START-UP

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MEDTECH INVESTING

Medical Device Investing 2010 And Beyond: Time To Challenge The Conventional Wisdom

A new analysis questions the assumption that bets in medtech companies pay off more quickly and surely than biopharma investments. However, when medical device companies win, they win big.

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- Historically, investing in medical device companies offered the benefits of lower capital intensity and the potential for a simplified path to market through a 510(k) market clearance.
- These benefits, as well as challenges in the biopharmaceutical sector, led some VC investors to increase their interest level in medical device investing in the mid-2000s.
- Now that the dust is settling, an analysis finds that relative to biopharmaceutical investments, medical device companies are more likely to have a binary outcome, require more time to exit, and are consuming an increasing proportion of capital in later rounds of financing.
- These trends are evident even before accounting for impending changes to the 510(k) regulatory pathway, and they should be considered when determining medical device allocations for venture capital portfolios.

For at least three years, venture capitalists have been frustrated by the external challenges facing private biopharmaceutical companies. A more stringent and unpredictable regulatory environment has increased the cost of achieving product approvals. Late-stage drug development in certain therapeutic areas, such as diabetes, has become so expensive that some investors are avoiding them entirely. Generic pharmaceuticals are posing a threat not just to the specific drugs they are replacing, but also to new drugs that may offer only incremental improvements. At the same time, and well before the collapse of Bear Stearns and Lehman Brothers, the nature of the biotech IPO has changed entirely. Gone are the days of investing $50 million to bring a compound to the clinic, followed by an IPO with a $200 million pre-money valuation. In this environment, what biotech venture capitalist wouldn't lift up his or her head and look for greener grass?

Prior to the financial crisis, one of the most natural places to look was the adjacent area of medical device investing. For years, conventional wisdom suggested that a successful medical device company could be developed with $50 million of invested capital and sold for $150 to $200 million. New medical devices could be brought to market more easily than new drugs, in an environment where "commercial stage" companies were having an easier time raising outside capital. Naturally, this piqued the interest of frustrated biopharmaceutical investors and led some VC investors to increase their emphasis on medical device investing. Indeed, venture capital dollars invested annually in US medical device companies more than doubled from $1.8 billion to $3.7 billion in the period from 2004 to 2007. In the same time period, venture capital dollars invested in biopharmaceutical companies increased only 14%, from $5.2 billion to $6 billion.

More recently, of course, the fundraising environment for all life science venture capital-backed companies – whether medical device or biopharmaceutical – has become much more challenging. Now that venture capital funding of both medical device and biopharmaceutical companies has slowed from 2007 peaks of $3.7 billion and $6 billion, respectively, what can we say about the conventional wisdom of yesterday?

We jointly analyzed investment trends between 2001 and 2009, comparing the medical device and biopharmaceutical industries in terms of venture returns, time to exit, types of exits, and other measures of the risk-reward profile of these two sectors.

We found that relative to biopharmaceutical investments, medical device companies have actually required more time to exit and were more likely to have a binary outcome, that is, to either pay off handsomely or not at all. In addition, medical device companies are actually consuming increasing amounts of capital in later rounds of financing. Unfortunately, these are the exact attributes that many investors are avoiding today, and are evident even before accounting for upcoming changes to the 510(k) regulatory pathway that are expected to further complicate the regulatory landscape. Unless medical device companies can demonstrate how they are different in key respects (e.g., positioned for shorter time to exit, less likelihood of a binary outcome), we expect fundraising for these companies to remain difficult. This in turn should impact medical device allocations and strategies within venture capital portfolios.

(For the purposes of our analysis we are using the VentureSource definition of the "medical device and equipment" segment, including companies that manufacture therapeutic devices, surgical devices, diagnostic equipment, medical lab instruments and test kits, medical supplies, and patient-monitoring equipment. Our definition of the "biopharmaceuticals" segment includes biotechnology therapeutics, drug delivery, drug development technologies, and pharmaceutical companies. Exits include companies that have had an initial public offering, have merged or been acquired, or have gone out of business.)

At a high level, the medical device sector does in fact offer advantages in terms of lower capital requirements and higher overall exit multiples.

Over the last five years, medical device investing has been significantly less capital intensive than biopharmaceutical investing. For companies that achieved an exit multiple less than 4x (four times invested capital), medical equipment and device companies consumed a substantially lower amount of capital prior to exit. (*See Exhibit 1.*)

Interestingly, both medical device companies and biopharmaceutical companies that achieved either a 4x+ return or zero return were able to do so with relatively modest amounts of invested capital. This suggests that in both sectors, the best and the worst investments declare themselves after relatively little capital has been invested. The key difference is in companies that deliver more modest returns between zero and 4x. Medical device companies were able to achieve these outcomes with roughly half the invested capital required by their biopharmaceutical peers. This reduced capital-to-exit in medical device companies will continue to be an attractive feature for VC investors who are seeking to "stretch" their available capital, either by making a larger number of investments in a given fund, or by maintaining the same number of investments in a smaller fund. The obvious and ongoing challenge for the biopharmaceutical investor is whether exits are attainable with less capital, either through a more virtual model or by focusing on less capital intensive therapeutic areas.

