

# Managing Compliance-Based Valuation of Medical Device Start-Ups

by B. Patrick Lynch, CFA

Reprinted from the November 2009 issue of *Medtech Executive* magazine. This excerpt is copyright of Canon Communications, LLC, and is used by permission.

In recent years, valuation issues have become increasingly important for start-up companies due to changing IRS and financial reporting rules, as well as increasing regulatory and shareholder scrutiny, which together compound potential troubles for start-up companies. In the past, industry specific start-up “rules of thumb” may have been sufficient to serve as

reasonable basis for any valuation concern (e.g. the “Silicon Valley Rule” that the value of a common share is equal to 1/10 of the value of the preferred share pricing in most recent capital round). While the simplicity of such rules can be appealing, the scrutiny of the IRS, SEC, and your auditors in combination with the potential liability associated with misreporting make it critical that value be determined and articulated in a credible fashion.

Valuation for start-up enterprises can be a tricky proposition. Regardless of industry, start-ups generally share a common set of operational characteristics and valuation needs that are distinct from mature firms. Because both the subject enterprise and valuation purpose are misfits within the context of typical valuation work, typical valuation practices are generally not applicable for start-up companies. Combined with the unique market dynamics and regulatory environment associated with the medical device industry, medical device start-ups present a unique set of valuation considerations.

Below, we will discuss common circumstances that give rise to the need for a valuation, basic valuation concepts, and specific valuation considerations relevant to medical device start-up companies.

## THE WHEN AND THE WHY OF BUSINESS VALUATION

The day-to-day activities of start-up companies, being in a formative phase, require significantly more attention from senior management than mature firms. As a result, many start-up company founder/managers can overlook pending valuation issues for more immediate operational concerns.

For start-ups, valuations are most often needed for employee stock option or equity compensation compliance purposes. For financial reporting purposes, SFAS 123R requires that employee stock option compensation be recorded as an expense at the fair value of the option grant as of the grant date. The issuance of IRS 409A has created tax implications for non-qualified deferred compensation plans, which includes the issuance of stock options and stock appreciation rights to employees at a



HEADQUARTERS

5100 Poplar Avenue, Suite 2600

Memphis, Tennessee 38120

901.685.2120 (P)

901.685.2199 (F)



discount. Given the severity of the tax implications, the rule effectively requires non-public companies that issue stock options or other forms of equity as compensation to obtain an independent, contemporaneous valuation of the relevant securities.

Other common valuation circumstances for start-ups involve advisory services and fairness opinions related to additional fundraising or exit events on behalf of company management for both planning purposes and to fulfill a fiduciary duty to shareholders. There is also a growing trend in venture capital funds obtaining independent valuation opinions or reviews of internal valuations related to compliance in reporting fund investments at fair value.

## **DEFINING THE “VALUE” OF A BUSINESS OWNERSHIP INTEREST**

Through casual observation, the value of an enterprise seems like an easy concept with a single definition. In reality, the appropriate definition of value varies depending on the circumstances surrounding each valuation engagement. The actual analytical framework for determining value is only developed once these aspects are defined. The following concepts are vital to understanding what is meant by “value” and are essential in defining an engagement with a valuation specialist.

## **STANDARD OF VALUE**

The standard of value establishes the particular definition of value used in a specific engagement. Identification of the appropriate standard of value is the first step of every valuation. So, what are the most common standards of value for start-up companies?

*Fair Market Value* is the most common standard of value used in business appraisals and is the standard used for 409A compliance related to equity compensation. Fair market value is defined by Revenue Ruling 59-60 as “the price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm’s length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.” A significant body of application guidance has been generated over the years through a variety of professional standards, government regulations, and court cases.

*Fair Value* can have one of two distinct meanings, depending on the situation. For start-up company valuation, fair value most commonly refers to the standard defined by FASB in SFAS 157 for financial statement reporting purposes. Here, fair value is “the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.” This definition of fair value is the relevant standard of value for valuations involved in SFAS 123R compliance for employee stock option compensation reporting.

