

FUNDING TRANSLATIONAL MEDICINE VIA PUBLIC MARKETS: THE BUSINESS DEVELOPMENT COMPANY

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A business development company (BDC) is a type of closed-end investment fund with certain relaxed requirements that allow it to raise money in the public equity and debt markets, and can be used to fund multiple early-stage biomedical ventures, using financial diversification to de-risk translational medicine. By electing to be a “Regulated Investment Company” for tax purposes, a BDC can avoid double taxation on income and net capital gains distributed to its shareholders. BDCs are ideally suited for long-term investors in biomedical innovation, including: (i) investors with biomedical expertise who understand the risks of the FDA approval process, (ii) “banking entities,” now prohibited from investing in hedge funds and private equity funds by the Volcker Rule, but who are permitted to invest in BDCs, subject to certain restrictions, and (iii) retail investors, who traditionally have had to invest in large pharmaceutical companies to gain exposure to similar assets. We describe the history of BDCs, summarize the requirements for creating and managing them, and conclude with a discussion of the advantages and disadvantages of the BDC structure for funding biomedical innovation.



1 Introduction

The process of translational biomedical innovation is becoming increasingly complex, expensive,

and uncertain. This implies that the traditional financing vehicles of private and public equity will become less effective for funding biopharma in the future, as the needs, expectations, and risk profiles of limited partners and shareholders increasingly diverge from the new realities of biomedical innovation.

In this paper, we describe a specific legal structure, the business development company (BDC), that can be used to raise money in the public equity and debt markets to facilitate investing in biomedical innovation, especially early-stage

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translational medical projects. A BDC is a type of closed-end investment fund that can partake of certain relaxed requirements under the *Investment Company Act of 1940* (the “*Investment Company Act*”), so long as it makes at least 70% of its investments in certain “eligible” portfolio companies. A BDC can elect to be treated as a Regulated Investment Company (RIC), under the Internal Revenue Code of 1986 (the “Code”), and thus not be required to pay U.S. federal corporate-level income taxes on income and net capital gains that it distributes to its shareholders as dividends on a timely basis. The BDC, used as a structure to make investments in multiple companies formed to commercialize biomedical innovation, would allow investors the opportunity to spread risk among a number of different drug trials, and thus increase the chances of participating in the long-term growth of a successful drug, along the lines of the “megafund” proposed by Fernandez *et al.* (2012).

For the purpose of this paper, we distinguish BDCs formed to make equity investments, which we refer to as venture capital BDCs (VC-BDCs), from BDCs whose primary purpose is to make debt investments, which we refer to as debt-BDCs. This distinction is important for successful fundraising and trading, since the market recognizes that debt-BDCs and VC-BDCs have different risks and rewards, especially over the short term. VC-BDCs are best suited for long-term investors who seek to benefit from the returns associated with biomedical innovation, and therefore may be particularly attractive to: (i) investors with medical expertise who can appreciate the risks of going through the FDA approval process, (ii) “banking entities,” which recently were generally prohibited from investing in hedge funds and private equity funds by the Volcker Rule,¹ but who are permitted to invest, subject to certain restrictions, in BDCs, and (iii) retail investors, who have traditionally only been able to invest in

large pharmaceutical companies to gain exposure to similar assets.

We begin in Section 2 with a discussion of the recent challenges in the biopharma industry that highlight the need for new funding vehicles like the BDC. We present a brief review of the history of BDCs and their basic structure in Section 3, and then describe VC-BDCs in Section 4. In Section 5, we describe the organizational structure of a typical BDC, and in Section 6 we turn to the basic mechanics of operating a BDC. Some of the practical advantages and disadvantages of the BDC structure are presented in Section 7, and we conclude in Section 8. More detailed legal and regulatory aspects of BDCs are provided in the Appendix.

2 Motivation

The life sciences sector is becoming increasingly paradoxical for researchers and investors alike. At the same time that scientific breakthroughs like gene sequencing and precision medicine are unraveling diseases that have confounded conventional medicine for centuries, capital flows have slowed to a trickle at the early stages of commercialization in biomedicine, making it increasingly difficult and risky to translate basic research findings into new clinical applications (Sweeney, 2013). Industry professionals have termed this capital shortage the “Valley of Death.”

While seed-stage biomedical research may be occurring at the bench, it is not being translated as effectively into clinical applications at the bedside. The process of the bench-to-bedside enterprise, of harnessing knowledge from the basic sciences to produce new drugs, devices, and treatment options for patients, is known as “translational research,” the interface between basic science and clinical medicine, and it is of the utmost importance for successful biopharma innovation (Woolf, 2008). The primary objective

of translational research is to arrive at a commercial bedside application, often in the form of a New Molecular Entity (NME) or a Biologics License Application (BLA), although the research can also entail the development of unanticipated or “non-derivative” products. However, the importance of this step also means that translational research is a bottleneck for future development.

For example, early-stage research is the primary source of valuable “first-in-class” NMEs and BLAs, first-in-class meaning drugs that use a new and unique mechanism of action for treating a medical condition (FDA, 2014). These innovations serve previously unmet medical needs, or otherwise significantly help to advance patient care and public health. Unfortunately, in recent years the number of medicines approved by regulatory bodies around the world has declined, whether first-in-class or variations on a preexisting theme. In the past decade, half as many NMEs were approved compared to preceding years (FDA, 2014). In 2007, the U.S. Food and Drug Administration (FDA) only approved 19

NMEs and BLAs, the fewest number since 1983 (Paul et al., 2010). Of the 27 new drugs granted FDA approval in 2013, only 33% were identified as first-in-class (FDA, 2014). Moreover, the number of new NMEs and BLAs has also sharply declined per dollar of investment.

Without a drastic improvement in the current model for translational research, the life sciences sector cannot sustain sufficient innovation to replace the loss of revenues due to patent expirations for successful products (Paul *et al.*, 2010). Only \$6 billion was spent on translational efforts in 2012, while \$48 billion was spent on basic research and \$125 billion on clinical development in the life sciences sector (Milken Institute, 2012).

One of the main challenges to biomedical innovation is the fact that the multi-stage process of drug development is too lengthy, risky, and expensive for any single investor to undertake from beginning to end. In contrast to the standard analogy of drug development as a marathon, a more apt analogy given current costs and complexities is a triathlon. Figure 1 depicts the different

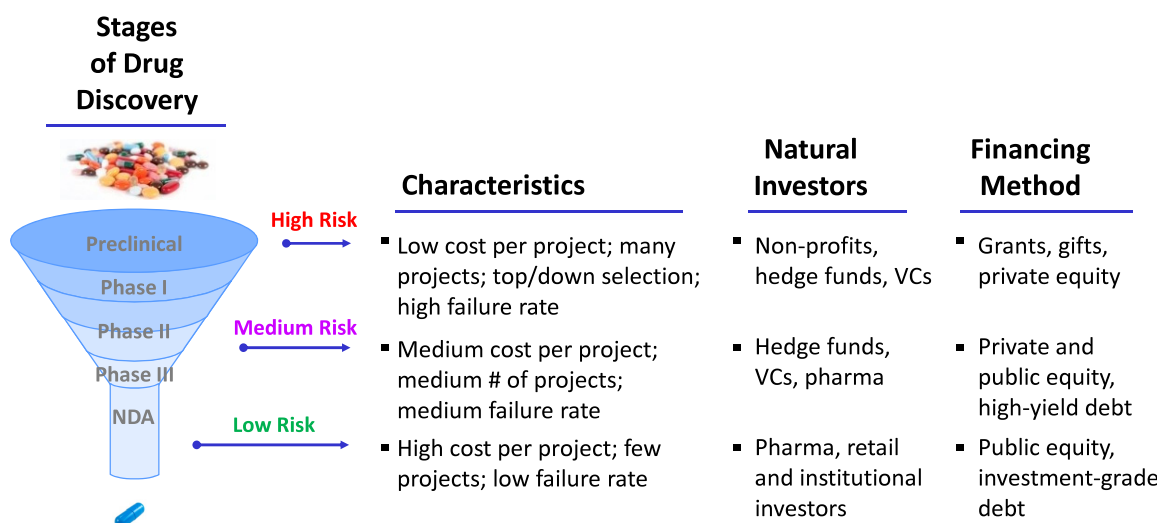


Figure 1 Relationship between the stages of drug discovery, their financial characteristics, the natural investors for each stage, and the most appropriate financing method. Earlier-stage assets are more risky; hence their financing vehicles naturally reflect investors with those risk preferences. *Source:* Lo and Naraharisetti (2014).

stages of a typical drug development program, and shows that the distinct risk/reward characteristics of each stage imply distinct investors drawn to the corresponding investment profiles. Early-stage research is much more difficult to finance with traditional sources of capital (Fernandez *et al.*, 2012). Innovative firms cannot secure capital for a host of reasons: investment returns are uncertain, they have little collateral to secure debt, and their capital is difficult to redeploy, since it mostly takes the form of intangible assets (Carpenter and Petersen, 2002; Hall, 2002). On average, commercializing one drug takes 14 years and \$1.3 billion, and for each success, there are 50 failures (WSJ, 2012). This risk profile is unpalatable to many investors.