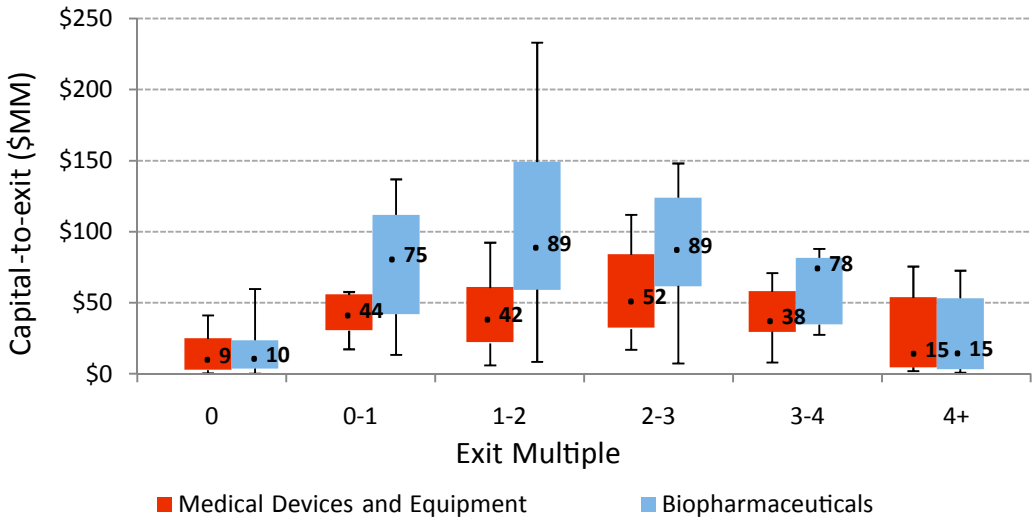
In addition to the advantage of lower capital intensity, the annual *net* exit multiple has been higher for medical device companies in five of six past years, and is higher on average over the last 15 years. Exhibit 2 depicts net exit multiples for biopharma and medical device venture capital investments in each of the past 15 years. For each year, net exit multiple is defined as the sum of total exit values for the year, divided by the total equity invested in the exiting companies.

These findings still hold after taking out two large medical device exits, **TomoTherapy Inc.** (which went public in 2007, raising $187 million) and **Accuray Inc.** (which raised $174 million in its 2007 IPO).

Taken together, we expect the lower capital requirements and potential for higher exit multiples will continue to make the medical device and equipment sector appear attractive to frustrated biopharmaceutical investors. That said, several dynamics have made medical device investing more challenging in recent years, and more risky than surface appearances may suggest. These companies are more binary, require more time to exit, and are consuming more capital in later rounds of financing.

