement, will that party have the opportunity to remedy the breach before the agreement is terminated? Can you terminate the agreement in the event of insolvency? Try to anticipate specific events that may occur and, if possible, address them expressly in the agreement. Other issues to consider include the duration of and the right to renew the agreement, whether and in what circumstances either party will be required to pay a termination fee, and in what circumstances either party may seek to change certain provisions of the agreement (e.g., by removing certain goods or services from the agreement). Because these are the types of issues that often end up being resolved through litigation, it would be prudent to seek legal advice before entering into important supply agreements.

VII.

APPENDIX



CONTRIBUTORS

CONSIDERATIONS FOR FORMING A BUSINESS ENTITY Start-Up Company Checklist for Privately Held Companies

MARY J. MULLANY is a partner in the Business and Finance Department of Ballard Spahr LLP and resident in the Philadelphia office. Much of her work with pharmaceutical, biotechnology, and life sciences companies focuses on mergers and acquisitions,

securities offerings and other corporate financing, and licensing agreements, including collaborations and joint ventures. Ms. Mullany holds a J.D. from Villanova University School of Law and an M.S.N. from Widener University.

DILIGENCE CHECKLIST/DATA ROOM REQUEST LIST

MATT MEZZANCELLO is a New York-based DataSite Director who specializes in the life sciences Industry. He is an active member of BioNJ and has participated in events for the New York Biotechnology Association as well as Pennsylvania Bio. Mr.

Mezzancello's dealroom experience ranges from small licensing deals to multibillion-dollar M&A transactions and spans all industries. He graduated from Lehigh University with a B.A. in psychology and a minor in philosophy.

GLOSSARY OF FREQUENTLY USED TERMS

This Glossary provides a guide of commonly used terms in venture capital negotiations, term sheets, agreements and transactions. The list is incomplete, and some definitions may have local, geographic or industry variations. Words and phrases that appear in *italics* are defined elsewhere in the Glossary.

"A" Round. A funding *round* in which Series A *preferred stock* is issued and sold to outside investors. This is typically the first institutional venture capital financing round (but may also include *angels* and other sophisticated investors). The "A" in the name comes from the use of *Series A Preferred Stock*, the *securities* issued in the round.

Accredited Investor. A person (including an individual, bank, trust, fund, or other entity) meeting certain net-worth or income qualifications such that it is considered sufficiently sophisticated to make investment decisions without the need for regulatory protections. Regulation D under the Securities Act provides a safe-harbor exemption for private placements to accredited investors (so that these offerings need not be registered with the SEC. Typical requirements for an individual (i.e., a natural person) to qualify as an accredited investor are: \$1 million net worth at the time of purchase, or annual income exceeding \$200,000 individually (or \$300,000 with spouse) in each of the two most recent years (with an expectation of reaching the same income level in the current year). Directors and executive officers of the issuer also qualify as accredited investors.

Accrued Dividends. See *Cumulative Dividends* and *Dividends*.

Advisory Board. A group of outside advisers to a portfolio company, typically with experience and/or contacts in the company's industry and markets, formed for the purpose of providing informal advice and assistance to the company's management concerning a variety of strategic, business and operating matters. An advisory board does not have the formality, role or duties of the company's Board of Directors.

Affiliate. An affiliate of a specified person is another person controlling, controlled by, or under common control with the specified person. This tracks a definition in *SEC* rules often used in venture capital documents. The SEC deems a company's *directors* and executive officers, as well

as controlling stockholders, to be affiliates of the company.

Affirmative Covenant. See Covenant.

Angel; Angel Investor; Angel Investment. Someone who provides funding (and, in many cases, other "value adds") to *start-up* and very *early stage* businesses. Angel investments usually precede investments by *venture capital funds* and usually provide *seed and early stage capital* of less than \$1 million to 2 million. Angel investors commonly are high-net-worth individuals (and often are accomplished entrepreneurs and former business executives).

Angel Groups. Organizations, associations and networking groups (sometimes including a raised "fund") formed for the purpose of facilitating angel investments in *start-up* and very *early stage* businesses.

Provision; Anti-Dilution Anti-Dilution Protection; Price Protection. A provision (in an option, warrant, or convertible security) intended to protect the holder from dilution of its ownership interest that may result from future sales or issuances of capital stock by the issuer. dilution protection adjusts the investors' ownership percentages if the company effects a stock split, stock dividend or recapitalization and, potentially, for future issuances of equity below certain per share prices. The result is that the investors will be issued more shares of common stock upon the conversion of their preferred stock. This protects the investors from the risk that they overpaid for their stock if the pre-money valuation turns out to be too high. See also Weighted Average Ratchet and Full Ratchet.

AntiFraud Rules. Rules and regulations, promulgated under federal and state securities laws, that prohibit (and provide for penalties and remedies in the event of) fraud, which includes material misstatements and omissions of material information in connection with the offer and sale of *securities*.

Authorized Shares. The total number of shares of *capital stock* that a company is authorized to issue in its certificate of incorporation.

Automatic Conversion. A feature of a *convertible* security, whereby that security, upon the occurrence of certain specified events or transactions,

automatically converts (without any action on the part of the holder or the *issuer*) into (and becomes) shares of *common stock*. See also *Convertible Preferred Stock*.

"B" Round. A funding *round* following the "A" *round*, in which Series B *preferred stock* is issued and sold to one or more outside investors (usually *venture capital funds*). This can be accomplished through existing and/or new investors. Subsequent rounds are called "C," "D," and so on.

Basket. Specific dollar limitations on *indemnity* claims or other provisions provided under an agreement (typically an investment or purchase agreement). For example, the agreement may provide that one party may bring indemnity claims against the other only if the aggregate amount of all claims exceeds a specified dollar amount. A "deductible" basket means that the specified dollar amount is exempt from, and only the excess over that amount is subject to, indemnity claims. A "threshold" (or "dollar-one") basket means that once the specified dollar amount is exceeded, the indemnified person can recover the full amount of all claims (from the first dollar).

Beneficial Ownership. Equitable rather than record ownership of *securities* (a term commonly used in venture capital documents). For purposes of Sections 13(d) and 13(g) of the *Exchange Act*, a beneficial owner of a security includes any person who, directly or indirectly, solely or jointly, holds (1) voting power, which includes the power to vote or to direct the voting of, such security; or (2) investment power, which includes the power to dispose of, or direct the disposition of, such security.

Best Efforts Underwriting. In a Best Efforts Underwriting, the underwriter is obligated only to use its reasonable best efforts to sell the stock that is being offered by the company in a *public offering*. The underwriter has the right to return any unsold shares to the company.

Blank Check Preferred Stock. Preferred stock that has been authorized in the charter of a corporation, but (i) the terms (and rights, preferences and limitations) have not yet been designated by the Board of Directors; and (ii) the stock has not yet been issued or sold to investors. Thus, shares of the authorized preferred stock may be designated, issued, and sold (pursuant to Board of Directors action) at a later date, with no requirement or need for shareholder vote or approval.

Blocking Rights. See Veto Rights.

Blue Sky Laws. State laws that address (and, to some extent, regulate) the offer and sale of *securities*, enacted largely to protect the investing public against securities fraud.

Board of Directors; Board. The governing body of a corporation, charged with oversight of the management and direction of the corporation. Individual directors are elected (usually annually) by shareholders to serve on the board, and they owe certain fiduciary duties to the corporation's shareholders. Venture capital funds typically have the right to elect a specified number of board members (and, together with founders/management, to elect one or more independent directors). See also Independent Director and Investor Rights Agreement.

Board Observer Rights. A contractually provided right for an investor (or its designee) to attend all regular and special meetings of the *board of directors* (and often meetings of board committees). This also typically includes the right to receive information and notices that are provided to board (and committee) members. A board observer does not have the right to vote as a board member and generally does not owe the company (as a board member) fiduciary duties.

Bootstrapping. Creative actions implemented by a *start-up* to minimize (or squeeze) expenses, work relationships, utilize resources, and/or build cash flow (and margin), thereby reducing, delaying or eliminating the need for external capital funding.

BRIC. Refers to the fast developing countries Brazil,) Russia, India and China.

Bridge Financing. Temporary (and sometimes emergency) limited funding that will eventually be replaced by permanent capital (from equity investors or debt lenders). In venture capital, a bridge loan is usually provided in the form of a short-term *note* (6 to 18 months) that converts to *preferred stock*. Typically, the bridge lender has the right to convert the note to preferred stock at a price that is discounted from the price of the preferred stock in the next financing *round*. The loan is intended to "bridge" the borrower to its next round of financing.

Bring-Down. The repetition (or the later date making current) of *representations and warranties* (included in an investment or purchase agreement) after the date on which they were originally made

(i.e., the agreement or signing date), principally in the context of conditions to the obligations of the parties to *close* an investment or acquisition transaction.

Broad-Based Weighted Average Ratchet. The most commonly used form of *anti-dilution provision* in venture capital transactions. See also *Weighted Average Ratchet*.

Burn Rate. The rate at which a business expends its (net) cash over a defined period (usually a month).

Business Judgment Rule. A legal presumption that judgments made by the *Board of Directors* of a *corporation* are presumed to be correct (i.e., in the best interests of the corporation and its shareholders) and will not be second-guessed by the reviewing court, so long as they are made in good faith, on an informed basis, without conflict or self-interest, and in a manner reasonably believed to be in the best interests of the corporation. This rule is grounded in state corporation law (i.e., the governing law of the state in which the corporation is organized).

Call Option. The right to buy a *security* at a specified price (or price range) within a specific time period. See also *Option*.

Cap. A maximum limit on *indemnity* claims or other provisions under a *definitive agreement*. Also referred to as a ceiling. *Participating preferred stock* may have the participation feature subject to a cap.

Capital Call. When a venture capital fund manager (usually a general partner in a limited partnership) requests or requires (pursuant to a previous pledge or commitment) that an investor in the fund (a limited partner) provide additional capital to the fund. Typically, the limited partners agree to a maximum investment amount, and the general partner makes a series of requests/demands for capital over time to the limited partners as opportunities to invest in portfolio companies arise.

Capitalization (or Cap) Table. A table showing the capitalization of a company, which typically includes all *securities* issued and outstanding by the company on a particular date, and the identity and security/share ownership of each security-holder (or, at least, of the significant ones). The cap table also lists the form of security (whether equity or debt), such as *common stock*, *preferred stock*, *warrants*, *options*, *senior debt* and *subordinated debt*.

Capital Stock. The units of ownership (such as *common stock* and *preferred stock*) in a *corporation*, usually evidenced by stock certificates, as authorized in the corporation's *charter* (consistent with the state of incorporation's corporate laws). See also *Equity Securities*.

Carried Interest; Carry. In a venture capital fund organized as a limited partnership, the general partner's share of the profits generated through the fund's performance. Typically, a fund must return the capital invested in it by limited partners plus an agreed hurdle rate (or preferred return) before the general partner can share in the profits of the fund. The general partner will then receive its agreed carried interest (also known as its "carry" or "promote"), which is the agreed share or split (with the limited partners) of the remaining profits. The carried interest, rather than the management fee, is the general partner's principal incentive to perform well and generate strong fund returns.

CDA. Stands for Confidentiality Agreement. See also Nondisclosure Agreement.

Change of Control; Change-of-Control Provision. A provision in an agreement pursuant to which one party's change of control triggers certain rights of another party, such as the right to terminate the agreement, or the acceleration or vesting of certain rights/interests/obligations under the agreement. What constitutes a "change of control" is often defined by reference to the sale or transfer of ownership of a specified percentage or amount of *voting stock* or assets, or a significant change in the composition of the *Board of Directors* (or other governing body).

Charter. The principal governing document of a company, as provided under the governing corporate law of the state of organization, prepared and filed when the company is first formed. Typically named the certificate of incorporation or articles of incorporation in the case of a corporation (or, in the case of a *limited liability company*, the certificate of formation).

Clawback. A contractual provision in a private equity or venture capital fund's governing documents that provides that, over the life of the fund, the fund's managers will not receive a greater share of the fund's distributions than what they agreed and bargained for. Generally, this means that the general partner of the fund may not keep more than a specified percentage (e.g., 20%) of the

fund's cumulative profits (and thus must return any "excess" to the fund's *limited partners*).

Closing. The process of consummating (or the consummation of) an investment transaction in which the requisite final (executed and delivered) legal documents and investment funds are exchanged and delivered. At the closing of an investment transaction, the investor receives the *securities* purchased, and the company receives funding.

Club Deal. An investment transaction in which several fund investors invest side by side in the same *round*. Although this term is most commonly used in *private equity fund/* buyout deals, it is also used in multifund venture capital transactions.

Committed Capital. The total amount of capital committed or pledged to a *private equity* or venture capital fund and available for the purchase of or investment in *portfolio companies*.

Common Stock. The most basic form of equity ownership, and a unit of ownership, in a corporation. Common stock is the most junior form of equity security. Usually, company founders, management, employees, and friends and family own common stock, while outside investors purchase and own preferred stock. Holders of common stock are entitled to vote for the election of directors and other matters requiring a shareholder vote; to the payment of dividends (if, as, and when declared and paid); and to distribution of all remaining proceeds in liquidation (after the claims of the secured and unsecured creditors and bondholders, and the liquidation preferences of the preferred stockholders, are satisfied).

Confidentiality Agreement. A stand-alone agreement or a provision in a letter of intent or definitive agreement, whereby one party agrees to treat as confidential, and not to disclose to others, nonpublic information received from the other party. Sometimes also called an NDA or nondisclosure agreement.

Conversion Ratio. The ratio used to determine the number of shares of stock into which a *convertible security* may be converted. In a venture capital transaction, this refers to the ratio that determines, at any point in time, the number of shares of *common stock* into which shares of *convertible preferred stock* may be converted.

Conversion Rights. Rights under which shares of *preferred stock* (or other *convertible securities*) "convert" into (and become) shares of *common*

stock. Can be automatic or mandatory (in certain specified events, such as a qualified sale, qualified IPO, satisfaction of financial performance targets, and/or approval by a specified vote of preferred stock holders), as well as voluntary (i.e., at the option of the holder). These rights are typically protected by anti-dilution provisions.

Convertible Preferred Stock. A type of *preferred stock* that is convertible into or exchangeable for shares of *common stock* at a specified (and adjustable) *conversion ratio*. Convertible preferred stock is clearly the most commonly used form of *security* for venture capital investment transactions. See also *Conversion Rights*.

Convertible Security. A security of a company that by its terms is convertible into exchangeable for another security of the same company (e.g., convertible preferred stock, convertible notes, and convertible debentures can be convertible into shares of common stock). See also Convertible Preferred Stock and Conversion Rights.

Corporation. A legal entity organized under state law through the filing of a *charter*. The corporation is owned by its stockholders (or shareholders), managed by its officers, and overseen/directed by its Board of Directors.

Co-Sale Rights. See Tag-Along Rights.

Covenant. A legal promise in a definitive agreement that obligates a party either to take an action such as maintaining key man life insurance on founders or maintain the size of the Board of Directors (referred to as an affirmative covenant) or refrain from taking an action (a negative covenant); or that requires the maintenance or achievement of some defined economic, operating or financial measure (a financial covenant).