In other circumstances, fair value can refer to the statutory standard of value applicable to cases involving dissenting minority shareholders with respect to corporate reorganizations or recapitalizations covered by the various state statutes. It may also have a specific meaning for divorce or under the securities laws for a given state. These statutory definitions of fair value (which are unrelated to the definition of fair value for financial statement reporting), however, are not commonly relevant in start-up company valuation.



Many start-up managers and venture fund managers often pragmatically observe that fair market value and fair value are different than the real world where buyers and sellers are very specific people who are individually motivated, uniquely informed, and are using something other than 100% cash to transact.

*Investment Value* is the value to a specific investor based on their particular investment requirements and opportunities. This value reflects the knowledge, expectations, synergies, and economies of scale of the particular investor. Investment value is generally used when valuation or investment banking professionals are advising their clients as to the merits of executing a specific transaction such as raising additional equity capital, selling the business, or completing an IPO. Investment value answers the questions – what’s it worth to them? Or what’s it worth to me?

A word of advice concerning who you choose to value your medical device start-up: associated with nearly every industry are niche consultants who sometimes practice valuation without the requisite command of how value is defined for a given circumstance and correspondingly how such value should be developed. Likewise, there are many valuation specialists without specific experience with the unique dynamics of the medical device industry. Given the incremental valuation complexities particular to medical start-up enterprises, it is important to remember that industry knowledge and valuation knowledge are not synonymous—and both are important.

## **APPROACHES TO VALUE**

There are three general approaches to determining business value – asset, income, and market. Under each approach there are specific ways to determine value that are commonly referred to as methods. As a general rule every valuation should consider each of these approaches. Ultimately, the conclusion of value will reflect consideration of one or more of these approaches (and perhaps various underlying methods) as being most indicative of value for the subject ownership interest.

### ***The Asset Approach***

The asset approach determines the value of the subject business by examining the cost that would be incurred by the relevant party to reassemble the company’s assets and liabilities. For start-up companies, the asset approach is generally inappropriate to apply unless the start-up is in a very early stage of operational development such that there has been no intellectual property or other intangible value developed internally. The asset approach can provide meaningful valuation benchmarks for start-ups that have recently completed fund-raising rounds.

### ***The Income Approach***

The income approach is based on the idea that the value for a given enterprise is created by the expectation of future cash flows and thus focuses on the capacity of a start-up company to generate future economic benefits. The mechanics of an income method require an estimate of future cash flows and an appropriate discount rate with which to determine the present value of future cash flows.

Methods under the income approach are wide ranging but typically fall into one of two categories: 1) single period capitalization of income; or 2) discounted future benefits. By nature, income expectations for medical device start-



up companies are often characterized by a period of anticipated operating losses and increasing capital needs, followed by an expected payoff in the form of proceeds from an IPO, strategic acquisition, or other exit event. Accordingly, single-period capitalization of income methods and conventional applications of discounted future benefits methods are rarely appropriate to use.

### ***The Market Approach***

The market approach compares the subject to similar businesses, business ownership interests, or other assets that have been recently transacted. Market methods include comparison of the subject interest with valuation metrics implied by investments in publicly traded companies and those implied by transactions involving controlling interests in similar companies. Consideration of prior completed financing rounds or other transactions in interests of a start-up is also a method under the market approach.

Guidance in SFAS 157 suggests that the market approach is the preferred approach when appropriate data is available in sufficient quantity and quality. Most start-ups are not near IPO or acquisition, however, so there is generally not sufficient information to implement the market approach to determine the enterprise value for start-up enterprises with the exception of the occasional very late stage start-up.

