

Valuation of Med-Tech

Start-ups

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Early Med-Tech Startup Valuation: Techniques and Issues¹

This paper explores issues in med-tech start-up valuation. Start-ups essentially have three phases: early stage, scaling stage, and exit stage (Vital, How Startup Valuation Works – Measuring a Company's Potential, 2013), in addition to an initial seed stage. In this paper, I begin by examining how start-ups in general are valued during each development stage. I then briefly examine traditional valuation techniques employed on more mature publically listed firms and how they contrast to the methods used on start-ups. Next, I move to examining med-tech start-ups more specifically, with a focus on early stage valuation. Med-tech firms have some unique issues, which may make valuation more difficult. Specifically, I examine the challenges of novel technology, the interplay between market size and willingness to pay, the role that the FDA plays, and how reimbursement affects final valuation. I conclude by recommending that investors take special care when investing in Med-tech companies. By understanding these limitations, investors can make more informed decisions.

Start-up Valuation

There are three stages of a start-up's lifecycle: early stage, scaling stage, and exit stage. In the early stage, the start-up has generally figured out some details of its product and its potential market size. At this point, the start-up may need additional funding to further its business goals. In the scaling stage, it may have some initial revenues or its product may still be in development, but it generally needs larger sums of cash to continue operations. In the exit stage, it will have released some sort of

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product and is usually, though not always, profitable. Profitable companies generally attract a more valuable initial public offering (IPO).

For start-ups, valuation and funding are very much interrelated. Without the need for funding, a valuation would be a superfluous exercise. However, funding comes with strings attached, usually by granting a certain equity stake in exchange for the money. The valuation of a start-up determines how much an investor will have to pay to have a given stake in it. So understanding start-up funding is key for understanding valuation. However, this section is not to examine how startup funding works, but rather the role that valuation plays in start-up funding. For clarification, a little background is necessary on the different types of funding for different stage start-ups.

Three common types of funding for start-ups include family and friends (FF), angel investors (AI), and venture capitalists (VC) (Vital, How Funding Works - Splitting The Equity Pie With Investors, 2013). These different funding sources generally follow a certain sequence, but not always and sometimes not each one is used. For example, a startup may transition from FF funding to VC, or may not have obtained FF funding at all.

FF funding generally occurs in the early stage of the start-up. In the early stage, valuation is much more art than science. Vital identifies three main drivers of valuation: traction, reputation, and revenues (Vital, How Startup Valuation Works – Measuring a Company's Potential, 2013). Traction is whether a product or service is already in release, that is, are people already using it? The second driver focuses on the reputation of the entrepreneur. Elon Musk, who founded Tesla and an early internet

financial company that later merged with PayPal (which Musk ran) among other startups, would get a higher valuation than I would even if we developed identical products with identical prospects. The final driver is simply revenue. If an entrepreneur is already receiving revenue from his or her product, he or she will generally get a higher valuation all else being equal.

In the early stage there is no easy, or complicated for that matter, formula to use to calculate the valuation. At this point, it is at best an educated guess on the promise of the technology of the product or firm. However, it matters greatly because valuation will affect how much of a share of the company an initial investor will own post-investment. For example, if the firm is valued at \$600,000 and a FF investor is willing to invest \$30,000, he or she will receive a 5% share.² If the firm is only valued at \$300,000, that investor may demand 10% for the same seed money. A start-up then generally needs at least one of the three identified drivers (but not always) in order to receive funding, but having more will lead to a higher valuation.

Als are the next main category of investors. Als are generally more experienced in start-up funding than FF investors but have somewhat similar motivations in that they want to help an early company succeed if it appears to have solid prospects for success. They are generally investing in the late early stage to early scaling stage. Als are looking to make a return from their investment, but it may not even be their primary motive. Like FF investors, Al's generally look to make money by the appreciation of the

² This is simplified, as an investment of \$30,000 cash will increase the value of the company by \$30,000. This is known as pre-money valuation and post-money valuation. The post-money value of the company will by \$630,000, and the investor will own about 4.76% of the company. If his or her goal was to own 5%, he or she would need to contribute about \$31,579.

value of their shares in the company, but they are more experienced in structuring deals and generally can offer better advice. They generally look to sell their shares at some point in the future, usually in 4-8 years (Kauffman Foundation, 2007).

