Medical Devices: Analyzing the Present Opportunity

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Executive Summary

It has been a bumpy road for medical devices over the past 10 years, as a confluence of factors (e.g. lengthy regulatory approval timelines, concerns over market adoption, and difficulty around reimbursement) has lowered returns and driven capital out of the market. This departure of capital has led to a substantial financing gap for companies, creating attractive entry multiples for investors still willing and sophisticated enough to navigate the current landscape. But any excitement about valuations must be tempered by an awareness of the difficulties that device investors still face. In this paper, we lay out the pros and cons for device investing as we see them today, in the hope of providing a fresh and unique analysis of the marketplace.

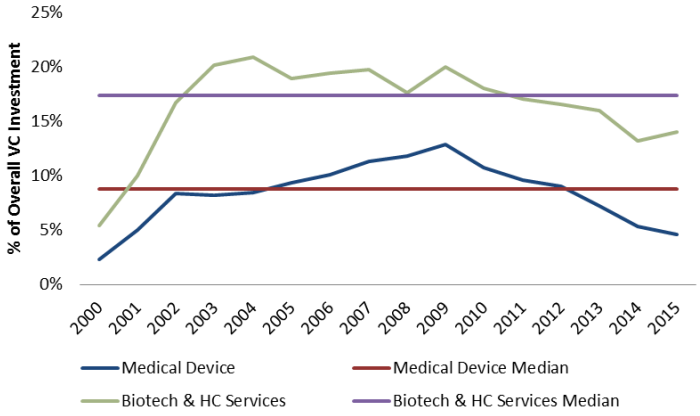
What is Driving Opportunity in Medical Devices?

1) Lack of Capital

Aggregate venture investment across all sectors has increased dramatically over the past several years. From 2011-2015, investment volume increased 20% per year; however, this increase in activity has primarily accrued to non-healthcare-related businesses. As shown in Figure 1, healthcare's percentage of total venture capital investment has fallen consistently since 2009. For biotech and healthcare services, the decline went from 20% of the overall market in 2009 to 14% in 2015, and for medical devices the decline over the same time period dropped from 13% to 5%.

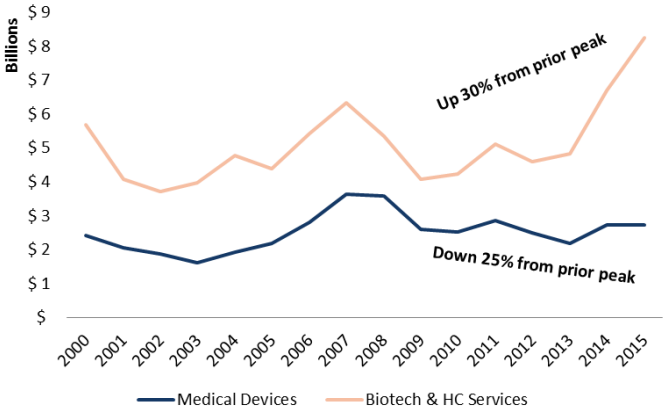
To accompany the data shown in Figure 1, we dug further within healthcare and looked at absolute investment amounts for medical devices versus biotech and healthcare services. From 2011-2015, investment in biotech and healthcare services companies increased 14% per year, and ended 2015 up 30% from the prior peak in 2007. For medical devices, the story has been much different. While investment activity from 2011-2015 saw a nominal increase of 1% per year, the aggregate deal value finished 2015 down 25% from the 2007 peak. This shows that over a full cycle, investment in biotech and healthcare services has largely trended upward, whereas the medical device space has taken a large hit to its capital base.

Figure 1: Medical Device vs. Broader Healthcare Investment (Relative)



Source: PwC

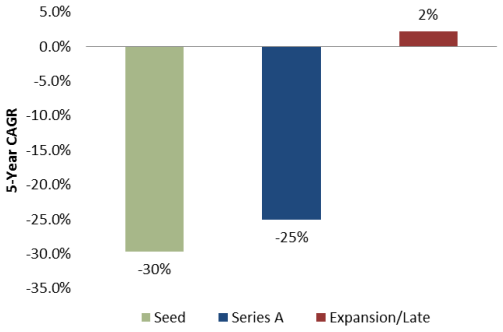
Figure 2: Medical Device vs. Broader Healthcare Investment (Absolute)



Source: PwC

Based on the findings shown in Figure 2, we dug yet another layer deeper to see if there has been any sort of pattern within medical devices to help explain the decline in investment volume over the past decade. As shown in Figure 3, a bifurcation in the medical device market has emerged. From 2011-2015, start-up investment in devices (i.e. Seed/Series A rounds) declined substantially, while investment in expansion/late stage devices increased by roughly 2% per year. This is in sharp contrast to what occurred leading up to the financial crisis (2006-2008), when Seed funding increased 55% per year and Series A funding increased 26% per year. As the data shows, this capital has largely been pulled out of the system, making it more difficult for innovative ideas to get funded.

