Market Entry And Exit By Biotech And Device Companies Funded By Venture Capital

Venture capital firms play some role in fostering new firm entry, but they play a more pronounced role in fostering successful firm exit.

by Lawton R. Burns, Michael G. Housman, and Charles A. Robinson

ABSTRACT: Start-up companies in the biotechnology and medical device sectors are important sources of health care innovation. This paper describes the role of venture capital in supporting these companies and charts the growth in venture capital financial support. The paper then uses longitudinal data to describe market entry and exit by these companies. Similar factors are associated with entry and exit in the two sectors. Entries and exits in one sector also appear to influence entry in the other. These findings have important implications for developing innovative technologies and ensuring competitive markets in the life sciences. [*Health Affairs* 28, no. 1 (2009): w76–w86 (published online 2 December 2008; 10.1377/hlthaff.28.1.w76)]

RESEARCHERS HAVE DOCUMENTED THE IMPORTANT ROLE played by new technology in rising health care costs, increasing clinical benefits, economic returns on innovation investment, new job growth and local economic development, and the U.S. global leadership position in life-science sectors that generates trade surpluses.[1] Where does this new technology come from? Decades of economic research documents that innovation is neither fostered by large firms nor prevalent in concentrated industries.[2] Instead, there is growing recognition of the important role played by small firms in technological innovation, particularly in the biotechnology and medical device sectors. This recognition has grown in the past decade, particularly as the research and development (R&D) pipeline of large pharmaceutical firms has dried up and been supplemented by the pipelines of smaller biotechnology firms.

But where do these small firms that are the purveyors of innovation come from? How are these new entrants financed? What are their market entry and exit patterns, and what factors are associated with these patterns over time? Such ques-

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DOI 10.1377/hlthaff.28.1.w76

tions are important topics for industrial organization economics (which studies the conditions necessary for competitive markets), organizational ecology (which studies the founding and failure processes of firms), and policymakers who value the benefits conferred by this new technology.

This paper describes the sources of financing for new firms in the biotechnology and medical device sectors, the role of venture capital funding, the importance of market entry and exit processes and their correlates, and the historical patterns of market entry and exit by biotech and device firms.

Public Policy Importance Of Firms' Entry And Exit

We define *entry* as the date of the firm's founding. We define *exit* as the unsuccessful dissolution of that company (via bankruptcy), the successful dissolution of that company (via acquisition by another firm), or its successful transition into the public markets (via an initial public offering, or IPO).[3] Organization researchers label entry and exit rates as "demographic processes" because of their resemblance to birth and death rates in a population of firms. These rates tend to be positively correlated across industries; the likelihood of one rate increases the likelihood of the other.

Entry and exit rates are important for several public policy reasons. First, they affect competition in product markets: the threat of new entry and the possibility of exit spur incumbent firms to compete more vigorously, which may have beneficial cost and quality benefits for buyers. The presence of competitive markets has antitrust implications, particularly in R&D-intensive industries where intellectual property (IP) laws help incumbent firms to protect their market position.

Second, entry and exit further contribute to market competitiveness by increasing the number and diversity of firms. Third, entry rates constitute one measure of entrepreneurship: new entrants increasingly provide the new product pipeline in both the biotechnology and medical device sectors. Conversely, the rates of different types of exit suggest the risks and rewards of entrepreneurship. This balance is important because entrepreneurial firms often serve as a source of technological learning and experimentation at the firm level, and as a source of evolution and change at the industry level. Larger incumbent firms are more conservative and less likely to make their own technology obsolete than other firms. They have increasingly acquired smaller new entrants to fuel their growth, thereby combining the innovative technology of the new entrant with the established marketing and distribution channels of the incumbent.