Early-stage research companies cannot secure capital from public equity markets as easily as large pharmaceutical companies. In the early stages of drug development, it is impossible to establish future trajectories of sales and profits (Sweeney, 2013). An established company with current earnings and profits is in a much stronger position to sell equity shares than an early-stage company which has yet to demonstrate its potential for upside. At the same time, traditional financial intermediaries are not viable alternatives either. Banks strongly prefer to make decisions based on financial accounting ratios, rather than future expected cash flows determined by innovative but highly speculative activity. Loans to early-stage companies, made against personal guarantees and liquid assets, often require collateral exceeding their value threefold. The risk appetite of traditional financial intermediaries is diametrically opposed to the intangible and high-risk/high-reward nature of investment in early-stage, preclinical biotechnology (Sweeney, 2013).

What are the current sources of capital for early-stage research? The answer is surprising. Most

early-stage biomedical research occurs within public institutions. In particular, universities produce approximately two-thirds of early-stage research (Heller and Eisenberg, 1998). However, these institutions often struggle inordinately to commercialize their discoveries (Sweeney, 2013). Public institutions possess limited competence in fast-paced, market-oriented bargaining, and limited resources for absorbing transaction costs, e.g., for patenting and licensing (Thursby *et al.*, 2000).

A public institution's obligation to the public stands in contrast to the statutory duty imposed on the directors of a corporation to act in the best interests of its shareholders by maximizing financial return.² For example, a politically accountable government agency such as the National Institutes for Health (NIH) may further its public health agenda by leveraging its intellectual property (IP) rights to ensure widespread availability of new therapeutic products at reasonable prices. This may serve a laudable social goal, but it also lowers the potential financial returns, creating a vicious cycle that deters further private investment. When the NIH sought to establish co-ownership of IP rights held by Burroughs-Wellcome on the use of azidothymidine (AZT) to treat the human immunodeficiency virus (HIV), its purpose was to lower the price of AZT, and to promote public health.³ In contrast, a private-sector firm is more likely to use its IP to maintain a lucrative product monopoly, which can reward shareholders and fund future product development (Heller and Eisenberg, 1998).

Thanks to the many recent breakthroughs in biomedicine, the amount of innovative biomedical research currently exceeds the available capital flow for translation into commercialized products (Fernandez *et al.*, 2012). This persistent investment deficit mandates a more comprehensive solution than public funding alone—it is

clear that the life sciences sector needs new financial approaches to early-stage drug development and other forms of biomedical innovation. If the current stagnancy in healthcare is to be overcome, greater private investment into biomedical research must be deployed—but deployed carefully, in a manner conducive to both upstream innovation and downstream product development and commercialization. Financial incentives can mobilize a broader set of stakeholders and a more expansive pool of assets, initiating a virtuous cycle of investor confidence that magnifies the likelihood of success. What is needed right now are models that break down the value chain to offer an acceptable return on investment (ROI) through each stage of research and development, effectively spreading the investment risk and reward throughout the entire R&D process.

The key to overcoming the barriers to capital flow posed by traditional sources of financing lies in the establishment of novel structures capable of appropriately and successfully tapping into capital markets. One such innovative structure is the “operating company,” which has been used by several businesses seeking to invest in biomedical innovation, such as Safeguard Scientifics and Arrowhead Research. An operating company refers to a corporate entity that has been formed primarily to perform all of the activities, and assume all of the accompanying risks, of a business.

However, an operating company is not ideal for risky, early-stage investment in biomedical research for reasons best illustrated through an example of a hypothetical investment in early-stage research on clinical cancer compounds, where the estimated success rate is very low (DiMasi *et al.*, 2013; Retzios, 2009; Pavlou and Reichert, 2004; Kola and Landis, 2004). For financing early-stage cancer research, the use of an operating company to limit risk exposure and

liability is legally possible only if the operating company is not inadvertently operating as an investment company. The *Investment Company Act of 1940* regulates investment companies registered under the act whose shares are offered to the public, such as mutual funds. However, the *Investment Company Act* defines an investment company very broadly, as any issuer that is, or holds itself out as being, primarily engaged in the business of investing, reinvesting, or trading in securities. Under the *Investment Company Act*, a company may be deemed to be an investment company if it owns, or proposes to acquire, investment securities with a value exceeding 40% of the value of its total assets (excluding government securities and cash items) on an unconsolidated basis, unless an exemption or safe harbor applies. As a result, operating companies can become “inadvertent” investment companies, especially if they invest in securities and conduct significant operations through subsidiaries that are not majority-owned (Glicksman and Callaway, 2014).

To avoid registration under the *Investment Company Act*, an operating company needs to fund projects through majority-owned subsidiaries, held for the long term. For companies such as Safeguard Scientific, which access the capital markets through an operating company to invest in healthcare companies that have “lesser regulatory risk and have achieved or are near commercialization,” this is an acceptable tradeoff.⁴ However, this structure is simply not conducive to companies developing cancer drugs within the FDA framework for approval, where, due to the binary outcome of the trials, a security will need to be monetized immediately after the completion of a successful drug trial, or disposed of if negative results ensue.

Additionally, the use of the operating company model for investing in multiple operating

subsidiaries requires that the operating company take a controlling interest in each portfolio company. In the case of funding research with high failure rates, like clinical cancer compounds, taking a controlling interest in each portfolio company is not feasible. If the investing company owns a controlling interest, the investing company will have greater exposure to risk due to higher ownership levels in the business activities conducted by the portfolio company.

Other investment company structures have been used to finance biopharma research, such as the traditional registered closed-end fund, an investment company registered under the *Investment Company Act* that is not freely redeemable and typically trades on a stock exchange. But a registered closed-end fund is more often used for investing in later stage, publicly traded biopharma companies, generally missing the private and small-cap companies involved in early-stage research. Registered closed-end funds have also recently been used for making healthcare investments in publicly traded companies,⁵ private companies, foreign securities, and private investment in public equities (“PIPE”) transactions.⁶ However, none of these vehicles offer the same degree of flexibility as the BDC.

3 A brief history of the BDC

In the 1970s, Congress was pressured by a perceived crisis in the capital markets to provide exemptions from the *Investment Company Act of 1940* (Tashjian, 1980; Boehm *et al.*, 2004). Private equity and venture capital firms believed that their capacity to provide financing to small businesses was blocked by a limitation in the *Investment Company Act*, which prevented these firms from becoming public companies without becoming registered management investment companies. It was argued that innovation was being stifled because registered management investment companies would be subject to the full

regulation of the statute, compliance with which would be unduly difficult (BDC Reporter, 2015). These considerations led Congress to enact the *Small Business Investment Incentive Act of 1980* (Boehm *et al.*, 2004), which, among other things, amended the *Investment Company Act* (the “1980 Amendments”).⁷ This legislation was the result of discussions between Congress, the Securities and Exchange Commission (SEC), and the venture capital industry, with the common goal of removing burdens on venture capital activities while maintaining investor protections.

The 1980 Amendments led to the creation of the BDC, a new form of closed-end investment fund, in order to facilitate the flow of capital to companies that were perceived as less capable of availing themselves of conventional forms of financing. The legislation also lessened several of the restrictions under the *Investment Company Act* to encourage participation in the regulated portion of the asset management industry, and created an incentive for funds to become BDCs.

Legislators believed that establishing BDCs would lead to the creation of a number of public vehicles that would invest in private equity, and thus increase the flow of capital to small, growing businesses. In the initial years following the 1980 Amendments, a number of BDCs were formed, including Merrill Lynch Venture Capital Inc. (1981), American Capital Ltd. (1986), and Capital Southwest (1988) (Bristow and Petillon, 1999). After their initial appeal in the 1980s, however, the popularity of BDCs declined in the following decade.