Prior financing rounds can provide meaningful indications of value for a particular equity class in a start-up, but differences in rights and preferences between various classes of equity create difficulties in translating value of one equity class (e.g., preferred stock) to another (e.g., common stock). Generally, medical device start-ups are funded by one or more financing rounds subsequent to the company's initial formation, and thus are capitalized by several classes of equity—which complicates the determination of enterprise value based on a given share value. However, such per share pricing information from capital rounds provides helpful valuation anchors in the form of upper or lower boundaries for enterprise value, and can credibly substantiate the reasonableness of valuation conclusions.

## **MEDICAL DEVICE START-UP VALUATION CONSIDERATIONS**

Ultimately, the value of a start-up company is a function of:

1. The range of potential exit values for the company if successfully developed;
2. The probability of achieving a successful exit;
3. The expected time period necessary to achieve a successful exit; and,
4. Expectations of future capital needs.

For medical device start-ups, exit events generally take the form of a strategic acquisition or an IPO. In either case, exit value will be driven by the relevant market characteristics combined with the expected impact the company will have on that market. At any given point in time, the probability of achieving successful exit and the expected time period necessary to achieve a successful exit will be a function of the development stage of the company as well as certain key indicators such as management quality.



**Market Characteristics.** All companies operate within a given market and this context is perhaps the most significant factor in the exit valuation of a medical device start-up. Even if a start-up has everything else in place, 100% market share of nothing is still nothing.

Market dynamics within the various medical device segments tends to share the same broad contours. The most significant market factor to consider for a medical device start-up is the absolute size and growth prospects for the pertinent market. Relevant measures in evaluating a particular medical device market often include the number of physicians performing procedures, the number of procedures performed in a given year, and the reimbursement rate per procedure.

Most new medical devices tend to be improvements on devices used in existing procedures, and thus have a readily-defined market at the start of the device development process. Less frequently, new devices offer revolutionary solutions for which there are no existing markets. Developing expectations of market characteristics in this situation is more difficult, but such products typically command far greater market impact.

**Market Impact.** Market impact can be defined as the market share that, if development efforts succeed, a medical start-up would likely command. Market impact is driven by the disruptive potential of the new technology and management's ability to develop the technology, execute the business plan, and fully realize the new technology's disruptive potential.

Other than the disruptive potential of the new technology itself, strategic acquirers in the medical device space commonly consider a variety of factors in evaluating the potential market impact of a new device:

- » Strength of intellectual property
- » Stability of design
- » Technical performance data
- » Support from animal studies
- » Support from human clinical studies
- » Completion of regulatory approvals
- » Reputation of "early-adopter" surgeons using device
- » Reliability of supply chain
- » Reliability of distribution partners
- » Availability of technical expertise (to facilitate transition after acquisition)



**Stages of Development.** The value of a given start-up is largely related to its level of operational development. Most medical device start-ups tend to follow similar patterns in operational development regardless of industry segment. Loosely speaking, medical device start-ups often follow the following development pattern:

1. Conceptual Design
2. Market Verification
3. Device Design Verification
4. Regulatory Approval
5. Human Clinical Trials
6. Initial Product Launch

Since the development of start-up enterprises is measured by the passing of various milestones, the meeting of milestones (or the lack thereof) contributes significantly to the valuation of a start-up. Passing certain milestones create a bigger impact on value than others; examples of such milestones include the completion of the initial round of financing, proof of concept, regulatory approval, delivery of product to customers, and profitability.

With the passing of each milestone, the level of uncertainty associated with the start-up decreases and thus drives value upwards. Generally, meeting later-stage milestones generates greater increases in value than that of earlier-stage milestones.

**Key Indicators.** Compared to mature enterprises, financial information for start-up companies is less frequently available and typically of lower quality. Due to this relative lack of information, qualitative factors such as the quality of the management team, clinical advisory team, and venture capital investor group become an important consideration, especially in the valuation of early-stage start-ups.