Exhibit 1

2005-2009 Exits: Range Of Capital-to-Exit

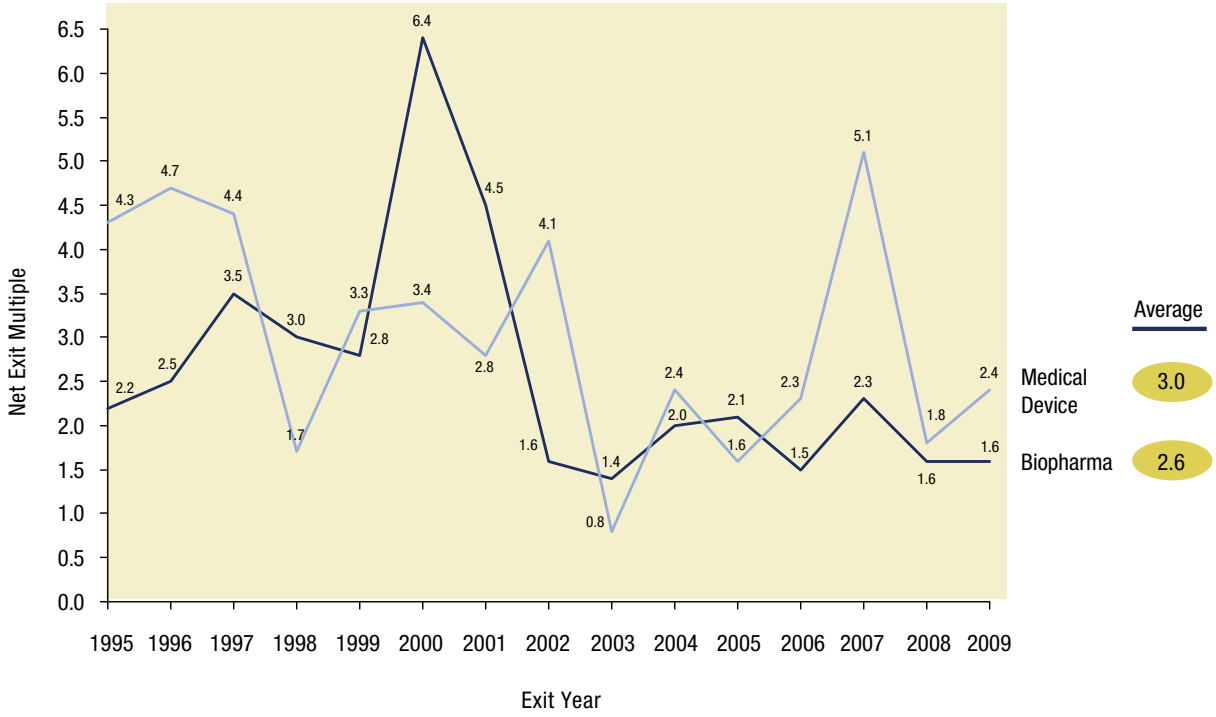


Note: Individual data points represent medians

SOURCE: SVB Analytics; Dow Jones / VentureSource

Exhibit 2

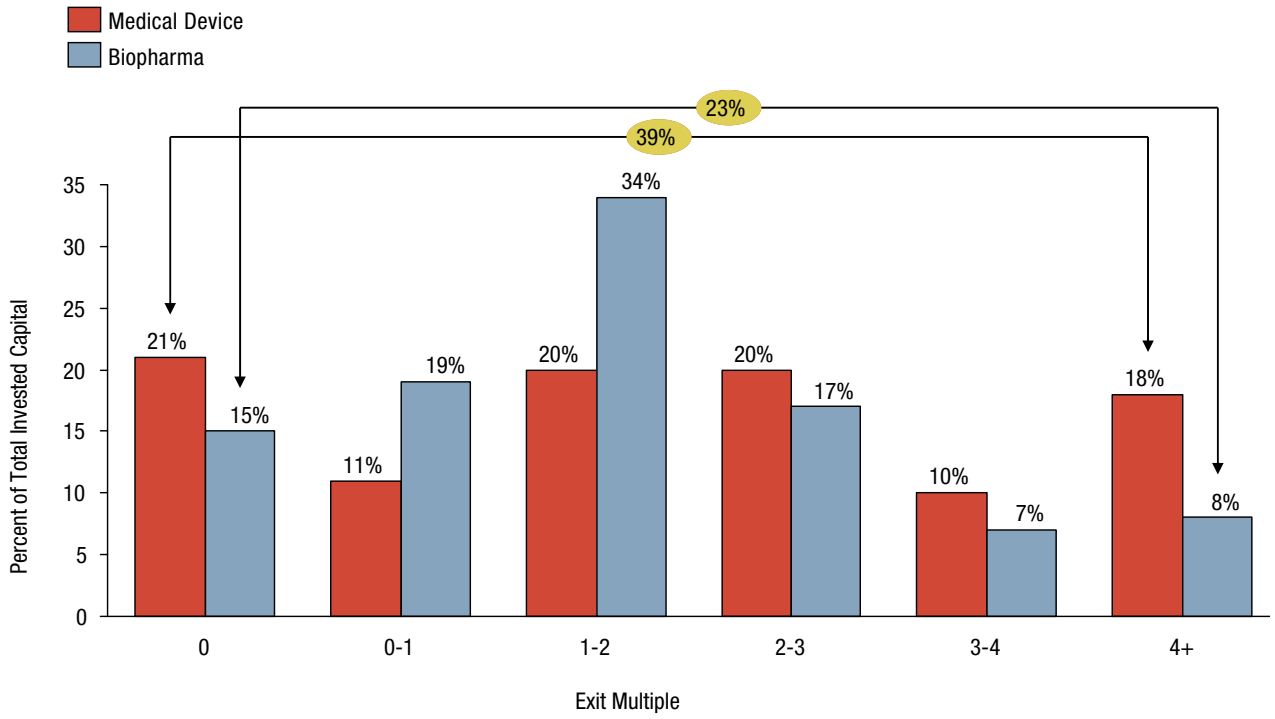
Annual Net Exit Multiples For Biopharma And Medical Device Venture Capital 1995-2009



SOURCE: SVB Analytics; Dow Jones/ VentureSource

Exhibit 3

Total Capital Invested By Exit Multiple 2005-2009



SOURCE: SVB Analytics; Dow Jones/VentureSource

Outcomes in venture-backed medical device and equipment companies are more binary, compared with biopharmaceutical companies.

