# Medtech Venture Capital Heads into Unfamiliar Terrain

It's more than a feeling; eight years worth of data indicate that it takes more time and more money to get to a medical device exit, and for all that, exit values are capped. Inflated valuations have contributed to the problem. It's time to reset the industry.

BY RICHARD M. FERRARI

- For venture investors in health care today, valuations and opportunities are not aligned.
- Medtech exit values are constrained; 88% of all exits since 2000 are below $300 million.
- There is a great deal of unpredictability now as to time to exit, capital required, and even the likelihood of a successful outcome, as clinical trial and reimbursement requirements become more stringent.
- It's time to reset valuations and the deployment of capital to more realistic levels.

*Over the last four years* the amount of capital flowing into the health care sector has remained robust—in fact, it's at an all time high, and that has many venture capitalists feeling both optimistic and concerned. The concerns are well founded, and not just because of the recent financial meltdown. The landscape in medtech investing is changing, and one need only look at two signposts to see that this is so: the exit values of VC-backed companies over the past eight years (lower than anticipated), and the amount of time required to achieve those exits (longer than ever before).

Many venture funds are raising ever larger funds in excess of $300 million. This buildup of cash has served to increase valuations and support a multitude of interesting but not well differentiated technologies. These phenomena were troublesome in and of themselves, but now, in a market in crisis, an even larger concern looms over venture capital investments: to what level will valuations be reset? This is an alarming concern for the venture-backed and public companies that need to raise money because they're at a stage where they still need to run and complete clinical trials or because they're preparing for initial product launch without much trend data. With public equity valuations crushed recently (**Xtent Inc.**, **Thermage Inc.**, **Insulet Corp.**, **Northstar Neuroscience Inc.**, and the list goes on) venture capitalists are naturally concerned that the values of many private companies will follow.

In the past, as record amounts of capital have poured into health care, the allocation of biotechnology and medical device sectors as a proportion of the total has remained consistent. However, since 2005 the increase in money flowing into the medical device sector has outpaced the biotechnology sector on a fairly significant basis; from 2005-2006 the increase in medical devices was 32% and from 2006-2007 the increase was 41% (*See Exhibit 1*).

This certainly is good news for the growing number of newly minted companies and seasoned entrepreneurs with ideas and technologies for every conceivable unmet medical need. However for the venture capital investor this increase in the number of ideas and technologies presents an unusual problem, a tremendous number of new companies and technologies to evaluate.

Venture capitalists rarely complain about deal flow; more deal flow is generally better than less deal flow. But in the last decade of venture investing the numbers of new companies and technologies have exploded within almost every clinical area, making it both challenging and crucial to identify the differentiated companies. At the same time, this explosion of newly funded companies runs counter to other market dynamics. Exit values for VC-backed companies are essentially capped; the time to exit for IPO or M&A for VC-backed companies has lengthened significantly; the amount of money required to achieve a successful outcome has greatly increased, and lastly, valuations have continued to rise, especially for the disruptive ideas and best-of-breed companies. When the dust settles over the next year with respect to the general market conditions, the disruptive and differentiated ideas will probably still garner the highest valuations but likely at lower levels than we have seen in the recent past.

## THE RUNWAY GETS LONGER

Subtle signs of these changes in health care investing began to be apparent a few years ago, but today there's no doubt. The time to market for device companies is increasing. The FDA has been raising the requirements ever so slightly over the last few years

with respect to safety and follow-up, not just for PMA oriented products but also for 510(k) products. In many clinical areas within the FDA the members of the old guard—those reviewers with many years of experience—are reaching retirement age and new younger reviewers are coming in. That inexperience is contributing to a longer process time. The FDA is also on the alert: over the past few years several highly publicized safety concerns have hit the press, late stage thrombosis in coronary stents, lead wires fracturing in defibrillation devices, and a number of other adverse events across a broad spectrum of clinical areas. These changes and events have created a situation in which the follow-up and clinical trials that the FDA requires to prove safety have become very expensive and difficult to administer, especially for early-stage VC-backed companies. In particular, some of the clinical areas in which our portfolio companies have experienced very costly, time consuming and complex clinical trials include congestive heart failure, spinal disc replacement, neurostimulation for obesity, pain and epilepsy, structural heart disease, interventional pulmonology, and coated stents.

