Emerging Innovation Ventures Require Enhanced Board Engagement

By Bernadette M. Broccolo and Michael W. Peregrine

Bernadette M. Broccolo and Michael W. Peregrine are partners in the Chicago office of McDermott, Will & Emery. They can be reached at bbroccolo@mwe.com and mperegrine@mwe.com.

Many health-care industry stakeholders are looking to diversify their approaches to investing in and accelerating the development and commercialization of biomedical, digital health and health-care technology discoveries. These organizations see an opportunity to improve patient care, fulfill their research and education missions, and enhance their overall fiscal performance. With this growing interest in developing innovation ventures, however, comes a clear need for enhanced board engagement and oversight of these initiatives.

Motivating Factors and Perceived Benefits

The increased interest in playing a more active and profitable role in commercialization ventures is certainly prominent among, but is by no means limited to, academic medical centers and their affiliated universities. Integrated delivery systems leading cancer, pediatric and other specialty hospitals, leading researchers, medical research foundations, and charitable foundations devoted to funding the acceleration of better treatments and cures for particular disease states, are all actively exploring and pursuing such collaborations. For many, these initiatives are particularly attractive as a way to further their clinical care, medical education and research missions; to tap discoveries that might otherwise be left in the “valley of death” that exists between the basic research the government is willing to fund and the later stage development industry is willing to fund; and to accelerate and enhance the monetization of intellectual property that goes beyond what can be accomplished through more traditional royalties under passive “out-licensing” arrangements.

The Investors

The number and types of investors in these ventures is often greater and more varied than in more traditional commercialization initiatives. In “home-grown” ventures initiated by an institutional provider, for example, the institution as well as board members, members of executive and clinical leadership teams, individual clinicians and scientists, and significant donors, all might have an interest in investing. Investment by key constituencies can generate meaningful and effective support for the initiative. However, complications, particularly in conflict of interest management, can arise from the fact that some or all of these investors may at the same time play an active role in the leadership, governance and management of the venture entity, in the further research and development undertaken by the venture to support commercialization, and ultimately in the purchase of the commercialized product marketed and sold by the venture entity. If appropriately identified and assessed at the very earliest stages of the innovation planning, conflict of interest complexities should not become major roadblocks; if not, however, they can undermine the integrity of the research and development and either cause major delays or bring the effort to a screeching halt after substantial investments of time and money have been made.
Venture Structures

The innovative, structural alternatives to passive out-license arrangements can be complex. They typically include some combination of one or more of several structural components: (a) a separate, affiliated entity created to serve as an “incubator” for innovation ideas; (b) an incubator entity or some other newly created affiliate that serves as a captive vehicle for funding innovation spin-offs spawned by the incubator; (c) various separately created entities to undertake the commercialization effort funded by the various investors; and (d) a license or outright transfer of the intellectual property rights in the discovery/invention to the commercialization entity. In some cases, the fund entity may invest in existing, unaffiliated entities rather than creating and investing in a new entity.

Funding

Funding sources and their motivations for investing also vary and might include venture capital and private equity firms, health-care industry product manufacturers, digital health and other health technology developers and vendors, the originating institution, and the various institutional stakeholders discussed above. Institutional provider participants will have both mission motivations and monetization objectives that need to be appropriately balanced and managed. Funding typically is a combination of cash and “in-kind” contributions (e.g., licenses to or transfers of intellectual property rights; provision of clinical, management and research services in return for equity). The institution may fund its investment from previously generated or donated unrestricted funds, or from donations that are directly and specifically targeted to emerging innovation initiatives but not restricted or tied in any way to use for innovation ventures in which the donor may also wish to invest directly.

Potential Risks

Complex health care innovation ventures are accompanied by complex strategic, financial and legal and regulatory risks. Important legal and regulatory considerations go beyond selection of structure and tax planning, particularly if investors will include non-profit, tax-exempt institutions or their board members, management, and affiliated individuals such as physicians and researchers, and funding includes in-kind contributions such as underlying intellectual property, clinical or research expertise, administrative expertise, or infrastructure (e.g., space, information technology) in return for equity. Such circumstances will trigger a broad cross section of federal and state laws, including state non-profit corporation laws, charitable trust laws, the Uniform Prudent Management of Institutional Funds Act, federal tax-exemption laws, federal “Sunshine” laws (regarding financial relationships between health-care providers and industry manufacturers), Medicare/Medicaid Anti-Kickback law and federal and state self-referral laws. Careful, front-end compliance planning and implementation is essential and should focus in particular on risk management considerations such as independent valuation of in-kind contributions, validation of underlying rights to the intellectual property contributed to and used by the venture, allocation of ownership and control rights in proportion to capital contributions, adoption of special control rights where necessary to manage tax-exemption risk, managing multi-dimensional conflicts of interest, structuring ongoing relationships between investors and the innovation entity on commercially reasonable terms, and establishing appropriate terms for disposition of assets in the event of a premature termination and dissolution of the venture.