An analysis of capital invested and capital returned over the past five years shows that medical device companies are more likely than biopharmaceuticals to yield a binary outcome. For our purposes, we consider a binary outcome to be either a large, positive exit (4x+ invested capital), or zero return of capital. Among medical device companies, 39% of capital invested yielded either a 4x+ return or a zero, compared with only 23% of capital invested in biopharmaceutical companies. (*See Exhibit 3.*) This difference is driven primarily by the higher proportion of 4x+ exits among medical device companies.

The 4x+ exits for these companies are successful in terms of exit size as well as exit multiple. For the time period 2005 to 2009, the median size of 4x+ exits was $225 million for medical device companies and $262 million for biopharma companies.

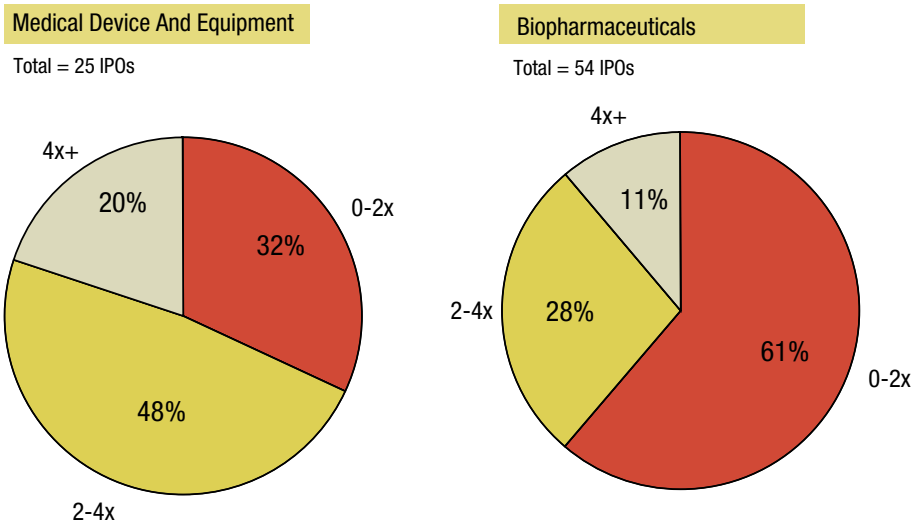
Furthermore, compared with biopharma investments, capital that is *returned* from a medical device investment is more likely to be the result of a big win. Of note, 58% of capital returned from medical device companies in the period 2005 to 2009 came from companies with a 4x+ exit multiple. In the same period, only 33% of capital returned from biopharmaceutical companies came from a 4x+ exit. The IPO market also supports the notion that "when medical device companies win, they win big." We know that IPOs are less frequent in the medical device arena compared with biopharmaceuticals. Indeed, except for a brief period from 2004 to 2007, there hasn't been a meaningful medical device IPO window in 12 years. However, when medical device IPOs do occur, multiples tend to be higher for these companies than for biopharmaceutical companies. (*See Exhibit 4.*) Over the last five years, 20% of medical device IPOs returned 4x+ invested capital, compared with 11% of biopharmaceutical companies.

This difference in IPO returns may be the result of medical device companies generally being more mature than their biopharmaceutical peers at the time of IPO. Of the 25 medical device IPOs between 2005 and 2009 noted in Exhibit 4, nearly 70% had revenues exceeding $1 million in their IPO year (including product sales and collaboration revenues), compared with approximately 35% of their biopharma peers. Conversely, medical device companies without revenues have a substantially harder time accessing the public markets. This further increases the risk profile of medical device companies, in this era of increasing regulatory uncertainty, more rigorous clinical trial requirements, and longer timelines before generating revenues.

Another measure of a company's binariness is its ability to withstand the strains of difficult capital markets following an equity boom. These are typically periods in which perceived weak portfolio companies are weeded out, as investors shunt money toward holdings with the highest potential return on invested capital. In the years following equity booms (2001–2003, 2008–2009), a significantly higher percentage of medical device exits are "out of business" as compared with their biopharmaceutical brethren. (*See Exhibit 5.*) On average, between 2001 and 2003, 57% of exits in the medical equipment and device sector were due to companies going out of business, compared with 37% of biopharmaceutical exits. In 2008 and 2009, an average of 33% of exits in the medical device and equipment sector were due to companies going out of business, versus 23% of biopharmaceutical company exits.

Exhibit 4

Total IPO Volume By Exit Multiple 2005-2009



SOURCE: SVB Analytics; Dow Jones/VentureSource

Exhibit 5

Out Of Business Exits Following Equity Boom Periods

	DEVICE	PHARMA	DELTA
2001-2003	57%	37%	20%
2008-2009	33%	23%	10%

SOURCE: SVB Analytics; Dow Jones/ VentureSource

These figures could either weigh in favor of medical device companies (if they are less likely to burn good money after bad) or against these companies (if they are too undercapitalized to weather difficult conditions), but in either case, these companies are more likely to face a binary outcome.