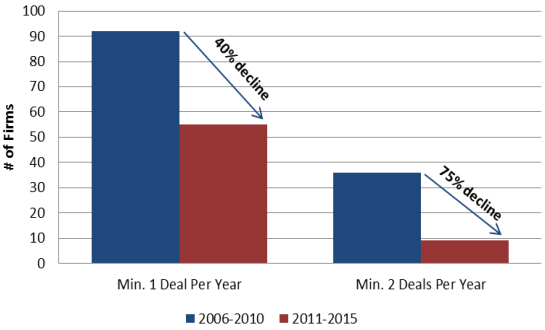
Figure 3: Medical Device-Dollars Invested (2011-2015)



Source: PwC, Silicon Valley Bank

This reduction in invested capital has been driven by a decline in the number of venture firms that focus on medical devices. As shown in Figure 4, from 2006-2010, we estimate there were roughly 90 firms that completed at least one deal per year (five deals over the full cycle) and around 35 firms that completed at least two deals per year (10 deals over the full cycle). Fast forward to 2011-2015, and we estimate that the number of firms completing at least one deal per year fell by 41% to around 55 groups, and the number of firms completing at least two deals per year fell by a staggering 75% to approximately 10 groups. Generally speaking, less capital and fewer market participants translates to a more favorable opportunity set for remaining players.

Figure 4: Venture Firm Activity in Medical Devices



Source: Preqin

2) Exit Environment

Over time, one criticism of medical devices has been the lack of a robust exit environment. While historically this claim has largely been true, the dynamics appear to be changing. As shown in Figure 5 (Page 3), there were 11 VC-backed medical device IPOs* in 2015, up slightly from 10 in 2014 and up significantly from only two in 2013. Furthermore, there has been a slight shift in mindset toward devices that have not yet received U.S. Commercial status (i.e. FDA approval). From 2011-2013, there were no IPOs for devices falling in this category; however, in both 2014 and 2015, there were three IPOs of devices that had not yet received FDA approval. On a relative basis, these figures pale in comparison to the biotech market; however, they still represent a meaningful shift within the device space. One caveat worth mentioning is that device IPOs tend to act more as financing events than liquidity events. This is particularly true for devices that go public prior to gaining FDA approval. In these instances, VC groups are unlikely to want to fully sell down their equity, since the bulk of value accretion lies in the post-regulatory phase of development.

A similar story has emerged in the M&A space (Figure 6, Page 3). The number of VC-backed M&A transactions* in 2015 (17 exits) was essentially in line with the prior year's mark of 18 exits, and it represented the second highest-volume year in recent memory. Similar to the IPO market, the M&A environment in 2015 saw an increase in the number of deals involving non-FDA approved devices. In fact, the magnitude of this shift was even more substantial than we saw in the IPO space. Of the 17 big exit M&A transactions in 2015, 65% involved devices that had not yet received FDA approval.

*Silicon Valley Bank defines an IPO as a public listing that raises proceeds of more than $25 million. On the M&A side, it reports "big exits," which it defines (for medical devices) as a transaction in which the upfront payment is $50 million or more.

Figure 5: VC-Backed Medical Device IPOs

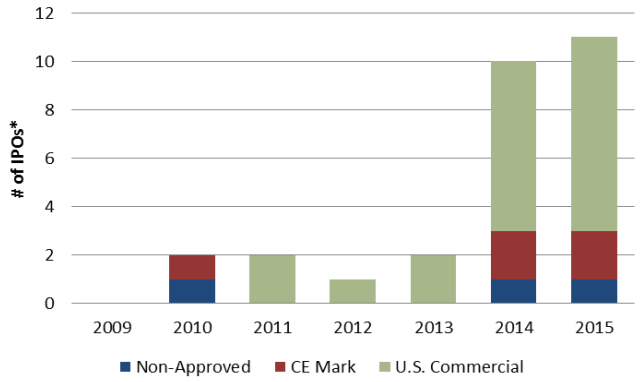
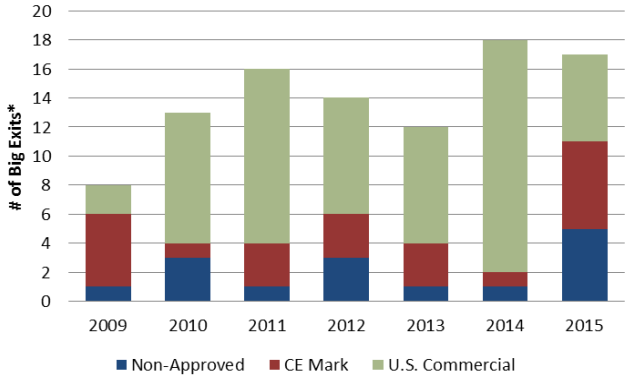