## FINAL THOUGHTS

Mercer Capital has valued a number of start-up enterprises in the medical device space over the years and we have witnessed many of the hardships and successes of such companies. We hope this introductory primer helps you better shop for business valuation services and understand valuation mechanics. We encourage you to extend your business dialogue to include valuation – sooner or later circumstances requiring independent valuation will arise, and early awareness will minimize the likelihood of potentially unpleasant surprises.

**B. Patrick Lynch**  
lynchp@mercercapital.com



# Mercer Capital

## At a Glance

Mercer Capital is an employee-owned independent business valuation and investment banking firm serving a global client base. We provide valuation consulting services to both private and public companies, as well as financial institutions.

Mercer Capital is big enough to handle your needs yet small enough to provide superior client service. For over 25 years we have been bringing uncommon professionalism, intellectual rigor, and technical expertise to every engagement. You can rely upon the expertise, experience, reputation, and critical thinking of Mercer Capital.

### Overview of Services

#### » Valuation Consulting

- › Business & Legal Entity Valuation
- › Limited Partnership Valuation
- › Buy-Sell Agreements
- › Estate & Gift Tax Valuation
- › Section 409a Valuation
- › Employee Stock Ownership Plans
- › Fairness & Solvency Opinions

#### » Financial Reporting Valuation

- › Goodwill Impairment Analysis
- › Alternative Investment Portfolio Valuation
- › Purchase Price Allocation
- › Intangible Asset Valuation
- › Employee Stock Option Valuation
- › Restricted Stock Option Valuation

#### » Litigation & Expert Testimony

- › Economic Damages
- › Buy-Sell Agreements
- › Securities Fraud Analysis
- › Marital Dissolution
- › Statutory Fair Value Controversies
- › Gift, Trust, and Estate Tax Disputes
- › Bankruptcy Litigation

#### » Investment Banking

- › Fairness & Solvency Opinions
- › M&A Representation
- › Recapitalizations
- › Management Buyouts
- › Board Presentations

### Key Facts

- › Founded in 1982
- › Over 7,000 engagements
- › Over 95% recurring client retention rate
- › Authored 10 books on valuation-related topics
- › 11 professionals hold the CFA designation the CFA Institute
- › Authored over 100 articles in outside publications on valuation-related topics
- › 7 professionals hold the ASA designation from the American Society of Appraisers
- › Wrote the seminal book on the valuation of financial institutions
- › 3 professionals hold the CPA designation from the AICPA
- › Participated in over 200 speaking engagements on valuation-related topics

# Mercer Capital at a Glance

Mercer Capital brings uncommon professionalism, intellectual rigor, technical expertise, and superior client service to every engagement, and we've got the numbers to prove it.

|  |  |  |
|--|--|--|
| Celebrating over<br><b>25</b><br>years of business           |  | We've participated in more than<br><b>7,000</b><br>engagements in various industries |
|  | We are proud to claim a<br><b>95%</b><br>recurring client retention rate |  |
| Over<br><b>20,000</b><br>subscribers receive our newsletters |  | Our professionals have authored<br><b>10</b><br>books on valuation-related topics    |

## Mercer Capital's Key Contacts

**Z. Christopher Mercer, ASA, CFA, ABAR**  
mercerc@mercercapital.com

**Timothy R. Lee, ASA**  
leet@mercercapital.com

**Andrew K. Gibbs, CFA, CPA/ABV**  
gibbsa@mercercapital.com

**Barbara Walters Price**  
priceb@mercercapital.com

**James E. Graves, ASA, CFA**  
gravesj@mercercapital.com

**Nicholas J. Heinz, ASA**  
heinzn@mercercapital.com

**Matthew R. Crow, ASA, CFA**  
crowm@mercercapital.com

**Travis W. Harms, CFA, CPA/ABV**  
harmst@mercercapital.com

**Lisa L. Doble, JD**  
doblel@mercercapital.com

**Jean E. Harris, CFA**  
harrisj@mercercapital.com

**Wendy S. Ingalls, CPA/ABV, CBA, ASA**  
ingallsw@mercercapital.com