BDCs made their way back into the financial mainstream in the 2000s (Smith, 2014). The increasing demand for capital by small and middle market companies, particularly because of increased regulation of banks stemming from the 2008 financial crisis and the demand by the public to provide such capital, has resulted in

a new growth of the BDC. As a result, BDCs are emerging as a realistic alternative for mainstream investors with an appetite for investments in early-stage research. In harnessing an entirely new sector of the investment community, the BDC provides a new way of funneling capital to biomedical innovation.

More formally, a BDC is a type of closed-end fund that benefits from certain relaxed regulatory requirements under the *Investment Company Act* in exchange for a requirement that the BDC will make 70% of its investments in “eligible portfolio companies.” While Section 2(a)(48) of the *Investment Company Act* enumerates several categories of qualifying assets, most BDCs own securities that qualify because they have been issued by an eligible portfolio company. An eligible portfolio company must be organized and have its principal place of business in the United States, and encompasses all private U.S. companies, as well as public U.S. companies with an equity market capitalization of up to \$250 million. A BDC is also obliged to “make available significant managerial assistance” to those companies.

BDCs can be structured with internal management, like an operating company, or with external management, like a private venture capital firm. They are typically publicly traded on a national stock exchange, but they can also be non-traded. If certain requirements are met, BDCs may qualify to elect to be taxed as “regulated investment companies,” or RICs, for federal tax purposes. The process is designed to avoid double taxation, whereby both the company and individual investors would be taxed. This qualification permits them to eliminate taxes on capital gains and income earned on the BDC’s investments at the BDC level.

BDCs provide mainstream investors access to investments in private company investments historically only available to institutional investors

or wealthy individuals through private funds. In contrast to many other forms of investment companies, a BDC is unique in that it provides shareholders with the ability to retain the liquidity of a publicly traded stock, while sharing in the benefits of investing in emerging-growth or expansion-stage privately owned companies. In this way, it can be structured similarly to a publicly held private equity or venture capital fund.

BDCs are exempted from some provisions of the *Investment Company Act*, and certain sections apply only to BDCs. These exemptions and provisions may make BDCs preferable for making investments in private companies compared to other types of closed-end funds registered under the *Investment Company Act*. For example, pursuant to Section 205(b)(3) of the *Investment Advisers Act of 1940*, as amended (the “*Advisers Act*”), investment advisers to BDCs are permitted to charge an incentive fee based on capital gains. However, registered closed-end funds are prohibited from doing so. Registered closed-end funds that trade on a stock exchange strike a net asset value (NAV) daily. BDCs are only required to value their assets on a quarterly basis, which is more congruent with valuing illiquid privately held securities.

4 The VC-BDC and translational medicine

Our proposal is to create one or more financing entities, in the form of a VC-BDC, to invest in multiple biomedical projects throughout various stages of their development cycles, financed in the public markets. When sources of private capital are sufficient, reliance on public investors is unnecessary, but this is clearly not the case for biomedical research. Increasingly, venture capital firms are demonstrating interest in attracting public investors, who are interested in the upside of start-up and pre-IPO companies. Such investments are coming to be seen as important,

and perhaps even necessary, components of a properly diversified investment portfolio (Boehm and Krus, 2001). Tapping the public markets to expand the pool of capital available for life science investment by bringing together investors is a viable option.

A BDC is superior to an operating company structure in reducing risk to an investor. An operating company can serve to limit liability, but it does so only in relation to one such business structure at a time. A BDC, however, affords an even greater degree of risk reduction. Multiple speculative investments require a much broader set of assets in order to achieve risk reduction, but this is precisely what a BDC is designed to do. By using a BDC to invest in multiple biomedical portfolio companies, the investor is granted an opportunity to spread risk among a number of different drug trials, thus increasing the investor's chances of participating in the long-term growth of a successful drug.

A BDC must invest at least 70% of its assets in U.S. companies that are either private, or publicly traded with a market capitalization of \$250 million or less. This regulatory requirement splits the investment universe into two broad groups. Traditional closed-end funds are generally favored over a BDC for investments in larger companies and/or foreign investments. For making investments in biomedical innovation in early stage, private companies, the BDC is the superior option.

The BDC facilitates investment in early-stage biomedical innovation by providing direct access to public equity and debt markets. Although investments in BDCs can take the form of equity or debt investments, almost all new BDCs have chosen a debt-investment focus. The VC-BDC is now a comparative rarity among today's BDCs.

Nevertheless, we believe the VC-BDC model—with its capacity for providing both permanent capital and managerial assistance—can more fully realize the original intent of the BDC, and allow institutions which conduct early-stage research to gain access to inputs which were previously inaccessible. Given the long-term nature of investments in the biopharma industry and the inherent regulatory hurdles, the mandate to provide managerial assistance may help a VC-BDC to maximize the value of its investments in a portfolio company (Markovich, 2012). For example, a VC-BDC can generate considerably greater resources for negotiating licenses on a case-by-case basis than can public sector institutions or small start-up firms, and can provide the knowledge required to make those steps with appropriate measures for mitigating risk and improving the ultimate commercial viability of any arising discoveries. We propose that this vehicle will be capable of bridging the translational research gap, and meeting a more diverse range of risk profiles in the investment community.

The VC-BDC has the potential to play a major role as a unique alternative to traditional financing, acting in synergy with the existing biotech venture capital industry to stimulate innovation. A natural business model follows from the binary nature of biomedical companies and the operating costs of a publicly traded, heavily regulated vehicle such as a BDC, in which an asset manager funds multiple biomedical start-up companies, thus distributing the costs (and risks) of multiple projects, with the objective of allowing gains from successful biomedical investments to compensate for companies which fail to survive the translational research process.

5 Organizational structure of the BDC

A BDC regulated under the *Investment Company Act* must be organized and have its principal place

of business in the United States, and must be operated for the purpose of making investments in the types of securities enumerated in the *Investment Company Act*. For a fuller description of qualifying securities and a BDC's legislatively required offer of managerial assistance toward the issuing firms, see the appropriate sections of the Appendix.

BDCs can be externally managed or internally managed. An externally managed BDC typically has no employees, and has an external investment adviser (a separate legal entity) to manage the BDC under the direction of the board of directors. An internally managed BDC has no external investment adviser, and the BDC is managed by its officers, who are typically its employees, under the direction of the board of directors.

BDCs are permitted greater flexibility regarding leverage, compensation, affiliated transactions, and restrictions for selling shares below NAV than registered closed-end funds, which we detail in this section.

5.1 Leverage

BDCs are less restricted than registered closed-end investment companies as to the amount of debt they can have outstanding. A BDC is permitted, under specified conditions, to issue multiple classes of indebtedness and one class of stock senior to its common stock, if its asset coverage ratio, as defined in the *Investment Company Act*, is at least equal to 200% immediately after each such issuance, which means that any debt or senior securities cannot exceed one-third of the BDC's total assets.⁸ For example, for each \$1.00 of senior securities (debt and preferred stock) issued, the BDC must have \$2.00 of assets at issuance. In comparison, registered closed-end funds are limited to issuing leverage at least equal to 300% immediately after each issuance—for each \$1.00

of debt issued, a registered closed-end fund must have \$3.00 of assets at issuance.⁹

A leveraged strategy of using indebtedness to expand their assets in investments is often an attractive provision for debt-BDCs. However, because of the risky nature of early-stage investments in biomedical innovation, VC-BDCs may determine not to use leverage to the same extent as their debt-BDC peers.

In addition, with respect to certain types of senior securities, the BDC must make provisions to prohibit any dividend distribution to shareholders or the repurchase of certain securities, unless they meet the applicable asset coverage ratios at the time of the dividend distribution or repurchase. A BDC may also borrow amounts up to 5% of the value of their total assets for temporary purposes.

5.2 Incentive compensation

Managers of closed-end funds are generally prohibited from receiving incentive compensation on the basis of capital gains, and are prohibited from having employee profit sharing plans. However, these restrictions have been relaxed under the 1980 Amendments for BDCs.

Section 205(b)(3) of the *Advisers Act* permits external investment advisers of BDCs to assess an incentive performance fee of up to 20% on a BDC's realized capital gains, net of all realized capital losses and unrealized capital depreciation over a specified period, typically annually. Like registered closed-end funds, a BDC may also charge a base management fee, which is typically determined by taking the average value of a BDC's gross assets, usually calculated at an annual rate of between 1.50% and 2.00%, paid quarterly in arrears, and an incentive fee based on income, including interest income, dividend income, and any other income, which is also

typically paid quarterly. The income incentive fee is typically calculated as the pre-base management fee net investment income for the quarter as a percentage of average assets managed, and the return is compared against a pre-determined hurdle rate (usually 2% a quarter or 8% annually).