Across the board, time to exit is as high or higher for medical device companies, compared with biopharma.

It may seem counterintuitive, because the medical device industry has historically enjoyed much shorter – by as much as 10 years – product development cycles than the pharmaceutical industry, but the median time to exit for medical device and equipment companies is at least as long as the time to exit for biopharmaceutical companies, across the range of exit multiples. (*See Exhibit 6.*)

In part these longer time frames to exit may reflect the need for medical device acquirers to see demonstrated revenue traction in a target company, as previously noted among medical device IPOs. This is in contrast to the biopharmaceutical arena, in which positive clinical data, proof of clinical relevance or anticipated regulatory approval may be more likely to drive a successful exit. Biopharmaceutical companies also have the advantage of being able to drive investor value through strategic alliances and/or licensing deals with one or more parties, which in some cases may even provide partial liquidity to investors prior to a full exit.

In addition to generally requiring less to time exit, the *most* successful biopharmaceutical companies (i.e., those that achieve a 4x return or better) tend to declare themselves much faster than the most successful medical device investments. Biopharmaceutical companies achieving a 4x return or better required a median of 43 months to exit, compared with 73 months for medical equipment and device companies. The acquisitions of CoreValve (now **Medtronic CoreValve LLC**) and **Acclarent Inc.** serve as good illustrations. CoreValve was founded in 2001, attained European approved of its percutaneous heart valve replacement system in 2007, and was acquired by **Medtronic Inc.** for $700 million in 2009. Acclarent, which was founded in 2004 and received FDA approval of its sinuplasty system in 2005, raised over $100 million in venture capital before being acquired by the **Ethicon Inc.** division of **Johnson & Johnson** for $785 million in early 2010. At the time of the acquisition, Acclarent reportedly had annual sales of nearly $100 million. A sustained trend toward larger acquisitions of more mature medical device companies is a challenging dynamic for medical device investors, whose business model previously relied on a robust number of $150 million or smaller acquisitions.

Of note, a long time to exit (>7.5 years) plagues both medical device and biopharmaceutical companies that achieve a zero to 1x return.

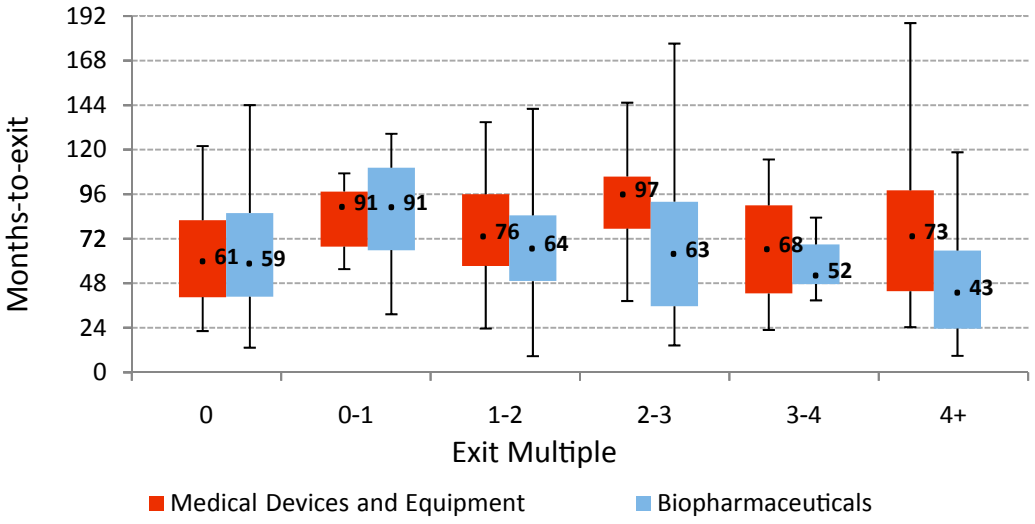
The longer time frames for successful medical device investments have significant implications for funds that are focused on delivering exits in five years or less – a particularly important consideration in the current, difficult VC fundraising environment. Funds that are committed to generating near-term returns for their limited partners may be less willing to take the longer-term bets of the medical device sector, or may be extremely selective in those investments.

Over the last five years medical device companies have consumed an increasing proportion of capital in the later rounds of financing (fourth or later), mitigating some of the benefit of reduced capital intensiveness.