The 510(k) route to approval is no longer the high-speed lane to market it once was, either. VCs are now confronted with 510(k) devices that are required to have six months—and in some cases one year—of follow-up, with heavier requirements for preclinical and bench testing than ever before as well.

Another key hurdle today is reimbursement. Granted, reimbursement has always been an important requirement for all new medical technologies, but frankly, in the late 90s and early 2000s many investors, entrepreneurs, and CEOs felt that if the product did not have a specific code or DRG initially that was acceptable as long as the product had real clinical value. It's a considerably different story today. CMS (Centers for Medicare & Medicaid Services) has made it clear that they are moving toward pay-for-performance criteria and will only be paying for those new technologies that not only show significant advancements in patient care but are also deemed reasonable and necessary.

Still, if medtech investing has recently come under pressure, one can't really say it's because of the FDA's requirements and the reimbursement challenges, because health care investors have always known that products need to be safe, efficacious, and covered by reimbursement. However those challenges are now added to several other trends that may not be so obvious, rising valuations being among them.

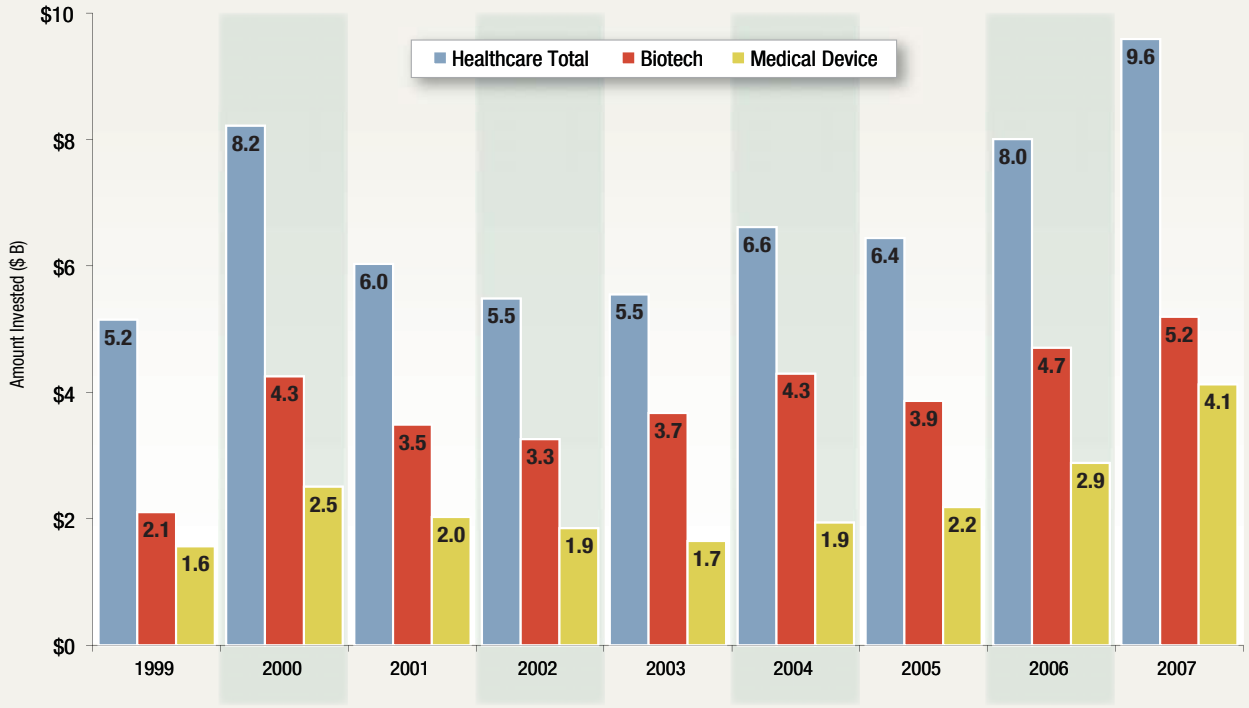
## THE IMPACT OF RISING VALUATIONS

Valuations have always been at the top of the minds of both the entrepreneurs and the venture capital investors, and for the most part, since 1999 through 2005 they have not fluctuated widely. As the following charts show, since 2005 valuation increases have been meaningful for any round, A, B, C, or later. Clearly one of the reasons for this increase has to do with the fact that beginning around 2004 record amounts of capital flowed into both biotech and medical devices.