Internally managed BDCs are permitted to pay incentive compensation either through a profit sharing plan or a stock option plan. Section 57(n) of the *Investment Company Act* permits an internally managed BDC to operate a profit sharing plan for directors, officers, and general partners, so long as the aggregate amount of profits distributed under such a plan does not exceed 20% of the BDC's net income after taxes in any fiscal year. Participation in the profit sharing plan by a BDC's directors or its general partners is permitted only by an order of the SEC.

Internally managed BDCs that do not operate a profit sharing plan are permitted to issue stock options to their directors, officers, employees, and general partners. Many BDCs have also obtained orders from the SEC permitting them to issue shares of restricted stock to their directors, officers, employees, and general partners.¹⁰

Internally managed BDCs may have different forms of compensation to attract and retain personnel, in addition to the incentive compensation. The varieties of compensation arrangements differ by company and include salaries, bonus arrangements, 401(k) plans, and deferred compensation plans.

5.3 *Affiliated transactions*

Registered investment companies are prohibited from entering into transactions with their affiliates under Section 17 of the *Investment Company Act*. However, Section 57, the analogous section for BDCs, is slightly less onerous than its counterpart. Section 57 addresses the ability of BDCs

to engage in certain types of transactions with affiliates. A BDC may not engage in specified transactions with its affiliates (directors, officers, investment adviser, their designated affiliates, and anyone controlling, controlled by, or under common control with the BDC). Depending on the nature of the affiliation with the BDC, transactions involving a BDC and one or more of its affiliates require either:

- Authorization by the “required majority” of the board of directors, which consists of a majority of the board, including a majority of disinterested board members and a majority of the board with no financial interest in the transaction; or
- An order of the SEC.

Many BDCs have obtained exemptions from the SEC, permitting certain co-investments with affiliated funds, subject to certain conditions.¹¹

5.4 *NAV determination*

Traditional registered closed-end funds, which generally invest their assets in liquid investments, must value their assets on a daily basis. In contrast, BDC assets must be valued on a quarterly basis, in connection with the issuance of their financial statements. All investment companies regulated under the *Investment Company Act*, including BDCs, are required to account for their investment portfolio at value. Value is defined as the market value of securities for which market quotations are readily available. For other securities and assets, value is defined as the fair value determined in good faith by the board of directors.

Because BDCs primarily invest in illiquid securities of private companies, they are only required to value their assets quarterly, as it would be difficult to value their assets daily as traditional registered closed-end funds are required to do.

The Financial Accounting Standards Board's statement ASC 820 (formerly FAS 157) requires that public companies' financial instruments generally be valued at their current market price, that is to say, they are "marked to market." Each debt and equity security is separately valued.

There is no single standard for determining fair value in good faith. Determining fair value requires that judgment be applied to the specific facts and circumstances of each portfolio investment, while employing a consistently applied valuation process. Accordingly, valuation of privately held, illiquid securities is a time-consuming, judgment-based process, involving copious amounts of documentation to substantiate any claims.

Valuation has important implications for issuing new shares: Section 63(2) of the *Investment Company Act* provides that, with the exception of an IPO, a BDC may not sell common stock at a price below NAV, after excluding selling commissions and discounts, unless a majority of its shareholders that are not affiliated persons of such BDC have approved such company's policy and practice of making such sales at its last annual meeting of shareholders within one year of the sale of securities.

6 Managing a BDC

In this section we address several issues regarding the management of a BDC, including compliance and reporting, fundraising, portfolio management, and cash management. For a fuller description of establishing the BDC as an RIC for tax purposes, and a comparison of debt-BDCs versus VC-BDCs, see the Appendix.

6.1 Compliance and reporting

BDCs are generally subject to the same reporting obligations of traditional public companies

under the *Securities Exchange Act of 1934* (the "Exchange Act"), and must file an annual report Form 10-K, quarterly reports on Form 10-Q, and all other forms, such as proxy statements and current reports on Form 8-K. If the BDC is listed on a national exchange, it must also comply with the requirements of the exchange. BDCs are also subject to compliance with Section 404 of the *Sarbanes-Oxley Act of 2002*, which requires management to document and test internal controls, among other things, and for auditors to test and report on those controls.

(Note: unlike registered closed-end funds that file N-CSRs and N-SARs, BDCs file their annual and quarterly reports on Forms 10-K and 10-Q.)

BDCs are required to make certain public disclosures of portfolio company information. When preparing their publicly filed financial statements, and/or registration statements, which are filed on Form N-2, BDCs must include: (1) value and cost of each portfolio company investment; and (2) for certain portfolio companies in which the BDC has a controlling interest, the BDC may be required to disclose certain financial information of the portfolio company, either in its audited financial statements or in the notes to the financial statements, subject to certain tests required by Rules 3-09 and 4-08(g) of Regulation S-X.

6.2 Fundraising for a biomedical BDC

Entrepreneurs seeking to raise funds for specific biomedical research should consult with investment bankers in the investment space to determine the best method for building a portfolio in connection with a public offering. However, some basic background is considered here.

Historically, asset managers with a successful track record could raise capital based on a plan to make investments in eligible portfolio companies. This practice is sometimes known as a "blind

pool.” However, the tightening of the credit markets in the wake of the recent financial crisis appears to have foreclosed the blind pool option for BDC IPOs. The market now requires that even successful asset managers have a portfolio of investments prior to completing an IPO (Talcott and Kerns, 2014).

However, this is not necessarily a bad thing for a biomedical VC-BDC. Steadily raising capital over time mitigates the challenges associated with deploying capital in a blind pool IPO, because management is able to deploy capital strategically as it is raised, rather than needing to find investable assets for the entire fund over a short time period.

Partly due to the challenging environment for blind pool IPOs, there has been a proliferation of non-traded BDCs over the last several years. While non-traded BDCs share certain features with traded BDCs, they are different in significant ways. Traded BDC shares are liquid, while a non-traded BDC’s shares are not traded on an exchange, and have limited liquidity (Investment Program Association, 2013).

Offerings of non-traded BDC shares are only available to investors who meet suitability standards established by the state where they live in order to participate in these offerings. (Investment Program Association, 2013). They are typically sold over an extended offering period through broker-dealers and financial advisors, rather than in a one-time IPO. The up-front fees of a non-traded BDC may be in the range of 11.5% to 15%.

Historically, the number of BDC offerings has been limited. Over the last decade it has ranged between zero and six each year. In 2012, 2013, and 2014, there were five, four, and five IPOs, respectively. The number of IPOs by BDCs in the pipeline is unclear, since the Jumpstart Our

Business Startups (JOBS) Act enables prospective issuers to confidentially file their registration statements and publicly announce their intentions late in the registration process.

Selling shares to retail investors can be attractive to issuers since institutions tend to demand lower prices during an offering. According to the Capital IQ information service, retail investors have been between 14% and 66% of an IPO for recent debt-BDC offerings, and 57% and 78% of an IPO for the two most recent VC-BDCs, Firsthand Technology Value Fund (2011) and GSV Capital (2011). Asset managers seeking to raise capital in the public markets through an IPO should consult with investment bankers to determine the process, timing, and viability for the offering.

6.3 *Investment portfolio management*

A key feature of a biomedical BDC is the ability to invest in a portfolio of assets, where “assets” are defined more broadly than for a traditional biotech VC that focuses exclusively on acquiring equity or convertible preferred interest in an entrepreneur’s startup. In addition to these investments, a BDC could also acquire royalty interests in patents, approved drugs, or even early-stage research that has not yet filed for patent protection, but for which there are IP rights agreements between the BDC and the owner of the IP rights (see the Appendix for further discussion of patents and BDCs).¹²

One of the main benefits of a portfolio of assets is, if the assets are chosen carefully, the portfolio can offer investors a more attractive risk/reward profile because of the benefits of financial diversification (Fernandez *et al.*, 2012). As long as the assets’ returns are not perfectly correlated, combining multiple assets into a portfolio can help reduce the volatility of individual investments. The amount of volatility reduction is inversely related to the pairwise correlations among the

assets' returns. Consider a simple example of a portfolio of n assets, each with identical expected return μ and return volatility σ . Assume that the pairwise return correlation between any two assets is identical and equal to ρ (where $-\frac{1}{n-1} \leq \rho \leq 1$). Then an equally weighted portfolio of these n assets will have expected return μ and volatility $\sigma_p = \sigma \sqrt{\frac{1}{n} + \frac{n-1}{n} \rho}$. This relation shows that, as the number of assets n increases, the portfolio volatility σ_p declines monotonically toward its asymptotic limit ρ .