Cram-Down Round. A funding *round* in which new investors (usually bringing substantial capital into the company and/or in a *down round*) demand and receive contractual provisions, contractual concessions, and new *securities* that significantly reduce (or *dilute*) the ownership percentage (and rights and protections) of previous investors. In a cram down round, the equity interests of the previous round investors are diluted, and the new investors own a greater equity interest in the company. See also *Washout Round*.

Credit Agreement. A definitive agreement under which one or more parties (the "lenders") provide credit facilities (i.e., funds available to be borrowed), such as a term loan and/or revolving

facilities, to another person (the "borrower"), subject to compliance with certain covenants and avoidance of certain events of default. The credit agreement typically provides for the most senior, secured credit arrangements of the borrower.

Cumulative Dividends. The right of a holder of preferred stock to receive accrued (and previously unpaid) dividends at a fixed rate in full before any dividends may be paid to the holders of any other, junior classes of capital stock (including common Thus, dividends may accrue and "accumulate" at a fixed rate (e.g., 6% to 9% per annum) or may simply be payable "when, as, and if declared" by a company's board of directors. Because venture-backed portfolio companies typically need to conserve cash (and thus do not pay dividends), employing a cumulative dividend feature means the liquidation preference of the underlying preferred stock increases by an amount equal to the accrued cumulative dividend. Cumulative dividends are often waived if the preferred stock converts to common stock prior to an IPO or other significant transaction, but may be included in the liquidation preference (or as an adjustment to the conversion ratio) for other purposes.

Cutback Rights. Cutback rights apply in situations where investors have exercised their registration rights and desire that some of their shares be sold under the company's registration statement filed in connection with the company's offering of securities. The underwriter in the company's offering of securities may determine that there is not a market for all of the shares that are proposed to be sold in the offering. cutback rights give the underwriter the right to reduce the number of the investors' shares that are being sold in the offering.

Data Room. The place or site (which can be virtual or web-based) in which a company's material documents, contracts, books and records are placed to be examined by potential investors in connection with their *due diligence*.

Debenture. Generally, longer-term *notes* issued to a number of investors (debenture holders) pursuant to an indenture and a debenture purchase agreement. See also *Note*.

Debt Security. A *security* representing a debt obligation of an *issuer*. A debt security is in many ways functionally equivalent to a bank loan, but the terminology is different: A lender makes loans to a borrower under a *credit agreement*, while an

issuer issues and sells debt securities to a purchaser, pursuant to an indenture or *note* purchase agreement.

Definitive Agreement. The final form of signed agreement to undertake and consummate a transaction (e.g., a venture capital investment transaction), which by its terms is legally binding and enforceable (subject to the fulfillment or waiver of certain specified conditions).

Demand Rights. See Registration Rights.

Dilution. A reduction in the percentage ownership or the value of *equity security* holdings of a given shareholder (e.g., a *founder*, employee or previous investor) caused by the issuance, or potential issuance, of additional equity securities (or rights to acquire equity securities).

Dilution Protection. See Anti-Dilution Provision.

Director. An individual member of a *corporation's board of directors*, usually elected annually by the corporation's shareholders.

Disclosure Schedule. An exhibit (or schedule) attached to a *definitive agreement* that describes exceptions to the *representations and warranties* (and, in some cases, *covenants*) of the parties in an investment transaction. Sometimes also called a *schedule of exceptions*. Once a definitive agreement is prepared by the investor's counsel, it is the *issuer's* obligation to prepare appropriate, complete and responsive disclosure schedules (which will form part of the definitive agreement). This is also part of the *due diligence* process.

Discounted Cash Flow (DCF). A valuation methodology whereby the present value of all future cash flows expected from a company is calculated (or "discounted") based on accepted valuation tools and assumptions.

Dividend. A payment (or distribution) that is authorized and declared by the *Board of Directors*, to be made in respect of the outstanding shares of *capital stock* (or class or series of such stock, on a *pro rata* basis). Dividends may be *cumulative*, *non cumulative*, participating and nonparticipating. See also *Cumulative Dividends*.

Dividend Preference. The right to receive preferential, priority treatment with respect to the declaration and payment of *dividends* on a particular *security* (typically, senior securities will receive this preference and priority treatment with respect to junior securities).

Down Round. A *round* of financing (i.e., a separate, later investment transaction) in which the valuation of the company (and thus the effective price per share) is lower than the valuation utilized (and embraced in securities issued and sold) in a previous round.

Drag-Along Rights. Contractual rights (typically provided in a shareholders' agreement or investor rights that allow one agreement) or investors/shareholders (often those holding a majority or a specified percentage of the outstanding shares) to force (or "drag") all other shareholders to agree to and/or participate in a specific action, such as the sale of the company, alongside the initiating investor/shareholder. This provision operates to prevent shareholders from blocking a sale of the company (approved by the majority) by refusing to sell their shares.

Draw Down. See Capital Call.

Due Diligence. The fact-finding process by which a potential investor investigates the *issuer* to assess a potential investment and the accuracy of information provided. This process typically involves a review of the issuer's business, financial, accounting, personnel, regulatory, and legal contracts, books, and records; discussions with management; visits to facilities; and review of other pertinent information. The purpose is to assess the desirability, value, terms, and potential risks and upside incident to an investment opportunity.

Due Diligence Out. A provision in a *definitive* agreement relating to an investment, which gives a party the right to terminate the agreement (and not *close* the investment transaction) if it is not satisfied with the results of its *due diligence* investigation.

Early Stage. The stage of development of a company at the beginning of its corporate life (and its journey from *start-up* to full maturity). Although definitions may vary by audience, industry and geography, the early stage of a company is commonly viewed as following the *seed* (formation) *stage* and before its middle or *growth stage*. Typically, a company in its early stage will have a core (but not complete) management team, a developed business plan, and a product or service (perhaps beginning to make sales), but no established customers, positive cash flow or profits.

EBIT; EBITDA. A company's earnings before interest and taxes (EBIT) or earnings before interest, taxes, depreciation and amortization (EBITDA) are both measures of a company's operating cash flow. These measures are often used by sophisticated investors as a basis for valuing the company and pricing their investment. A key valuation methodology is based on a comparison of comparable private and public companies' values as a multiple of EBIT or EBITDA, properly discounted.

Elevator Pitch. A very concise oral presentation, lasting only a few minutes (the duration of an elevator ride), by an entrepreneur (or business owner or manager) to a potential investor concerning the business model, strategy, market and solution (and the compelling investment opportunity presented) of the company in question.

Equity Securities. Securities evidencing the equity and ownership rights in (the capital stock of) a company or business entity. In a corporation, equity securities include common stock, preferred stock, options, warrants and the rights (including conversion rights and exchange rights) to acquire these. Together, the equity securities represent the ownership of the company.

Event of Default. An event, act or occurrence that allows a party to a *definitive agreement* to exercise specific remedies under that agreement, such as the acceleration of the obligation to repay debt under a *credit agreement*.

Exchange Act. See Securities Exchange Act.

Exercise Price. The price at which an *option* or *warrant* can be exercised (i.e., the purchase price for the shares or *securities* covered by the option or warrant).

Exit; Exit Strategy. The means (or plan) by which a *venture capital fund* (or other investor) monetizes and realizes a return on its investment in a *portfolio company*. This typically comes when the portfolio company is sold to another person, goes public in an *IPO*, or recapitalizes (e.g., *leverages* its balance sheet and pays *dividends* to and/or purchases *securities* from shareholders).

Expansion Stage. The stage of development of a company characterized by a complete management team, a proven business model (and product/service), customers, profitability, and a substantial increase in revenues (and, perhaps, revenue channels).

Federal Exemptions From Registration; Section 4(2); and Regulation D. When a company makes an offer to sell its securities (including, shares of stock, options, warrants, and convertible debt), the company must either register the stock with the SEC pursuant to a Registration Statement filed under the Securities Act, or the company must issue the stock pursuant to an exemption from the registration requirements of the Securities Act. The most common exemption from registration is Section 4(2) of the Securities Act, which exempts from the registration requirements of the Securities Act "transactions by an issuer not involving any public offering" (i.e., private placements). The shares that are issued in a private placement are referred to as restricted shares, and they cannot be resold unless they are registered under the Securities Act or pursuant to an exemption from registration. Regulation D, promulgated by the SEC, provides several "safe harbors" under Section 4(2) of the Securities Act if the offering meets certain criteria specified in Regulation D.

Financial Covenant. See Covenant.

Finder. A person who helps to arrange an investment transaction, usually by introducing one or more potential investors to a fund-seeking company.

Firm Commitment Underwriting. In a firm commitment underwriting, the underwriter agrees to buy all of the shares that are offered by the company in a public offering at a fixed price and then resells those shares to the public at the higher offering price. Before signing the underwriting agreement for a firm commitment underwriting, the underwriter contacts investors and solicits "indications of interest" that are nonbinding obligations of the investors to purchase the shares from the underwriter. The underwriter will not sign the underwriting agreement until it has accumulated "indications of interest" for at least the number of shares of stock that are being offered by the company. The underwriter cannot return any unsold shares to the company.

First Offer Rights. See Right of First Offer.

First Refusal Rights. See Right of First Refusal.

Follow-On Funding; Follow-On Investment. An additional investment in a company made by its existing (or previous) investors. *Portfolio companies* often require more than one *round* of funding.

Form 8-K. Form 8-K is a report that a company must file with the *SEC* to report certain "material" events that might affect its business or financial condition.

Form 10-K. Form 10-K is a comprehensive overview of a company's business and financial condition that the company must file with the *SEC* within 90 days after the end of each fiscal year.

Form 10-Q. Form 10-Q is an overview of a company's business and financial condition that the company must file with the *SEC* within 45 days after the end of each of the first three quarters of each fiscal year. The company will file a Form 10-K at the end of each fiscal year.

Form S-1. Form S-1 is the Registration Statement that is filed with the *SEC* in connection with a company's *initial public offering* and when it is not eligible to use a *Form S-3*.

Form S-3. Form S-3 is a short form *registration* statement that permits a company to incorporate by reference information that is contained in its previous periodic filings that it made with the SEC under the Exchange Act (Form 8K's, Form 10-K's, Form 10-Q's, etc.). To be eligible to use Form S-3, a company must have been public for more than 12 months and be current in its Exchange Act filings.

Form S-4. Form S-4 is the *registration statement* that a company uses to register shares of its stock that it is issuing in an acquisition or merger to the stockholders of the target company.

Form S-8. Form S-8 is the *registration statement* that a company uses to register shares of its stock that are issuable to employees pursuant to the company's stock option plans or stock award plans.

Forced Buyback. See Mandatory Redemption.

Founder(s). The original owner(s) of a business entity who started, organized and participated in the conceptual development of the entity. Typically, a founder owns only *common stock* and manages the company until it has sufficient resources to attract and retain professional management.

Founders' Shares; Founders' Stock. Founders' Stock refers to the shares of the *common stock* that are issued to the *founders* of a company upon its establishment. The founders' stock may be

subject to a *stock restriction agreement* that provides for vesting of the founders' stock over time.

Founder Vesting. A requirement imposed by outside investors that *founders' shares* "vest" (in effect, be earned) over a period of years before they are fully owned (and may be sold or transferred). This is typically required (if at all) early in the valuation and investment process (e.g., *seed* and *early-stage* financings) to ensure that *founders* do not receive a windfall from their initial share allocations and to discourage founders from leaving the company or selling their shares prematurely.

Friends and Family Financing. Investment capital or an investment *round* provided by the friends and family members of the *founders* (and perhaps the initial management) of an *early stage* company.

Full Ratchet. A type of anti-dilution provision that is favorable to the investor (and most unfavorable to the company). It adjusts the exercise price or conversion ratio of a security to the lowest price at which securities (including convertible securities, options and warrants) are, or any single share is, issued after the issuance of the subject security (i.e., the one entitled to the full ratchet provision). As a result of the implementation of a full ratchet, founders, management, and others who own common stock typically suffer substantial dilution.

Fully Diluted. The number of shares (typically expressed as outstanding shares) representing the total potential ownership of a company, including all issued shares of *capital stock*, the conversion of all *convertible securities*, the exchange of all exchangeable *securities*, and the exercise of all *options* and *warrants*. This is an important (i) methodology for calculating any per share ratios; (ii) entry/line item in the *capitalization table*; and (iii) consideration in valuation discussions (and the negotiation of *anti-dilution provisions*).

Fully Paid and Non-Assessable Stock. Stock on which no further payments can be demanded by the issuing company and stock to which the holder's liability is limited to the amount paid for the stock, rather than the amount of the *issuer's* debts.

Gatekeepers. Intermediaries (e.g., attorneys, accountants, bankers and consultants) whom *venture capital funds* use as sounding boards and advisers in sourcing and gaining introductions to potential *portfolio company* investments.

General Partner. With respect to a venture capital fund organized as a limited partnership, the person responsible for all aspects of managing the fund, including communicating with limited partners, raising funds, making portfolio investment decisions, nurturing portfolio companies, and assisting with exits. The general partner, which retains liability for the actions of the partnership, earns a management fee as well as an agreed share of the fund's profits (known as the carried interest). See also Limited Partners and Limited Partnership.

Growth Stage. The stage of development of a company when it has already received one or more *rounds* of financing and is beginning to generate revenue (at an increasing rate) from its proven product or service. Follows the *early stage*, and precedes the *expansion* stage.

Hockey Stick Projections. The upward shape of a graph or chart showing revenue, *EBIT*, customers, or some other financial or operations measure that increases dramatically at some point in the future. *Founders*/entrepreneurs have been known to develop business plans that include hockey stick projections to attract the interest of potential investors (including venture capitalists).

Hurdle Rate. The minimum preferred return to limited partners in a venture capital fund (organized as a limited partnership) to be achieved before the general partner's (or manager's) carried interest is permitted. A hurdle rate of 10% means that the venture capital fund must achieve a return of at least 10% per annum on invested assets (for its limited partners) before the remaining profits are shared (with the general partner) according to the carried interest arrangement. Also referred to as the preferred return.

Incentive Stock Options (ISOs). Incentive Stock Options are *options* that satisfy certain criteria under the Internal Revenue Code. Principal among these is that ISOs may be granted to employees only and the *exercise price* must be equal to or greater than the fair market value of the underlying stock on the grant date. The advantage of ISOs is that any gain on the sale of the stock is treated as capital gains instead of ordinary income at the time the underlying stock is sold; provided that the option holder satisfies certain holding periods that are imposed by the Internal Revenue Code. (However, the option holder may be subject to alternative minimum tax when the option is exercised.)

Incubator. An organization or entity designed to host and nurture *start-up* companies (including business concepts and new technologies) to the point that they become attractive to professional management, *angels*, and even *venture capital funds*. An incubator typically provides both physical space and some or all of the services – back-office/administrative, legal, accounting, technical, support/networking, etc. – needed for a business to proceed from concept to *early stage*. Incubators typically charge both a fee and a percentage of the equity for these services.

Indemnity; Indemnification. Provisions in a definitive agreement providing one party post-closing legal rights against the other party for breach of the other's representations and warranties or covenants that survive the closing, as well as the right to recover legal fees and expenses incident to prosecuting such legal rights. Often subject to a basket, a cap, and other negotiated limitations and exclusions.

