The Life Science Executive’s FUNDRAISING MANIFESTO

BEST PRACTICES FOR IDENTIFYING CAPITAL IN THE BIOTECH AND MEDTECH ARENAS

Dennis Ford
The face of early stage life science investment is changing. Alternative investors, such as family offices, endowments, foundations, hedge funds, mid-level private equity firms, and angel syndicates, are participating in the space with greater frequency as alternatives to the classic venture capital (VC) funding model. In the face of this evolution in early stage life science funding, entrepreneurs need to be aware of the various legal and regulatory matters that govern the capital-raising process. In this chapter, I will provide you with a brief overview of the more noteworthy of these matters. The information presented is not intended to, nor does it, constitute legal advice. Rather, my purpose is to convey general information across a broad range of topics relevant to raising capital and highlight important issues that you should be aware of as you build your business. The business of offering and selling securities is always evolving, and the laws and regulations surrounding such offerings are currently undergoing intense revision and updating by federal and state regulators. If you are an entrepreneur in the life science space, I advise you to seek appropriate legal counsel to discuss how these complex matters relate to your individual circumstances. The consequences of noncompliance—such as regulatory action and investor lawsuits—can be harsh, even fatal, especially for start-ups with little margin for error in any aspect of their business.
The Players

The process of raising capital by selling equity shares in your company is regulated at both the federal and state levels, with the most important regulatory body being the U.S. Securities and Exchange Commission (SEC). For some offerings that use a financial intermediary, such as an investment banker, the Financial Industry Regulatory Authority (FINRA), formerly known as the National Association of Securities Dealers (NASD), may also play a role. In addition, the state securities regulatory authorities in any state in which the company is offering or selling securities may also play a role. The SEC is charged with interpreting, administering, and promulgating rules under the two main securities laws: the Securities Act of 1933 and the Securities Exchange Act of 1934. These laws have been around for decades and are, depending on your perspective, either mainstays that have provided the foundation for generations of economic vitality and growth or a set of Depression-era relics that have outlived their usefulness. The past two years have been marked by considerable anticipation of major modernizations in federal securities laws, but the pace of real evolution of these laws continues to be measured at best.

Generally speaking, disclosure—telling your investors about not only the opportunity but also the material risks involved with an investment in your company—is the primary focus of federal and state securities law. Simply stated, issuers get into trouble not because their companies and ideas fail but because unhappy investors claim that they were not told the truth about the specific risks. One way to attempt to make the right disclosure is to register the offering with the federal and appropriate state securities regulators, filing a prospectus, providing voluminous disclosure, and responding to comments and questions of the regulators before engaging in the sales process. Federal and state securities laws generally require that securities offerings be registered unless certain exemptions are available. Registration works for large transactions such as IPOs, but it is far too time-consuming and expensive for early stage companies. Therefore, as a practical matter, start-ups must find the appropriate exemption from the registration requirement.

The most common exemption is available via a so-called private placement exemption under Section 4(a)(2) of the Securities Act of 1933, which
provides that transactions “not involving a public offering” are exempt from registration. In particular, Rule 506 under Regulation D of the Securities Act provides a safe harbor so that issuers meeting its requirements know that their transaction will be exempt. This safe harbor provides a number of advantages: for one, it permits the issuer to sell shares to an unlimited number of “accredited investors” and not more than 35 nonaccredited investors. Better yet, it preempts state securities laws: if you qualify for the Rule 506 exemption, then you do not have to worry about complying with substantive state laws requiring registration or exemptions but merely have to pay fees and provide copies of the federal filings and other routine documentation. This makes it a lot easier to complete the financing round. In practice, virtually every funding deal with a U.S.-based venture capital (VC) firm, family office, strategic partner, or other institutional investor is exempt under the Rule 506 safe harbor.

You should seek the advice of counsel when examining the exclusions available under the Securities Act, as the penalties of noncompliance can be quite onerous.