Figure 2 illustrates this diversification pattern as a function of the number of assets for various levels of correlation. For assets that have uncorrelated returns, portfolio volatility declines continuously with the number of assets, from 50% for one asset to only 9.1% for 30 assets. However, for higher levels of correlation, the diversification benefits of multiple assets are not as pronounced. For example, with 75% pairwise return correlation, even 100 assets yield only a modest 6.6 percentage-point reduction in volatility.

Therefore, one of the primary objectives of the biomedical BDC portfolio manager is to select assets that are as uncorrelated—or even negatively correlated—as possible. This objective seems obvious, particularly from a financial risk/reward perspective, but it flies in the face of industry practices, due to the highly specialized knowledge required to evaluate and manage biomedical assets. Managers who develop expertise in one scientific area naturally seek to make use of that expertise over time, and may not see the value, or have the time and resources, to develop expertise in several areas simultaneously. From the investor's perspective, however, there is considerable value in a simultaneous approach. Hence the biomedical BDC will have to be organized in parallel teams, each specializing in asset selection within a relatively narrow field, with an additional “asset allocation” team responsible for balancing investments across these specializations to optimize the risk/reward characteristics of the entire portfolio. In this respect, managing a biomedical BDC is

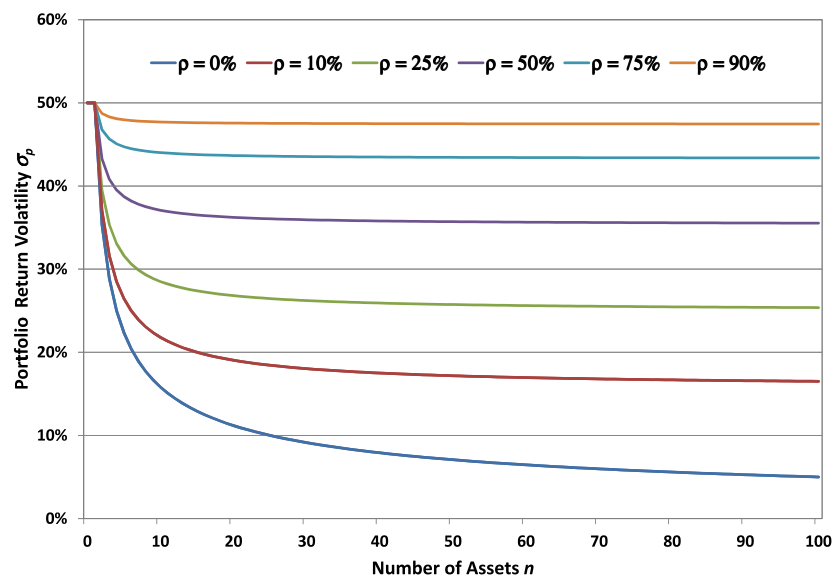


Figure 2 Return volatility of a portfolio of n identical assets with pairwise correlations of 0%, 10%, 25%, 50%, 75%, and 90% for $n = 1, \dots, 100$.

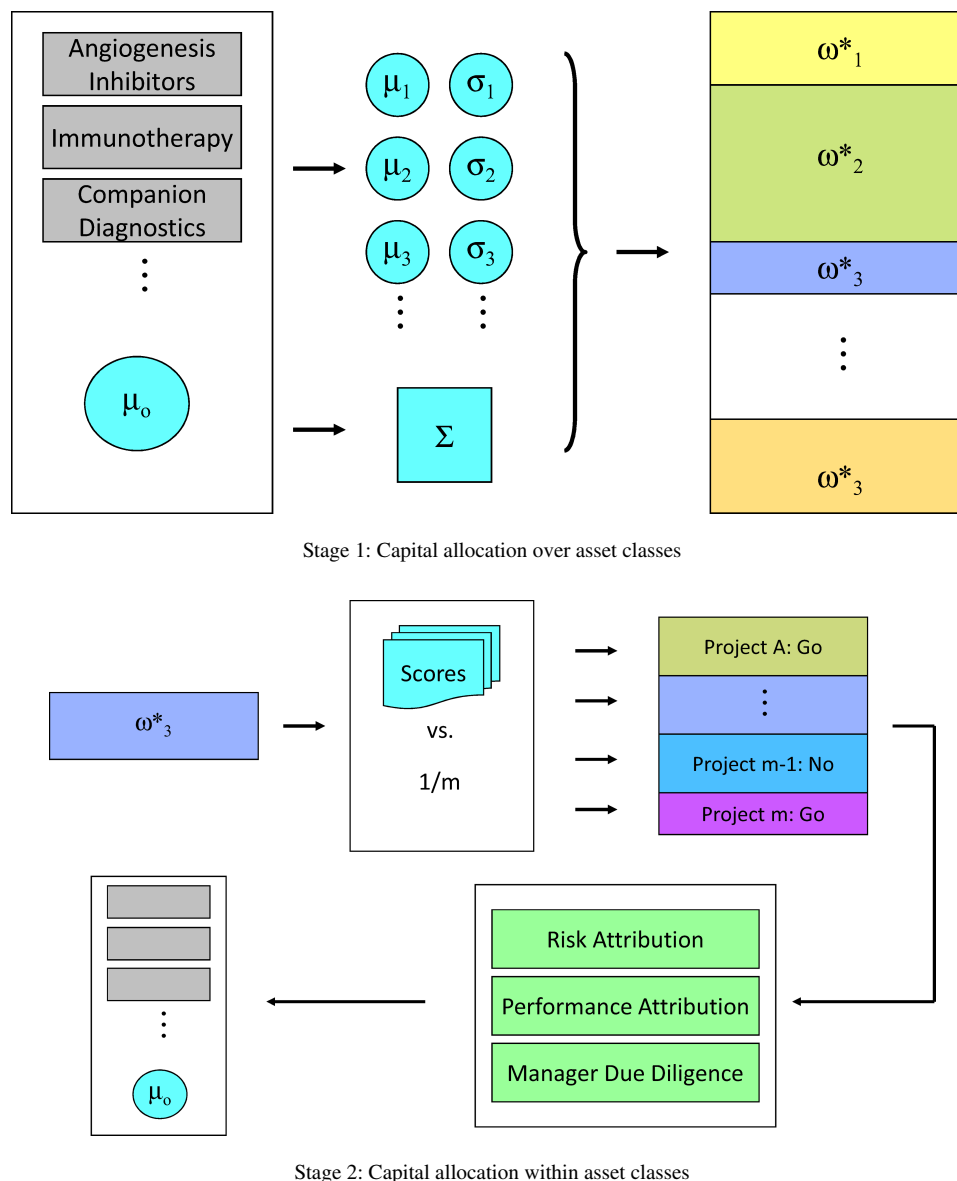


Figure 3 Asset allocation (Stage 1) and asset selection (Stage 2) for a biomedical BDC.

not unlike managing a fund of hedge funds, and Figure 3—adapted from the fund-of-hedge-funds context (Lo, 2010, Ch. 8)—illustrates how such a process might be organized.

6.4 Cash portfolio management

Biomedical BDCs differ in one important respect from venture capital and private equity funds:

they receive their investment capital at the time of their equity or debt offering, but deploy it over time as they identify sufficiently attractive investment opportunities. Unlike a VC fund that only issues capital calls when the capital is needed, a BDC generally receives its capital upfront, and must decide how to manage it. If it invests the capital in safe and liquid assets, such as short-term U.S. government debt, the low yield will be

a drag on the BDC's overall performance, but if it invests in higher-yielding assets, such as the S&P 500 Index or hedge funds, there is a significant risk of loss due to normal market fluctuations, and a risk of illiquidity when the capital is needed.

One solution is to strike a balance between these two extremes. By using liquid instruments such as stock-index futures, bond futures, and exchange-traded funds (ETFs), one can generate market exposure as close as possible to the investment mandate of the BDC, while managing the overall risk and illiquidity of the cash. For example, a BDC with an oncology mandate might invest in a diversified portfolio of publicly traded equities in biotech and pharma companies with cancer therapeutics as their primary business focus. The overall risk of this portfolio can be managed by using a combination of S&P 500 Index futures and biopharma ETFs¹³ (e.g., the SPDR S&P Biotech ETF or the iShares NASDAQ Biotechnology Index Fund), to either hedge or accentuate the BDC cash portfolio's exposures to the biopharma industry. As investment opportunities arise, these positions can be easily liquidated to free up the required amount of cash.