Figure 6: VC-Backed Medical Device M&A



Source: Silicon Valley Bank
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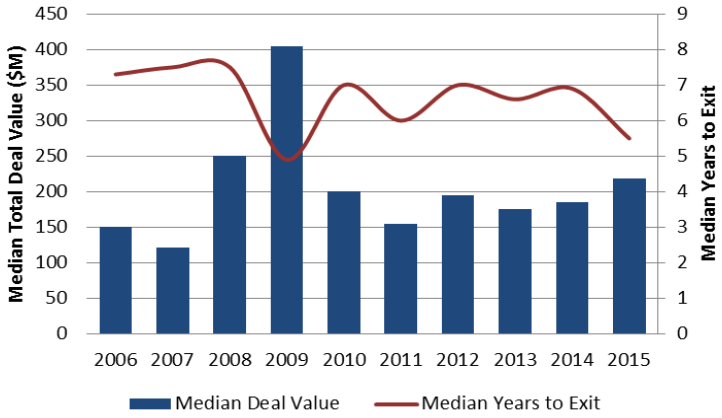
It is important to point out that, within the M&A space, it is not just the number of transactions that has increased. The value of these exits and the time required to achieve them have also turned more favorable. As shown in Figure 7, the median total deal value increased 18% YoY in 2015. The median value of $219 million remained well below the previous high of $405 million seen in 2009, but still marked the third highest annual value in the past decade. Complementing this increase in exit value was a decrease in the median number of years required to reach an exit. That number declined to 5.5 years, which was the second-lowest value seen in the last decade (2009 was 4.9 years).

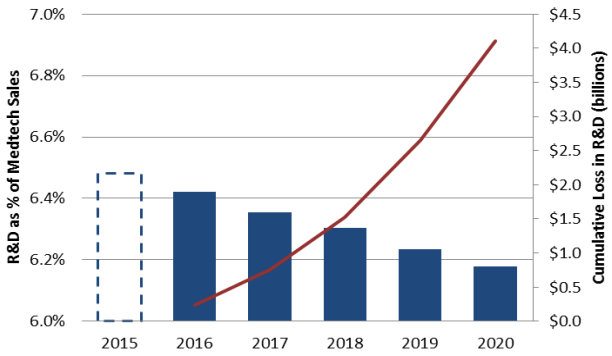
Figure 7: VC-Backed Medical Device M&A: Values and Time Horizon



Source: Silicon Valley Bank
Note: As above, data is shown for what Silicon Valley Bank defines as "big exits."

Although it is difficult to determine whether the trend of acquiring device companies pre-FDA approval will continue, the underlying fundamentals suggest this dyanmic could persist. The key to this lies in R&D expenditure for large medical device companies. Forecasted R&D activity is expected to grow over the next five years, but at a slower pace than sales. As a result, as shown in Figure 8, the percentage of incremental sales going toward internal development is set to steadily decline through 2020. While the percentage decrease is not glaring in terms of magnitude, the cumulative dollar opportunity cost of the decline from 2016-2020 is estimated to be over $4 billion.

Figure 8: Projected R&D Spend by Large Device Companies



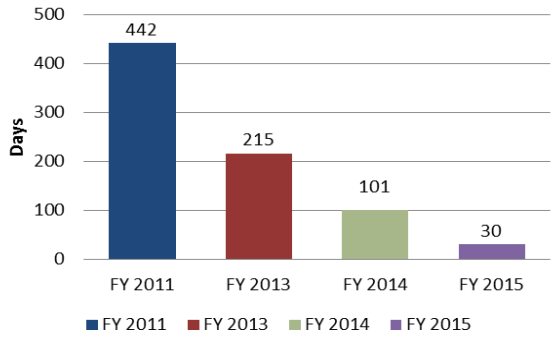
Source: Evaluate
Note: Opportunity cost is calculated using the difference in projected R&D % of sales compared to historical average of 6.5%.

