

The Medical Device Milestone Map

Medtech start-ups from inception to exit: what are the key milestones and what are the ACTUAL timelines and costs?

A data-driven approach to figuring out the new reality of medical device venture capital investing.

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Medical device venture capital investing has changed significantly since the onset of the economic downturn.

Fundamental concepts and premises, such as capital intensity, company stage at exit, the degree of difficulty in obtaining regulatory approval and exit valuations, are undergoing major shifts.

These shifts are likely to have a considerable effect on the medical device venture capital ecosystem. This is what prompted the research that led to this article – a test of the generally-accepted rules-of-thumb used daily by investors and by those seeking funding vis-à-vis recent industry statistics.

Every professional in the medical device venture capital industry is familiar with the experience of having participated in an introductory meeting with the founder of an early stage medical device start-up.

The founder defines the unmet clinical need, quantifies the vast addressable market and proudly displays what looks like a piece of garden hose duct-taped to a few cables. While agreeing that the ‘prototype’ is a bit rough around the edges, he is certain that – with a little imagination – you can surely see how his invention will revolutionize the medical device industry.

All he needs is an investment of a few million dollars and two – no more than three – years to obtain regulatory approval. Then the company will be acquired for hundreds of millions of dollars, providing you – the investor – with an extraordinary return on your investment.

Granted, this is an exaggeration. But these widely-used ‘All I need...’ statements mask a host of underlying assumptions that drill down to the very core of venture capital investing in medical devices.

WHAT ARE WE ASSUMING?

There seem to be five major assumptions hiding in a typical ‘All I need...’ statement:

1. The key milestones that a company will have to achieve to bring its product to market.
2. The time it will take to achieve those milestones.
3. The stage of the company when it is acquired.
4. The amount of capital the company will burn prior to being acquired.
5. The expectations regarding company valuation at exit.

These assumptions determine the potential investment multiple and return-on-investment that a venture capital fund can expect from a portfolio company. They also influence the amount of reserves a fund earmarks for follow-on investments – a key component in a fund’s ability to continue supporting a company. But perhaps most importantly, these assumptions create an anchor of initial expectations – a ruler by which the fund determines the attractiveness of a proposed investment and measures a portfolio company’s performance throughout the lifetime of the investment.

1. THE MILESTONES

There is a core set of milestones that apply to the vast majority of medical device start-ups:

Development Stage Milestones:

- **Market requirements document (MRD)** is essentially the premise on which a start-up is based. The document describes the current state of the universe, highlighting not only what is there but also what is missing from it, setting the stage for formulating ‘the need’ that a start-up is responding to.

The MRD then outlines – in great detail – the product that will be developed. This includes product features, usability requirements, cost targets and the clinical and economic value propositions.

While technical in nature, the MRD is prepared from the end-market perspective, which makes this an important business document as well.

- **Product requirements document (PRD)** is the translation of the requirements outlined in the MRD into the comprehensive set of technical specifications and performance thresholds required of the materials, components, sub-assemblies and the finished product.

An important section of the PRD is risk assessment, a process that includes:

- the identification of design, use and process risks;
- an assessment of the risks' frequency of occurrence and the severity of their outcomes;
- a review of the steps taken to mitigate those risks.

Companies developing medical devices the use of which exposes patients to potential safety concerns will also be required to carry out a clinical risk-benefit analysis.

- **Design reviews** will take place throughout the product development process to evaluate the design against its requirements. In each review the design will be examined against different sets of criteria, including technical specifications, small- and large-scale manufacturing, risk assessment and usability.

Design reviews will occur at different levels: components and sub-assemblies will be reviewed first as stand-alone modules and then a second time as part of the fully-integrated finished product.

- **Engineering prototype** is the first tangible embodiment of the conceptual design. It is likely the product of several iterations of both the preliminary and detailed design processes.
- **Design freeze.** After the sub-assemblies and the engineering prototype have undergone verification (confirmation that the design output meets the design input requirements) the company will lock down its product design by declaring a design freeze.

The design freeze will trigger activation of design change controls, a set of procedures for the identification, documentation, verification, validation and approval of changes before their implementation.

Any changes made to function or features after a design freeze is declared will apply to the next-generation device.

- **Clinical unit.** Following design validation (confirmation that the requirements for a specific intended use can be fulfilled consistently) the company will have a clinical unit. This is the device with which the start-up will perform its pre-clinical, clinical and regulatory processes.

For this finished product the company will prepare a device master record, which will later serve as a critical first step in the transfer-to-production process.

- **Pre-clinical validation.** The company will use the clinical unit in an animal model, testing for safety and for initial efficacy (including comparison to predicate devices that have been cleared and are in use in medical practice).

Every development process incurs setbacks and delays:

- A component or sub-assembly may not perform according to specifications.
- Design constraints may limit the ability to incorporate the full set of features outlined in the MRD.
- The results of a pre-clinical trial may require varying degrees of product redesign.

Yet development plans rarely factor sufficient delays into their timelines or funding requirements.

Many companies these days are completing large financing rounds that are broken down into milestone-based tranches. This financing structure provides a start-up with the security of knowing it is sufficiently funded for the foreseeable future, freeing management to focus its attention on developing the product and building the company. But for this to succeed, the company has to achieve its milestones within the timelines and budgets to which it has committed.

Now, think of a 3-month delay in the development process at a time when a start-up is burning \$400k per month. The company will be \$1.2m short to reach the milestone that triggers the next cash infusion. Whether that milestone was part of a tranching financing round or whether it was supposed to trigger a new external financing round – there is now a \$1.2m funding gap that needs to be filled.

Medical device start-ups literally cannot afford to assume (and create expectations for) a 'hiccup-free' development process. They need to proactively plan for setbacks and delays in sub-processes that entail a higher degree of risk.

Clinical & Regulatory Milestones:

- **First in human** is the first time an investigational device is used on human subjects. Assuming the procedure's safety and efficacy end-points are met, a few additional procedures may be performed to create an initial base of clinical experience in the use of the product.