Accredited and Nonaccredited Investors

Most early stage capital raises are limited to “accredited investors.” What is an accredited investor? Generally, an accredited investor is an individual with a net worth, or combined net worth with his or her spouse, of $1 million\(^1\) or a gross income during each of the past two calendar years that exceeds $200,000 (or $300,000 when combined with the annual income of his or her spouse). Additionally, institutional investors, such as corporations, partnerships, trusts, banks, savings and loan associations, insurance companies, and employee benefit plans, may be accredited investors as long as certain dollar thresholds and other requirements are met. Accredited investors also include directors and certain executive officers

\(^1\) Since passage of the 2010 Dodd-Frank Act, individuals are no longer entitled to include the value of their primary residence in their net worth in determining their status as an accredited investor. Likewise, the related amount of indebtedness secured by such person’s primary residence up to its fair market value is excluded, except to the extent that the residence is “underwater,” that is, the mortgage exceeds the value of the residence.
of the company; for example, the president or a vice president in charge of a particular business unit or a director may be an accredited investor even if that natural person does not satisfy the net worth or gross income thresholds noted earlier.²

Also, as mentioned earlier, Rule 506 under Regulation D, the preferred exemption, does permit a limited number of nonaccredited investors to participate in a Regulation D offering. However, because of the additional extensive and detailed information required, this almost never happens in practice.

Some offerings do include nonaccredited investors, by necessity or choice. For example, an initial seed round might include founders as well as friends and family investors who might not qualify as accredited investors. You can successfully create an offering to these investors, but the information requirements are more significant and you should make sure that each investor can properly assess the risk and can afford to sustain the loss of his or her entire investment. Also, having nonaccredited stockholders can make the sale of your company a more cumbersome and expensive process if the buyer wants to acquire your company in a stock-for-stock deal. The buyer will be offering securities to your nonaccredited investors and will have to comply with the additional disclosure requirements. You should consult with legal counsel and carefully weigh the pros and cons, both present and future, of offering securities to nonaccredited investors.

**Terms of the Deal**

Once you have determined the type of offering you are seeking to conduct, and the type of investors to whom you wish to offer securities, you need to determine the form and terms of your securities offering.

In structuring an early stage offering, one critical variable is the pre-money value of the company (see “A Word About Dilution”). At the ini-

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² Start-ups are sometimes tempted to “pack” the list of “executive officers” in order to ease regulatory hurdles. Directors and officers should be appointed for bona fide purposes, not merely to escape the reach of securities laws.
tial stages, the company often lacks credible indicia of value, making it difficult for the company and the investor to agree. If the valuation is too high, the investor will perceive an insufficient return on a very risky investment and will reject the deal. If it is too low, the company is giving up too much equity.

Convertible notes can help solve this problem. In a convertible note transaction, the investor makes the investment in the form of debt and agrees to convert the debt into equity securities in a later round, usually at a discount and subject to a “conversion cap,” or upper limit on the conversion valuation, to protect the investor. Convertible note deals can be comparatively easy to structure and efficient to close, and they offer an alternative to a dilutive equity round early on. However, companies need to consult their advisors both as to the terms of the conversion (which can be surprisingly dilutive to the founders, especially with a conversion) as well as issues relating to interest and tax reporting that accompany these deals. Some companies and their advisors are experimenting with classes of preferred stock that carry the economic attributes of convertible notes but are not classified as debt and do not trigger interest issues.

If the company can agree with the investor as to the pre-money valuation of the company, then usually an equity deal makes the most sense. There are two main forms of early stage equity transactions: the company-led “private placement memorandum” model and the investor-led negotiated term sheet and set of preferred stock closing documents. A private placement memorandum, or PPM, is more commonly used when an intermediary is involved and is usually used for investors who are not likely to demand control over the process or extensive post-closing investor protections. In general, the PPM should contain biographical information relating to key executives, a description of the company’s business model, technology, and competitive attributes, as well as information about the risks of investing in the company. In drafting an effective PPM, the company should try to make full and fair disclosure of the company’s opportunity and risks, even while protecting proprietary matters that a manager may wish to keep confidential (for example, the company’s core technology). You should carefully track copies of the PPM and make sure that it goes only to selected investors. A well-drafted PPM
that discloses all the material risks and factors will help to protect the company from later claims.

The investor-led term sheet, with extensive investor-led due diligence and a full set of investment documents, is used by venture capital firms and more sophisticated angel investors and alternative investors. The National Venture Capital Association has developed a set of model documents,\(^3\) which are used for most equity deals led by top-tier VC firms and are increasingly prevalent across the board with a wide variety of angel groups and individual investors.