Closer analyses of the data, along with our industry experiences from investing in the space, lead to several observations.

Exhibit 1

**Health Care Venture Capital Investment (1999-2007)**

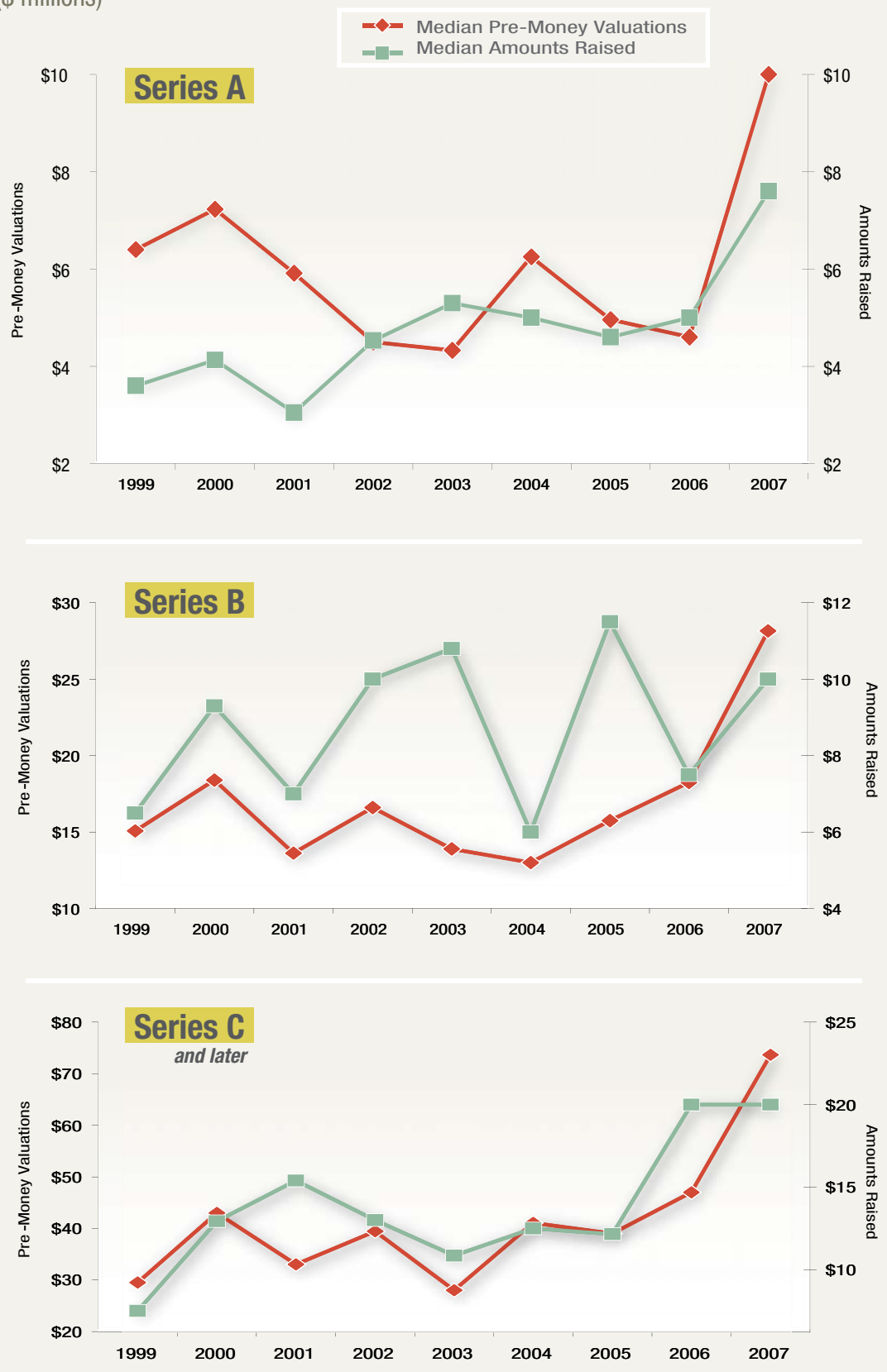



SOURCE: De Novo Ventures

Exhibit 2

**Medical Device Valuations**

($ millions)




SOURCE: De Novo Ventures

First, the valuation charts indicate a relationship between increasing pre-money valuations—specifically on Series A and Series C—and the increase in the amount of money raised.