Valuation at this scaling stage is a little more scientific than at the early stage, though art is very much still in play. Most-startups at this point are still not profitable and thus a discounted cash flow (DCF) valuation is still not helpful. Even if it is profitable, questions such as the rate of growth can greatly influence the results. A common technique at this point is to value the start-up based on similar start-ups at a similar stage. To do this, a potential investor may take a group of identified similar companies and pick a metric, for example number of users or revenue (if the firm in question has revenue.) He or she then takes the valuation assigned to those companies divided by this metric to arrive at a multiple. That multiple is then taken times the users or revenue (or something else) of the start-up being valued.

The final main category of start-up funding is VC funding. Unlike Als, VCs are primarily driven by the profit potential of investing in a start-up. They are generally looking to bring a start-up to some sort of exit, through either IPO or acquisition (Vital, How Startup Valuation Works – Measuring a Company's Potential, 2013). At this stage, valuation is somewhat more of a science than an art, but art is very much in play. VCs generally value a company by something aptly called "The Venture Capital Method" (Payne, 2011). Essentially, this method first estimates what the exit value of the firm will be upon IPO or acquisition, then determines a required return on investment based on the risk of the investment. This rate is usually no lower than 30% internal rate of return

(IRR). The exit value is then divided by the required return to arrive at a post-money value, that is, the value after the cash investment. Finally, subtracting the amount of the investment from the post-money value gives the pre-money value, which was the value of the firm before any investment. The amount of the investment and the required return then determine what percentage of the start-up the VC will receive upon the investment.

Traditional Methods

In order to contrast valuation of start-ups and traditional firms, in this section I will take a brief detour to examine the methods of valuing traditional firms. When valuing established firms, analysts can use several valuation methods, but the most common of these is DCF valuation. The DCF method values companies based on all of that firm's future cash flows discounted back to the time that the analysis was done. The complexity in the model comes from estimating the firms free cash flows for a future set of years. There is a certain amount of art in this, from estimating growth rates to future federal tax policies. The analysis is generally easier if the firm projects to grow at a consistent pace for a long time.

DCF does have its downsides. It can be hard to calculate if future cash flows are unstable or are estimated to grow at a fast rate. Financial models can assist with this, but larger amounts of data are usually required. This data is usually accessible for public companies, but can be very difficult or impossible to acquire for private or closely held firms without a friendly relationship. Both of these downsides make DCF difficult to use for startups, especially in the early stage. Early stage startups usually will have little to no current revenue, much less free cash flow, which makes calculating future cash

flows very difficult. Also, it can be nearly impossible for an outside analyst to value a firm which has no cash flow and for which he or she has very little information.

However, a VC may use a DCF analysis to determine the exit value of the start-up. When a VC is looking to invest, the start-up generally does not yet have positive cash flows. At that point, however, the start-up has some established customers or technology that would make it easier to do a DCF with projected cash flows at the time of the desired exit.

Another method to value a traditional firm is market capitalization. The market cap of a firm is simply the stock price of the firm multiplied by the number of shares outstanding. This is essentially the amount of money it would take to purchase the firm outright. The major upside of the method is that it is easy to calculate and it is transparent, meaning there is no special information that an analyst would need to figure it out. The downside for start-up valuation is that start-ups by definition have no market cap because they do not trade on any sort of market.

A final way to value a firm is simply to add up its assets and subtract its liabilities. While this may work for small firms, it is generally unfeasible for large firms. More importantly, however, is that this valuation says nothing about the company's future ability to provide return for its investors. This method, however, has some usefulness in limited cases. For example, if a start-up has a patent for a product that shows promise but the start-up has not been able to gain funding or momentum, the value of this start-up may simply be the value of the patent.

Special Considerations for Med-Tech Start-ups

Med-tech start-ups generally have all of the above issues in valuation, but they also have other challenges. This section explores the challenges provided by novel medical technology, the role of the FDA, and the role on reimbursement in the third-party payer system in the United States. Emphasis is placed mainly on the challenges encountered in early stage start-up valuation.