Enhanced Governance Engagement

The intended charitable and scientific benefits of emerging innovation ventures do not relieve or insulate board members from the fiduciary duty diligently to oversee the assessment and management of the relative benefits and risks, both when making the decision to invest and throughout implementation of the initiative.

The complexity and degree of all potential enterprise risks, particularly the conflict of interest risks, calls for governance oversight by a fully disinterested governance body—typically either a fully disinterested, ad hoc committee or the disinterested members of an existing board committee or subcommittee. Great care should be taken to separate the role of such an independent body in all respects from the role of other board committees that will be involved in oversight of the venture (e.g., the strategic planning, finance, investment and innovation committees) and that may include as members one or more interested individuals (e.g., executive leadership or investors). The tenure of the disinterested governing body should extend to both the initial decision to pursue the venture and the oversight of it throughout its entire life cycle.

The elements of such disinterested governance oversight and engagement should include, but are not limited to, the following:
Emerging Innovation Ventures Require Enhanced Board Engagement, Health Law Reporter (BNA)

**Mission Compatibility**

The fundamental, threshold issue is whether the proposed investment serves an identified mission-based organizational purpose that is consistent with and supportive of the organization's strategic plan and financial resources, particularly with regard to clinical care, research and education. A relevant, but not determinative consideration is whether the impetus for the investment derives from within the organization—constituents loyal to its mission—or from outside investors with broader and potentially conflicting objectives and loyalties.

**Board Level Competencies**

The involvement of directors with appropriate subject matter expertise and experience is essential to make informed decisions concerning whether to invest and to provide ongoing oversight of its operation. Reliance on the advice of outside experts and executive management is permitted and appropriate, but no substitute for the engagement of qualified directors that is essential to effective, ongoing board-level discourse on the investment.

**Understanding the Venture and its Component Parts**

One of the most important fiduciary governance challenges is to understand both (a) the venture structure, including the various investors, their legal status, their goals and objectives, their relationship to the venture and one another, and the nature of their respective contributions and interests; and (b) the venture funding sources, such as cash contributions, other forms of equity investments, management fees, and grants and donations from (or through) individuals and philanthropic organizations.

**Financial Prudence and Stewardship**

The board is responsible for assessing and overseeing the financial prudence of the investment in all of its facets. A fundamental task will be confirming that the financial projections and other indicators are consistent with statutory and internal investment guidelines, and commensurate with capital, debt, and other financial commitments.

**Legal and Regulatory Risk Management**

Oversight of legal and regulatory risk management in all aspects of the venture investment and operations is essential for effective risk management that is consistent with the board-approved risk profile.

**Potential for Conflicts**

Establishing a mechanism to assess and manage actual or apparent conflicts of interest throughout all levels and phases of the venture is essential to manage conflict of interest risks under state and federal law. Effective conflict of interest oversight will require an understanding of applicable law, industry standards and prevailing best practices that govern the fiduciary obligations and an ability to distinguish between and among the various interests and corresponding fiduciary obligations of the various investors. A particularly critical task in this regard will be development and implementation of policies, procedures, guidelines and tools for identifying, assessing and managing the full spectrum of potential conflicts that can arise from the financial and associational interests of potential investors such as board members, executive leadership, physicians and researchers.

**Conclusion**

Innovation ventures are an increasingly important means for both academic medical centers and integrated delivery systems to further their patient care, research and education missions while enhancing their overall fiscal viability and strength. Supporting the ability of individual stakeholders such as physicians, clinical leaders, board members and others to be investors in these ventures will undoubtedly support both the mission motivations and intellectual property monetization objectives of the initiating institution. However, their sheer complexity and the degree of associated enterprise risk call for an active, focused and disinterested level of board engagement to assess and achieve the proper balance between the potential risks and the anticipated rewards.