As noted previously, one of the presumed benefits of medical device investing has been the belief that these companies were generally less capital intensive, driven in part by lower trial costs and simpler paths to product approval compared with biopharmaceuticals. This was reflected in the fact that most venture capital dollars invested in medical device companies were allocated to the third round of financing or earlier. Between 2003 and 2006, only 34 to 39% of capital invested in medical device companies was allocated to fourth rounds or later. (*See Exhibit 7.*) However, over the last three years that proportion has increased to 39 to 57% of invested capital, suggesting that these companies are requiring more rounds of financing and longer maturation times than historic norms. The absolute dollar

Exhibit 6

2005-2009 Exits: Range Of Months-to-Exit



SOURCE: SVB Analytics; Dow Jones / VentureSource

amount invested in these companies in later rounds has increased as well, growing from $1 billion in 2006 to nearly $2 billion in 2009.

Over the same period of time, capital invested in biopharmaceutical companies in the fourth round or later (venture capital only, not including cash from licensing deals) has remained fairly steady between approximately 34 and 42%. In terms of absolute dollars, the amount invested in these companies in later rounds has hovered between $1.5 billion and $2.2 billion since 2003.

Time will tell whether the trend toward investing more capital in later rounds of financing will continue in medical devices, or if a new watermark has been set. In either case, the historic model that saw reduced capital needs for medtech is threatened. More capital in later rounds of financing may also be a harbinger of longer times to exit. Time to exit for medical device companies, which is already longer than for biopharmaceutical companies, may be getting worse.

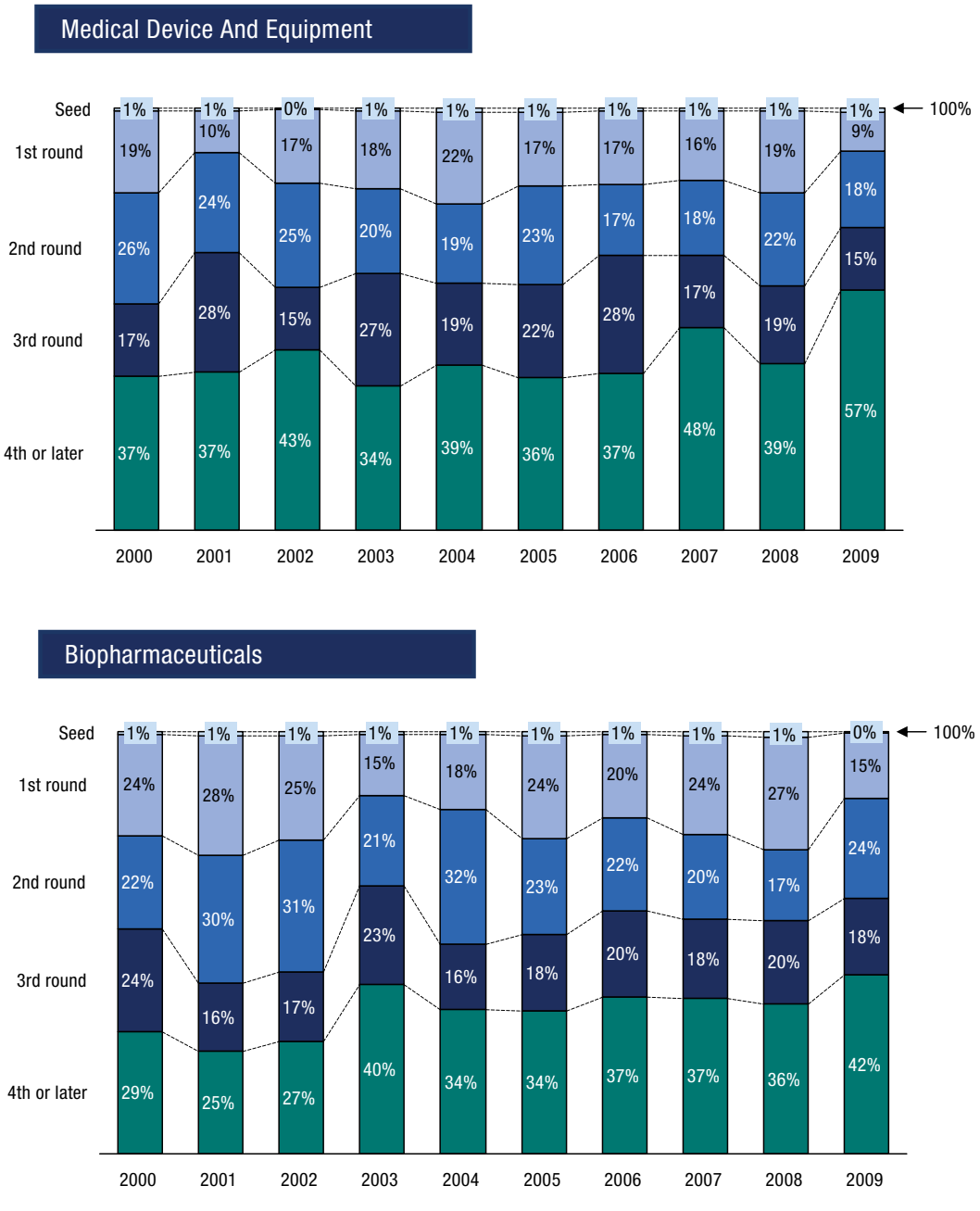
Looking ahead, the exit "queue" for medical equipment and device companies is substantially longer than for biopharma companies.