Independent (or Disinterested) Director. A member of a *Board of Directors* who has no ties or affiliations with either company insiders (e.g., *founders* and management) or outside investors. *Investor rights agreements* commonly provide for the election of one or more independent directors. For public companies, *SEC* and stock exchange rules provide elaborate, detailed definitions and requirements as to who qualifies as an independent or disinterested director.

Initial Public Offering (IPO). A corporation's first offer and sale of stock to the public pursuant to a registration statement (and prospectus) filed with and declared effective by the SEC under the Securities Act. Typically, the IPO is underwritten by an investment banking firm, with the shares listed or quoted on a national securities exchange or stock quotation system (such as the New York Stock Exchange, American Stock Exchange, or NASDAQ). The company accomplishes an Initial Public Offering by filing a registration statement (generally on Form S-1) with the SEC. Most initial offerings public are firm commitment underwritings.

Institutional Investors. Large, asset-rich organizations that invest their funds in a variety of investments and asset classes and on an ongoing, professional basis; typically banks, insurance companies, pension funds, investment companies, mutual funds, and endowments. Together with high-net-worth individuals, these comprise the

most significant investors (and *limited partners*) in venture capital funds.

Intellectual Property (IP). A business's intangible (nonphysical) but often valuable assets, such as its patents, trademarks, copyrights and "brand." The protection of intellectual property can create distinct competitive advantages and can be vital to a venture's fund-raising and growth prospects.

Internal Rate of Return (IRR). The interest/discount rate (expressed as a return on capital invested) at which a specific amount of capital invested today would have to grow to reach a specific value at a specific time in the future. This is the standard, accepted benchmark that venture capital funds (and their limited partners) utilize to measure and compare their relative performance.

In the Money. An *option* or *warrant* that would generate profits if exercised now (the opposite of Out of the Money), or an option that has intrinsic value. An option or warrant is In the Money when the market price of the underlying stock is greater than the *exercise price*.

Investor Rights Agreement. A key definitive agreement in a venture capital investment transaction, typically providing for various obligations of the issuer and existing owners, and rights of new investors.

ISOs. See *Incentive Stock Options*.

Issued and Outstanding Shares. A company's issued and outstanding shares refer to the total number of shares of stock that the company has actually issued to stockholders on a particular date.

Issuer. A business entity that issues (or proposes to issue) *equity securities* and/or *debt securities*. In a venture capital investment transaction, the issuer is the company or *corporation* that is the subject of the financing.

Later Stage. The stage of development of a company that has proven its concept, achieved significant and increasing revenues (compared to its competitors), and is approaching (or has achieved) break-even or positive cash flow. Typically, a later-stage company has completed its expansion stage and is nearing a liquidity or exit event.

Lead Investor. The person or *venture capital fund* that organizes a *round* of financing, leads the round (e.g., in such matters as *due diligence*, valuation, *LOI* preparation, negotiations, documentation and

closing), and usually contributes the largest amount of capital to the round.

Letter of Intent (LOI). A written expression, in the form of a letter, of two (or more) parties' intentions to effect an investment transaction. It summarizes the material terms of the deal and other matters, and serves as the basis for preparing a definitive agreement. By its terms, an LOI generally is not legally binding (except that it may include certain legally binding provisions – typically those addressing confidentiality, no-shop agreements and expenses). Sometimes also referred to as a term sheet, memorandum of understanding, or agreement in principle.

Leverage. Commonly refers to the addition of debt (via borrowings) to a company's capital structure in order to magnify potential equity returns.

Limited Partners. With respect to a *venture capital* fund organized as a *limited partnership*, high-networth individuals and *institutional investors* that contribute capital to the fund are not involved in the management of the fund, and enjoy limited liability with respect to actions by the fund. See also *General Partner* and *Limited Partnership*.

Limited Partnership. With respect to a venture capital fund, a legal entity comprised of a general partner, which manages the fund, and limited partners, who contribute capital but have limited liability and are not involved with the management of the fund. The most common form of organization adopted by venture capital funds. See also General Partner and Limited Partner.

Limited Liability Company (LLC). An entity, created via authorizing state statutory provisions (and typically a *charter* and LLC operating agreement) that offers limited liability to its members (or owners) and is eligible for *pass-through entity* tax treatment.

Liquidation. The process of selling off the (remaining) assets of a company and distributing the proceeds to the company's equity holders, in accordance with their preference or *priority* and *pro rata* interests, after the satisfaction of all debts and liabilities. In the context of *preferred stock*, certain events or transactions (such as a *change of control*) may constitute a "deemed liquidation" (thereby entitling the holder to receive the *liquidation preference* applicable to its shares of *preferred stock*).

Liquidation Preference. The right to receive a specific value or amount for shares of *preferred stock*

(or *equity securities* with preferential rights) if the company is *liquidated* (or deemed to be liquidated) in *priority* to amounts to be distributed on other (junior) securities. The liquidation preference is usually fixed at the original investment amount.

Liquidity Event. See *Exit*.

Lock-Up and Market Stand-Off Agreement. In connection with a public offering of stock, the underwriters typically insist that certain stockholders of the company agree not to sell their shares of the company for some period of time (usually 180 days and which is referred to as the lock-up period) after the company's public offering. A market stand-off agreement is the agreement that the underwriters require those stockholders sign agreeing to this restriction.

LOI. Acronym for a *letter of intent*.

Management Fee. An annual fee, typically fixed at a percentage of the *limited partners*' capital commitments to the fund, designed to cover the basic costs of running and administering a *venture capital fund*. The management fee is not intended to work as incentive compensation for the *General Partner* – that is the purpose of the *carried interest*.

Mandatory Conversion. A mandatory conversion occurs when a triggering event happens upon which the *convertible security* converts no matter what the investor then desires. Typically, upon the closing of a *qualified initial public offering*, the investors are required to convert their shares of *preferred stock* into shares of *common stock* at the applicable *conversion price* or *conversion ratio*.

Mandatory Redemption. The right of a security holder (e.g., of convertible preferred stock) to require the redemption (i.e., repurchase by the issuer) of some or all of the security held at a specified (or determinable) price and after a specified period of time has elapsed (a sufficiently long period such that the holders of the security, if they have not achieved liquidity by then, are disappointed and require negotiation leverage to cause the company to pursue an exit strategy). The purchase price is usually the original investment price plus any accrued and unpaid dividends. Also referred to as a forced buyback.

Market Capitalization. The aggregate value of a business based on the dollar value of all issued and outstanding *securities*. The market cap is computed by multiplying the number of outstanding shares by the current price per share.

Memorandum of Understanding (MOU). See *Letter of Intent*.

Milestone-Based Investing. See Staged Investing.

Minority Protections. Rights provided to minority shareholders affording protection against actions taken (or potentially taken) by majority or controlling shareholders. May include *veto rights*, *tag-along rights*, *preemptive rights*, etc.

MOU. Acronym for a memorandum of understanding.

Narrow-Based Weighted Average Ratchet. A form of *anti-dilution provision* used in venture capital transactions. See also *Weighted Average Ratchet*.

NASD. The abbreviation for the National Association of Securities Dealers which is a self-regulating organization that is responsible for regulating stockbrokers and dealers.

NASDAQ. The abbreviation for the National Association of Securities Dealer Automated Quotations systems which facilitates stock trading on the NASDAQ Stock Market.

NDA. Acronym for a nondisclosure agreement.

Negative Covenant. See Covenant.

Non-Qualified Stock Options (NQSOs). Non-qualified stock options are *options* that do not satisfy one or more of the criteria to be *ISOs*. A company can issue NQSOs to nonemployees and the *exercise price* may be less than the fair market value of the underlying stock on the grant date. Unlike ISOs, when NQSOs are exercised, the option holder is subject to ordinary income tax on the difference between the exercise price and the fair market value of the underlying stock on the date of exercise.

No-Shop. An agreement (usually in the *letter of intent* or *term sheet*) whereby the *issuer* gives an investor an exclusive right during a limited time period to negotiate and enter into a *definitive agreement* with the issuer, and agrees not to solicit or encourage other investment proposals during that period or to talk (or, if specified, to provide information) to other potential investors.

Non-Compete. A contractual provision in which one party agrees not to work for another (competitive) party or engage in activities that are competitive with (or to organize, manage or own a business competitive with) the other party. In connection with an investment transaction, founders as well as senior management and key

employees are typically asked to enter into non-compete agreements.

Noncumulative Dividends. Dividends that are payable to owners of preferred stock at a specific point in time only (i) if there is sufficient cash available to pay the dividends after all company expenses are paid, and (ii) as, if, and when declared by the Board of Directors. If cash flow is insufficient, the preferred stock owners will not receive dividends with respect to that time period and will have to wait until the Board of Directors declares dividends in the future.

Nondisclosure Agreement (NDA). An agreement often used by entrepreneurs and emerging business owners (before delivery of a business plan, financial statements, product information, customer information, projections, etc., to potential investors) to protect the confidentiality of company-related information to be provided to third parties. See also *Confidentiality Agreement*.

Non-Qualified Stock Options (NQs or NQSOs). Non-qualified stock options are options that do not satisfy one or more of the criteria to be ISOs. A company can issue NQSOs to nonemployees and the exercise price may be less than the fair market value of the underlying stock on the grant date. Unlike ISOs, when NQSOs are exercised, the option holder is subject to ordinary income tax on the difference between the exercise price and the fair market value of the underlying stock on the date of exercise.

Non-Solicit. A provision in a *definitive agreement* or a *letter of intent* prohibiting one party for a specified period from soliciting for employment the employees of the other party. Also referred to as a no-raid provision. The provision can also be expressed as a restriction on hiring such employees (as opposed to soliciting them), in which case it is referred to as a no-hire provision.

Note. A document that evidences a debt obligation of a company (specifying, among other things, the amount borrowed, applicable interest rate, *covenants*, *events of default*, and maturity). The company in this case is referred to as the obligor, and the person advancing the funds is referred to as the holder. Longer-term notes are often referred to as *debentures*.

NYSE. The abbreviation for the New York Stock Exchange, which is the world's oldest (it was founded in 1792) and largest stock exchange.

Option. The right to purchase *equity securities* in a company at a specified price (referred to as the *exercise price*) within or over a specified time period. Primarily awarded to management and key employees, typically awarded in the discretion of (and with the terms and provisions determined by) the *Board of Directors* or a board compensation committee, pursuant to a shareholder-approved option (or incentive compensation) plan.

Option Pool. The number of shares of *common stock* that are set aside for issuance upon the exercise of *options* or other equity-based incentives, to be granted by the *Board of Directors* in the future to management and key employees (and perhaps others). The amount of the option pool varies (from 7.5% to 25%), but it averages around 15% of *fully diluted shares*.

Outstanding Shares. The number of shares of stock that have been issued and are in the hands of investors/shareholders. This does **not** include treasury shares or shares that may in the future be issued in the event (i) *convertible securities* are converted, (ii) exchangeable securities are exchanged, or (iii) *options, warrants*, and other rights to purchase stock are exercised.

Pari Passu. Equally; ratably; without preference. Generally used to describe *securities* that are to be treated as being of equal priority. Investors with Pari Passu rights will share in equal speed and equal proportion. Thus, the *liquidation preferences* are paid to the investors pari passu, meaning at the same time or at the same level and without regard to the order in which the investments were made. If the proceeds of the *liquidation* are insufficient to pay all of the liquidation preferences, then the investors divide the proceeds on a *pro-rata* basis.

Participating Preferred Stock. A type of preferred stock that is entitled to participate (or share) with holders of common stock in dividends and/or liquidation payments (after and in addition to collecting any stated liquidation preference or dividend rights). Where participating preferred stock is utilized, the participation feature may be subject to a cap (e.g., at two or three times the investment amount). If the investors do not have participation rights, they must choose either to receive their liquidation preference or convert their shares of preferred stock into common stock and participate on a pro rata basis with the holders of common stock in the liquidation proceeds. See also Participation.

Participation. The right of a holder of preferred stock to enjoy the rights associated with its preferred stock and also to participate in any benefits available to common stock without converting to common stock. This may occur with respect to the liquidation preference (where a series of preferred stock has the right to receive its liquidation preference and then also to share in whatever funds remain to be distributed to common stock holders) and dividends (where, after a holder receives its cumulative dividend, it also has the right to receive any dividend payable on the common stock).

Pass-Through Entity. An entity that is generally disregarded for federal income tax purposes, resulting in no entity-level taxation and the entity's owners or partners recognizing income tax burdens and benefits (which "pass through" the entity) immediately, whether or not they have received a distribution. The most common pass-through entities are "S" corporations, limited liability companies, limited partnerships, and limited liability partnerships.

Payment-in-Kind (PIK). A feature of a *security* pursuant to which *dividends* (in the case of an *equity security*) or interest (in the case of a *debt security*) are paid in the form of additional *securities* of the same type, instead of cash.

Pay-to-Play Provision. A contractual provision requiring an existing investor to participate on a pro rata basis in a subsequent investment round, especially a down round. If the investor does not so participate, then it suffers specific adverse consequences, including automatic conversion to common stock or a "shadow" preferred stock, loss of the right to participate in future rounds, loss of anti-dilution protections, loss of veto rights, and loss of board representation rights. These provisions are intended to keep the investment syndicate in place to continue to fund the company by being punitive to nonparticipating investors.

Piggyback Rights. See Registration Rights.

Portfolio Company. A *target* company in which a *venture capital fund* has invested and holds an ownership interest.

Post-Money Valuation. The value of a *portfolio company* immediately after a funding *round*. The post-money value is the *pre-money value* plus the amount of funds invested in the current round. For example, if investors in the current round invest \$10 million in a company that is valued at

\$15 million pre-money, the resulting post-money value is \$25 million.

Preemptive Rights. The right of a stockholder to participate in future issuances of *equity securities* by a company, through the purchase of additional equity securities, so as to allow that stockholder to maintain its proportionate ownership interest.

Preferred Stock. A class of equity capital ownership of, and a unit of ownership in, a corporation, which (i) may be entitled to dividends (on a cumulative or noncumulative basis) and (ii) is entitled to a preference or priority in payment as compared to common stock. This priority may be in respect of the payment of dividends or the making of distributions in liquidation, or both. Whether through the certificate of designation or the investor rights agreements, holders of preferred stock typically enjoy various rights and benefits that holders of common stock do not. Generally, these rights and preferences include affirmative covenants, anti-dilution protection, conversion rights, co-sale rights, dividend preference, drag-along rights, liquidation preference, preemptive rights, price protection, protective provisions or negative covenants, redemption rights or put rights, registration rights, and rights of first refusal. Preferred Stock is designated by series such as Series A, Series B, and so forth. See also Convertible Preferred Stock.

Pre-Money Valuation. The (agreed-upon, theoretical) value of a company immediately prior to the current investment round. This value is determined by negotiation and is calculated (mathematically) by multiplying the number of outstanding (or fully diluted) shares before the current round times the agreed (or derived) purchase price per share in the round. example, if a venture capital fund agrees to invest \$5 million in a company with an agreed pre-money value of \$10 million and with one million shares outstanding, then the fund would receive 500,000 shares (or shares of preferred stock convertible into 500,000 shares of common stock) at a purchase price of \$10 per share. See also Post-Money Valuation.

Price Protection. See also Anti-Dilution Protection.