Medtechs are in a constant race to stay competitive relative to peers, and remaining competitive requires ongoing innovation. If that innovation is not coming internally through R&D, then device companies will have to look outside their walls in order to fill the pipeline.

3) Improved Regulatory Environment

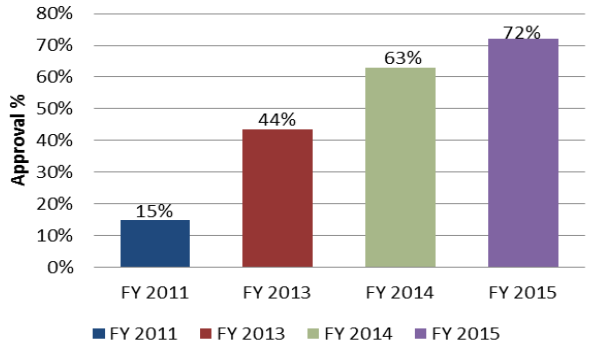
The FDA approval process has historically been a long, convoluted sequence of events. However, recent data suggests the FDA is working to streamline its process, with the goal of making device approvals more efficient and predictable. Both the time to approval to begin an IDE study (i.e. prerequisite for conducting human trials) and the total time to decision for both PMAs and 510(k)s* (i.e. final FDA approval) have improved significantly in the last few years (Figures 9 and 11). There has also been a marked increase in the percentage of IDE studies receiving full approval within two cycles (Figure 10). A key aspect of all of this is likely the FDA's renewed focus on better communication between applicants and the agency. This is evident in the decreased amount of original applications that are denied by the agency. Through 2015, the percentage of original PMA applications approved was 98% (Figure 12), the highest it has been in at least the last 15 years. The fact that the FDA seems to be making the path to approval more predictable could continue to help strategics be more comfortable acquiring companies before they have obtained FDA approval.

Figure 9: Median Days to Full IDE Study Approval



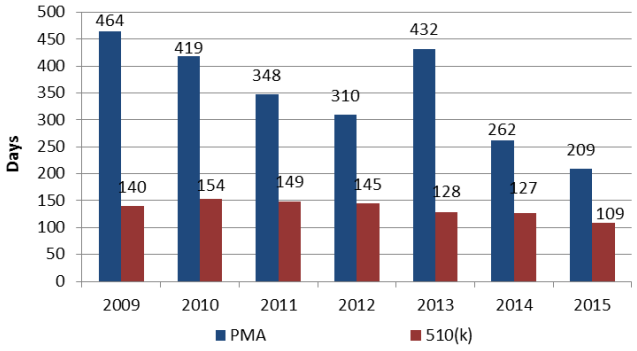
Source: FDA
*Data as of 6/30/2015
**2015 cohort still open; number is subject to change

Figure 10: % of IDE Studies Fully Approved Within Two Cycles



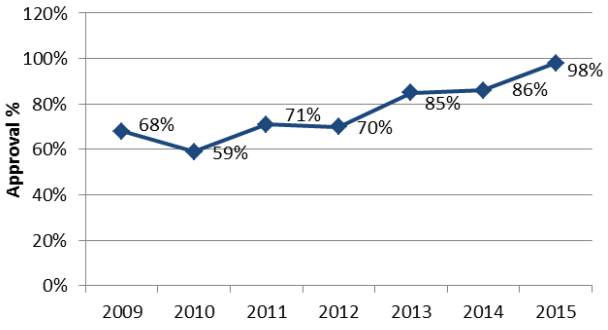
Source: FDA
*Data as of 6/30/2015
**2015 cohort still open; number is subject to change

Figure 11: Average Days to FDA Decision



Source: FDA
*Approvals include original applications only, received as of 12/31/2015
**2013, 2014, and 2015 cohorts are still open; numbers are subject to change

Figure 12: % of Original PMAs Approved



Source: FDA
*Approvals include original applications only, received as of 12/31/2015
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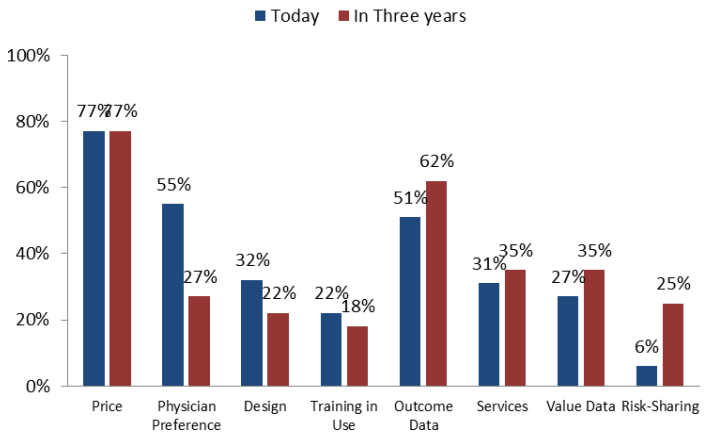
Considerations on Risk