Over the last eight years, Series A pre-money values for medical device deals have increased 38% and the amount of money raised has increased 84% (*See Exhibit 2*). Similarly, for Series C rounds, the pre-money has increased 71% and the amount of money raised has increased 55% over the last eight years.

The Series A rounds in particular have experienced the greatest percentage increase in capital raised. With respect to Series A, the increase in pre-money appears to be the result of venture capitalists putting more money into the better deals initially in order to meet their company's objective for a certain percentage of ownership. In other words, if the pre-money valuations have continued to rise, then in order to own a certain target percentage the venture capitalist must invest more money initially, as compared to a few years ago when Series A valuations weren't as high.

Ownership targets are ultimately influenced by exits. So, in today's environment, in which the majority of M&A exit values have been less than $150 million, the more you own earlier the better. Simply stated, 35% ownership

of a company sold for $100 million returns about $35 million to the fund, while 10% of the same company returns only $10 million. The difference in ownership and return achieved in this example is meaningful.

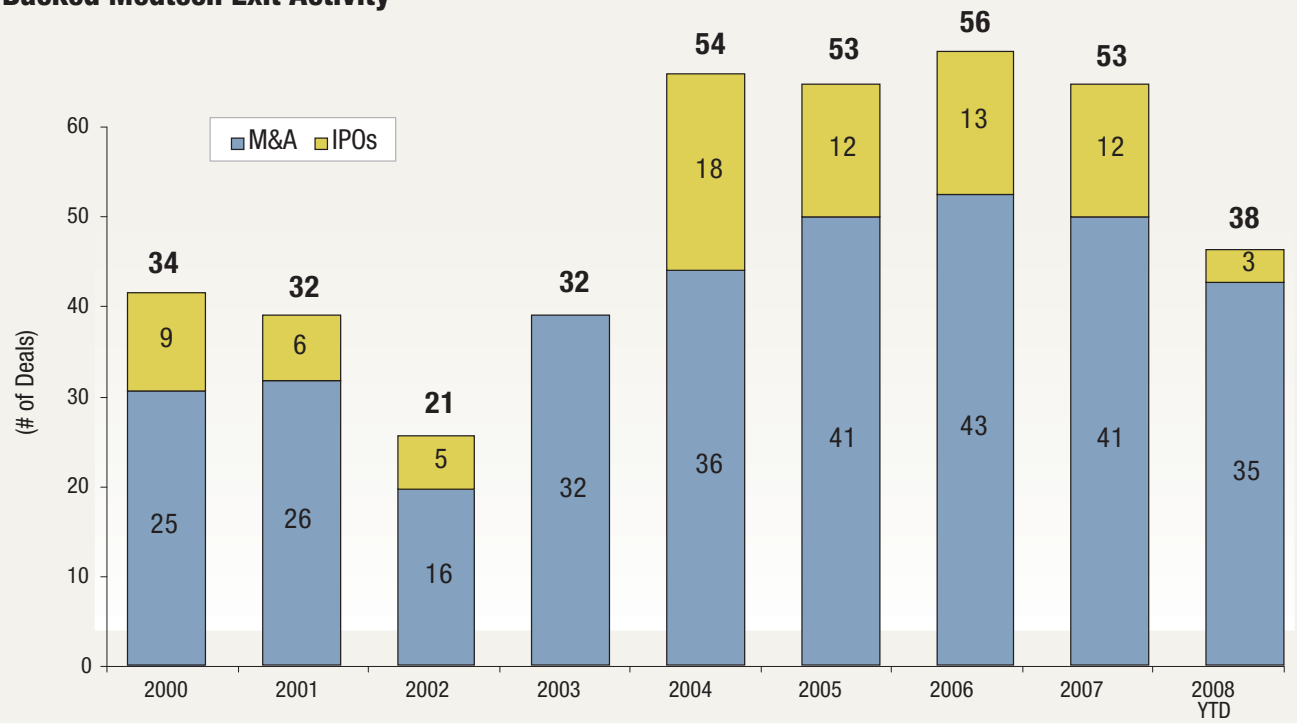
We also noticed that when it comes to the Series C rounds and later, the trend points to companies raising "just enough" capital, and this later-stage strategy is likely due to three primary factors:

1. **An inability to predict outcome.** Historically, later stage rounds theoretically offered lower risk, but today this is not the case. Today's environment of increased FDA requirements, clinical trial risks, market adoption questions, and constrained exit options decreases our ability to predict an outcome that provides a multiple that meets many venture capitalists' criteria. In addition, venture capitalists have target ownership percentages that they would like to achieve in the later stage rounds, just as they do in the earlier stage rounds. But the valuations are significantly higher at the later stage, and therefore the amount of the capital at risk to achieve even a modest return is significantly more than in the earlier rounds. This would not be a problem if the reward were commensurate with the risk, but recent data on IPOs and M&A shows otherwise. Seventy-percent of IPOs six months post the offering are under water. So although risks in later stage rounds should be lower, it is difficult to accurately predict—and realize—an outcome with the desired target multiples.

2. **Valuations continue to increase.** The trend of continually increasing valuations is a major concern and has many ramifications. As previously mentioned the data over the last eight years for venture-backed exits encompassing both IPOs and M&A activities shows the following: 67% of the exits since year 2000 are in the range of $20-$150 million and only 21% of the exits over the same period of time are between $150-$300 million. In short, 88% of the exits are below $300 million. If valuations continue to increase

Exhibit 3

**VC-Backed Medtech Exit Activity**




| | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 YTD |
|---|---|---|---|---|---|---|---|---|---|
| IPOs | $ 1.7 | $ 1.7 | $ 1.4 | $ 0.0 | $ 3.8 | $ 2.2 | $ 2.7 | $ 4.5 | $ 0. 6 |
| M&A | 2.5 | 2.7 | 0.7 | 2.7 | 3.2 | 3.9 | 4.9 | 2.9 | 2.1 |
| Total | $ 4. 2 | $ 4.4 | $ 2.1 | $ 2.7 | $ 7.0 | $ 6.1 | $ 7.6 | $ 7.4 | $ 2.7 |

Note: IPO values represent the pre-money equity value at the time of the IPO. M&A values represent the announced transaction value. Only includes deals with announced values greater than $20mm (or values not disclosed but believed to be greater than $20mm) and only includes guaranteed payments (i.e. does not include performance-based earn-outs).

SOURCE: SEC filings, company press releases, SDC and FactSet as of April 2, 2008

while exit values remain capped the industry will be in a stalemate.

3. **This round may not be the last round.** As all investors know the later stage round may not be the last round, especially when you consider many of the dynamics previously mentioned. Over the last eight years we have seen the amount of cash required for many of the VC-backed start-ups increase significantly; the time it takes to achieve an exit has almost doubled so that it's now seven to nine years; and, as noted, exit values are constrained. This reality is why we have seen an increase in the amount of money raised in rounds C and later, but not at the same rate as earlier rounds. Therefore, a conservative approach is to provide "just enough capital," and to reserve capital for future rounds to buy more time in light of an unpredictable outcome. This trend was already apparent before the recent events on Wall Street, and in light of that added uncertainty the issue of capital reserves to support company investments is of critical concern for many venture funds and their investments.

**Recent data shows that 73% of the companies that went public between 2006 and 2008 are trading below their IPO price.**

## BEWARE THE B ROUND

The trends for Series B rounds are less clear. As you can see from Exhibit 2, the data is almost erratic, and one might conclude that if you have not already been part of the Series A syndicate, the Series B round offers a great deal of risk. In many cases the valuations are significantly higher than in the Series A round, but the risks, predictability of outcome, and accomplishments are not much different than they were at Series A, so the higher valuation is not necessarily warranted. According to Exhibit 2, overall valuations have remained fairly constant up until 2006. The amount of capital raised, however, has fluctuated wildly. One year it's up and the next it's down.

As investors we're trying to understand the true capital requirements and needs of the Series B companies. The companies are still relatively young with many hurdles still to come and investors and CEOs have neither figured out the true amount of capital required nor the time to exit for these B round financings. The market dynamics of IPOs and M&A feed back into considerations of B round capital commitments, and the overall effect is an erratic pattern of B round investing.