Public Policy Importance Of Venture Capital

Venture capital firms play a major role in financing the start-up of new firms, especially in the biotech and medical device sectors. Venture capital–backed firms constitute 40 percent of employment in biotechnology and 83 percent of employment in the medical devices industry.[4] In addition to this direct effect, venture

capital–funded start-ups have a job-multiplier effect on other economic sectors and contribute to the health of several state economies by virtue of their impact on jobs, sales revenues, and economic growth.[5] In terms of patient care, venture capital–backed firms have pioneered several breakthrough technologies for the diagnosis and treatment of cancer (Herceptin, Avastin, Erbitux) and coronary heart disease (implantable cardioverter defibrillators, angioplasty).

Funding Sources For Start-Up Companies

To execute a successful business model in biotechnology or medical devices requires substantial time and capital. Industry data show that R&D spending as a percentage of sales is relatively high in both pharmaceuticals (13 percent) and medical devices (11–12 percent), and especially high in biotechnology (23+ percent), compared to telecommunications, automobiles, electronics, and aerospace.[6] Entrepreneurs and chief executive officers (CEOs) of these companies rank raising capital to fund their businesses as a top priority.

Biotech and device start-ups are privately financed in various ways before they go public via IPOs and follow-on public offerings.[7] We focus here on venture capital financing because of the role it plays as a primary funding source for companies in the seed to early clinical stage. Venture capital firms also play an important role for later-stage firms seeking to go public but needing additional capital. Venture capital financing is the number-one private source of financing for medical devices and the number-two source of financing for biotechnology firms (behind debt). Finally, venture capital financing has outweighed IPO financing of biotechnology and medical devices throughout most of the 1998–2007 period.[8]

Correlates Of Market Entry And Exit

We investigate here market entry and exit by biotech and device firms with venture capital funding. We seek to improve policymakers' understanding of these two important technology sectors, what their entry and exit patterns look like over time, what their correlates are, and whether these phenomena differ between sectors. These two sectors have varying characteristics that may be associated with any observed differences.[9] On the product side, the medical device sector has shorter product life cycles (18–24 months), more rapid proof-to-concept and commercialization, smaller research expenditures, a greater emphasis on development over research, and a lower likelihood of external licensing compared to biotechnology. On the financial side, the medical device sector has enjoyed higher profitability, higher IPO returns to investors, and higher barriers to entry.

A review of the evidence from corporate entrepreneurship, industrial organization, innovation, organizational ecology, and corporate strategy suggests several classes of factors that are associated with entry and exit.[10] We briefly summarize these factors below.

■ **Market entry.** The probability of firm entry in a given year is influenced, both

positively and negatively, by the number of prior entries. A higher number of prior entries exerts a positive, legitimizing effect on new market entry, allowing start-ups to acquire the resources needed to grow and survive. On the other hand, the number of prior entries exerts a negative effect via heightened competition.[11]

In a similar fashion, market entry is positively associated with prior merger and acquisition (M&A) activity in the sector, the number and valuation of prior IPOs for firms in that sector, and the amount of venture capital funding invested in firms in that sector. All of these provide additional legitimizing effects for new entrants and strong signals of the likelihood of good exits for investors. Conversely, market entry in one sector may be negatively associated with similar activity in another sector, which can serve to siphon off capital and investor interest. Finally, new entry can be influenced by environmental conditions, such as cyclical swings in the U.S. economy, which can increase or decrease access to capital.

■ **Market exit.** Different types of exit (bankruptcy, M&A, IPO) likely have different correlates. In the interest of parsimony and exposition, we collapse M&A and IPO, label them as "good exits" (from the firm's perspective), and contrast them with bankruptcy ("bad exits"). We further assume that factors positively associated with one are negatively associated with the other. In contrast to market entry, analyses of market exit include firm-level as well as market-level factors.

As with prior entries, the number of prior exits exerts both positive and negative effects on market exit: the presence of few exits suggests high prospects for survival, while the presence of many exits suggests that there is room for new entrants. Other market or environmental factors that might influence exit include the broader economic cycle (which is tied to industry M&A levels) and the presence of geographic clusters ("hot spots").