Exhibit 1A

Pre-Clinical Product Development Milestones

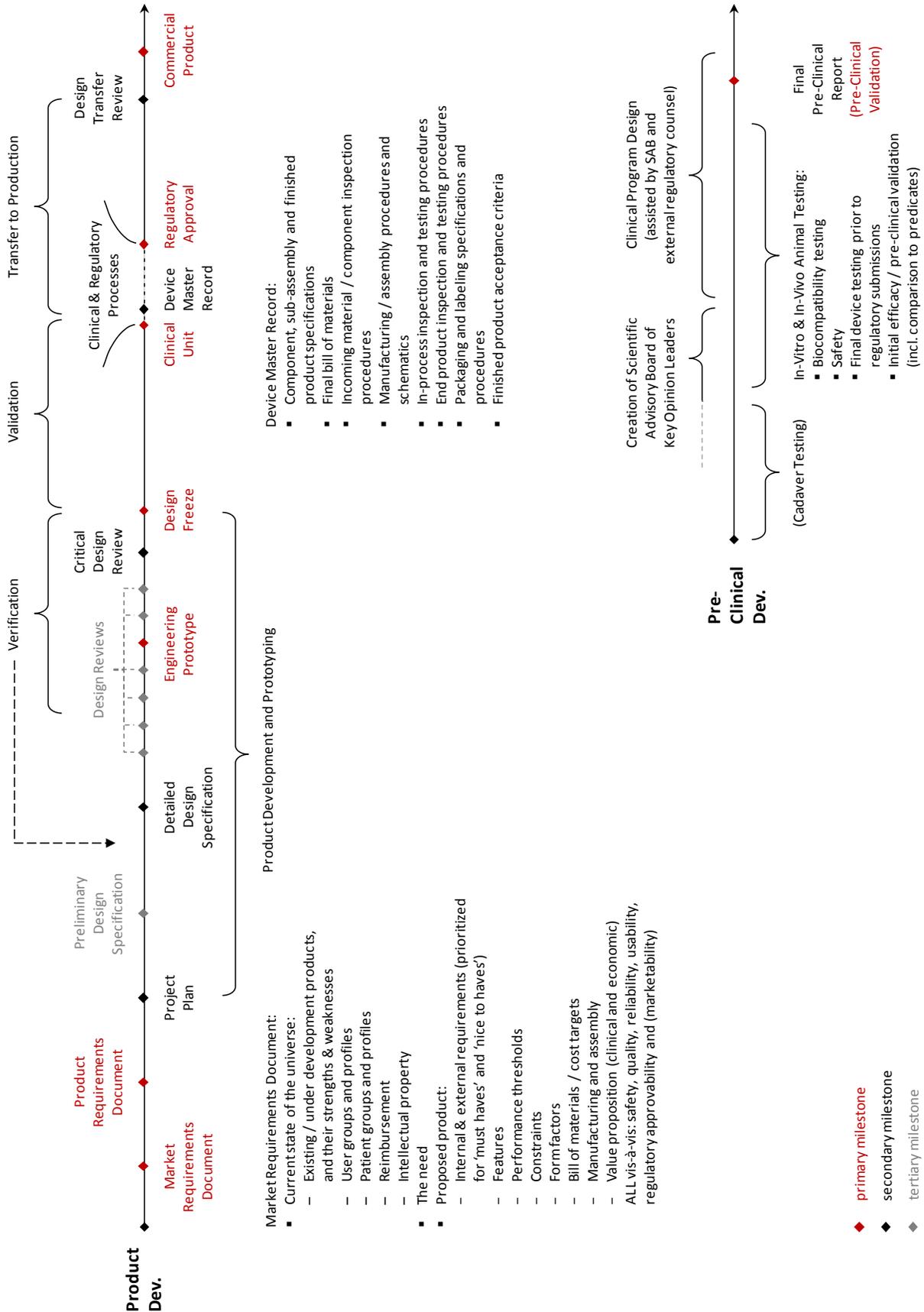
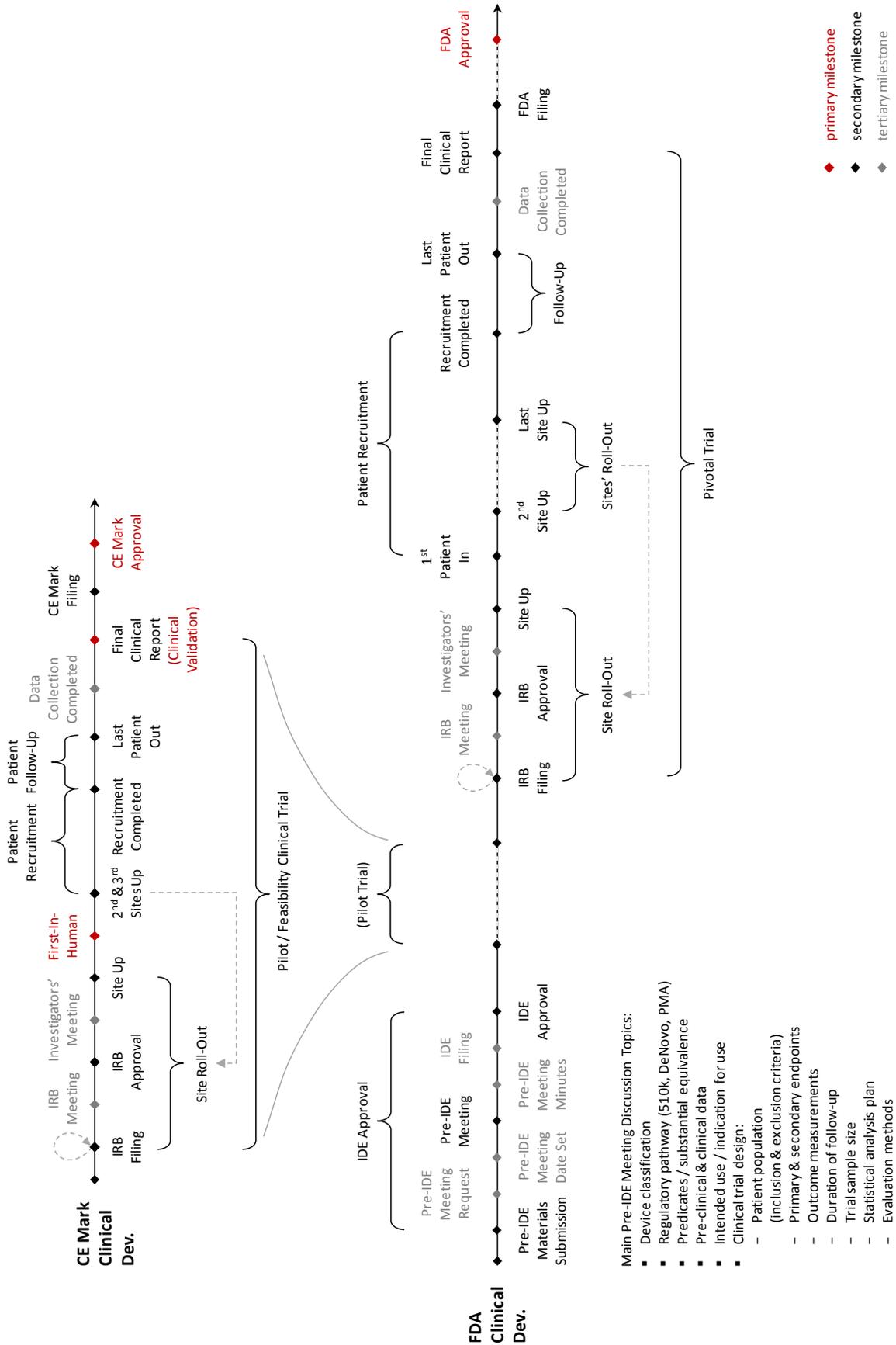