One key question on investors' minds is the fate of many companies that have been funded in the last 10 years, but have yet to achieve an exit as defined by an M&A transaction, IPO, or going out of business. The vast majority of these companies are continuing to consume capital, and are placing a stress on VC firms that have many portfolio companies to support and may have limited reserves or limited remaining lifespan of the committed fund.

A clogged sink is a compelling analogy to this problem. At any point in time, the sink has water in it, that is, the universe of venture capital dollars that are currently invested in private, active, life science companies. New water, that is, fresh capital, is pouring into the sink as new investments are made. The fresh capital mixes with the capital that has already been deployed. Over any period of time, the fresh capital and the existing capital are exiting at the bottom of the sink – through M&A, IPOs, or going out of business. Problems arise when the sink is clogged, and the rate of capital inflow significantly exceeds the rate of capital outflow. This is exactly the situation we've been in over the past decade. From 2001 to 2009 the ratio of annualized equity raised (water flowing into the sink) to annualized equity exiting (water

Exhibit 7

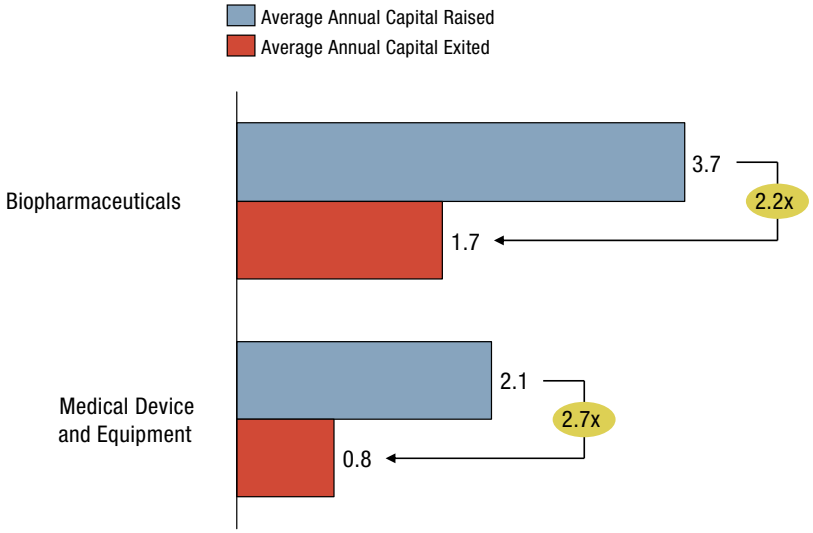
Invested Capital Allocation By Series, 2000-2009



SOURCE: SVB Analytics; Dow Jones/VentureSource

Exhibit 8

Capital Raised To Capital Exited Ratios, 2001-2009
$ billions



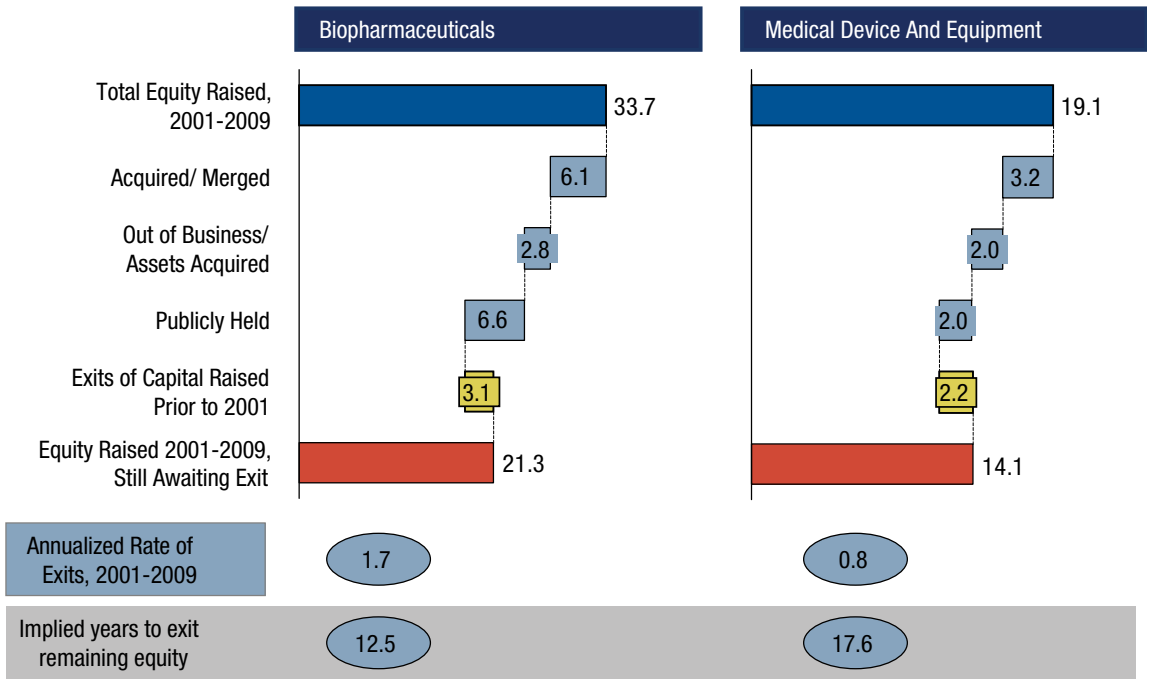
SOURCE: SVB Analytics; Dow Jones/VentureSource