## EXITS ARE CONSTRAINED. WHY?

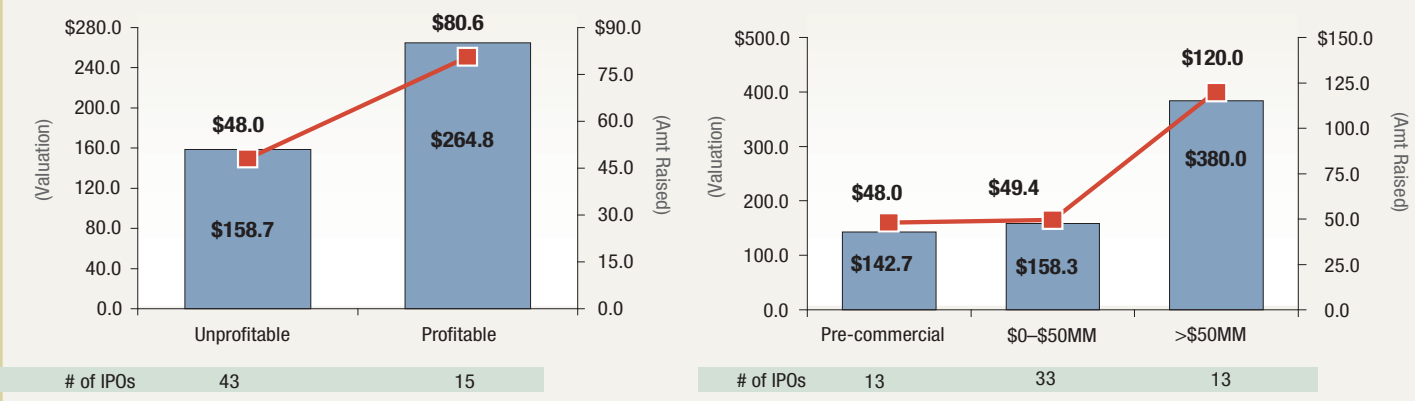
VC-backed exits for both IPOs and M&A have been constrained over the past years, as indicated in Exhibits 3 and 4. IPOs have been on a decline since 2000 and finally hit bottom in 2003 when there wasn't a single IPO. The overriding question is "Why?" One would be tempted to conclude that it has to do with a lower quality of companies leading into the trough period, but that's not the case. The companies that exited between 2000 and 2002 were quite differentiated with solid business models: companies like Kyphon Inc. in spine (since acquired by **Medtronic Inc.**); **CTI Molecular Imaging Inc.** in biomarkers (now part of **Siemens AG**); orthopedics company **Wright Medical Group Inc.**, **Align Technology Inc.** in the self-pay market for orthodonture, **Oratec Interventions Inc.** (acquired by **Smith & Nephew PLC**) and surgical robotics company **Intuitive Surgical Inc.** The nuclear winter of 2003 was due to much deeper overall concerns with the economics of health care.

Many of the exits that we saw after 2003, on the other hand, were not necessarily of the same caliber. We have seen the exits of an ever increasing number of companies with very modest ini-

Exhibit 4

**Medtech IPOs 2004 - 2008**

($ Millions)