Exhibit 1B

Clinical and Regulatory Milestones



Main Pre-IDE Meeting Discussion Topics:

- Device classification
- Regulatory pathway (510k, DeNovo, PMA)
- Predicates / substantial equivalence
- Pre-clinical & clinical data
- Intended use / indication for use
- Clinical trial design:
 - Patient population (inclusion & exclusion criteria)
 - Primary & secondary endpoints
 - Outcome measurements
 - Duration of follow-up
 - Trial sample size
 - Statistical analysis plan
 - Evaluation methods

- **Clinical validation** is obtained after a device has been used successfully in a pilot trial in which all clinical end-points were achieved. The sample size of a pilot trial is usually equal to the minimal number of patients necessary for the results to hold statistical significance.
- **CE Mark** is the regulatory approval that enables a company to sell its device in European countries. Obtaining the CE Mark means that the company is compliant with the European medical device directive that applies to its device.
- **510(k) clearance / DeNovo approval / PMA approval** are the regulatory routes that enable a medical device company to commence commercial sales in the U.S.

510(k) clearance is the route in which the FDA applies the least amount of controls, making it the shortest and least demanding pathway.

The core principal underlying the 510(k) is proving that a device is substantially equivalent to a predicate device (or multiple devices) that has been cleared previously.

PMA approval is the process intended for high-risk devices. It is the most rigorous of the device pathways,

subject to the strictest controls and requiring significant tiered clinical development that encompasses hundreds of patients and spans a prolonged period of time.

As with the development process, medtech start-ups should expect delays in their clinical and regulatory processes:

- The FDA may designate a device to a PMA pathway, whereas the company was expecting a 510(k).
- The company may incur delays in obtaining IDE approval. (See Sidebar: The Kips Bay Medical IDE timeline).
- The FDA may require a trial sample size that is larger than a company originally anticipated.
- A company may not roll-out sites or recruit patients to participate in its clinical trial as quickly as planned.
- The occurrence of a major adverse event may require suspension of patient recruitment until the company can show that the adverse event was not caused by its device.

Medical device companies need to identify sub-processes in their clinical and regulatory development plans that are at risk to incur delays and build ‘cushions’ into their timelines and fundraising plans.

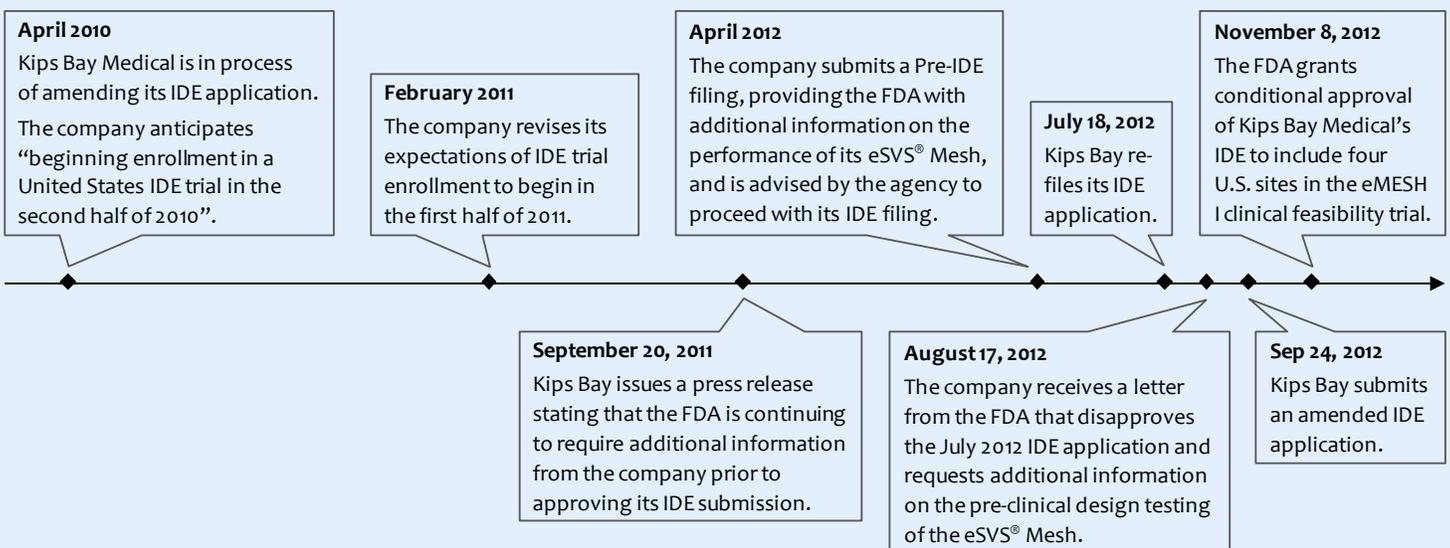
The Kips Bay Medical IDE Timeline

Founded in May 2007, Kips Bay Medical is developing the eSVS® Mesh, an extravascular knitted nitinol prosthesis designed to maintain the patency of autologous saphenous vein grafts in patients undergoing coronary artery bypass graft (CABG) surgery.