Although such "overlay" programs are routine in the institutional investment community, they may not be as familiar to traditional biotech VC investors, and will need to be explained to them in detail. In particular, it will be important to specify to investors in advance all of the parameters of an overlay program, so as to be as transparent as possible. Overlays should not be used to generate significant amounts of investment return for the BDC, but instead should be seen as a way to manage the BDC's cash to facilitate and be consistent with its mission.

7 Practical considerations

VC-BDCs have many benefits for funneling capital to biomedical innovation, most notably in

the creation of permanent capital for long-term research. However, there are also drawbacks to using VC-BDCs for investing in biomedical innovation, including relatively high operating costs.

The primary benefit of forming a VC-BDC to fund biomedical innovation is the creation of permanent capital compared to current venture capital practices. There are a number of reasons for venture capital's shortcomings in biomedical innovation. Small capitalization companies often have longer time periods to IPO than the typical ten-year lifespan of private VC funds (Weild and Kim, 2008). Syndicates of VC investors tend to fracture, resulting in the inability to raise capital for subsequent rounds of financing, even if the technology is ultimately successful. Finally, private venture capitalists are often hesitant to bring VC-backed companies public at earlier stages because internal rates of return are based on exit values due to provisions in limited partnership agreements that require them to distribute shares to limited partners at the time of an IPO. An exclusive focus on generating returns upon an IPO, in order to make distributions to limited partners at the peak of the company's valuation, may actually undermine growth of valuation post-IPO.

Unlike private VC firms, VC-BDCs have patient permanent capital. They can more easily align their interests with biomedical entrepreneurs than private VC firms, thereby making decisions that create value for the technology. VC-BDCs can tailor their investment horizons to suit the programs within the portfolio. Accordingly, early-stage research can be emancipated from financially driven business deadlines, and instead permitted to follow the most scientifically productive path. This is of particular importance to the life sciences sector, where untimely interruptions due to financial constraints destroy considerable economic value. Even potential financial disruptions

can alter the direction of strategic research during early-stage discovery. Tailoring investment horizons eliminates these effects.

The VC-BDC has the additional benefit of giving the venture capitalist access to retail investors who are otherwise not permitted to make investments in private funds. Federal securities laws prohibit retail investors from investing in private equity or VC funds. However, retail investors are allowed access to this asset class through a VC-BDC.

The VC-BDC has another advantage under federal securities law. Currently, the so-called “Volcker Rule” prohibits certain bank investors from investing in certain funds.¹⁴ The Volcker Rule is intended to curb risky bank practices, and generally prohibits banking entities from investing in hedge funds and private equity funds, including VC funds, which are referred to as “covered funds.” However, registered investment companies and BDCs are specifically excluded from the definition of covered funds, and have seen renewed interest from banking entities. Since the rule’s release, several banking entities have filed a registration statement to sponsor BDCs for investing in debt investments.¹⁵ It is our belief that in time, banking entities may elect to sponsor, manage, or invest in VC-BDCs with objectives similar to private VC funds subject to restriction under the Volcker Rule. For these investors, the VC-BDC creates liquidity, since it typically trades on a national stock exchange, unlike an investment in a private fund. Moreover, a VC-BDC has greater transparency than a private fund, owing to the public filing requirements.

A VC-BDC can raise permanent capital in the public markets, compared with private VC partnerships that need to separately raise capital for each ten-year fund. VC-BDCs also have more flexibility in raising capital in the public markets than private equity partnerships, which generally

raise capital in the form of contributions by limited partners. VC-BDCs can raise capital in a variety of manners, in the form of common stock, preferred stock, notes, and rights, and by using leverage through credit facilities.

However, there are several drawbacks to using a VC-BDC to invest in biomedical innovation. The primary drawback of BDCs is the expense. Externally managed BDCs have a high fee structure, and internally managed BDCs have high expenses. Being public is also expensive. The SEC has estimated that the average cost of achieving initial regulatory compliance for an IPO is \$2.5 million, followed by an ongoing compliance cost, once public, of \$1.5 million per year.¹⁶ Companies frequently underestimate the costs associated with an IPO, which include direct costs, such as underwriter discounts and auditor, legal, and financial fees, as well as longer-term costs, particularly with respect to compliance (PwC, 2012). BDCs have additional expenses relating to the complicated regulatory regime for legal and compliance requirements. Finally, because BDCs frequently raise capital in the public markets, transaction costs with regard to banking fees and transaction expenses are significant. VC-BDCs that raise capital in the public markets can have a lower cost of capital than other forms of financing, but only if enough capital is raised to absorb its operating expenses.

In addition to being expensive, BDCs are heavily regulated. Because a BDC is a hybrid of an operating company and an investment company, it is subject to multiple layers of regulation. BDCs are subject to the compliance rule under the *Investment Company Act*, which requires that the BDC adopt policies and procedures reasonably designed to prevent violations of federal securities laws. BDCs are also subject to compliance with Section 404 of the *Sarbanes-Oxley Act of 2002*, which requires management to document

and test internal controls, and for the auditors to test and report on those controls. Additionally, investment advisers to externally managed BDCs are subject to the compliance rule under the *Advisers Act*, which has requirements similar to the *Investment Company Act* compliance rule. Like mutual funds, BDCs must adopt codes of ethics.

Lastly, another challenge of operating a BDC is the difficulty of raising capital by selling shares below its NAV. As described in Section 5, with the exception of an IPO, a BDC may not sell common stock at a price below NAV without shareholder approval. While many debt-BDCs do receive such approval, getting shareholders to agree to such discounts may be more challenging for a VC-BDC with portfolios of growth stocks.

8 Conclusion

The opportunities for developing novel therapeutics have never been greater, but the challenges to the biopharma industry are daunting. Because of the increasing complexity, cost, and duration of drug development, investors are shifting assets toward other investments with more attractive risk/reward profiles. By creating diversified portfolios of biomedical projects financed by more patient capital, biopharma entrepreneurs can improve the risk-adjusted returns of their ventures and tap into new sources of capital such as retail investors, pension funds, insurance companies, sovereign wealth funds, and other institutional investors.

These innovations are beginning to emerge outside of the United States in jurisdictions with more flexible capital-market regulations. For example, on March 25, 2015, the Irish life sciences investment company Malin raised €330 million in an IPO on the Irish Stock Exchange to “acquire majority or significant minority equity positions in private, pre-IPO, pre-trade sale operating businesses in the life sciences industry”

(Reddan, 2015). Three months later, PureTech—a U.S.-based biotech startup engine that specializes in creating and incubating early-stage companies targeting significant unmet medical needs—debuted on the London Stock Exchange and raised \$171 million (Garde, 2015). This may be the start of a new trend in biomedical investing in which the traditional VC funding model is replaced by permanent capital raised through public offerings, yielding funds that can then be deployed more patiently and opportunistically over longer periods of time. The BDC structure is ideally suited for this purpose.

A Appendix

In this Appendix, we provide more detailed information about various aspects of the BDC structure, including restrictions on the type of investments BDCs can make, the relationship it can have with its portfolio investments, the requirements for becoming an RIC for tax purposes, a comparison between VC- and debt-BDCs, and issues around patents and BDC IP.

A.1 Qualifying investments

A BDC is required to have at least 70% of its total assets in “qualifying investments,” which is measured at the time of each new investment. While the *Investment Company Act* enumerates several categories of qualifying assets, by and large, most BDCs own securities that qualify because they have been issued by an “eligible portfolio company.” To be an eligible portfolio company, an issuer must be organized and have its principal place of business in the United States, and encompasses all private U.S. companies, as well as U.S. public companies with an equity market capitalization of up to \$250 million.

Investment companies, or companies that would be investment companies but for certain exceptions set forth in the *Investment Company Act*, do

not count as eligible portfolio companies. In order to be a qualifying asset, the securities must be purchased in transactions not involving a public offering.

A BDC has discretion to invest in any other investments with the remaining 30% of its portfolio. BDCs have historically invested in non-qualifying assets that do not fall within the “70% basket” to provide a source of cash flow to the VC-BDC, which otherwise invests in securities generating little immediate income. BDCs can also use the 30% basket to diversify the portfolio, which may contribute to attracting capital from investors.