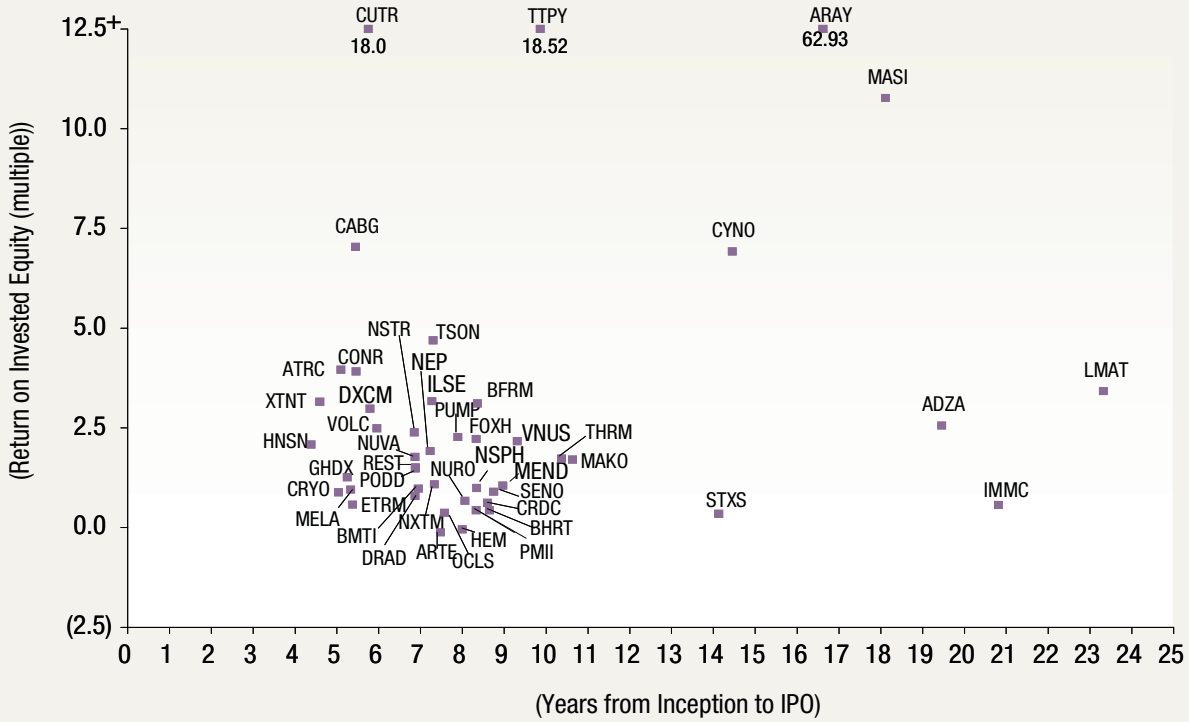



SOURCE: De Novo Ventures

Exhibit 5

## Medtech IPOs 2004-2008 YTD

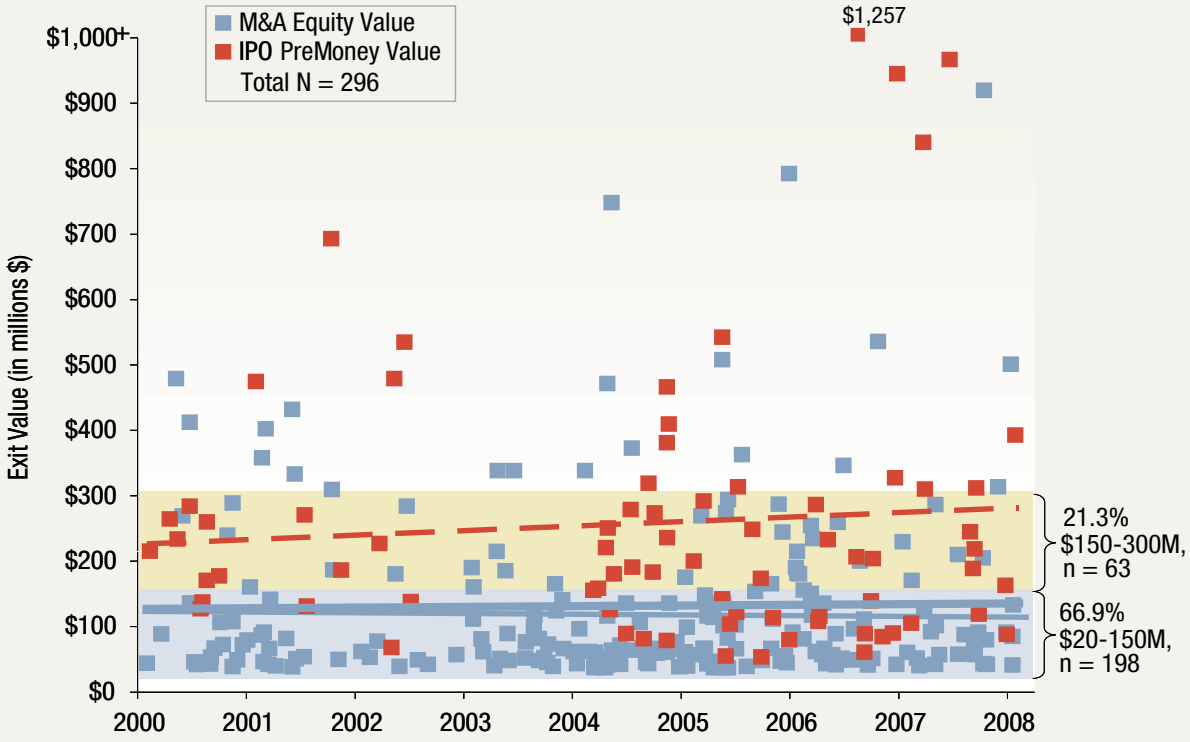



Note: Return on invested equity is calculated by dividing pre-money equity value at IPO by total equity raised pre-IPO (as a proxy of equity value at exit) minus one.