Priority. The status of one creditor or *security* holder having a claim or right (e.g., as to *dividends* or distributions in *liquidation*) that is superior to the claims or rights of another creditor or security holder. The superior claim/right is referred to as *senior*, and the other claim/right is referred to as junior or, in the case of debt, *subordinated*.

Private Equity Fund. A fund typically organized as a *limited partnership* for the purpose of making equity investments in private businesses. Some private equity funds are structured as buyout funds, focused on acquiring all or a controlling equity interest in the *target* business, with the transactions typically financed with a substantial amount of *senior*, *subordinated*, and sometimes mezzanine financing.

Private Placement; Private Offering. The offer and sale of *securities*, not involving or in connection with a *public offering* and exempt from the *registration* requirements of the *Securities Act*. In short, a way to raise capital from sophisticated (often institutional) investors without registering the offering or the securities with the *SEC*. Note that even exempt private placement offerings are subject to federal and state *antifraud rules* (and may be subject to other state securities laws). See also *Accredited Investor*.

Private Placement Memorandum (PPM). A disclosure document that sets forth (i) the terms of the *securities* to be offered in a *private placement*; and (ii) a description of the business, operations, product/service, market, competition, ownership, management, and financial condition of the *issuer* (resembling a detailed business plan). Often also includes risk factors and financial projections. Also referred to as a (private) offering memorandum.

Pro Rata. Apportionment based on relative ownership interests (typically, as a percentage of outstanding shares).

Prospectus. A prospectus is a document included in an *issuer's registration statement* and contains all disclosure to be given to potential investors. The issuer must give a prospectus to all potential purchasers of the company's *securities* in the offering. An issuer's preliminary prospectus is called a "red herring" because it contains red legends on the front cover.

Protective Provisions or Negative Covenants. protective provisions or negative covenants give the investors the right to approve certain corporate actions. Typical protective provisions give the investors the right to approve amendments to the company's certificate of incorporation and bylaws, future issuances of stock, the declaration and payment of *dividends*, increases in the company's *option pool*, expenditures in excess of approved budgets, the incurrence of debt, the sale of the company, the license or sale

of *intellectual property*, and changes in the company's line of business.

Public Offering. A corporation's offer, issuance and sale of shares to the public (i.e., a large number of unaffiliated investors) pursuant to a *registration statement* (and *prospectus*) filed with and declared effective by the *SEC* under the *Securities Act.* Typically, public offerings by VC-backed companies are underwritten by one or more investment banking firms, and the shares are listed or quoted on a national securities exchange or stock quotation system. See also *Initial Public Offering*.

Put Option. The right to sell a *security* at a specified price (or price range) within a specific time period. See also *Call Option* and *Option*.

Qualified IPO; QPO. An initial public offering that meets certain contractually defined criteria (e.g., a minimum gross proceeds amount and/or a minimum share price multiple vs. the original investment amount). The criteria are usually designed to ensure a sufficiently robust IPO such that the IPO shares will trade on a major securities exchange (e.g., NASDAQ or New York Stock Exchange). The occurrence of a QPO may trigger certain events (e.g., automatic conversion of preferred stock into common stock and/or loss of certain preferred stock holder rights).

Qualified Sale. A sale (or change of control) of a portfolio company that meets certain contractually predefined criteria (e.g., a minimum gross proceeds or valuation amount, and/or a minimum share price multiple vs. the original investment amount). The criteria are usually designed to produce a sufficiently robust sale to ensure a good return to preferred stock holders (in view of their liquidation preference and conversion and other rights). The occurrence of a qualified sale may trigger certain events (e.g., automatic conversion of preferred stock into common stock and/or loss of certain preferred stock holder rights).

Redeemable Preferred Stock. Preferred stock that, by its terms, enables the stock holder to require that the *issuer* redeem (or repurchase) the preferred stock for a specific amount within or following a specific time period. The *redemption* feature is also referred to as a *put option* or *put right*.

Redemption. The repurchase (and cancellation) by an *issuer* of its own *securities* from a holder, prior to their maturity (if any), pursuant to the terms of the *securities*. This may be presented as a right or

an obligation of the issuer. See also Forced Buyback.

Redemption Rights or Put Rights. Redemption rights or put rights give the investors the right to require the company to repurchase the investors' stock after a period of generally four to seven years. The repurchase price for the stock may be based upon the amount of the *liquidation preference*, the fair market value of the stock as determined by an appraiser, or the value of the stock based upon a multiple of the company's earnings.

Registration. The process under which shares of an *issuer* are registered with the *SEC* under the *Securities Act* in preparation for a sale of the shares to the public in a *public offering*. As part of this process, the *SEC* typically reviews and comments on the issuer's *registration statement*.

Registration Rights. Rights of a holder to have securities registered with the SEC (on a registration statement) in connection with a later public offering by the issuer. Demand rights require (i.e., permit the holder to force) the holder's shares (or a portion thereof) to be so registered. Piggyback rights permit the holder to add (or "piggyback") its shares (or a portion thereof) onto another person's or the registration statement (and public offering). Typically, the investors cannot exercise their demand registration rights until after the company is public and only if a minimum amount of shares is demanded to be registered. However, absent this restriction, the investors could exercise their demand registration rights and require the company to conduct an initial public offering.

Registration Statement. A Registration Statement is a disclosure document that a company (known as the *issuer*) files with the *SEC* pursuant to Section 5 of the *Securities Act* in order to register its shares of stock so that they can be sold to the public and become freely tradeable. It contains a description of the issuer's business and financial condition and of how the proceeds of the offering will be used. It also includes background information on the issuer's executive officers and *directors*, information on the issuer's capitalization, and audited financial statements.

Regulation D; Reg D. A series of SEC-adopted rules (under the Securities Act) that provide transactional "safe harbor" exemptions for private placement transactions from the registration requirements of the Securities Act. See also Private Placement; Private Offering and Accredited Investor.

Representations and Warranties. Provisions in a *definitive agreement* by which a party makes certain statements of fact as of a specific time, statements that are binding upon it (and for which other parties can pursue remedies in the event of a breach). These factual statements, exceptions to that are set forth in *disclosure schedules*, are often subject to a negotiated *survival period* and accompanied by an *indemnity* obligation from the maker of the statements.

Restricted Shares. Shares of stock acquired in a private placement; this stock is considered restricted and may not (absent registration) be resold until after an appropriate holding period has expired (or some other available registration exemption is satisfied). A registration statement is a disclosure document that a company (known as the issuer) files with the SEC pursuant to Section 5 of the Securities Act in order to register its shares of stock so that they can be sold to the public and become freely tradeable. It contains a description of the issuer's business and financial condition and of how the proceeds of the offering will be used. It also includes background information on the issuer's executive officers and directors, information on the issuer's capitalization, and audited financial statements.

Return on Investment (ROI). The proceeds yielded from an investment, over a specific time period, calculated as a percentage of (and thus a return on) the original investment.

Revolver; Revolving Facility. A form of *senior debt*, documented through a revolving *credit agreement*. These loans – up to a maximum amount, and subject to the initial and ongoing satisfaction of certain financial and other *covenants* and avoidance of *events of default* – can be borrowed, repaid and reborrowed within a specific time period.

Right of First Offer. A provision, typically in a *shareholders' agreement* or *investor rights agreement*, that prohibits a shareholder from selling her/his shares for a defined period unless she or he has first offered to sell the shares to the other shareholders (or to other specified shareholders) at the price and on the terms fixed by the selling shareholder.

Right of First Refusal. A provision, typically in a *shareholders' agreement* or *investor rights agreement*, that prohibits a shareholder from accepting a bona fide offer made by a third person to purchase the shareholder's shares unless and until the company and other specified shareholders are first given the

opportunity to purchase the shares at the same price and on the same terms.

Road Show. The marketing process during a *public offering* in which the management of an *issuer*, together with the underwriters, meets with groups of prospective investors to stimulate interest in the issuer and the offering.

Round. An investment transaction (or financing event) in which a private company receives funding from outside investors. Venture-backed companies typically receive more than one round of venture capital funding. The term "first-round funding" does not necessarily mean that the company has received no previous outside capital (particularly if from one or more *angel investors*). The first round typically refers to the first investment transaction involving participation by one or more *venture capital funds* or *institutional investors*. See also "A" Round and "B" Round.

"S" Corporation. A corporation that, by proper and qualifying "election" timely filed with the Internal Revenue Service, does not pay income taxes; instead, like a partnership, its owners/stockholders pay income taxes on their proportion of the corporation's profits at their individual income tax rates. See also *Pass-Through Entity*.

SBIC. Acronym for *Small Business Investment Company*.

Schedule of Exceptions. See *Disclosure Schedule*.

SEC. Acronym for the Securities and Exchange Commission. An independent U.S. regulatory agency responsible for administering and enforcing the federal securities laws, including the Securities Act and the Securities Exchange Act.

Securities Act. The Securities Act refers to the Securities Act of 1933 that was intended to protect investors by ensuring that persons offering to sell stock provided accurate and complete information about the stock being sold. The Securities Act requires the *registration* of *securities* or the sale of securities pursuant to an exemption from registration and the disclosure of all material information regarding the *issuer* and the securities being sold so that investors may make informed investment decisions.

Securities Exchange Act. The Securities Exchange Act of 1934, as amended; the federal statute that regulates, among other things, the securities markets and exchanges, periodic

reporting (Form 8-K, Form 10-Q, Form 10-K) by public companies, insider trading, proxy solicitations, and tender offers. Also referred to as the 1934 Act.

Security; Securities. Legal instrument(s) that represent(s) an equity or debt interest in an *issuer*. Shares of *capital stock*, *warrants*, *options*, *notes*, *debentures*, and bonds are examples of securities.

Seed Capital; Seed Financing; Seed Round. Investment capital provided (usually in the first round) to a venture in the start-up or seed stage. Typically funded by angels, friends and family, and some venture capital funds that focus on seed and early stage financings. The seed round is usually structured as an investment in common stock (perhaps including warrants) but also may be structured as a loan, convertible loan, or investment in preferred stock.

Seed Stage. The initial stage of a business or venture when it has just been organized and its *founders* are developing the venture's business plan, product or service, and initial financing plan. Sometimes also referred to as the *start-up* stage.

Senior Debt. Debt with *priority* in right of payment over junior (*subordinated*) debt, which is generally secured by the assets of the borrower. May take the form of a term loan or a *revolving facility*, in each case under a *credit agreement*.

Series A Preferred Stock. See "A" round and preferred stock.

Shareholders' Agreement. An agreement among the shareholders of a company regulating the governance of the company, the ownership and transfer of its *equity securities*, and other matters. Often contains provisions relating to preemptive rights, drag-along rights, tag-along rights, rights of first offer/refusal and veto rights.

Shell. An entity with no significant assets, business or operations.

Small Business Investment Company (SBIC). An investment firm licensed by the U.S. Small Business Administration (SBA) to obtain matching federal loans for its venture capital/private equity investments. An SBIC will generally have access to \$2 in credit (in the form of low-interest loans, drawn down on a deal-bydeal basis) for every \$1 that it invests in a portfolio company meeting certain requirements.

Staged Investing. An investment in a company structured to be funded in stages (or installments),

with the initial installment at the first *closing* and then subsequent installments if the company meets certain specified milestones (e.g., hiring key managers, reaching a revenue hurdle, meeting project development deadlines, landing a specified number of customers) or if an agreed time period lapses. Also referred to as *milestone-based investing*.

Start-Up. A company or business in its formative or *seed stage*.

Stock Option. See option, incentive stock options, and non-qualified stock options.

Stock Pool. See option pool.

Stock Restriction Agreement. A stock restriction agreement gives the company the right to purchase a decreasing number of the shares of *Common Stock* owned by a *founder* over of a period of generally three to four years if the founder's employment with the company is terminated. Generally, the repurchase price of the shares is the same price that the founder paid for the shares. Under a stock restriction agreement, a founder's shares will vest as the company's repurchase rights lapse over the term of the agreement. Even though the unvested shares are subject to the company's repurchase rights, the founder has full voting and other rights with respect to all of the shares.

Stock Split. A change in a company's number of shares outstanding that doesn't change a company's total market value shareholder's percentage ownership in the company. The additional shares are issued to existing shareholders at a rate expressed as a ratio. For example, a 2-for-1 stock split doubles the number of shares outstanding. An investor holding 100 shares of a \$60 stock, after a 2-for-1 stock split, would have 200 shares of \$30 stock. Importantly, the percentage ownership in the company remains the same. Stock combinations and stock dividends have similar effects as stock splits.

Strategic Investors. Corporate or individual investors that add strategic value to their equity investments through industry experience, expertise and contacts. These investors can assist companies in operations, finance, marketing, sales, intellectual property, acquisitions and other disciplines, as well as in raising additional capital and effecting exit strategies.

Subordinated Debt. Debt that is *subordinated* (and thus inferior) in right of payment to other

more *senior debt* in the event of *liquidation*, insolvency or bankruptcy. Subordinated debt is sometimes also called "high-yield debt" (given the high interest rate it bears).

Survival; Survival Period; Survive. Representations and warranties and covenants in a definitive agreement that, by their terms, continue to operate and that, if breached, may serve as the basis of an indemnity claim after the closing are said to "survive" the closing. The period during which such representations and warranties and covenants continue to operate (and serve as the basis of an indemnity claim) post-closing is referred to as the survival period. Thus, the survival period operates as a contractually specified statute of limitations.

Sweat Equity. Equity ownership received (typically, by *founders*, employees and consultants) as a result of and in exchange for work, deliverables or expertise (the "sweat"), as opposed to a cash investment.

Tag-Along Rights. Contractual right of a minority investor/shareholder (typically provided in a *shareholders' agreement*) to sell its stock (on a *pro rata* basis) along with and at the same price as the *founder* or majority shareholder, if either the founder or majority shareholder elects to sell stock to a third party. In this way, the minority investor/shareholder is permitted to "tag along" with the selling shareholders. Also referred to as *co-sale rights*.

Target. The recipient of funding in an investment transaction. For example, in a typical venture capital transaction, the target is the *issuer* of the *preferred stock;* upon the *closing,* the target becomes a *portfolio company* of the investing *venture capital fund* or *funds.* The word also refers to a company or business entity being acquired in an acquisition transaction.

Term Sheet. An abbreviated, high-level written summary (sometimes in list or bullet-point format) of the material terms of a potential investment transaction and serving as the basis for preparing one or more *definitive agreements*. A term sheet may have a binding exclusivity or *no-shop* provision whereby the company and the *founders* agree that they will not initiate or hold discussions with other potential investors for some period of time after the term sheet is signed. Also, some investors require the company to pay their legal fees and *due diligence* expenses even if the investment set forth in the term sheet does not close for any reason. See also *letter of intent*.

Underwater. The state of being "out of the money." An *option* or *warrant* is underwater if the current fair market value of the underlying stock is less than the option or warrant *exercise price*.

Venture Capital Fund. A fund typically organized as a *limited partnership* for the purpose of making equity investments in private businesses believed to have exceptional growth potential (and the promise of yielding super-sized returns on the fund's capital).

Veto Rights. Rights granted to certain shareholders (or to some or all of a class or series of shares) to vote on or approve certain specified actions or transactions by an issuer (e.g., additional borrowings financings, or capital expenditures over a specified amount, an IPO, transactions with affiliates, sale or other change of control). Thus, without the vote or consent of the shareholders holding these rights, the action in question may be vetoed or blocked. Veto rights are one type of minority protection. Also often referred to as blocking rights.