Novel Technology

The technology, service, or process that a start-up is developing may be novel. This novel technology may have unclear prospects because there are no similar products yet on the market and/or it has not yet undergone any research trials. There are generally six stages of development for a medical technology: conceptual design, market verification, device design verification, regulatory approval, human clinical trials, and initial product launch (Mercer Capital, n.d.). The risks of novel design generally can be reduced by appropriate rigor in the first three stages of development.

After the first stage, which generally marks the formation of the start-up with an idea, comes the market verification stage. Two major considerations are at play here: the potential size of the market and the willingness of each consumer to pay. In general, a larger market is better than a smaller market. However, if the start-up's product has low efficacy for a wide population and thus there is a low willingness to pay, its prospects are limited. Conversely, a novel technology may have high efficacy for a small target population with a high willingness to pay and may have better prospects. Current examples abound in the pharmaceutical industry. Pharma firms have identified diseases targeting small populations as a growth market because they can charge very

high amounts for drugs that treat rare diseases. So, for rare diseases, the market size is small but willingness to pay is very high because there is no other treatment. In general, valuations will be highest for start-ups with the right combination of market size and willingness to pay. Early stage start-ups generally will have a target market-size but lack data on efficacy. As the start-up moves through trials, data on efficacy will become more reliable and greatly increase or decrease the valuation of the start-up. In any case, if the start-up feels it has a viable market, it can refine the design to ensure efficacy and prepare for the FDA.

The FDA's Role

As a start-up passes each step of development, it will have a higher valuation in general. The next step can be the most crucial, because human trials can begin after FDA approval. The FDA, then, has a large effect on the valuation of start-ups because of its power to approve or reject technology. The FDA's role in unique among industries as it essentially carries veto power over a start-up's product. For early stage start-ups, this situation can be murky, but more so with start-ups with novel technology. For example, if a start-up has a product with similar functionality or purpose as other technologies that already carry FDA approval, it will generally have a higher valuation than a start-up with a novel product and unclear FDA prospects. Also, if the start-up has a large market with willingness to pay but unclear FDA prospects, it is still likely to have a relatively high valuation because of the promise of the technology.

Not all med-tech devices are equal in the FDA's eyes, however, and the class of device that a start-up is developing can influence the valuation because of approval

uncertainty and costs to get approval. However, this can be offset because the more difficult products to certify generally can obtain a higher price in the market. In any case, the FDA has three main classes of med-tech device: Class I, II, and III (US. Food and Drug Administration, n.d.)

Class I devices are low-risk devices, such as dental floss, that are used on the outside of the body and that either have a low risk of failure or a low risk of injury should a failure occur. Class II devices have a higher set of risks, but are still generally used outside the body. Class III devices pose the highest risk to health should a failure occur and generally are used inside the body. For example, a pacemaker is a class III device.

The last major hurdle for a med-tech start-up (or any product for that matter) is human trials. A start-up that has cleared all previous hurdles will generally command a high valuation, but initial success in tests and regulatory approval do not matter without success at this stage.

Reimbursement

Finally, the role of reimbursement in the third-party payer system in the U.S. health insurance market plays a role in valuation of start-ups. Specifically, the fact that a start-up is aiming for its device to be reimbursable will influence valuation. A firm may be targeting a device to be over the counter, which still generally would require FDA approval but would not be reimbursable. This type of product would be for a large market with a low willingness to pay.

A different set of considerations apply if a firm is targeting its product to be reimbursable. Generally, health insurance companies will require FDA approval for a device to be reimbursable. Uncertainty over approval will also lead to uncertainty over whether the product will also be reimbursable. All of this will impact valuation, because if consumers are not paying the full price of the device (some of which is picked up by the insurance company), their overall willingness to pay will be higher because they are not bearing the full price.

Conclusion

Valuation of med-tech start-ups, especially early stage start-ups, can be challenging because of uncertainties surrounding the nature of the industry. All start-ups have uncertain valuation in their early stages in that their future free cash flows are unknown and nearly impossible to predict with any certainty. Med-tech firms have extra uncertainty stemming from several considerations. First, novel technology has uncertain chances of success and markets. Second, the FDA has a large impact on the viability of a start-up because of its approval process. Finally, whether or not a start-up desires the product to be reimbursable and the chances of approval all affect valuation. A smart investor will take these extra precautions to heart when investing in a med-tech firm.



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