The device obtained CE Mark in May 2010 based upon the safety and effectiveness clinical data generated by a 90-

patient multi-center clinical trial conducted outside the U.S.

The company encountered a delay of more than 2½ years in obtaining IDE approval (see timeline below). Even then, the approval was conditional, requiring staged enrollment and allowing only a handful of patients to be implanted in the first stage. During this 2½ year period the company’s operating cash burn totaled \$15.1m, an average of \$502k per month.



Sources: Kips Bay Medical SEC filings and press releases

Commercialization Milestones:

- **First U.S. and OUS purchase orders.** Transitioning from a development stage to a commercial stage company is a landmark event for a start-up, signaling an entirely new level of maturity and capability.

The first sale under CE Mark and the first sale under FDA clearance is each a milestone unto itself. However, the first U.S. sale is held in higher regard because this is the primary commercial market and because the FDA regulatory process is considered more rigorous than that of regulatory bodies in other countries.

- **Cash flow breakeven** is the day a medical device company becomes self-sufficient as it no longer depends on its investors for future cash infusions.

Until companies reach relatively high revenue levels (usually triple-digit millions) they are likely to swing back and forth between cash flow positive and negative, as periods of accelerated growth require investments in

infrastructure to keep ahead of the expansion.

This milestone is usually beyond the realm of venture-backed medtech companies. By this stage the company is likely to have been acquired or has carried out an IPO.

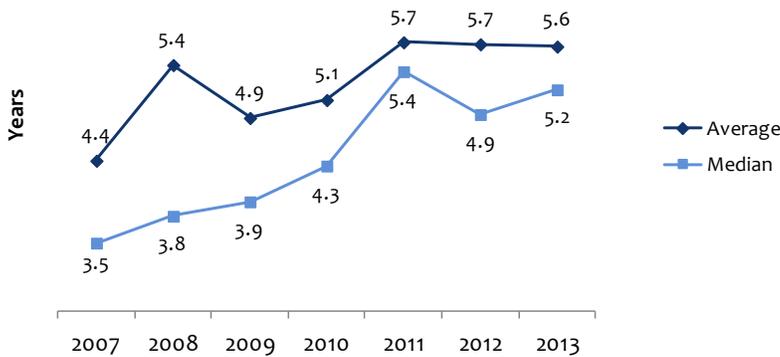
Milestone maps for the development, clinical and regulatory stages are detailed in Exhibits 1A and 1B. These maps contain a comprehensive set of milestones shared by the majority of medical device start-ups.

Primary milestones are often inflection points that enable a medical device start-up not only to raise additional capital, but to do so at a higher valuation than that of the previous financing round.

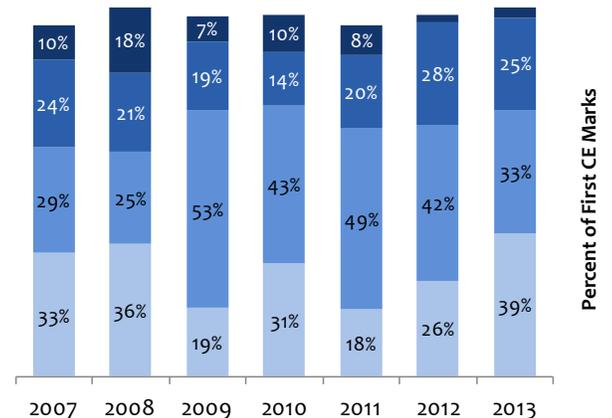
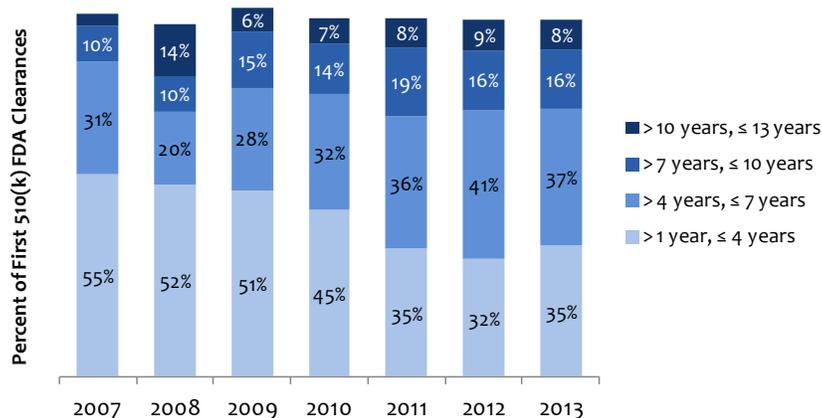
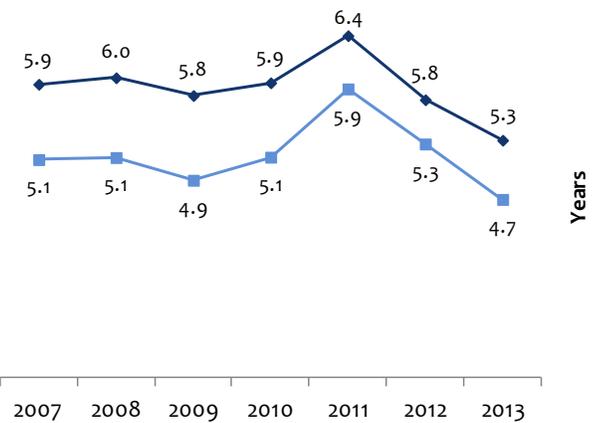
The development, pre-clinical, and clinical processes can and will vary from one medical device start-up to the next, depending on the type of product, the company's go-to-market strategy and its ability to raise capital. Consequently, start-ups should tailor this 'master list' of milestones to their own unique set of circumstances.

Exhibit 2

Time to First 510(k) Clearance*
(excl. outliers of <1 year and >16 years)
N=491, of which are 92% are Class II devices



Time to First CE Mark* for '510(k)' Companies
(excl. outliers of <1 year and >16 years)
N=288



* Time to first regulatory approval is measured as time elapsed from company inception to the first 510(k) clearance and first CE Mark a company obtains.

2. TIME TO REGULATORY APPROVAL

Historically, U.S. start-ups were focused on the domestic market as their primary commercialization target, making FDA clearance the primary objective. Obtaining CE Mark was a secondary milestone, pursued only after a start-up had obtained FDA clearance. In the last several years, the average time from company inception to first 510(k) was 5.2 years and the average time to first CE Mark was 5.9 years.