1) Reimbursement and Market Adoption

Even if a device gains FDA approval it remains far from guaranteed to receive adequate reimbursement from insurers. As the healthcare system has moved from a fee-for-service model to a value-based model, new medical devices have been tasked with proving not only clinical efficacy, but a tangible ability to create value and remove costs from the system. The process for gaining reimbursement is even further complicated by the need to obtain a code that allows doctors to get paid for using the device. While some procedures can leverage existing codes, others will have to apply for a new code. In the latter case, it could be difficult for devices to gain payer support until the new code is issued and it has gained widespread market interest/usage. This puts innovative device companies in a tricky situation—they cannot get reimbursement until they prove market adoption, but they cannot gain market adoption until the healthcare community knows they will be paid for implementing the new procedure. Further, even for devices that are equivalent to existing products in market and should therefore be able to leverage an existing code, there is no guarantee that payers will value the device enough to offer widespread reimbursement.

For devices that are able to obtain FDA approval, market adoption remains one of the primary risks to gaining scale and profitability. In an evolving healthcare world, an innovative product can still fail if it cannot effectively appeal to end-market buyers and users. As shown in Figure 13, the factors that drive device spending today are not necessarily the factors that will drive spending in the future. Today, price and physician preference are the two most important drivers of device spending. Looking forward, while price is expected to remain the most critical element in the purchasing decision process, clinical efficacy and other value-driven data points (assumed to include considerations on reimbursement) are projected to increase in importance and make inputs such as physician preference less relevant. As this trend takes hold, it is expected that groups such as finance and procurement departments will take a larger and more influential role in purchasing decisions. This will require new medical device companies to appeal to a different set of end users than was required in the past. It is also important to consider that adoption risk can vary across the different types of approvals or clearances from the FDA.

Figure 13: Factors Driving Medical Device Spending



Source: E&Y

2) Market Depth

Another issue that can adversely impact device companies is the lack of depth within certain healthcare verticals. The market wants new and innovative products; however, if a device only appeals to a small subset of the healthcare universe, there is unlikely to be enough user demand and money to provide deep and lasting support for the product. For investors, this can equate to compressed returns that do not appropriately reward them for the underlying risk of their investment. The trick is to find a device that offers a truly compelling technological innovation, but still sells into an end market deep enough to support scalability and reward innovation.

3) Relative Returns

On top of market depth is the issue of relative returns. While median exit values for devices have gone up recently, they still trail biotech median exit values by roughly half. Some of this is likely driven by the lower cost and development times for devices versus drugs; however, devices can still face much of the same binary risk as drugs. So while the improved exit figures for devices are promising, the story may fall flat when viewed in relative terms. From 2005-2015, Silicon Valley Bank compiled data on "big exits" (Silicon Valley Bank defines a "big exit" as a transaction in which the upfront payment is $50 million or more for medical devices and $75 million or more for biotech), which shows a substantial difference in VC-backed M&A exit valuations for biotech versus medical devices. On average, the median upfront and total deal valuations for biotech were 1.9x and 2.2x larger, respectively, than for medical devices. While this differential in outcomes cannot and should not be relied upon by investors on a go-forward basis, the reality is that within healthcare, biotech appears to offer returns capable of providing greater upside to investors (and hence, better compensation for risk).

Conclusion

Certain market dynamics in the medical device space point to opportunity for investors. These dynamics include a reduction in the amount of capital targeting the space, an improved exit environment, and apparent easing at the regulatory level. However, with this opportunity still comes risk. Some of this, such as market depth, can largely be accounted for and solved for at an early stage by investors. However, issues such as reimbursement and market adoption can still lead to unpredictable outcomes, even for quality technologies. Likewise, there is no robust evidence to suggest that relative to biotech, device exit values offer sufficient reward for the risk taken by investors. These ongoing issues are likely to result in a landscape that remains underpenetrated going forward. While this could further support the opportunity set for investors who decide to remain in the space, we question the ability of existing players to consistently navigate the risks of device investing and also produce convex, venture-like returns.