At the firm level, the company's age can influence market exit in various ways. Firms can suffer from liabilities of newness (exit is more likely among younger firms), obsolescence (exit is more likely among older firms), and adolescence (exit is more likely among middle-aged firms). Different processes underlie these different patterns.[12] Liabilities of newness arise from the firm's small size and difficulty in attracting labor and capital. Liabilities of obsolescence arise from firm inertia and unresponsiveness to changing market conditions.[13]

Because success in resource acquisition figures so prominently in the effects of firm age, we also consider the impact of capital and human resource stocks on market exit. Firms with more rounds and greater levels of venture capital financing, as well as a greater number of venture capital investors, are more likely to have a successful exit. With regard to internal human capital, successful exits may be more likely among firms with larger boards and more experienced executives. With regard to external human capital, successful exits may be more likely among firms whose venture capital funders have more rounds of investment experience and experience with more companies. Finally, successful exits may be more likely among start-up firms that have a track record of acquiring other firms. Such firms

may have built up either scale advantages or product portfolios that public investors and larger firms find attractive.

Study Data And Methods

■ **Data sources.** To examine the patterns and correlates of market entry and exit among biotechnology and medical device firms, we used the VentureXpert database on all start-up companies that solicit venture capital financing.[14] Using the Venture Economics Industry Code (VEIC)—which classifies firms within a sector according to similar technologies—we sampled all firms in the two sectors for which founding, financing, acquisition, or IPO dates were available.[15] This yielded a sample of 863 biotechnology and 889 medical device firms. The database provides a description of each start-up company's characteristics and events, which allowed us to construct the start-up's life history: founding date, financing rounds, acquisition, and IPO.[16]

■ **Market-entry models.** We modeled market entry at the VEIC level within each sector using regression analysis. Our dependent variable was the annual number of firm entries. We measured the independent variables used to predict entry in the prior year or two years.

We included two sets of entry and exit variables to explain market entry. First, based on previous evidence, we expect entry to be associated with the number of entries, exits, and incumbents in the VEIC. Second, we suspect that there are "interindustry effects" with respect to market entry, so that prior entries and exits in one sector (medical devices) influence current entries and exits in the other sector (biotechnology). Our regression models thus estimated entry for biotech and device start-up companies together.

We also included four other types of variables to explain entry. We measured the amount of venture capital money invested at the VEIC level and more broadly at the sector (biotechnology, medical device) level, and then we interacted these measures with an indicator for the other sector. This allowed us to explore interindustry financial effects: does increased investment in the medical device sector during one year influence the number of biotechnology entries in a subsequent year? We measured the impact of M&A activity on entry by the number and value of acquisitions within each VEIC. Finally, we controlled for broader economic trends by including the percentage change in gross domestic product (GDP) over the prior year.[17]

■ **Market-exit models.** We modeled market exit at the individual firm level using survival analysis techniques capable of dealing with active firms with no date of exit. Our models calculate a firm's likelihood of exit as a function of several broad classes of variables: external human capital, internal human capital, financial capital, M&A activity, firm age and size, and industry characteristics.

External human capital reflects the experience of the start-up's private equity investors. This experience is measured by the number of distinct financing rounds that each venture capital firm participates in and the total amount invested. Inter-

nal human capital refers to the number of board members and the experience of its board and its executive team. The financial capital available to the start-up company is measured by the cumulative number of financing rounds in which the company has participated, the cumulative amount of money raised, and the cumulative number of times that any venture capital firm has invested in the company.