However, 510(k) clearance is not obtained as quickly or as easily these days as it was in the past: in the previous decade, the median period for a medtech start-up to achieve its first premarket clearance was 4.1 years (from inception). In the last three years this timeline increased by 12 months – to 5.1 years. (See Exhibit 2). This additional year creates a multi-billion dollar burden on medical device start-ups and life-science venture capital firms.

The increase in time to FDA clearance is the result of two main causes:

- **Lengthening of the product development process.** Medical devices under development are becoming more and more complex, as evidenced by increasingly long 510(k) filings. (See Exhibit 3).

The prolonged product development process delays the start of the clinical and regulatory processes, which results in a delay in FDA clearance.

- **Lengthening of the regulatory process.** In recent years the U.S. regulatory process has suffered from lack of consistency and predictability, resulting in a prolonged timeline to FDA clearance or approval.

Two measurable manifestations show:

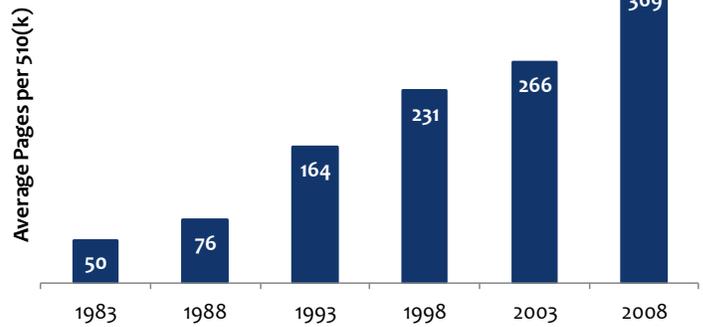
- A considerable increase in the FDA’s review time of premarket submissions. During 2000-2006 the average time to decision for a 510(k) was 14 weeks. By 2010 it had increased by 60% to 22 weeks. (See Exhibit 4).
- A 100% increase in the percent of 510(k)s in which the FDA requests additional information on the first review cycle. (See Exhibit 5).

As a result of the increase in the time and effort required to obtain FDA clearance, some medical device start-ups have begun shifting their strategy – postponing the U.S. regulatory process in favor of obtaining CE Mark earlier.

This change in strategy allows for earlier commercialization (an increasingly important milestone with venture capital funds) and is instrumental in building a strong body of clinical evidence – one that can usually be leveraged later on to support the U.S. regulatory process.

Exhibit 3

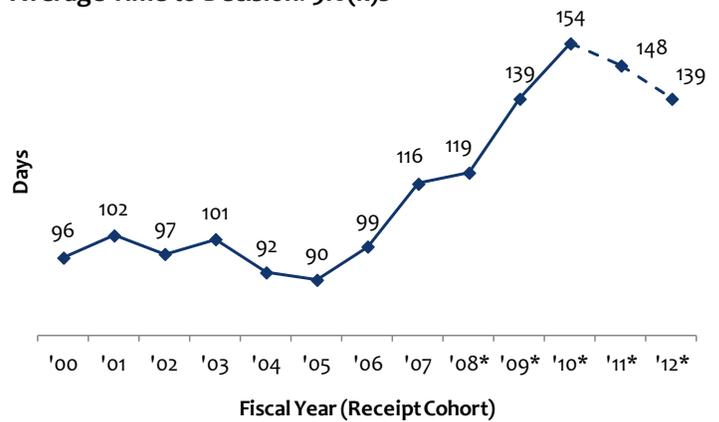
Average Pages per 510(k)



Source: CDRH Preliminary Internal Evaluations – Volume I, August 2010

Exhibit 4

Average Time to Decision: 510(k)s

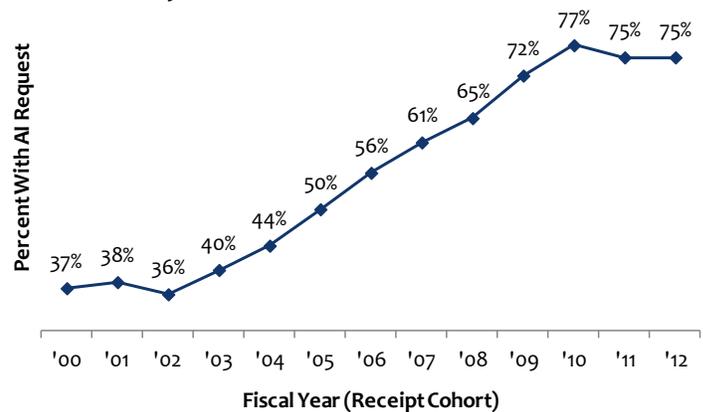


* Cohorts still open; FY 2011 cohort is 99.8% closed and FY 2012 cohort is 97.6% closed - average times will increase

Sources: FDA’s Medical Device Program 2013: Looking Back and Looking Ahead, May 2013. CDRH Update, IMDMC Annual Meeting, November 2013.

Exhibit 5

Percent of 510(k)s with Additional Information Request on 1st FDA Review Cycle



Source: FDA’s Medical Device Program 2013: Looking Back and Looking Ahead, May 2013

3. COMPANY STAGE AT EXIT

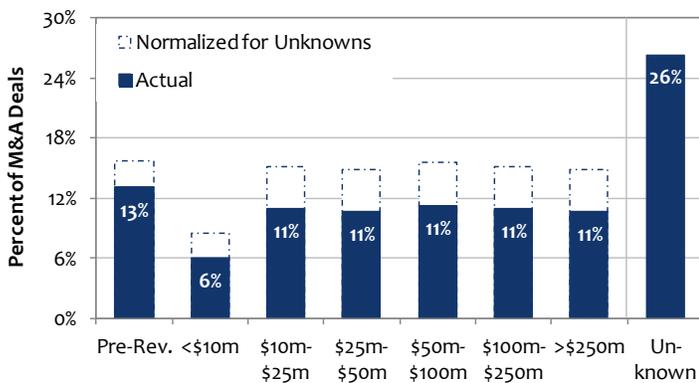
FDA clearance has been perceived as the primary milestone to trigger an acquisition. To this day, many business plans end with the regulatory approval milestone – disregarding the time, infrastructure and funding required to carry out even a limited commercial launch.