**A Word About Dilution**

Dilution may be the most feared aspect of early stage capital raising and may also be the least well understood. Nonetheless, fear of being diluted hinders early stage investors from investing in life science start-ups, especially when it appears that the company will need significant additional equity before becoming cash-flow positive. As an entrepreneur, you should remember that dilution is what you are trying for. You start with 100% (less any cut that a university licensing you the technology might take), and someday, when the company is sold, you’ll have zero. The real question is how much dilution is appropriate at any given stage? In an early stage offering, the biggest questions are:

- What is the company worth now?
- How much money does the company need at this stage of development?
- What milestone is the company going to achieve with the funds?
- How much will the valuation increase as a result?

One easy way to think of this matrix of factors is that the percentage that the investors will hold will be equal to (a) the number of dollars they invest divided by (b) the total “post-money valuation,” (that is, the pre-money valuation plus the dollars raised in the offering), as illustrated in Figure 1.1.

“Everything else” includes not only all founders’ stock, friends and family shares, and any options issued before the transaction but also typically includes an option pool of between 10% and 20% of the total equity. Thus, the pre-money valuation is a critical factor, as it is the primary determinant of how much of the company the founders will own after the transaction. Other factors also affect the post-deal founders’ share. In the example, assume that the company is raising $2,000,000 instead of $1,000,000 and that the investors are requiring a post-closing option pool of 20% in order to attract and retain a management team. Now, the investors get 33% of the company, and after subtracting the 20% option pool, the founders’ stake has gone from 80% to 47% on a “fully diluted basis,” meaning including all issuable shares under options, etc. as if they were already issued. But increase the valuation from $4,000,000 to $6,000,000 and the same deal leaves the founders with 55%.

Dilution is a key component of evaluating the deal for an entrepreneur, as it affects both the economic relationship among the stakeholders and control of the company. A common fallacy is the idea that the founders need to retain a majority of the issued and outstanding shares on a fully diluted basis. In reality, this is cold comfort, because professional investors will invariably require a number of control and veto rights that attach to their preferred stock, so your ownership of an outright majority is not as meaningful as you might think. The better approach is to review the documents carefully. Are there appropriate checks and balances on the investors’ control? More importantly, what is the imputed value of the founders’ shares after the transaction? If it is increasing, then dilution is working the right way from that standpoint.
You need to work with experienced legal and financial advisors to understand the type of dilution and control risks that you and other early stage investors face, to interpret and negotiate the various provisions of the deal documents that can affect dilution, and to model dilution accurately on a pro forma basis. Dilution is a necessary and even desirable aspect of fundraising, but you need to be aware of its effect so that you can raise the right amount of money, at the right time, and at a valuation that fairly reflects both the company’s value and the risk being taken by the investor.

Alternatives to Venture Capital

The traditional VC path in the life science space appears to be under stress. Many industry observers proclaim that life science VC is a broken model and no longer able to achieve required returns for the venture fund limited partners. Some stalwarts maintain that life science VC actually outperforms other sectors of the VC asset class. Whoever is right, the fact is that there are a growing number of alternatives to traditional VC of which every early stage life science entrepreneur should be aware. In the rapidly evolving life science space, with several different models emerging, finding the right funding partner is becoming an increasingly complex task.

Some of the more attractive alternatives include:

- **Corporate VC.** Large pharmaceutical and other companies may make good investment partners. Corporate venture capitalists can add a strategic fit in terms of therapeutic or diagnostic and can provide significant assistance in clinical strategy. Entrepreneurs need to choose a corporate VC partner with care. The entrepreneur is likely to be attached to the partner, for better or for worse, whereas the corporate venture capitalist may change strategic direction or simply make new budget priorities.

- **Venture philanthropy.** Foundations and family offices with a focus on specific diseases or research paths are increasingly emerging in the life science space. Foundations can provide funding ranging from grants to milestone development payments to terms that resemble standard VC-preferred stock deals. Founda-
tions are mission driven, not purely bottom-line driven, so they may be seen by entrepreneurs as more dependable than corporate partners over the long haul.

- **Government funding.** NIH funding is non-dilutive and plentiful: NIH provided over $630 million in Small Business Innovation Research (SBIR) funding in fiscal year 2012. If you take SBIR funding, you will become subject to special government accounting and audit requirements. SBIR awards are typically capped at $150,000 for phase I awards and $1,000,000 for phase II awards.

### General Solicitation

For 80 years, the biggest rule to remember in conducting a private placement of securities was that the offering process could not involve any “general solicitation,” meaning advertisements, notices, articles, TV, radio, and other forms of mass communication. In 1933, the idea of what constituted a “general solicitation” was fairly clear. Over the years, though, methods of mass communication have proliferated greatly. Also, today’s start-ups find ever more investor conferences, business incubators, and other opportunities to present their case. Participation in these events may constitute “general solicitation” under the law.