flowing out of the clogged drain) is 2.2x for biopharmaceutical companies, and 2.7x for medical device companies. (*See Exhibit 8.*)

Importantly, even though fewer venture capital dollars have flowed into medical equipment and device companies compared with biopharmaceutical companies, the exit "queue" for medical device companies is much longer because the rate of exit is slower. To assess the length of a theoretical exit queue for biopharma and medical device companies, we first calculated an annualized rate of exits for the period 2001 to 2009. In the biopharmaceutical sector a total of $15.5 billion of invested venture capital achieved an exit from 2001 to 2009 ($6.1 billion acquired/merged, $2.8 billion out of business/assets acquired, $6.6 billion publicly held), yielding a $1.7 billion annualized rate of exits. (*See Exhibit 9.*) The same calculation for medical equipment and device companies yields a $0.8 billion annualized rate of exits. At this pace, it will take approximately 17.6 years for all of the capital invested in medical equipment and device companies between 2001 and 2009 to achieve an exit. This is 40% longer than a similarly defined exit queue for biopharmaceutical companies. Although this is an artificial view of the world, this situation presents a clear challenge for venture investors given a typical fund lifespan of 10 years.

Exhibit 9

Pace Of Venture Capital Exits, 2001-2009
$ billions



Note: Includes all rounds of domestic venture equity raised from 2001-2009 for biopharmaceuticals and medical devices & equipment; data excludes health care services and medical software/ information services companies.

SOURCE: SVB Analytics; Dow Jones/VentureSource

What are the drivers of these longer times to exit? Clearly a combination of factors is at work, including depressed IPO markets and a general reduction of available risk capital. Other causes appear to be disproportionately affecting the rate of exits for medical device and equipment companies, including the higher hurdles that must be met before buyers – whether public markets or large companies – are willing to provide an exit. Just as importantly, what can be done about it? In this new dynamic, we are already seeing investors spending more time focused on how any given investment will achieve an exit, and ensuring that reserves (and co-investors) are adequately resourced to get companies across a more distant finish line. Management teams of medical device and equipment companies that are seeking to raise capital should be especially aware of these challenges, and be prepared to answer the inevitable question of why their companies are different.

Not long ago, frustrations in the biopharmaceutical sector, including a challenging regulatory environment, difficulty accessing capital for large, expensive late-stage trials, and growing threats from generics increased the relative attractiveness of medical device investing. Historically, medical device companies have required less capital to achieve an exit, and the 510(k) approval process offered a simplified path for new products to reach the market. We continue to see attractive medical device investment opportunities, and large exits are still occurring with attractive returns to investors, in some cases for development-stage companies. As recently as November 2010, Medtronic announced that it would pay $800 million up front plus commercial milestones to acquire **Ardian Inc.**, a development-stage hypertension device company with $66 million invested. In the same month, **Boston Scientific Corp.** announced it would acquire **Sadra Medical Inc.**, which is developing a percutaneous aortic valve replacement system, for $225 million up front plus up to $225 million in milestones. However, we find that relative to biopharmaceutical investments, medical device companies have required more time to exit, are more likely to have a binary outcome, and are consuming increasing amounts of capital in later rounds of financing. In addition, the backlog of medical equipment and device companies awaiting an exit is substantially larger than that for biopharmaceutical firms. These challenges are evident even before accounting for the potential impact of changes to the 510(k) process for medical devices, and should be considered when determining biopharmaceutical and medical device allocations for venture capital portfolios, and when developing medical device investment strategies.

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