SOURCE: SEC filings, VentureSource and FactSet as of April 2, 2008

Exhibit 6

## VC-Backed Medtech Exits




SOURCE: De Novo Ventures

tial revenues and even some that were years from revenue due to pending FDA trials. These companies went public on the hope of accelerating revenues once positive clinical trial results were achieved. Some notable examples of these were **NxStage Medical Inc.** in the home dialysis market, **Restore Medical Inc.** (part of Medtronic in sleep apnea), Northstar Neuroscience Inc. in stroke, and Xtent Inc. with a drug-eluting stent. As already mentioned, several of them have seen their valuations plummet in the public markets recently.

Recent data shows that 73% of the companies that went public between 2006 and 2008 are trading below their IPO price, and the majority of those have experienced 30%-80% price declines. This drastic devaluation is analogous to the debacle in the mid-1990s when a number of companies hit the IPO market with questionable business models, and a comparison with the recent sub-prime debacle in the mortgage industry might be apt. The medtech industry must not lower its standards with respect to what constitutes an IPO-worthy company.

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Another interesting observation is that since 2004 the numbers of both IPOs and M&A deals have remained relatively constant. Now, however, 2008 does not appear to be trending positively as far as IPO-related exits are concerned. Exhibit 4 captures data from the IPO market between 2004 and 2008 and indicates median pre-money valuations and amounts raised. The data reveals the difficulty of venture capital investing today: there is a great risk for investors of subsequent rounds if the earlier rounds were not priced correctly.

As the chart indicates, the majority of venture-backed companies that pushed for an IPO were not profitable, and those companies that are profitable demonstrate a significantly higher valuation. It comes down to properly valuing VC-backed companies for their accomplishments and the opportunity they represent. For companies, the lesson is "cash is king;" that is, they need to focus on running capital-efficient companies. For VCs, the takeaway is that if they continue to push up the valuations of unprofitable companies with valuations that are not matched correctly to opportunities, the bubble will burst. Eventually all markets that get ahead of themselves suffer the consequences: valuations will drop as pre-money gets reset to more normal historical levels.

## EXITS HAVE BEEN SMALLER AND LATER

Medical device companies are now experiencing prolonged development periods compared to the past. As Exhibit 5 indicates, the average lead time to an exit is seven to nine years for companies in a large variety of clinical spaces, although there are some interesting outliers with respect to both time lines and return on equity invested. Northstar Neuroscience and **FoxHollow Technologies Inc.** (in peripheral vascular disease; part of **ev3 Inc.**) were the norm, going public after 8 years, while radiation oncology company **Accuray Inc.** waited 17 years. **MAKO Surgical Corp.**, with a minimally invasive platform for knee surgery was in the middle, with a 10 year journey to an exit. The data points to the importance of running capital-efficient companies because funds will need to carry them longer and further. This finding again underscores the importance of matching valuations of private companies to the opportunities, all within the context that it might take longer than anticipated to succeed.

As mentioned earlier, eight years of M&A data, displayed in Exhibit 6, indicate that 88% of all exits are $300 million and below. A closer look shows that transaction values are trending even lower than that; 67% of the exits are between $20-150 million and only 21% are between $150-$300 million.

Coupled with the length of time required to achieve an exit, the ever larger amounts of capital invested, and increased unpredictability on the regulatory and reimbursement fronts, these shrinking exit values have many VCs questioning whether the old system of venture investing in medical devices is broken. Indeed, things have really changed from the days when medical devices represented opportunities that were quick to prototype in which capital could be efficiently deployed to get a company to an early exit.

I would argue that the system is not broken, but that values need to be reset. There are still tremendous clinical opportunities that require better solutions given the advancing age of the world population. As new companies are created and technology is developed to improve the clinical outcomes—better therapies, improved diagnostics and better delivery of care—the investment in start-ups will remain robust and the exits in M&A and IPOs will rebound. But only if valuations within all stages of VC investing match the opportunity. Early stage teams need to be cognizant that the higher demands for proving clinical efficacy via clinical trials will continue, products without reimbursement won't necessarily gain investment dollars or achieve exits, and of course companies need to be mindful of capital efficiency.

Let's get back to basics. Let's build real companies with real products that create value. Only then will IPOs return with investors ready to buy on the market. In that world, exits in M&A will be richer.

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