The data do not support such an assertion: less than 1 in 6 medtech acquisitions and only 1 in 3 medtech start-up acquisitions are performed while a company is still pre-revenue. (See Exhibit 6).

Exhibit 6

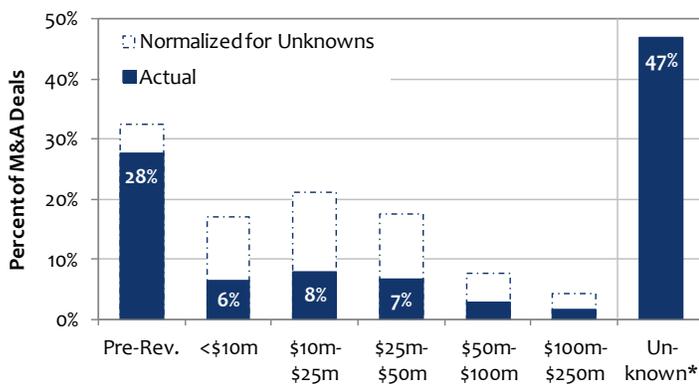
Company Revenues at Exit: All MedTech Acquisitions

(For Deals >\$10m Taking Place since Jan 1, 2000. N=711)



Company Revenues at Exit: MedTech Start-Up Acquisitions

(For Deals >\$10m Taking Place since Jan 1, 2000. N=312)



* Most of which are commercial-stage start-ups.

Selling a start-up at the pre-revenue stage is sometimes referred to as ‘selling the dream’ – when there is very little clinical evidence, when physicians’ willingness to adopt has not been established and when the economic value proposition is still unproven in practice.

At <\$10m annual revenues, the company is making some commercial headway. Potential acquirers are usually familiar with the company by this time but they tend to ‘wait and see’ if the ramp-up is successful before making a purchase offer.

The \$10m-\$25m range is where medtech start-ups historically sought funding from public markets. However VC funds are increasingly supporting companies into and beyond this revenue bracket, as evidenced by an increase in large financing rounds performed by commercial stage start-ups looking to expand their commercial efforts:

- In October 2013, **LensAR** raised \$87m to support continued commercialization of its laser cataract surgery system throughout the major medical markets worldwide.
- In July 2013, **Tria Beauty** raised \$45.5m in equity and a structured debt facility to launch multiple new devices, expand distribution and accelerate its growth.
- Following a \$150m equity round in 2011, **Valeritas** closed a \$100m structured debt financing in June 2013 to support the commercialization of its V-Go[®] insulin delivery device.

This extended period of venture-backed ownership and the increase in total amount invested may require adjustments from start-ups and venture capital funds alike:

- Medical device start-ups should extend their business and fundraising plans to include initial commercialization efforts. This will result in a more realistic set of expectations and create a better alignment of interests between companies and their investors.
- Venture capital funds may need to adjust their business model by:
 - Investing in fewer companies per size of fund and allocating greater reserves per company for follow-on investments. For example, a \$250m fund that had originally targeted a portfolio of 20 start-ups may reduce that number to 16 companies.
 - Changing their portfolio mix - preferring mid-to-late stage deals over early stage deals, as the former have a somewhat lower risk profile, require a shorter time to mature and need less money to reach exit.
 - Reevaluating their target return-on-investment and investment multiples – two fundamental parameters by which the venture capital industry is measured.

2+3= TIME TO EXIT

Only 25% of acquisitions in the medtech industry occur within 6 years of a company’s inception. (See Exhibit 7).

There is likely a high degree of overlap between these ‘early acquisition’ companies and the ‘pre-revenue’ companies in Exhibit 6 – especially in light of the time to first 510(k) clearance or CE Mark being 5-6 years.

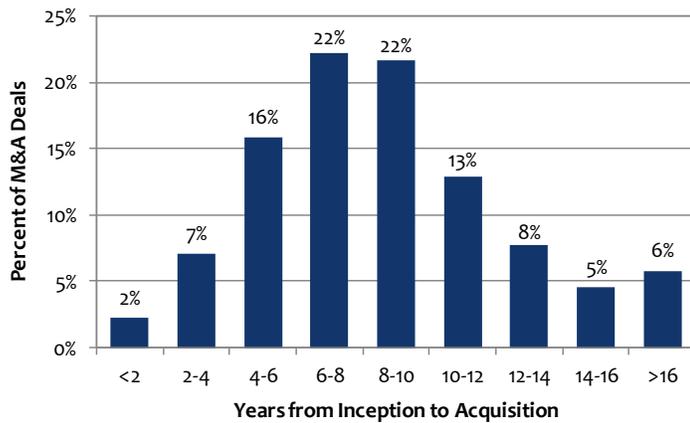
Clearly, an early-stage (pre-revenue) or quick (≤ 6 years) exit is the exception – not the rule.

A medical device start-up creating expectations (internally, and with its investors) for such an exit needs to have compelling arguments and evidence from comparable companies supporting the validity of such a claim.

Exhibit 7

Time to Exit: From Start-Up Inception to Acquisition

(For Deals >\$10m Taking Place since Jan 1, 2000. N=310)



This time-to-exit distribution tightly coincides with the typical life cycle of a venture capital fund:

- The first six years of a fund are the active investment period, in which the fund makes initial investments and builds out its portfolio of start-ups.
- The next four years of a fund’s 10-year life cycle are dedicated to follow-on investments (portfolio maintenance) and to realization of investments.
- Many funds will be able to obtain two 1-year extensions, prolonging the life of the fund to 12 years. This period is almost exclusively focused on realization of investments.

There is usually a strong correlation between a fund’s stage and the stage of its new investments – newly formed funds tend to invest in earlier-stage companies and funds nearing the end of their active investment period usually invest in later-stage companies.

A fund that is nearing the end of its active investment period is likely to have earmarked the majority of its reserves to its existing portfolio companies. Moreover, a fund at this stage will not be able to spend six years building up a start-up as it will be under pressure to begin realizing its investments and making distributions to its limited partners.

When raising capital a medical device start-up needs to be cognizant of the vintage of the funds it is pitching. There needs to be an open discussion regarding a potential investor’s ability to continue supporting the company and making follow-on investments beyond the current round.

4. CASH BURN

The amount of capital a start-up will need until it is acquired is one of the (if not THE) most defining pieces of information for the company and its investors. It is also the most difficult to estimate with any acceptable degree of accuracy.