Voting Stock. Stock giving the holder the right to vote for the election of the *issuer's Board of Directors* generally (and not just upon the occurrence of certain events, such as the failure to pay *dividends* or breach of a *covenant*).

Warrant. A *security* that provides the holder with the right to purchase stock (*equity securities*) at a specified price (referred to as the *exercise price*) within or over a specified time period. Similar to an *option*, but typically issued to third parties (not *directors*, employees, or insiders) in connection with the issuance of *debt securities*.

Washout Round. A financing *round* whereby previous investors, *founders* and management/employees suffer substantial *dilution* (and loss of rights). As a result of a washout round, the new investors usually gain majority ownership and control of the *issuer*.

Weighted Average Ratchet. A type of anti-dilution provision, which applies a weighted average formula to adjust the exercise price or conversion ratio of a security downward based on the sale price and number of common equivalent shares issued by the company (in a subsequent down round) after the issuance of the first security. The broad-based weighted average ratchet is the most commonly used anti-dilution formulation in venture capital transactions. In essence, the effect of the share issuance in the down round is spread over a large

number or broad base of shares (all *fully diluted* outstanding shares, including unexercised options and outstanding *convertible securities*). In a *narrow-based weighted average ratchet* (a protection more favorable to the investor), the effect of the share issuance in the down round is spread over a smaller number or base of shares (e.g., issued and outstanding shares only).

START-UP COMPANY CHECKLIST

(Assumption is all of these will be privately held – no publicly traded companies!)

By Mary J. Mullany, Partner, Ballard Spahr LLP

TYPE OF ENTITY

Choices are corporation (subchapter "C" or subchapter "S," see tax discussion below), partnership (limited or professional LLP) or limited liability company (LLC). The choice of entity is very important because it will impact lots of decisions. Some things to think about:

- How many owners? Are they related?
 What is the business of the enterprise?
 What is the exit strategy (i.e., run the business, sell in a designated period to others, go public?)
- Do different owners need different rights of ownership? For example, if you have any venture or private equity owners, they will probably want a preferred return, governance rights, etc. On the other hand, if it is a family business you may not need flexibility in the types of equity.
- How complicated is the business model?
- Is the entity being formed for a specific purpose, such as holding real estate? If so, you want a pass-through entity, such as an LLC. If it is a subsidiary of another company, an LLC is also probably easier now.

STATE LAW ISSUES

The law of the state sets forth the rights and obligations of the various interested people, i.e., owners, officers, directors, employees. Most people consider Delaware and Nevada as having the most advanced laws that favor the entity, as compared with the owners. North Dakota (yes, North Dakota!) is out there advertising its shareholder-friendly corporate law.

State law also implicates the tax laws. For example, Pennsylvania state tax law is a mess – corporate taxes apply to entities such as LLC, and it is hard to dissolve in Pennsylvania once you are formed – lots of paperwork. Delaware is easier all around. You can form a company in any state jurisdiction and then qualify it to do business in jurisdictions where it operates the business. That

way, you only have to pay Pennsylvania tax (for example) on the income earned in that state, not on income earned in other states.

State sales tax is a big issue for anyone selling products or services, including over the internet. There are no easy "bullets" here, but don't forget about this issue.

INCOME TAX ISSUES

The big decision is whether you want the entity taxed as a corporation or whether you want the income tax obligations to "flow through" to the partners/owners.

- If you set up a "C" corporation, that is taxed as a corporation and it pays income tax at the corporate level. So, suppose the corporation makes \$1 million in revenue in 2009 and has \$500,000 in expenses, it has \$500,000 as profit. It would need to pay tax on the \$1 million in revenue, minus any applicable deductions. The corporate tax rate can range from relatively small (12% to 15%) to more substantial (25% to 35%). Then, if the corporation wants to declare a dividend to its shareholders to dividend out the profit, those shareholders pay tax on that dividend (currently at 15%). This is what is known as "double taxation." arises all the time to hamper corporate transactions. For example, if you sell the assets of a C corporation, the money is paid to the company. The company then pays the tax and distributes the remainder as a dividend to its shareholders, who then pay another tax. It limits your ability to use an asset transaction if you are a "C" corporation. The only times I use it anymore are public traded companies, companies too big to be an "S" corporation but that know they will go public and some professional entities that have to be corporations.
- If you set up a "flow through" or "pass through" entity, there is no income tax at the entity level; rather all elements of profit and loss flow through to the owners. The

choices here are an "S" corporation, a partnership or an LLC.

An "S" corporation — a corporation that files an election to be taxed as a partnership. You can't have more than 100 shareholders; they all have to be individuals (no corporate owners allowed) and they all have to be U.S. citizens.

A partnership – usually a limited partner. This type of entity has one partner in charge, called the general partner, and the limited partners cannot have governance control of the entity - they are basically passive investors. You can have as many limited partners as you want. There are special rules for family limited partnerships that get you good tax treatment from an estate perspective. I usually see limited partnerships used for things like real estate development ventures, ownership of real estate (each building is owned by a separate partnership) and franchise of a business.

An LLC – This is increasingly the most common form of entity because it is most efficient from a tax perspective but does not have to have lots of governance. An LLC can have as many owners as you want. They can be other entities and they can be non-U.S. citizens. The owners can hold different interests so that the flow of money goes the way you want.

In each of these, the owners have to understand that they are getting all the tax obligations. In my example above for a "C" corporation, let's say the "S" corporation, partnership or LLC wants to hold on to \$250,000 of its revenues to grow the business, so it is distributing only \$750,000 to the owners. The owners still have to pay tax on the full \$1 million in revenues. So, you need to make sure that there are tax distributions made to the extent of any profits allocated to them. If this entity is in a state where the personal income tax rate is 4%, then the tax distribution would be equal to the highest federal personal income tax rate (36%) and the highest state rate (4%), so the tax distribution would be 40% of the taxable income of the entity.

GOVERNANCE

Corporation – A corporation must have directors and officers. It can be as simple as one person who is the sole director and all of the officers. Generally you need at a minimum a president, secretary and treasurer. I don't like to have the president and secretary be the same person, because lots of times the secretary has to certify that the president signed an agreement or other document.

- State law governs when a corporation has to have meetings of the shareholders.
- You don't have to pay directors for their service, but you certainly can.
- Increasingly even privately held companies are looking for "independent" directors to give them a fresh look at the business.
- The directors have the overall control and approval authority, but it is the officers that operate the business.

"S" corporation - the same as "Corporation" above

Partnership – The general partner controls and has all the authority. Usually the general partner is another entity, such as a corporation or an LLC.

• You don't generally need to have a meeting of the limited partners every year.

LLC – An LLC can be member-managed or manager-managed. You can have as much or as little governance as you want. If it is a simple single or two-member LLC, I usually have it be member-managed and then they don't have to hold meetings, etc. – just operate the business. If it is a larger group of owners, I generally structure the governance like a corporation, i.e., have a Board of Managers and officers.

 You don't have to hold meetings of the owners, but you can.

CHARTER DOCUMENTS

Corporations

 Articles (or Certificate) of Incorporation – filed with the State Corporation Bureau – its contents are driven by the statute

- Bylaws Usually forms are available. Set forth the rights and duties of the shareholders, directors and officers.
- Shareholders' Agreement This sets forth any governance rights (i.e., right to elect directors) and any restrictions on the ability to sell or buy shares of stock).
- May need to advertise the formation (check the business law code of the state).
- Need a Tax ID number (IRS Form SS-4).
- Annual filings with the state pretty benign, but need to do it.
- Need a registered office in the state of formation. If incorporating in a state where the entity has no offices, there are services that will serve as the registered office for an annual fee.
- Franchise tax based usually on number of shares or income. Can be a trap for the unwary. For example, for a Delaware corporation the franchise tax maxes out at \$150,000 a year, but you can get to that level if you have more than 500,000 shares. Lots of people like to issue thousands or millions of shares of stock, where you get the same ownership percentage but have less authorized shares.

Partnership

- Articles (or Certificate) of Limited Partnership – very simple document – date of formation, location of registered office, that is it. Filed with the state.
- Don't need Tax ID number because tax obligations are in the partners.
- Usually have an agreement of limited partnership that sets forth the governance rights of the general partner, any restrictions

on buying or selling partnership interests and what items require partner approval.

LLC

- Articles (or Certificate) of Formation very simple document – date of formation, location of registered office, that is it. Filed with the state.
- Operating Agreement This is the document that sets forth the governance, the flow of funds, the rights of members, managers (if any) and officers (if any). It can be as flexible as you want, but it needs to match the business deal. You would also put any restrictions on the sale of member interests in here.

OTHER ISSUES

D&O Insurance – If you have managers, directors, officers – buy D&O insurance. It is relatively inexpensive, but very important.

Corporate formalities – minute book; stock records. It is very important to keep the charter documents together and, if there is some sort of Board or shareholder meetings, have minutes and keep them all together. Stock or other ownership records are really important. It can be as simple as a spreadsheet showing ownership, but you have to maintain it.

Minute books and stock certificates – You can buy minute books from a company called M. Burr Keim. The book costs about \$200. You can also buy stock certificates from them.

Nonprofit entities – You set up a nonprofit under state law and then file a form with the IRS to get tax-exempt status (Form 1023).

TYPICAL DILIGENCE CHECKLIST/DATA ROOM REQUEST LIST

By Matt Mezzancello, DataSite Director, Merrill Corp.

FINANCIAL INFORMATION

Annual and quarterly financial information for the last three years

- Income statements, balance sheets, cash flows, and footnotes
- Planned versus actual results
- Management financial reports
- Breakdown of sales and gross profits by:
 - Product Type
 - o Channel
 - o Geography
 - Current backlog by customer (if any)
 - Accounts receivable aging schedule

Financial projections

- Quarterly financial projections for the next three fiscal years
 - o Revenue by product type, customers and channel
 - o Full income statements, balance sheets, cash
- Major growth drivers and prospects
- Predictability of business
- Risks attendant to foreign operations (e.g., exchange rate fluctuation, government instability)
- Industry and company pricing policies
- Economic assumptions underlying projections (different scenarios based on price and market fluctuations)
- Explanation of projected capital expenditures, depreciation, and working capital arrangements
- External financing arrangement assumption

Capital structure

Current shares outstanding

- List of all stockholders with shareholdings, options, warrants or notes
- Schedule of all options, warrants, rights, and any other potentially dilutive securities with exercise prices and vesting provisions
- Summary of all debt instruments/bank lines with key terms and conditions
- Off balance sheet liabilities

Other financial information

- Summary of current federal, state and foreign tax positions, including net operating loss carryforwards
- Discuss general accounting policies (revenue recognition, etc.)
- Schedule of financing history for equity, warrants, and debt (date, investors, dollar investment, percentage ownership, implied valuation and current basis for each round)

PRODUCTS

Description of each product

- Major customers and applications
- Historical and projected growth rates
- Market share
- Speed and nature of technological change
- Timing of new products, product enhancements
- Cost structure and profitability

CUSTOMER INFORMATION

- List of top 15 customers for the last two fiscal years and current year-to-date by application (name, contact name, address, phone number, product(s) owned, and timing of purchase(s))
- List of strategic relationships (name, contact name, phone number, revenue contribution, marketing agreements)

- Revenue by customer (name, contact name, phone number for any accounting for 5 percent or more of revenue)
- Brief description of any significant relationships severed within the last two years. (name, contact name, phone number)
- List of top 10 suppliers for the last two fiscal years and current year-to-date with contact information (name, contact name, phone number, purchase amounts, supplier agreements)

COMPETITION

Description of the competitive landscape within each market segment, including:

- Market position and related strengths and weaknesses as perceived in the marketplace
- Basis of competition (e.g., price, service, technology, distribution)

MARKETING, SALES AND DISTRIBUTION

Strategy and implementation

- Discussion of domestic and international distribution channels
- Positioning of the company and its products
- Marketing opportunities/marketing risks
- Description of marketing programs and examples of recent marketing/product/public relations/media information on the company

Major customers

- Status and trends of relationships
- Prospects for future growth and development
- Pipeline analysis

Principal avenues for generating new business Sales force productivity model

- Compensation
- Quota average

- Sales cycle
- Plan for new hires

RESEARCH AND DEVELOPMENT

Description of R&D organization

- Strategy
- Key personnel
- Major activities

New product pipeline

- Status and timing
- Cost of development
- Critical technology necessary for implementation
- Risks

MANAGEMENT AND PERSONNEL

Organization chart

- Historical and projected headcount by function and location
- Summary biographies of senior management, including employment history, age, service with the Company, years in current position

Compensation arrangements

- Copies (or summaries) of key employment agreements
- Benefit plans

Discussion of incentive stock plans

Significant employee relations problems, past or present

- Personnel turnover
- Data for the last two years
- Benefit plans

LEGAL AND RELATED MATTERS

 Pending lawsuits against the company (detail on claimant, claimed damages, brief history, status, anticipated outcome, and name of the company's counsel) Pending lawsuits initiated by company (detail on defendant, claimed damages, brief history, status, anticipated outcome, and name of company's counsel)

Description of environmental and employee safety issues and liabilities

- Safety precautions
- New regulations and their consequences

- List of material patents, copyrights, licenses, and trademarks (issued and pending)
- Summary of insurance coverage/any material exposures
- Summary of material contacts
- History of SEC or other regulatory agency problem, if any

LIST OF VENTURE CAPITAL FIRMS

Please note the funds included in this list are general venture capital funds. They are not all funds that invest in the life sciences industry. Entrepreneurs interested in funding should research these funds via their websites and network before approaching these funds.