A.2 *Managerial assistance*

A BDC must either control or offer to provide “significant managerial assistance” to portfolio companies that it treats as qualifying assets for the purpose of the 70% qualifying assets standard. As described in the *Investment Company Act*, “significant managerial assistance” means any arrangement whereby a BDC, through its directors, officers, employees, or general partners, offer to provide, and if accepted, does provide, “significant guidance and counsel concerning the management, operations, or business objectives and policies of a portfolio company.”

In practice, the managerial assistance that a BDC provides can take many forms, and depends on the particular needs of a portfolio company. In enacting the requirement, Congress recognized that the assistance provided would vary. Common examples of managerial assistance include assisting portfolio companies in: (1) establishing policies and strategy; (2) finding directors and management team members; (3) establishing and managing relationships with financing sources; and (4) evaluating acquisition and divestiture opportunities. In many cases, members of a BDC

may attend portfolio company board meetings, or even hold seats on the board.

Notably, BDCs need only offer such assistance. Whether or not a portfolio company accepts the offer has no bearing on compliance with the requirement.

A.3 *RIC requirements*

Like registered investment companies, BDCs may qualify for treatment as an RIC under Subchapter M of the *Internal Revenue Code* for federal income tax purposes. In general, an RIC is not taxed on its income or gains to the extent it distributes such income or gains to its shareholders. In order to qualify for favorable RIC tax treatment, BDCs must, in general, (1) annually derive at least 90% of their gross income from dividends, interest, and gains from the sale of securities and similar sources (the income test); (2) quarterly meet certain investment asset diversification requirements; and (3) annually distribute at least 90% of investment company taxable income as dividends. Any taxable investment company income not distributed will be subject to corporate-level tax. Any taxable investment company income distributed generally will be taxable to shareholders as dividend income.

It should be noted that in the context of making investments in biomedical innovations which typically have revenue-producing IP through licensing fees, or royalty interests in late-stage development biopharmaceuticals with royalty payments, these licensing fees and royalty payments may not be qualifying assets for the purpose of the income test. Accordingly, BDCs that elect to be treated as RICs typically make investments in corporations in which the IP is housed so that the “bad income” is not attributable to the RIC.

To satisfy the asset diversification requirements, at the end of each quarter, at least 50% of a BDC’s

assets must be invested in cash, cash items, U.S. government securities, securities of other RICs and other securities that, with respect to the BDC, do not represent more than 5% of value of the BDC's total assets. Furthermore, a BDC cannot own more than 10% of the voting stock of any one issuer, and cannot invest more than 25% of the value of its total assets in the securities of any one issuer (other than U.S. government securities and securities of other RICs), or of two or more issuers that are controlled by the company and that are engaged in the same or similar trades or businesses, or related trades or businesses.

It should be noted that BDCs set up for biomedical research may qualify for an exception for the method of calculating the asset diversification tests set forth in Section 851(e) of the Code in the case of an RIC that furnishes capital to development corporations. This exception is available only to RICs that have been certified by the SEC (not earlier than 60 days prior to the end of the investment company's taxable year) "to be principally engaged in the furnishing of capital to other corporations that are principally engaged in the development or exploitation of inventions, technological improvements, new processes, or products not previously generally available." After receiving certification from the SEC, the BDC is subject to a more lenient asset diversification requirement for tax purposes. This exception would enable a BDC focused on biomedical research to own more than 10% of the voting interest in biomedical companies, provided that the issuer has not held the investment for more than ten years.

A.4 Debt-BDCs versus VC-BDCs

Why are most current BDCs debt-BDCs rather than VC-BDCs? Prior to 2003, most BDCs were internally managed. BDC activity increased in 2003 after the successful IPOs of two externally managed BDCs: TICC Capital Corp. (TICC),

formerly Technology Investment Capital Corp., and Apollo Investment Corporation (AINV). In late 2003, TICC completed a \$130 million IPO, which had a significant impact on the financial markets' perception of an externally managed BDC (Boehm *et al.*, 2004). Following TICC's success, AINV raised \$930 million in less than three months, catching the attention of other asset managers. These IPOs highlighted the fact that BDCs made it legally possible to charge two performance fees—one based on capital gains and the other based on income. By May 2004, 13 potential IPOs proposing to raise more than \$6.7 billion had been filed. All of these new BDCs were debt-BDCs.

Since the proliferation of debt-BDCs in the 2000s, the BDC industry has matured from one that was initially dominated by internally managed funds to an industry of largely yield-driven vehicles that are externally managed by some of the largest U.S. asset management platforms. In 2000, there were only seven BDCs, but as of December 31, 2014, there are more than 70, with more than \$51 billion under management. During the two-year period ended Dec. 31, 2014, traded BDCs collectively raised \$9.5 billion in capital, including approximately \$5.5 billion in follow-on equity offerings, \$1.8 billion in senior note offerings, and \$1.2 billion in convertible debt offerings, and nine BDCs completed IPOs raising \$1 billion.¹⁷

The main challenge of forming a VC-BDC to fund biomedical innovation is creating market demand, owing to the poor historical performance of equity-focused BDCs. There are several reasons for their poor performance. The most successful BDCs in terms of price-to-book ratios are those that have high, consistent dividend yields. Investment strategies more focused on capital gains, such as VC investments, have more difficulty in paying a dividend because there is typically no income stream until a portfolio

company has an exit event such as an IPO or acquisition.

Investments in VC-BDCs are long-term growth plays, and have limited to no dividend distributions in their early stages. For VC-BDCs to become more widely accepted, market participants would need to shift their expectations and view equity-focused VC-BDCs differently than debt-focused BDCs.

Another possibility is that VC-BDCs create innovative investment objectives that include some sort of dividend yield, quarterly share buy-backs, or the use of the 30% basket to increase income to either offset the VC-BDCs expenses or pay some sort of dividend distribution. Paying smaller dividends but at an increased pace, such as on a monthly schedule, may also serve to differentiate VC-BDCs from traditional debt-BDCs.

Another reason for the historical lack of returns for investors in equity-based BDCs is the absence of re-marketing. While all BDCs are marketed during the IPO, the average analyst would not have the time or capacity to commit to understanding the multitude of portfolio companies in an equity-based BDC's portfolio. Both analysts and retail investors find it difficult to evaluate a portfolio of a VC-BDC because the portfolio companies are only valued quarterly, and are not marked to market on a daily basis. Additionally, in the context of funding biomedical innovation, the analysts would need specialized scientific expertise to understand the technologies. Therefore, particular effort must be made to determine the best plan of action for the re-marketing of a VC-BDC post-IPO.

Despite these obstacles, there have been signs of a resurgence of VC-BDCs focused on making equity investments. In addition to Harris & Harris Group (1995) and MVC Capital (1999)—both of which have been operating as VC-BDCs

for quite some time—newer VC-BDCs include Firsthand Technology (2010) and GSV Capital (2011). The pace at which the VC-BDC industry grows in the future will depend on the performance of the existing VC-BDCs, the strength of the overall market, and a change in the perception of VC-BDCs that are inappropriately compared with debt-BDCs.

A.5 *Patents*

Although a scientific discovery may be groundbreaking, the receptiveness of the business community to its further development will hinge on different criteria. The ultimate profitability of scientific research depends on the ability to carve out a monopoly in that space in order to make that research profitable. That monopoly is granted in the form of a patent.

In order to be granted a patent, an invention must meet three criteria: it must be (1) new; (2) non-obvious; and (3) have utility. In order to be valid, the invention must represent something new, over and above the entire knowledge base in a particular area of research (“prior art”), including published papers, products, and other patents. It must not be obvious from that prior art, but should present an “innovative step” above that body of work. Finally, a patent is not an abstract idea, like a formula. It must be reduced to an invention or something practical in order to qualify for patent protection.

The ultimate patent application will disclose the invention to a sufficient degree to enable any third party to read it and recreate the invention without assistance. The patent application will also define the scope of the invention in the claims of the application, which will describe the idea the entrepreneur seeks to protect. Intellectual property expertise should be sought throughout this process.

There is one important mistake that entrepreneurs can make in the patent application process, which may not be readily apparent: the premature disclosure of the invention. The patent monopoly is granted to an inventor in order to make valuable inventions available for public use at the end of a patent term. However, if the invention has already been disclosed in a published paper or at a conference more than 12 months prior to a patent filing, this defeats the purpose of a patent monopoly. It is important that inventors do not undermine the ultimate commercial viability of their research by prematurely disclosing it. Venture capitalists and investors prefer to see that adequate mechanisms are in place to protect against disclosure, such as non-disclosure agreements (NDAs). These can be discussed with legal counsel.