In September 2013, the SEC finalized a rule, required by the Jumpstart Our Business Startups (JOBS) Act, permitting general solicitation in certain cases. At first glance, it seemed that this new rule would quickly make it easier for start-ups to raise funds by advertising on the company’s website, sending out emails, tweeting on the company’s Twitter account, etc. However, it has not been that simple, and so far, the new rule has not really opened up access to capital in the way that was envisioned by its congressional sponsors. First, the rule requires that in a deal with general solicitation, not only must all of the purchasers of the securities be accredited

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investors (as is common in any Rule 506 deal) but also that the issuer must take reasonable steps to “verify” that the purchasers of the securities are accredited investors. This step of “verification” has met with some resistance among the community of angel investors that should be the natural targets of general solicitations. Investors have objected to the idea of providing tax returns or other personal information in order to verify accredited investor status.

Also, the new attention to the issue of general solicitation has, ironically, focused attention on types of general solicitation that used to fall through the cracks. Start-ups as well as federal and state regulators have long ignored the general solicitation rule as it applied to pitches made at business plan competitions and industry conferences. Now, due to increased attention, start-ups are being importuned to make sure that their presentations do not constitute a solicitation of interest in an investment (though it is hard to imagine why else these companies would be pitching at a business plan competition in the first place). So, paradoxically, the statutory removal of the ban on general solicitation has, so far, created more complications than it has removed. Hopefully, the angel investment community will find some way to get comfortable with verifying accredited investor status, and issuers will be able to expand their reach into the investor community, as the JOBS Act intended.

A Word About Brokers and Finders

Launching and growing a company is a full-time entrepreneurial endeavor, and raising capital can be a specialized skill. Founders of life science start-ups, consumed with building their company and achieving technical milestones, frequently turn to third parties to help find investors. You should be aware, though, that accepting these services may raise certain regulatory concerns. The business of finding investors for early stage companies requires licensure as a broker or investment adviser on both the federal and state levels. If you use an unlicensed broker or finder to sell securities, then you may be subject to regulatory sanctions, including offering rescission to investors who were so solicited. Self-described “finders” without licenses proliferate in the start-up community. Many of these individuals
insist that their work is legal, that they have been doing it for a long time, and/or that they are not subject to license requirements because they are not negotiating deal terms, or because they are acting as a “finder” only, or because they maintain some paper relationship with a licensed broker to provide “clearing” services. These rationales are usually wrong. If you are approached by an unlicensed individual offering services to help you find investors, be wary and seek the advice of qualified securities counsel before proceeding.

**Structuring the Company to Meet the New Funding Environment**

In addition to selecting the right funding from the right partner on the right terms, a successful life science entrepreneur can form and grow the company to better utilize smaller-sized, less dilutive financing rounds. “Virtual” companies can stay small and efficient by outsourcing functions from financial to clinical activities; using incubator space that is shorter term and more flexible (this also sometimes comes with access to laboratory facilities); and using contract work instead of hiring full-time employees. To operate successfully in a virtual environment, you need to assess and deal with a wide range of legal issues, including:

- Employment and independent contractor laws respecting early team members
- Privacy laws and regulations that might apply to your clinical and user information
- Intellectual property, nondisclosure, and competition issues that arise in contracted services agreements

**Summary**

In conclusion, this is an exciting time to be in the early stage market. Current market circumstances stand to reward the entrepreneur who can assess and exploit the legal risks and opportunities successfully. You should be sure to stay apprised of the opportunities offered by these emerging legal
realities; don’t overstate the opportunity and/or understate the risks involved, but rather provide your investors with full and fair disclosure of the facts material to their investment decision. Be aware of new means of offering securities and alternative investor classes, but also remember that the best solution for one company might not work for another. Obtain good counsel from legal, tax, and accounting professionals and incorporate that counsel into your business plan. And finally, learn and use best practices relating to your business. They may or may not be legally required, but are increasingly recognized, and demanded, by both institutional and individual investors.

Gerard O’Connor’s practice focuses on business matters ranging from mergers and acquisitions and corporate finance to intellectual property. He represents clients in a variety of industries, including life sciences, clean energy technology, renewable energy, venture capital, and professional services.

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