As of March 2011

ABS Capital Partners

Headquarters

400 East Pratt Street, Suite 910 Baltimore, MD 21202-3116 Phone: 410-246-5600

Fax: 410-246-5606

Web: www.abscapital.com

E-mail: abscapital@abscapital.com

Accuitive Medical Ventures Primary Headquarters

2905 Premiere Parkway, Suite 150

Duluth, GA 30097 Phone: 678-812-1107 Fax: 678-812-1117

E-mail: lpotter@amvpartners.com

Adams Capital Management Primary Headquarters

500 Blackburn Avenue Sewickley, PA 15143 Phone: 412-749-9454 Fax: 412-749-9459

Fax: 412-749-9459 E-mail: info@acm.com

Allegis Capital Regional Office

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Palo Alto, CA 94301 Phone: 650-687-0500 Fax: 650-687-0234

American Capital *Headquarters*

Two Bethesda Metro Center, 14th Floor

Bethesda, MD 20814 Phone: 301-951-6122 Fax: 301-654-6714

Web: www.american-capital.com E-mail: info@americancapital.com

American Capital Los Angeles Office

11755 Wilshire Boulevard, Suite 2400

Los Angeles, CA 90025 Phone: 310-806-6280 Fax: 310-806-6299

Web: www.americancapital.com

American Capital *Philadelphia Office*

Three Hundred Four Falls, Suite 380 300 Conshohocken State Road West Conshohocken, PA 19428

Phone: 610-238-0210 Fax: 610-238-0230

Web: www.americancapital.com

Ampersand Ventures Regional Office

12555 High Bluff Drive, Suite 380

San Diego, CA 92130 Phone: 858-259-4664 Fax: 858-259-8384

E-mail: info@ampersandventures.com

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75 14th Street, 24th Floor Atlanta, GA 30309 Phone: 404-920-9000

Fax: 404-920-9001

ARCH Southwest

6300 Bridgepoint Parkway Building One, Suite 500 Austin, TX 78730 Phone: 512-795-5830

Fax: 512-795-5849

Armada Venture Group Primary Headquarters

3475 Piedmont Road, NE, Suite 450

Atlanta, GA 30305 Phone: 404-442-1500 Fax: 404-442-1501 E-mail: info@avcg.com

Aster Capital

Regional Headquarters 1751 South 4800 West

Salt Lake City, UT 84104 Phone: 801-990-1223 Fax: 801-665-3136

Athenian Venture Partners

California

Athenian Venture Partners - San Diego Office

San Diego, CA

Web: www.athenianvp.com

AT&T Ventures

Primary Headquarters

295 North Maple Avenue, Suite 7202M2

Basking Ridge, NJ 07920 Phone: 908-221-2574

Baird Venture Partners

Wayne Office

175 Strafford Avenue Wayne, PA 19087-7777 Phone: 610-975-0929 Fax: 610-975-0922

Web: www.bairdprivateequity.com E-mail: bvp@rwbaird.com

Bay City Capital

750 Battery Street, Suite 400 San Francisco, CA 94111 Phone: 415-676-3830 Fax: 415-837-0503

Web: www.baycitycapital.com

BD Ventures

Primary Headquarters

c/o Becton Dickinson & Co MC070 One Becton Drive

Franklin Lakes, NJ 07417-1883

Phone: 201-847-4052 Fax: 201-847-4874

Benefit Capital Companies *Primary Headquarters*

3235 North Pioneer Road Logandale, NV 89021-0542

Phone: 702-398-3222 Fax: 702-398-3700

E-mail: mail@benefitcapital.com

Ben Franklin Technology Partners of Southeastern Pennsylvania

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Building 100 Innovation Center, The Navy Yard

4801 South Broad Street, Suite 200

Philadelphia, PA 19112 Phone: 215-972-6700 Fax: 215-972-5588

Web: www.sep.benfranklin.org E-mail: info@sep.benfranklin.org

Bioadvance – The Biotechnology Greenhouse Corporation of Southeastern Pennsylvania

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3701 Market Street Philadelphia, PA 19104 Phone: 215-966-6214 Fax: 215-966-6215

Web: www.bioadvance.com E-mail: info@bioadvance.com

Biogen Idec New Ventures Headquarters

5200 Research Place San Diego, CA 92122 Phone: 858-401-8000 Fax: 858-431-8750

Web: www.biogenidec.com/site/new-

ventures.html

E-mail: newventures@biogenidec.com

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Cardinal Partners Princeton Office

230 Nassau Street Princeton, NJ 08542 Phone: 609-924-6452 Fax: 609-683-0174

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Comcast Interactive Capital *Primary Headquarters*

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Convergent Ventures

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10537 Santa Monica Boulevard, 3rd Floor

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Cordova Ventures *Primary Headquarters*

4080 McGinnis Ferry Road, Suite 1201

Alpharetta, GA 30005 Phone: 678-942-0300 Fax: 678-942-0301

Core Capital Partners Primary Headquarters

1401 I Street, Suite 1000 Washington, D.C. 20005 Phone: 202-589-0090 Fax: 202-589-0091

Cross Creek Capital Primary Headquarters

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Fax: 801-533-9828

Delaware Investments U.S., Inc

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Phone: 215-255-1200

Devon Park Bioventures Headquarters

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Domain Associates LLC San Diego Office

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DuPont Capital Management Primary Headquarters

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Echostar

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Edison Venture Fund Primary Headquarters

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Endpoint Group Late Stage Fund LP *Headquarters*

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EnerTech Capital Partners Primary Headquarters

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Hansen Gray

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Inglewood Ventures Headquarters

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Johnson & Johnson Development *Primary Headquarters*

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Maryland Venture Fund Headquarters

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Web: www.meridian-venture.com

Mission Ventures Primary Headquarters

11455 El Camino Real, Suite 215 San Diego, CA 92130-2046 Phone: 858-350-2100

Fax: 858-350-2101

E-mail: info@missionventures.com

Montagu Newhall Associates Maryland Office

100 Painters Mill Road, Suite 700 Owings Mills, MD 21117 Phone: 410-363-2725

Fax: 410-363-9075

Web: www.montagunewhall.com

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James Kim—General Partner
jim@montagunewhall.com

New Enterprise Associates Baltimore Office

1119 St. Paul Street Baltimore, MD 21202 Phone: 410-244-0115 Fax: 410-752-7721

Web: www.nea.com

Newspring Capital *Headquarters*

Radnor Financial Center

555 E. Lancaster Avenue, Suite 520

Radnor, PA 19087 Phone: 610-567-2380 Fax: 610-567-2388

Web: www.newspringcapital.com E-mail: info@newspringventures.com

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scheidegger@nextechventure.com

Myoung-Ok Kwon—Partner kwon@nextechventure.com

Nextstart Capital Primary Headquarters

3650 Mansell Road, Suite 310 Alpharetta, GA 30322

Phone: 770-643-5521

E-mail: sam@nextstartcapital.com

Noro-Moseley Partners Regional Office

3600 Mansell Road, Suite 100 Alpharetta, GA 30022 Phone: 404-233-1966 Fax: 404-239-9280

E-mail: info@noro-moseley.com

Novitas Capital *Primary Headquarters*

435 Devon Park Drive, Suite 801

Wayne, PA 19087 Phone: 610-293-4075 Fax: 610-254-4240

Web: www.novitascapital.com E-mail: info@novitascapital.com

Novitas Capital Regional Office

15 Bonnie Way Allendale, NJ 07401 Phone: 610-254-4286 Fax: 610-254-4246

Osage Ventures Headquarters

50 Monument Road, Suite 201 Bala Cynwyd, PA 19004 Phone: 484-434-2255

Fax: 484-434-2256

Web: www.osageventures.com

Oxford Bioscience Partners Regional Office

650 Town Center Drive, Suite 810

Costa Mesa, CA 92626 Phone: 714-754-5719 Fax: 714-754-6802

Pappas Ventures

2520 Meridian Parkway, Suite 400

Durham, NC 27713 Phone: 919-998-3300 Fax: 919-998-3301

Web: www.pappasventures.com/index.html

Submit business plans to:
Deal Flow Manager
Pappas Ventures
P.O. Box 110287
Research Triangle Park, NC 27709

Paperboy Ventures LLC Headquarters

1875 K Street NW, Suite 700 Washington, D.C. 20006 Phone: 202-496-9220 Fax: 202-496-9320

Web: www.paperboyventures.com E-mail: info@paperboyventures.com

Perseus LLC

Headquarters

2099 Pennsylvania Avenue, NW, 9th Floor

Washington, D.C. 20006 Phone: 202-452-0101 Fax: 202-429-0588

Web: www.perseusllc.com E-mail: info@perseusllc.com

Pfizer Strategic Investments Group Primary Headquarters

150 E. 42nd Street

150/39/18 New York, NY 10017 Phone: 212-733-7034

Fax: 212-883-4873

E-mail: psig-info@pfizer.com

Polaris Venture Partners Boston Office

1000 Winter Street, Suite 3350

Waltham, MA 02451 Phone: 781.290.0770 Fax: 781.290.0880

PricewaterhouseCoopers

Regional Office

10 Tenth Street, Suite 1400 Atlanta, GA 30309

Phone: 678-419-4155 Fax: 678-419-4200

Proquest Investments – West Coast Office California

12626 High Bluff Drive, Suite 325

San Diego, CA 92130 Phone: 858-847-0315 Fax: 858-847-0316

Web: www.proquestvc.com E-mail: patd@proquestvc.com

Provco Group Headquarters

795 East Lancaster Avenue, Suite 200

Villanova, PA 19085 Phone: 610-520-2010 Fax: 610-520-1905

Web: www.provcogroup.com E-mail: info@provcogroup.com

Quaker Bioventures Headquarters

Cira Centre, 2929 Arch Street Philadelphia, PA 19104-2868

Phone: 215-988-6800 Fax: 215-988-6801

Web: www.quakerbio.com

Qualcomm Ventures

Headquarters

5575 Morehouse Drive San Diego, CA 92121 Phone: 858-587-1121

Web: www.qualcomm.com/ventures E-mail: corpcomm@qualcomm.com

Questmark Partners Headquarters

One South Street, Suite 800 Baltimore, MD 21202 Phone: 410-895-5800 Fax: 410-895-5808

Web: www.questmarkpartners.com

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Radio One

Primary Headquarters

5900 Princess Garden Parkway, 8th Floor

Lanham, MD 20706 Phone: 301-306-1111 E-mail: IR@radio-one.com

Reicon Capital

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3290 Northside Parkway NW Atlanta, GA 30327-2245 Phone: 404-841-9990

Red Abbey Venture Partners LLC

Headquarters

2330 West Joppa Road, Suite 330

Baltimore, MD 21093 Phone: 410-494-7401 Web: www.redabbey.com

Research Corporation Technologies Headquarters

5210 East Williams Circle, Suite 240

Tucson, AZ 85711-4410 Phone: 520-748-4400 Fax: 520-748-0025 Web: www.rctech.com

E-mail: attention@rctech.com

Research Corporation Technologies Los Angeles Office

10956 Weyburn Avenue, Suite 222

Los Angeles, CA 90024 Phone: 310-824-1700 Fax: 310-824-1774 Web: www.rctech.com

Rincon Venture Partners Primary Headquarters

803 Chapata Street

Santa Barbara, CA 93101 Phone: 805-969-5484 Fax: 805-845-2270

Robin Hood Ventures

3711 Market Street - 8th Floor Philadelphia PA 19103 Corporate Address:

Corporate Address: Malvern, PA 19355 Phone: 215-966-6220 Fax: 484-214-0114

info@robinhoodventures.com

Rock Hill Ventures, Inc. *Headquarters*

100 Front Street, Suite 1350 West Conshohocken, PA 19428

Phone: 610-940-0300

Web: www.rockhill-ventures.com E-mail: mrw@rockhill-ventures.com

Roth Capital Partners LLC San Diego Office

12275 El Camino Real, Suite 120

San Diego, CA 92130 Phone: 858-509-2500 Fax: 858-509-0790 Web: www.roth.com

Rustic Canyon Partners Primary Headquarters

2425 Olympic Boulevard, Suite 6050 West

Santa Monica, CA 90404 Phone: 310-998-8000 Fax: 310-998-8001

E-mail: info@rusticcanyon.com

Safeguard Scientifics

435 Devon Park Drive, Building 800

Wayne, PA 19087 Phone: 610-293-0600 Fax: 610-293-0601

Web: www.safeguard.com

SAIC Venture Capital Corporation Headquarters

10260 Campus Point Drive San Diego, CA 92121 Phone: 702-328-8495 Web: www.saic-vcc.com

E-mail: investments@saic-vcc.com

SAIC Venture Capital Corp. *Primary Headquarters*

7455 W. Washington Avenue, Suite 290

Las Vegas, NV 89128 Phone: 702-893-2100 Fax: 702-893-0168

E-mail: investments@saic-vcc.com

Sanderling Ventures San Diego Office

4401 Eastgate Mall San Diego, CA 92121 Phone: 858-677-0828 Fax: 858-677-0800

Web: www.sanderling.com

SCP Partners

Headquarters

1200 Liberty Ridge Drive, Suite 300

Wayne, PA 19087 Phone: 610-995-2900 Fax: 610-975-9546

Web: www.scppartners.com E-mail: info@scppartners.com

Shepherd Ventures Headquarters

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Web: www.shepherdventures.com E-mail: info@shepherdventures.com

Shipley Raidy Capital Partners LLC *Headquarters*

P.O. Box 32

Conshohocken, PA 19428 Phone: 610-941-9090 Fax: 610-828-4131

Web: www.srcapital.com E-mail: srcp@srcapital.com

Sofinnova Ventures San Diego Office

BIOCOM VC Suites

4510 Executive Drive, Suite 206

San Diego, CA 92121 Phone: 858-550-0959 Web: www.sofinnova.com E-mail: info@sofinnova.com

Sorrento Ventures Headquarters

4370 La Jolla Village Drive, Suite 1040

San Diego, CA 92122 Phone: 858-452-3100 Fax: 858-452-7607

Web: www.sorrentoventures.com

E-mail: investment@sorrentoventures.com

South Atlantic Venture Funds *Regional Office*

1239 O G Skinner Drive West Point, GA 31833 Phone: 706-645-8758

Fax: 706-643-5067

Southeastern Technology Fund

Regional Office

3290 Northside Parkway, Suite 840

Atlanta, GA 30327 Phone: 404-816-5933

Southpointe Ventures Primary Headquarters

3525 Piedmont Road, Suite 510

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Phone: 610-567-1000

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The Broe Group *Primary Headquarters*

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The Mid-Atlantic Angel Group Funds I & II, LP (MAG I & II)

Chris Starr, Founder and Executive Director

Phone: 215-972-6700 x3061

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Third Rock Ventures, LLC

29 Newbury Street; 3rd Floor

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Thomas, McNerney & Partners

Connecticut Office:

One Stamford Plaza

263 Tresser Blvd, Suite 1600

Stamford, CT 06901 Phone: 203-978-2000 Fax: 203-978-2005

San Francisco Office:

150 Spear Street, Suite 1050 San Francisco, CA 94105

Phone: 415-541-8600 Fax: 415-541-8980 Executive summaries to:

E-mail: kthoraldson@tm-partners.com

TL Ventures

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Web: www.tlventures.com E-mail: info@tlventures.com

Total Technology Ventures Primary Headquarters

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Atlanta, GA 30309 Phone: 404-347-8400 Fax: 404-347-8420

Toucan Capital Corporation

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Web: www.toucancapital.com E-mail: info@toucancapital.com

Transition Partners Limited Primary Headquarters

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E-mail: terry@transitionpartnersltd.com

UTFC Financing Solutions *Primary Headquarters*

699 E. South Temple, Suite 220 Salt Lake City, UT 84102 Phone: 801-741-4200 Fax: 801-741-4249

UV Partners

Headquarters

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Web: www.utahventures.com

UV Partners

Manhattan Beach Office

720 31st Street

Manhattan Beach, CA 90266

Phone: 310-546-2777 Fax: 310-546-6757

Web: www.utahventures.com

Valley Ventures Headquarters

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E-mail: businessplans@valleyventures.com

Venture Associates Primary Headquarters

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Atlanta, GA 30339 Phone: 770-984-5373 Fax: 404-699-0781

E-mail: info@vpfund.com

Veritas Venture Partners Regional Office

145 Staghound Court Alpharetta, GA 30005 Phone: 770-619-0121 Fax: 770-619-0191

Village Ventures Regional Office

1700 Lincoln Street, Suite 2000

Denver, CO 80206 Phone: 330-318-6512 Fax: 801-457-6932

E-mail: info@vistavc.com

Vista Ventures Primary Headquarters

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Boulder, CO 80302 Phone: 303-543-5716 Fax: 303-543-5717