Funding requirements will vary greatly depending on the type and complexity of the device, scope of clinical development, and company stage at acquisition.

Initially, a start-up’s activities will be focused on product development activities with a skeleton staff. As the company matures, its activities will broaden to include clinical trials, regulatory processes, manufacturing and, ultimately, sales.

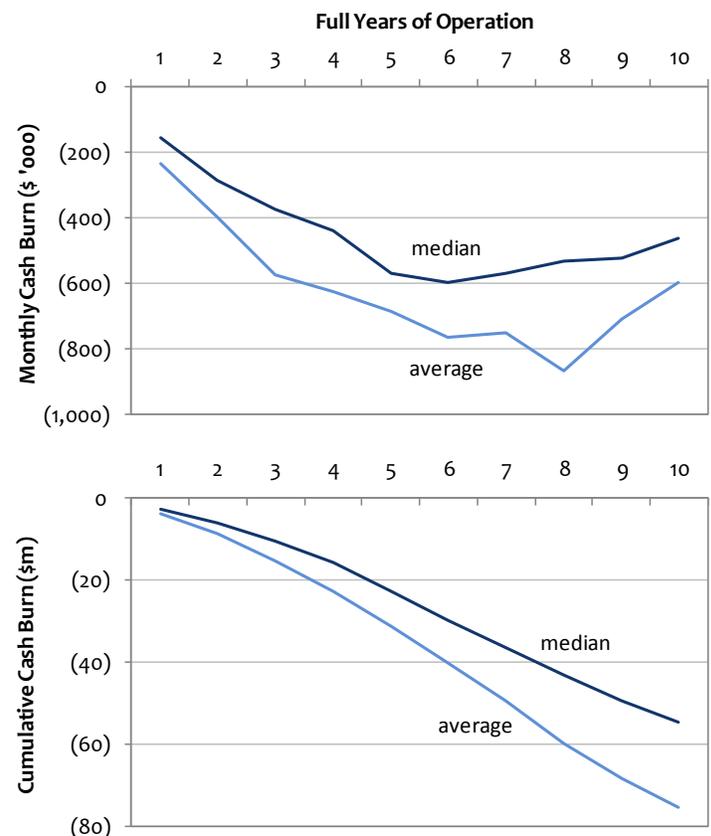
Hand in hand with the expansion in activities, the company will build out its team to include additional positions that it did not need to staff from day one. These include a quality assurance position, a clinical and regulatory team, a full-time CFO and eventually a VP Sales and sales representatives.

As such, a start-up’s cash burn will increase dramatically over time – from as little as \$50k a month in its first year to \$1.0m (or more) per month when it is carrying out a clinical trial or initiating commercial launch of its product. (See Exhibit 8).

Exhibit 8

Cash Burn in the First Decade of a Medical Device Start-Up

(N=1,196 company years between 1990 and 2012)



As long as the cash burn is within the approved budget and enables the company to achieve its goals – all is well. It is when the cash burn does not yield the expected outcomes that assumptions and plans need to be reevaluated.

The average and median time-to-exit for medical device start-ups is 8.8 years and 8.2 years, respectively. By this time, a medical device company may have burned between \$45m and \$65m. (See Exhibit 8).

The \$100m Club

Examples of companies that have been acquired:

- **Acclarant** raised approximately \$103m prior to being acquired by Ethicon for \$785m in December 2009. At the time of acquisition the company had revenues of \$22m.
- **OptiMedica** raised \$102m in venture capital prior to being acquired by Abbott in July 2013 for \$250m upfront plus \$150m in milestone payments. At acquisition OptiMedica had FDA clearance and CE Mark for close to 7 years - each.
- **Salient Surgical** raised \$129m in venture capital prior to being acquired by Medtronic for \$525m in July 2011. At acquisition the company had annual revenues of \$100m.
- **Zonare Medical Systems** raised \$173m in venture capital prior to being acquired by Mindray Medical for \$102m in June 2013. Zonare has been selling commercially for several years and had annual revenues of \$64m at exit.

There are at least 45 active (yet-to-be-exited) medical device start-ups that have raised more than \$100m in venture capital. Some examples are detailed in the following table:

Company	Medical Field	Founded	Years Since Inception	VC Raised to Date	First 510(k) Clearance	Years Since First 510(k)	Years Since First CE Mark
Aptus Endosystems	Peripheral vascular	6/2002	11.4	\$100m	11/2011	2.0	2.5
ConforMIS	Orthopedics	3/2004	9.7	\$182m	3/2005	8.7	5.9
EndoGastric Solutions	Gastroenterology	4/2003	10.7	\$155m	3/2007	6.7	unknown
InfraReDx	Cardiovascular	11/1999	14.0	\$131m	6/2006	7.4	2.6
Mevion Medical Systems	Oncology	2/2004	9.8	\$126m	6/2012	1.5	1.7
NeuroNetics	Neurology	4/2003	10.7	\$128m	10/2008	5.2	1.5
OmniGuide	Surgery	5/2000	13.5	\$111m	5/2005	8.6	6.4
SuperSonic Imagine	Imaging	4/2005	8.7	\$128m	8/2009	4.3	5.4
TherOx	Cardiology	6/1994	19.5	\$113m	11/1997	16.1	12.2

Sources: SEC filings, company press releases and the FDA searchable 510(k) database

These companies, which have developed devices that target all the major medical fields, have been active for more than 10 years, have raised an average of \$130m each and have had U.S. and European regulatory clearances for numerous years.

The vast majority, if not all, of these start-ups have commenced commercial operations – in the U.S. as well as abroad.

Companies that exit sooner or those that are developing medical devices lower in complexity and in risk profile are likely to need less funding. However, more and more start-ups are breaking the \$100m threshold in their cumulative venture capital fundraising. (See Sidebar: The \$100m Club).

Medical device companies requiring such large amounts of capital will need to build funding syndicates. These syndicates can range from three to six or more venture capital funds.