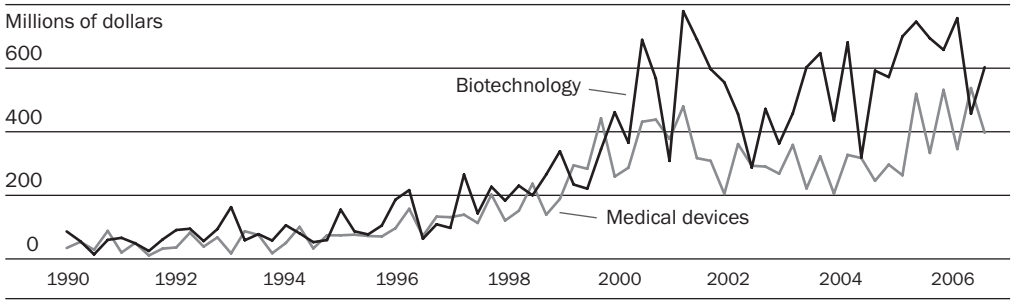
The start-up's M&A activity is measured here by the cumulative number of acquisitions made and their cumulative value. The firm's age was calculated as the number of days elapsed since its founding; we also included a squared-age term to investigate the various liabilities of age. To study size, we developed a proxy measure by counting the number of executives at the time of data collection, along with its squared term. We also included a binary variable to denote whether or not the firm is located within a biotechnology or medical device "hot spot."

The firm's industry characteristics are represented by binary indicators for each VEIC and the number of annual entries, good exits, bad exits, and incumbent firms for that VEIC by year. We included two indicator variables to denote significantly increased venture capital and entrepreneurial activity during the 1999–2001 and 2005–2006 periods. We also included a measure of the percentage change in GDP to control for broader economic cycles.[18]

Evidence On Entries And Exits By Venture Capital–Funded Firms

■ **1990–2006 trend in venture capital financing.** We first compiled the data on all venture capital financing rounds in which companies participated. Exhibit 1 presents quarterly time-trend data on venture capital financing during 1990–2006 for the biotechnology and medical device sectors. Overall, there is an upward drift in venture capital financing in both sectors. Throughout much of the 1990s, the level of venture capital financing of the two sectors was roughly comparable. Such financing of the two sectors also tended to move up and down together. After 2000, financing levels in the two sectors diverged. Moreover, periods of low venture capital ac-

EXHIBIT 1
Venture Capital Financing In Biotechnology And Medical Devices, By Industry, Quarterly 1990–2006



SOURCE: VentureXpert database, 2008.

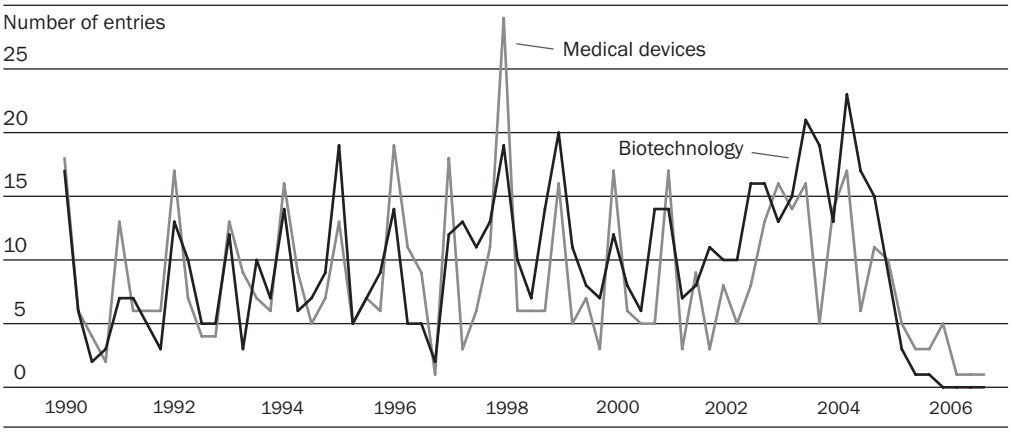
tivity in one sector tended to correspond with periods of high activity in the other. This suggests that venture capital interest in each sector heats up and cools down and that this interest in the two sectors may be inversely correlated.