E-mail: info@vistavc.com

Vista Ventures Regional Office

19 Old Town Square, Suite 238 Fort Collins, CO 80524

Phone: 970-495-1800 Fax: 970-482-3840

E-mail: info@vistavc.com

vSpring Capital Primary Headquarters

2795 East Cottonwood Parkway, Suite 360

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Washington, D.C. 20016 Phone: 202-244-3790 Fax: 202-244-3791

Winward Ventures

Headquarters

600 B Street, Suite 1900 San Diego, CA 92101 Phone: 619-234-6800 Fax: 619-234-6886

Web: www.windwardventures.com E-mail: mailbox@windwardventures.com

Wye River Capital, Inc. *Primary Headquarters*

522 Chesapeake Avenue Annapolis, MD 21403 Phone: 410-267-8811 Fax: 410-267-8235

E-mail: info@wyeriver.net

Yablon Enterprises Primary Headquarters

720 S. Second Street P.O. Box 7475

P.O. Box /4/5

Steelton, PA 17113-7475 Phone: 717-939-4545

SAMPLE ONE-WAY CDA

CONFIDENTIALITY AGREEMENT

This Agreement is made by and between, a	[corporation/limited
liability company],1 with its principal place of business at	
with its affiliates, "Disclosing Party") and, a[c	corporation/limited liability
company]1 with its principal place of business at	² (together with its
affiliates, "Receiving Party"). Each of the Disclosing Party and Receiving Par	ty is sometimes hereinafter
referred to individually as a "Party" and together as the "Parties."	
WILLEDEAC de Devier motorille leine to consein linearies form	
WHEREAS, the Parties mutually desire to engage in discussions [cond] ³ (the "Purpose").	cerning/ for the purpose of
WHEREAS, the Disclosing Party intends to disclose to the Receiving	Party in the course of such
discussions certain Confidential Information (as hereinafter defined).	,
,	
NOW, THEREFORE, in return for receiving the Confidential Inform	nation, the mutual promises
contained herein, and intending to be legally bound hereby, each Party agrees as for	ollows:
"CONFIDENTIAL INFORMATION" SHALL MEAN THE INFO	
DISCLOSING PARTY DISCLOSES TO THE RECEIVING PART	
PROPRIETARY TECHNOLOGIES, PRODUCTS AND BUSINESS TI	
PARTY CONSIDERS TO BE CONFIDENTIAL ⁴ INCLUDING, BU	
[], SCIENTIFIC KNOWLEDGE, KNOW-HOW, PRO	
TECHNIQUES, TRADE SECRETS, FORMULAE, PRODUCTS, BU	-
CUSTOMER REQUIREMENTS, DESIGNS, SKETCHES, PHOTO	
SPECIFICATIONS, REPORTS, STUDIES, FINDINGS, DATA, INCLUI	
TO ANY RESEARCH PROJECT, PROOF OF PRINCIPAL, PRECI	
STUDIES, WORK IN PROCESS, FUTURE DEVELOPMENT, PLANS (
MARKETING AND BUSINESS PLANS) OR OTHER RECORDS, BIC	
AND/OR SOFTWARE, WHETHER IN ORAL, WRITTEN, GRAPHIC	JK ELECTRONIC FORM

Always include the type of entity and its state of organization. For example, "a Delaware corporation" or "a Maryland limited liability company." This information will be required if the agreement ever needs to be enforced. It is much easier to get the information at the outset.

Always include the full address of the business, including zip code. For individuals, include the home or primary residence. As above, this information will be required if the agreement ever needs to be enforced.

Always clearly define the purpose. This will control how the receiving party can *use* the information and therefore provides significant protection against misuse. If the purpose is left blank, vaguely refers to a "potential transaction" or repeats what the last CDA said, this protection can be lost.

Some parties want all information to be marked confidential for it to fall within the protection of the agreement. If proprietary information is inadvertently disclosed without such mark, or verbal or visual disclosures are not promptly summarized in a notice, then the disclosed information will not be protected. This presents a real danger. On the other hand, some complain that compliance with the definition as written can be difficult because of the breadth and less than objective nature of the definition.

⁵ Some parties may wish to insert specific reference to products or technologies, which is advised whereever possible.

OR BY VISUAL OBSERVATION. "CONFIDENTIAL INFORMATION" SHALL ALSO INCLUDE ANY UNPUBLISHED INFORMATION CONCERNING THE DISCLOSING PARTY'S BUSINESS, RESEARCH ACTIVITIES AND INTERESTS WITH WHICH THE RECEIVING PARTY BECOMES FAMILIAR IN ITS CONTACTS WITH THE DISCLOSING PARTY IN CONNECTION WITH THE PURPOSE, AND ANY NOTES, SUMMARIES, COPIES, ANALYSES OR OTHER WRITINGS PREPARED BY THE RECEIVING PARTY OR ITS EMPLOYEES CONSULTANTS OR ADVISERS BASED ON ANY CONFIDENTIAL INFORMATION DISCLOSED HEREUNDER.

RECEIVING PARTY AGREES TO MAINTAIN THE DISCLOSING PARTY'S CONFIDENTIAL INFORMATION IN CONFIDENCE AND NOT TO DISCLOSE SUCH CONFIDENTIAL INFORMATION TO ANY THIRD PARTY EXCEPT AS PROVIDED UNDER SECTION 3 WITHOUT THE PRIOR WRITTEN CONSENT OF THE DISCLOSING PARTY. INFORMATION SHALL NOT BE CONSIDERED CONFIDENTIAL OR SUBJECT TO THESE OBLIGATIONS IF IT:

- (a) Was rightfully in the possession of Receiving Party prior to the date of disclosure by the Disclosing Party of such information to the Receiving Party;
- (b) Was available to the public prior to the date of disclosure to the Receiving Party by the Disclosing Party;
- (c) Becomes part of the public domain by publication or by any other means except an unauthorized act or omission on the part of the Receiving Party or its employees, consultants or advisers;
- (d) Is supplied to the Receiving Party on a nonconfidential basis by a third party who is under no obligation to the Disclosing Party to maintain such information in confidence;
- (e) Is independently developed by the Receiving Party without the use of or reference to any information disclosed by the Disclosing Party, which can be proven by written records; or
- (f) Is required by law or regulation or court or administrative order to be disclosed, provided that where practicable the Receiving Party shall have first given prompt notice to the Disclosing Party of such required disclosure, consults and cooperates with the Disclosing Party on the advisability of taking legally available steps to resist or narrow the scope of the required disclosure and, if no protective order is sought or obtained, discloses only that portion that is legally required and uses reasonable efforts to seek and obtain confidential treatment of any disclosed information.

RECEIVING PARTY AGREES TO LIMIT ACCESS TO DISCLOSING PARTY'S CONFIDENTIAL INFORMATION TO THOSE OF ITS EMPLOYEES, CONSULTANTS AND ADVISERS WHO HAVE A NEED TO KNOW IN ORDER TO EFFECTUATE THE PURPOSE AND WHO HAVE BEEN INFORMED OF THE OBLIGATIONS OF CONFIDENTIALITY IMPOSED BY THIS AGREEMENT. RECEIVING PARTY AGREES TO BE RESPONSIBLE FOR ANY BREACH OF THIS AGREEMENT BY ITS EMPLOYEES, CONSULTANTS OR ADVISERS.

RECEIVING PARTY SHALL NOT USE, NOR PERMIT ITS EMPLOYEES, CONSULTANTS OR ADVISERS TO USE, THE OTHER PARTY'S CONFIDENTIAL INFORMATION FOR ANY PURPOSE OR REASON OTHER THAN THE PURPOSE.

NEITHER THIS AGREEMENT NOR THE DISCLOSURE OF CONFIDENTIAL INFORMATION SHALL BE DEEMED BY IMPLICATION, ESTOPPEL OR OTHERWISE, TO VEST IN RECEIVING PARTY ANY LICENSE OR OTHER RIGHTS IN ANY PATENTS, TRADE SECRETS, OR OTHER INTELLECTUAL PROPERTY RIGHTS OF DISCLOSING PARTY.

RECEIVING PARTY FURTHER AGREES THAT ALL COPIES OF DISCLOSING PARTY'S CONFIDENTIAL INFORMATION DISCLOSED TO IT WILL BE RETURNED TO THE

DISCLOSING PARTY PROMPTLY IF EITHER PARTY SHOULD TERMINATE NEGOTIATIONS WITH RESPECT TO THE PURPOSE, OR UPON REQUEST BY THE DISCLOSING PARTY; PROVIDED, HOWEVER THAT ALL DOCUMENTS, NOTES, ANALYSES, SUMMARIES AND OTHER WRITINGS PREPARED BY THE RECEIVING PARTY, ITS EMPLOYEES, CONSULTANTS OR ADVISERS BASED ON THE CONFIDENTIAL INFORMATION RECEIVED AND ALL COPIES THEREOF MAY BE DESTROYED RATHER THAN GIVEN TO THE DISCLOSING PARTY; AND PROVIDED FURTHER THAT ONE COPY OF ALL SUCH INFORMATION MAY BE RETAINED IN THE LEGAL FILES OF THE RECEIVING PARTY FOR THE SOLE PURPOSE OF DETERMINING OBLIGATIONS HEREUNDER.

EACH PARTY UNDERSTANDS AND ACKNOWLEDGES THAT THE OTHER PARTY HAS IN THE PAST, MAY CURRENTLY AND IS EXPECTED TO CONTINUE TO CONSIDER TRANSACTIONS OR PROJECTS WITH MANY OTHER INDIVIDUALS, COMPANIES, UNIVERSITIES OR OTHER ORGANIZATIONS. NOTHING IN THIS AGREEMENT IS INTENDED TO LIMIT SUCH ACTIVITIES AND NEITHER PARTY IS UNDER ANY OBLIGATION TO ENTER INTO ANY NEGOTIATION OR TRANSACTION WITH THE OTHER PARTY.

THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE SUBSTANTIVE LAWS OF THE [COMMONWEALTH OF PENNSYLVANIA]⁶ U.S.A. THIS AGREEMENT MAY NOT BE ASSIGNED BY EITHER PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF THE OTHER. NO PARTY SHALL BE DEEMED TO HAVE WAIVED ANY PROVISION OF THIS AGREEMENT UNLESS SUCH WAIVER IS IN WRITING SIGNED BY A DULY AUTHORIZED REPRESENTATIVE OF SUCH PARTY.

EACH PARTY HEREBY REPRESENTS AND WARRANTS THAT IT HAS NOT ENTERED AND WILL NOT ENTER INTO ANY AGREEMENTS INCONSISTENT WITH ITS OBLIGATIONS UNDER THIS AGREEMENT. RECEIVING PARTY ACKNOWLEDGES THAT DISCLOSURE, DISTRIBUTION OR USE OF DISCLOSING PARTY'S CONFIDENTIAL INFORMATION CONTRARY TO THE TERMS OF THIS AGREEMENT WILL CAUSE IRREPARABLE HARM FOR WHICH DAMAGES AT LAW WILL NOT BE AN ADEQUATE REMEDY, AND RECEIVING PARTY AGREES THAT THE PROVISIONS OF THIS AGREEMENT MAY BE SPECIFICALLY ENFORCED BY A COURT OF COMPETENT JURISDICTION IN ADDITION TO ANY OTHER AVAILABLE REMEDY.

THIS AGREEMENT CONTAINS THE COMPLETE UNDERSTANDING OF THE PARTIES WITH RESPECT TO THE SUBJECT MATTER HEREOF. THE OBLIGATIONS UNDER THIS AGREEMENT SHALL EXPIRE ON THE [_____]⁷ ANNIVERSARY OF THE DATE OF THIS AGREEMENT, WHICH SHALL BE THE LAST DATE ON WHICH BOTH PARTIES HAVE SIGNED THIS AGREEMENT.

Applicable law and jurisdiction can become a lightning rod. The main issue is whether the desired state or other jurisdiction has laws and courts that will enforce the agreement in a meaningful way. Generally, the applicable law should not be worth a battle over one U.S. state versus another, but is worth the effort if another country's laws are suggested. The issue with the jurisdiction is "home turf" and expense of enforcing or litigating the agreement.

The expiration of the obligations should have an end date that is long enough to ensure protection, but should also be a rational length of time. Anywhere between three to twelve years can be used, with five to seven being the most common.

IN WITNESS WHEREOF, each of the Parties has caused this Confidentiality Agreement to be signed by its duly authorized representative.

AGREE	ED TO AND ACCEPTED:
	:
By:	
Name:	
Title:	
Date:	
	:
By:	
Name:	
Title:	
Date:	

SAMPLE TWO-WAY CDA

TWO-WAY CONFIDENTIALITY AGREEMENT

This Agreement is made by and between, a[corporation/limited
liability company], with its principal place of business at
with its affiliates, ", a [corporation/limited liability company]
with its principal place of business at2 (together with its affiliates
with its principal place of business at2 (together with its affiliates ""). Each of and is sometimes hereinafter referred to individually as a
"Party" and together as the "Parties."
WHEREAS, the Parties mutually desire to engage in discussions [concerning/for the purpose of] ³ (the "Purpose").
WHEREAS, either Party may elect to disclose (the "Disclosing Party") to the other Party (the "Receiving Party") in the course of such discussions certain Confidential Information (as hereinafter defined).
NOW, THEREFORE, in return for receiving the Confidential Information, the mutual promises contained herein, and intending to be legally bound hereby, each Party agrees as follows:
"CONFIDENTIAL INFORMATION" SHALL MEAN THE INFORMATION THAT THE DISCLOSING PARTY DISCLOSES TO THE RECEIVING PARTY RELATING TO ITS PROPRIETARY TECHNOLOGIES, PRODUCTS AND BUSINESS THAT THE DISCLOSING PARTY CONSIDERS TO BE CONFIDENTIAL ⁴ INCLUDING, BUT NOT LIMITED TO [], SCIENTIFIC KNOWLEDGE, KNOW-HOW, PROCESSES, INVENTIONS, TECHNIQUES, TRADE SECRETS, FORMULAE, PRODUCTS, BUSINESS OPERATIONS, CUSTOMER REQUIREMENTS, DESIGNS, SKETCHES, PHOTOGRAPHS, DRAWINGS, SPECIFICATIONS, REPORTS, STUDIES, FINDINGS, DATA, INCLUDING DATA RELATING TO ANY RESEARCH PROJECT, PROOF OF PRINCIPAL, PRECLINICAL OR CLINICAL STUDIES, WORK IN PROCESS, FUTURE DEVELOPMENT, PLANS (INCLUDING CLINICAL MARKETING AND BUSINESS PLANS) OR OTHER RECORDS, BIOLOGICAL MATERIALS, AND/OR SOFTWARE, WHETHER IN ORAL, WRITTEN, GRAPHIC OR ELECTRONIC FORM

Always include the type of entity and its state of organization. For example, "a Delaware corporation" or "a Maryland limited liability company." This information will be required if the agreement ever needs to be enforced. It is much easier to get the information at the outset.

² Always include the full address of the business, including zip code. For individuals, include the home or primary residence. As above, this information will be required if the agreement ever needs to be enforced.

Always clearly define the purpose. This will control how the receiving party can *use* the information and therefore provides significant protection against misuse. If the purpose is left blank, vaguely refers to a "potential transaction" or repeats what the last CDA said, this protection can be lost.