Venture capitalists, regardless of whether they structure themselves as private partnerships or VC-BDCs, also prefer that steps have been taken toward the ultimate commercialization of an entrepreneur's research. In the biomedical sector, this generally means that steps have been taken toward the prosecution of a patent. A patent provides entrepreneurs with several tools in their arsenal. As long as an entrepreneur is practicing within the claims specified in the patent filing, he or she is in a better position to protect him or herself in the event of litigation. Patents can also be used offensively to exclude competitors from practicing an entrepreneur's invention, as specified in the claims of the filing.

Investors like patents for several reasons. First, a patent provides investors with some reassurance that the entrepreneur's research has identified something new. Second, it signals that the entrepreneur has the ability to exclude other competitors from the market, thus rendering the research more lucrative, and signaling that the entrepreneur will not be solely relying on the investors in order to get their product to

market first. Third, the granting of a patent implies that certain hurdles have been overcome, which makes future obstacles to the commercialization of the research less likely. Fourth and finally, particularly in a risky sector, a patent reassures investors that the entrepreneur has some assets to fall back on if the business plan ultimately falls short of its envisioned commercial path.

Entrepreneurs can strengthen their bargaining positions by taking manageable steps toward the above process before approaching venture capitalists. There are three main qualities that venture capitalists look for in early-stage investment opportunities from an IP perspective: (1) freedom to operate; (2) ability to exclude others; and (3) evaluation of third party agreements.

A.6 Freedom to operate

A new biomedical enterprise cannot normally afford litigation. Patent lawsuits cost about \$500,000 per claim if brought to trial.¹⁸ "Freedom to operate" (FTO) is the ability to produce and sell the biomedical research, without infringing another patent. Investors will seek reassurances that no such "blocking patents" exist, or that, if they do, an entrepreneur has adequate license rights to capture the anticipated body of work, and preclude the viability of any such lawsuit. These license rights commonly come from a variety of institutions. (VC-BDCs commonly work with entrepreneurs to evaluate and secure the necessary license rights through an option agreement or a license agreement.)

To increase their value in the eyes of investors, entrepreneurs may wish to conduct preliminary patent searches, obtain relevant licenses, or obtain an FTO opinion from legal counsel. An FTO opinion identifies any patents that will block or severely limit the company's ability to market a product, or establish a dominant patent position.

This assures investors of the entrepreneur's ability to function in the marketplace in view of the patent rights of others.

A.7 *Ability to exclude others*

Investors look for entrepreneurs with an ability to exclude competitors from the market. While a patent prevents someone other than a patent owner from making, using, selling, or offering to sell what is covered by the claims of a patent application, the precise wording of those claims may affect the extent to which a patent will confer a concurrent ability to exclude others, thus increasing the chances of a costly infringement lawsuit. In this regard, it is important to seek the opinion of qualified legal counsel, who can assist entrepreneurs with their IP strategy. A robust offensive and defensive IP strategy aligned with a business plan can stymie infringement suits, as well as amass a proactive IP portfolio that can be licensed out in order to generate additional revenue, and thus render the company more valuable to investors (Braidwood and Ertel, 2005).

A.8 *Evaluation of third-party agreements*

Finally, investors will seek assurances that there are no encumbrances on their ability to generate a sufficient return on their investment. These encumbrances are most often found in the entrepreneur's existing contracts with third parties, including, but not limited to: license agreements for background IP, which may establish restrictive boundaries surrounding an application or "field of use" of the research; or employment contracts with staff, which may fail to include "non-disclosure" or "assignment" provisions ensuring that all ideas, inventions, and discoveries developed within the scope of employment flow through to the company.¹⁹

These provisions may transfer IP rights under terms that dramatically affect investors' ability

to make a return on their investment, and must therefore be thoroughly canvassed by IP counsel. In the biomedical sector, where university professors or graduate students often first develop key technology, agreements should be studied to ensure that a university cannot assert its rights to the IP, or that government actors cannot practice the invention without compensation. In drug discovery and development, where small companies commonly have pre-existing collaborations with larger companies, it becomes important to examine contractual rights.²⁰ In order to increase their value to investors, entrepreneurs may seek a legal opinion assuring investors that the path to commercialization is clear, prior to delivering their pitch.

In sum, venture capitalists, including VC-BDCs, are ultimately seeking assurances that their chosen investment is a sound one. This is determined on the basis of the entrepreneur's legal and IP rights. By assembling some or all of the above pieces into a coherent IP strategy in line with their business objectives, entrepreneurs can make the investment process significantly easier. Conducting advance due diligence with an IP attorney can clarify and streamline an entrepreneur's objectives, as well as to conduct an inventory of IP assets and documents for inspection, which may speed up investors' due diligence process and close a deal more quickly.

Notes

- ¹ See Dodd-Frank Wall Street Reform & Consumer Protection Act, Pub. L. No. 111-203, §619, 124 Stat. 1376 (2010) ("Dodd-Frank" or the "Act"); Bank Holding Company Act, 12 U.S.C. §1851 (2014); and Proprietary Trading & Certain Interests In and Relationships With Covered Funds, 79 Fed. Reg. 31 (Jan. 31, 2014).
- ² See *Cede & Co. v. Technicolor, Inc.* 636 A.2d 956 (Del. 1993).
- ³ See *Burroughs Wellcome Co. v. Barr Labs., Inc.* 40 F.3d 1223 (Fed. Cir. 1994).

- ⁴ See Safeguard Scientific Annual Report on Form 10-K for Fiscal Year ended Dec. 31, 2013 (File No. 001-0562) filed March 7, 2014.
- ⁵ See, for example, Tekla Capital Management LLC Registration Statement, available at <http://www.sec.gov/Archives/edgar/data/1604522/000110465914054511/0001104659-14-054511-index.htm>; and BlackRock Science and Technology Trust, available at <http://www.sec.gov/Archives/edgar/data/1616678/000119312514351997/d791791dn2a.htm>.
- ⁶ See, for example, Annual Report on Form N-CSR for Tekla Healthcare Investors (HI) for the year ended September 30, 2014; and Annual Report on Form N-CSR for Tekla Life Science Investors for the year ended September 30, 2014.
- ⁷ See Small Business Investment Incentive Act of 1980, Pub. L. No 96-477, 94 Stat. 2275 (1980).
- ⁸ Lemke, Lins, Regulation of Investment Companies §12:06 (October 2014).
- ⁹ See http://www.ici.org/faqs/faq/faqs_closed_end#ii.
- ¹⁰ See Harris & Harris Group, Inc., Investment Company Act Release 30027 (April 2012); Hercules Technology Growth Capital, Inc., Investment Company Act Release No. 29303 (June 2010); MCG Capital Corporation, Investment Company Act Release 29210 (April 2010); Main Street Capital Corporation, Investment Company Act Release No. 28768 (June 16, 2009); see also Triangle Capital Corporation, Investment Company Act Release No. 28718 (May 5, 2009).
- ¹¹ See, for example, Garrison Capital Inc., *et al.*, Investment Company Act Release No. 31409 (January 12, 2015); TPG Specialty Lending, Inc., *et al.*, Investment Company Release No. 31379 (December 16, 2014); Monroe Capital Corporation, *et al.*, Investment Company Release No. 31286 (October 15, 2014).
- ¹² We note that royalty interests in and of themselves would likely not be qualifying income for the purpose of the RIC income requirement.
- ¹³ Section 12(d)(1) of the *Investment Company Act*, among other things, restricts an investment company from owning more than 3% of another investment company.
- ¹⁴ Dodd-Frank Wall Street Reform & Consumer Protection Act, Pub. L. No. 111-203, §619, 124 Stat. 1376 (2010) (“Dodd-Frank” or the “Act”).
- ¹⁵ See publicly filed documents for Goldman Sachs BDC, Inc. and Credit Suisse Park View BDC, Inc.
- ¹⁶ Proposed Rules: Crowdfunding, 78 Fed. Reg. 66428, 66509 (col. 2) (Nov. 5, 2013).
- ¹⁷ See Dealogic and Prospect News, available at <http://www.dealogic.com/login/> and <http://prospectnews.com/>.
- ¹⁸ See World Intellectual Property Organization, available at http://www.wipo.int/sme/en/documents/venture_capital_investments_fulltext.html.
- ¹⁹ See http://www.buildingipvalue.com/n_us/97_101.htm.
- ²⁰ This list is by no means exhaustive, and will be further explored in a forthcoming publication.

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