Examples of companies that have gone public:

- **GI Dynamics** (ASX:GID) raised \$114m in venture capital prior to its September 2011 IPO. The company initiated commercial operations OUS shortly afterwards, but is not expected to obtain FDA approval prior to 2016.
- **Globus Medical** (NYSE:GMED) raised \$129m in venture capital prior to its August 2012 IPO, in which the company raised \$21m (and selling shareholders received \$84m). At IPO Globus Medical's TTM revenues totaled \$363m and its operating margin was 30%.
- **Tandem Diabetes Care** (NASDAQ:TNDM) raised \$142m in venture capital prior to its November 2013 IPO, which took place one year after the commercial launch of the company's t:slim insulin delivery system. Tandem raised \$138m in its IPO at a pre-money valuation of \$200m.

A funding syndicate will afford a medtech start-up access to a larger pool of money. In parallel, each of the syndicate participants will have a sense of security from sharing the risk and from knowing that there are enough resources in aggregate to support the company until it is acquired.

However, there can be drawbacks to funding syndicates: an earlier vintage fund that is under pressure to begin realizing its investments, or a fund that has depleted its reserves and is unable to make additional investments, may lobby for an earlier exit at a lower valuation while a fellow investor may want to continue funding the company and hold out for that higher exit valuation.

A medical device company funded by a syndicate of investors needs to be aware of these potential conflicts of interest and must actively manage them when they arise.

5. EXIT VALUATIONS

Valuation of a pre-revenue or early-revenue company is more art than science. However, the qualitative factors influencing the valuation are fairly clear:

- **Factors specific to the target company** include uniqueness of the device and its underlying technology, the extent of the product's disruption to current medical practice, strength of the intellectual property protecting the device and the clinical body of evidence supporting the safety and efficacy of the device.
- **External factors** encompass the addressable market size and its growth prospects, reimbursement coverage and the landscape of competitive products – those currently in use as well as those under development.
- **Factors specific to the acquirer.** There are three main groups of considerations affecting the acquirer's willingness to pay:
 - **Economic.** The revenues and profits that can be generated from the acquired product by leveraging the acquirer's existing sales and support infrastructure.
 - **Strategic.** The acquired device may fill a gap in the acquirer's product portfolio, may enable the acquirer to leapfrog its competitors and increase its market share, or may serve as the acquirer's entrance into a new market altogether.

From the defensive prospective, the acquirer may be better off purchasing a company over letting one of its competitors buy it.

Also, the potential acquirer faces the 'build vs. buy' dilemma: how much effort, time and money will it take for the acquirer to internally develop the device it is

purchasing? And how will the decision effect its positioning in the market?

- **Financial.** The accumulated (and future) losses of a start-up and the goodwill or intangible assets associated with the acquisition may provide the acquirer with quantifiable tax benefits.

When gearing up for an exit process, medical device start-ups usually focus on preparing extensive documentation and quantitative models to best support the company-internal and business environment related factors.

Paying greater attention to- and addressing the acquirer-specific considerations will sharpen and enhance the value proposition underlying the proposed acquisition, potentially yielding a higher exit valuation.

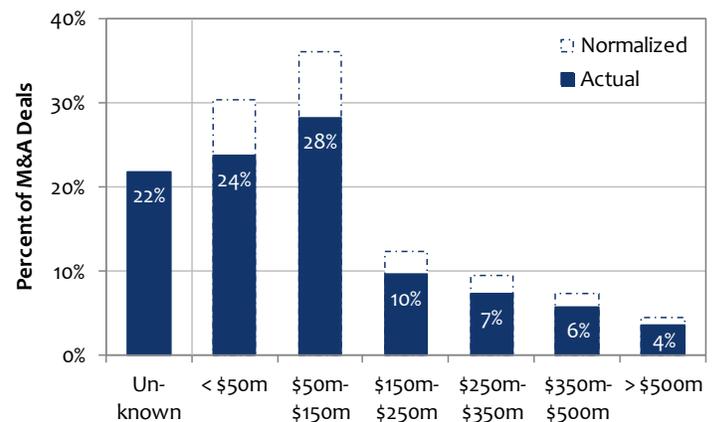
The exit valuation 'sweet spot' in medical device venture capital investing is the \$150m-\$350m range. But this range accounts for only 17% of all medtech start-up acquisitions (22% normalized for 'unknowns'). (See Exhibit 9).

As with time-to-exit, entrepreneurs pitching to potential investors visions of high exit valuations need to have convincing supporting data why their company is going to exit in the top deciles of all medical device start-ups.

Exhibit 9

MedTech Start-Up Exit Valuation (\$m)

(For Deals >\$10m Taking Place since Jan 1, 2000. N=312)



Exits taking place in the \$50m-\$100m valuation range account for 19% of medtech start-up M&A deals (24% normalized for 'unknowns'). This valuation range is at the low end of the target exit valuation for venture-backed medtech companies, as it is likely unable to support the venture capital funds' target investment multiples or target return-on-investment.

However, the culmination of a venture capital fund's performance is measured at the portfolio level rather than per company.

Each portfolio will have a small number of investments that yield exceptional returns, some that yield mediocre outcomes and some investments that are written down in their entirety. This is the very nature of the venture capital industry.

CONCLUSIONS

It seems that many of the rules-of-thumb commonly applied to medical device venture capital investing in the past are no longer accurate:

- Regulatory approval is not necessarily the ‘holy grail’ of milestones. The majority ($\frac{3}{5}$) of start-ups are acquired post-commercialization as opposed to pre-revenue.
- Only a minority ($\frac{1}{4}$) of medtech start-up acquisitions will take place within six years of a start-up’s inception.
- Many medtech start-ups will need more than \$25m to reach exit – some will require double that amount and a ‘select’ few will raise more than \$100m in venture capital prior to exit.
- Not every company will be acquired for \$250m (or more). Indeed, between 40% and 55% of start-up acquisitions are in the double-digit millions of dollars.

Start-ups basing their ‘all I need...’ statements on information generated by the type of data-driven approach presented in this article will be taken more seriously by potential investors.

Venture capital funds can apply this methodology as a decision-supporting tool in their due-diligence process, in setting the terms for initial as well as follow-on investments, in allocating reserves among portfolio companies and in building investment multiple and ROI models.

This type of analysis enables venture capital funds and medtech start-ups to frame their expectations more objectively and realistically – a process that is likely to result in an improved alignment between funds and their portfolio companies throughout the lifetime of the investment.

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The author is grateful to [Roger Carolin](#), [Gerri Henwood](#), [Gil Kaminski](#) and [Ofri Vaisman](#) for their insightful contributions to this article.