Some parties want all information to be marked confidential for it to fall within the protection of the agreement. If proprietary information is inadvertently disclosed without such mark, or verbal or visual disclosures are not promptly summarized in a notice, then the disclosed information will not be protected. This presents a real danger. On the other hand, some complain that compliance with the definition as written can be difficult because of the breadth and less-than-objective nature of the definition.

⁵ Some parties may wish to insert specific reference to products or technologies, which is advised whereever possible.

OR BY VISUAL OBSERVATION. "CONFIDENTIAL INFORMATION" SHALL ALSO INCLUDE ANY UNPUBLISHED INFORMATION CONCERNING THE DISCLOSING PARTY'S BUSINESS, RESEARCH ACTIVITIES, AND INTERESTS WITH WHICH THE RECEIVING PARTY BECOMES FAMILIAR IN ITS CONTACTS WITH THE DISCLOSING PARTY IN CONNECTION WITH THE PURPOSE, AND ANY NOTES, SUMMARIES, COPIES, ANALYSES OR OTHER WRITINGS PREPARED BY THE RECEIVING PARTY OR ITS EMPLOYEES, CONSULTANTS OR ADVISERS BASED ON ANY CONFIDENTIAL INFORMATION DISCLOSED HEREUNDER.

EACH PARTY AGREES TO MAINTAIN THE OTHER PARTY'S CONFIDENTIAL INFORMATION IN CONFIDENCE AND NOT TO DISCLOSE SUCH CONFIDENTIAL INFORMATION TO ANY THIRD PARTY EXCEPT AS PROVIDED UNDER SECTION 3 WITHOUT THE PRIOR WRITTEN CONSENT OF THE DISCLOSING PARTY. INFORMATION SHALL NOT BE CONSIDERED CONFIDENTIAL OR SUBJECT TO THESE OBLIGATIONS IF IT:

- (a) Was rightfully in the possession of Receiving Party prior to the date of disclosure by the Disclosing Party of such information to the Receiving Party;
- (b) Was available to the public prior to the date of disclosure to the Receiving Party by the Disclosing Party;
- (c) Becomes part of the public domain by publication or by any other means except an unauthorized act or omission on the part of the Receiving Party or its employees, consultants or advisers;
- (d) Is supplied to the Receiving Party on a nonconfidential basis by a third party who is under no obligation to the Disclosing Party to maintain such information in confidence;
- (e) Is independently developed by the Receiving Party without the use of or reference to any information disclosed by the Disclosing Party, which can be proven by written records; or
- (f) Is required by law or regulation or court or administrative order to be disclosed, provided that where practicable the Receiving Party shall have first given prompt notice to the Disclosing Party of such required disclosure, consults and cooperates with the Disclosing Party on the advisability of taking legally available steps to resist or narrow the scope of the required disclosure and, if no protective order is sought or obtained, discloses only that portion that is legally required and uses reasonable efforts to seek and obtain confidential treatment of any disclosed information.

EACH PARTY AGREES TO LIMIT ACCESS TO THE OTHER PARTY'S CONFIDENTIAL INFORMATION TO THOSE OF ITS EMPLOYEES, CONSULTANTS AND ADVISERS WHO HAVE A NEED TO KNOW IN ORDER TO EFFECTUATE THE PURPOSE AND WHO HAVE BEEN INFORMED OF THE OBLIGATIONS OF CONFIDENTIALITY IMPOSED BY THIS AGREEMENT. EACH PARTY AGREES TO BE RESPONSIBLE FOR ANY BREACH OF THIS AGREEMENT BY ITS EMPLOYEES, CONSULTANTS OR ADVISERS.

NEITHER PARTY SHALL USE, OR PERMIT ITS EMPLOYEES, CONSULTANTS OR ADVISERS TO USE, THE OTHER PARTY'S CONFIDENTIAL INFORMATION FOR ANY PURPOSE OR REASON OTHER THAN THE PURPOSE.

NEITHER THIS AGREEMENT NOR THE DISCLOSURE OF CONFIDENTIAL INFORMATION SHALL BE DEEMED BY IMPLICATION, ESTOPPEL OR OTHERWISE, TO VEST IN EITHER PARTY ANY LICENSE OR OTHER RIGHTS IN ANY PATENTS, TRADE SECRETS, OR OTHER INTELLECTUAL PROPERTY RIGHTS OF THE OTHER PARTY.

EACH PARTY FURTHER AGREES THAT ALL COPIES OF THE OTHER PARTY'S CONFIDENTIAL INFORMATION DISCLOSED TO IT WILL BE RETURNED TO THE DISCLOSING PARTY PROMPTLY IF EITHER PARTY SHOULD TERMINATE

NEGOTIATIONS WITH RESPECT TO THE PURPOSE, OR UPON REQUEST BY THE DISCLOSING PARTY; PROVIDED, HOWEVER THAT ALL DOCUMENTS, NOTES, ANALYSES, SUMMARIES AND OTHER WRITINGS PREPARED BY THE RECEIVING PARTY, ITS EMPLOYEES, CONSULTANTS OR ADVISERS BASED ON THE CONFIDENTIAL INFORMATION RECEIVED AND ALL COPIES THEREOF MAY BE DESTROYED RATHER THAN GIVEN TO THE DISCLOSING PARTY; AND PROVIDED FURTHER THAT ONE COPY OF ALL SUCH INFORMATION MAY BE RETAINED IN THE LEGAL FILES OF THE RECEIVING PARTY FOR THE SOLE PURPOSE OF DETERMINING OBLIGATIONS HEREUNDER.

EACH PARTY UNDERSTANDS AND ACKNOWLEDGES THAT THE OTHER PARTY HAS IN THE PAST, MAY CURRENTLY AND IS EXPECTED TO CONTINUE TO CONSIDER TRANSACTIONS OR PROJECTS WITH MANY OTHER INDIVIDUALS, COMPANIES, UNIVERSITIES OR OTHER ORGANIZATIONS. NOTHING IN THIS AGREEMENT IS INTENDED TO LIMIT SUCH ACTIVITIES AND NEITHER PARTY IS UNDER ANY OBLIGATION TO ENTER INTO ANY NEGOTIATION OR TRANSACTION WITH THE OTHER PARTY.

THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE SUBSTANTIVE LAWS OF THE [COMMONWEALTH OF PENNSYLVANIA], U.S.A. THIS AGREEMENT MAY NOT BE ASSIGNED BY EITHER PARTY WITHOUT THE PRIOR WRITTEN CONSENT OF THE OTHER. NO PARTY SHALL BE DEEMED TO HAVE WAIVED ANY PROVISION OF THIS AGREEMENT UNLESS SUCH WAIVER IS IN WRITING SIGNED BY A DULY AUTHORIZED REPRESENTATIVE OF SUCH PARTY.

EACH PARTY HEREBY REPRESENTS AND WARRANTS THAT IT HAS NOT ENTERED AND WILL NOT ENTER INTO ANY AGREEMENTS INCONSISTENT WITH ITS OBLIGATIONS UNDER THIS AGREEMENT. EACH PARTY ACKNOWLEDGES THAT DISCLOSURE, DISTRIBUTION OR USE OF THE OTHER PARTY'S CONFIDENTIAL INFORMATION CONTRARY TO THE TERMS OF THIS AGREEMENT WILL CAUSE IRREPARABLE HARM FOR WHICH DAMAGES AT LAW WILL NOT BE AN ADEQUATE REMEDY, AND EACH PARTY AGREES THAT THE PROVISIONS OF THIS AGREEMENT MAY BE SPECIFICALLY ENFORCED BY A COURT OF COMPETENT JURISDICTION IN ADDITION TO ANY OTHER AVAILABLE REMEDY.

THIS AGREEMENT CONTAINS THE COMPLETE UNDERSTANDING OF THE PARTIES WITH RESPECT TO THE SUBJECT MATTER HEREOF. THE OBLIGATIONS UNDER THIS AGREEMENT SHALL EXPIRE ON THE [_____]⁷ ANNIVERSARY OF THE DATE OF THIS AGREEMENT, WHICH SHALL BE THE LAST DATE ON WHICH BOTH PARTIES HAVE SIGNED THIS AGREEMENT.

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Applicable law and jurisdiction can become a lightning rod. The main issue is whether the desired state or other jurisdiction has laws and courts that will enforce the agreement in a meaningful way. Generally, the applicable law should not be worth a battle over one U.S. state versus another, but is worth the effort if another country's laws are suggested. The issue with the jurisdiction is "home turf" and expense of enforcing or litigating the agreement.

The expiration of the obligations should have an end date that is long enough to ensure protection, but should also be a rational length of time. Anywhere between three to twelve years can be used, with five to seven being the most common.

IN WITNESS WHEREOF, each of the Parties has caused this Two-Way Confidentiality Agreement to be signed by its duly authorized representative.

AGREED TO AND ACCEPTED:					
 :					
Ву:					
Name:					
Title:					
Date:					
:					
Ву:					
Name:					
Title:					
Date:					

BALLARD SPAHR'S EMERGING GROWTH INNOVATION NETWORK BEGIN TM PROGRAM

The Purpose

We at Ballard Spahr believe that it is important to support and devote resources to grow technology and life sciences companies in the communities in which we practice. To promote the creation and development of such companies, we have established **B**allard's Emerging Growth Innovation Network (BEGINTM). BEGIN is a cutting-edge program designed entrepreneurship in the regions in which Ballard Spahr has offices. The goal is to provide highquality legal counsel designed to nurture and develop early stage growth companies and introduce them to the kinds of business-services providers they will need for growth. Ballard Spahr has offices in major cities where opportunities for commercializing technologies abound, including Philadelphia, Bethesda, Salt Lake City, Baltimore, Phoenix, Denver and Atlanta. Ballard Spahr is active in the business community, with a specific focus on emerging companies and venture capital.

The Process

Under the BEGIN Program, representatives from the firm meet, at no cost, with entrepreneurs, scientists, technology transfer officers, corporate development executives, and others seeking to launch or spin out businesses engaged in commercializing technologies in areas with significant growth opportunities. We counsel clients by, among other things, reviewing and providing preliminary legal input on the company's business plan and patent portfolio, and assessing both legal and other needs. The process is similar to that conducted by venture capitalists and private equity firms in evaluating potential investments (although ours is from a legal perspective). Thereafter, if a company or an entrepreneur is selected, we would enter into a formal relationship on terms that are mutually beneficial.

The Program

Companies in the BEGIN Program are able to establish a dynamic, long-term relationship with Ballard Spahr. Elements of the relationship include:

- Devoting a significant amount of time to learning the company's business strategy and industry
- Offering alternative billing arrangements developed by the team working with the company and tailored to the company's needs, including, among other things, a deferral of fees until a first round of capital has been raised or use of a blended rate
- Providing access to experienced lawyers while involving junior attorneys to ensure effective, efficient representation
- Providing advice on corporate, tax, intellectual property, securities, employee benefits, and other issues relevant to the company's business
- Introducing companies to angels, venture capitalists, governmental agencies, bankers, investment bankers, and other investors as funding sources
- Introducing companies to potential strategic partners
- Providing educational opportunities at no cost to familiarize entrepreneurs with fund-raising, intellectual property, corporate tax, securities, and other issues confronting such companies

Our Experience

Ballard Spahr has a demonstrated record of providing a broad array of legal services and advice to emerging companies and those who invest in them. A hallmark of the firm and its lawyers is the commitment of our resources to nurturing entrepreneurs and their businesses. We invest the time to understand our clients' businesses.

Ballard Spahr has a prominent multidisciplinary practice group that focuses on life sciences, biotech, medical devices, information technology, communications, and venture capital. This practice group advises pre-revenue as well as revenue-generating companies. With several patent professionals (including Ph.D.s and an M.D.), we can handle breakthrough, complex

technologies and are experienced in transforming your ideas into a valuable IP portfolio. The lawyers in this group are seasoned, experienced practitioners who have devoted a significant amount of time to working with early stage companies. As a result, we are familiar with the issues that early stage companies encounter and have helped them to successfully work through those issues.

The firm has broad, deep networks and significant relationships with: technology transfer offices in corporate development universities; executives and others engaged in commercializing investors, technology; and angel venture capitalists, and other investors, bankers, and government agencies that fund technology commercialization. Thanks to these relationships, the firm can provide high-quality, cost-effective legal services and introduce other business services through its BEGIN Program that are designed to accelerate the growth of emerging companies. BEGIN reflects Ballard Spahr's commitment to devote resources to this effort.

Program Services

Depending on the specific needs of the company, the BEGIN Program offers participants such services as:

- Reviewing and recommending the form of entity
- Recommending a capital structure (e.g., levels of debt and equity)
- Preparing governing documents and agreements with shareholders or members, employees, and independent contractors (including shareholders agreements, operating agreements for limited liability companies, employment agreements, confidentiality and nondisclosure agreements, and assignment of inventions agreements)
- Advising on private placements and related offering materials and securities filings

- Structuring licenses and related technology agreements
- Reviewing patent, copyright and trademark protection
- Analyzing the client's goals and technology and recommending a patent strategy to protect and enforce the client's intellectual property by understanding the competitive marketplace (Patentscape®)
- Obtaining patents to create revenue-producing assets and minimize potential competition
- Performing due diligence analysis of the client's intellectual property, including evaluating validity and enforceability of patents, strength and breadth of patent claims, and freedom to operate in the marketplace
- Assisting in out-licensing or in-licensing IP to maximize value for the client's future growth
- Assisting with the selection of auditors and other advisers and professionals
- Using our experience as lawyers to review and assist with business plan preparation
- Providing introductions to potential funding sources, including venture capitalists, angels, venture accelerators, and government sources
- Providing introductions to potential business partners and mentors for the executives
- Acting as legal counsel to assist with preparation of presentations to potential investors
- Participating in periodic meetings to discuss strategic and operating plans and execution of those plans

Ballard Spahr believes that its BEGIN Program can make a difference and accelerate the growth of emerging companies by providing them with broad and deep legal services and introducing them to an array of business services.

Ballard Spahr

Ballard Spahr's Life Sciences/Technology attorneys have more than 40 years of collective experience advising pioneering high-tech and life sciences businesses nationwide. Our counsel is fueled by a broad knowledge base and real-world experience from attorneys who have advanced scientific degrees and industry experience. We advise front line businesses engaged in discovery, development, and commercialization activities and the institutions that support them through contract research, data-mining, analytical and product development, formulation and production. Our attorneys work with our clients' investors and financial advisers to help secure financing through private and public offerings of equity and debt securities. For each client, at any stage of development, we bring a deep bench and practical experience to bear on the individual challenges they face and help them successfully start and grow their businesses.

About Merrill DataSite®

Merrill DataSite is a secure virtual data room (VDR) solution optimizing the due diligence process by providing an efficient and secure method for sharing key business information between multiple parties. Merrill DataSite provides unlimited access for users worldwide, as well as real-time activity reports, site-wide search at the document level, enhanced communications through the Q&A feature and superior project management service – all of which reduce transaction time and expense. Merrill DataSite's multilingual support staff is available around the world, 24/7, and can have your VDR up and running with thousands of pages loaded within 24 hours or less. Visit www.datasite.com for more information or to schedule a demontration.