This may occur in several ways: company failures (bad exits) in one sector lead venture capital firms to seek out new opportunities in the other, and company successes (good exits) in one sector encourage venture capital investors to abandon the other. Venture capital investments in medical devices, for example, typically serve as a portfolio hedge against the uncertainties of the biotechnology industry. Compared to biotech, medical device firms have a more straightforward business model, based on lower investment in basic research and higher emphasis on development and commercialization that leads to more predictable and faster revenues.[19] The alternation between sectors can also occur when company successes (IPO exits) later disappoint investors. For example, the 1996 class of medical device firms that exited via IPOs lacked products that could be successfully commercialized. Their disappointing results led venture capital firms and investors to shift to biotechnology firms.

To investigate this possibility, Exhibits 2 and 3 depict the number of new entries and exits, respectively, by biotechnology and medical device firms during 1990–2006. The exhibits depict steady demographic trends and competitive conditions in these two sectors. There were roughly ten to fifteen new entries and exits each quarter, which suggests an association between the two processes. Indeed, entry is positively correlated with good exits ($r = 0.61$) and bad exits ($r = 0.30$). The countercyclical activity between biotechnology and medical devices holds for new entries after 2000 and for exits across the entire time period.

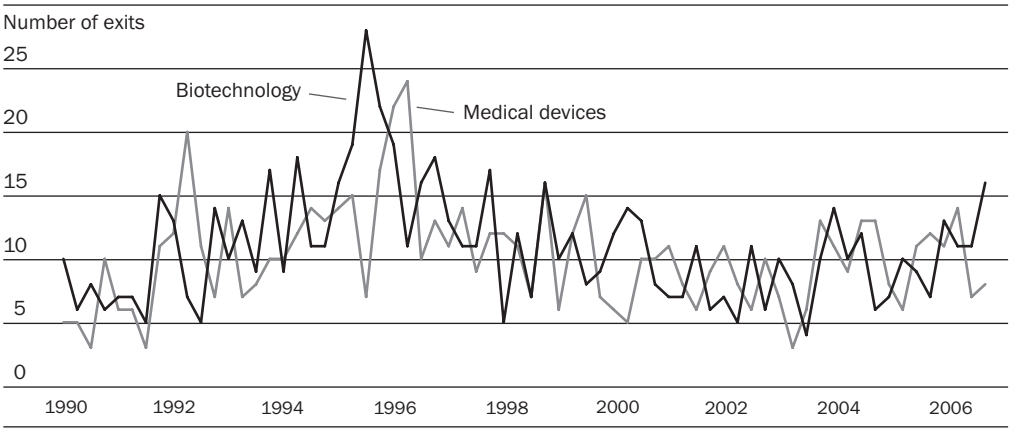
■ **Multivariate analysis of market entry.** Regression results for market entry

EXHIBIT 2
Biotechnology And Medical Device Firms' Market Entry, By Industry, Quarterly 1990–2006



SOURCE: VentureXpert database, 2008.

EXHIBIT 3
Biotechnology And Medical Device Firms' Good Market Exits, By Industry, Quarterly 1990–2006



SOURCE: VentureXpert database, 2008.

are presented in our online Technical Appendix.[20] The results confirm some of our expectations. Market entry exhibits a curvilinear (inverse-U-shape) relationship with the number of firms operating at the VEIC level, which suggests that a number of firms are needed to legitimize entry but that too many competitors deter entry. The same pattern is observed at the broader biotechnology-sector level, but not in the medical devices sector.

Contrary to our expectations, market entry is associated with neither the number and valuation of M&As nor venture capital funding of biotechnology or medical device firms. This suggests that firms do not enter the market in response to the availability of venture capital financing. More likely, firms enter the market with promising science/technology and backed by personal capital or other investors and then look for venture capital funding later. Venture capital funding is nevertheless important for supporting those start-ups whose promising technology pans out in terms of actual product sales.

We did find strong evidence of correlated entry rates. Higher prior entry at the sector level led to higher current entry for both biotech and device firms. For medical device firms, the number of prior good exits deters new entry (significant effect), while the number of prior bad exits promotes entry (insignificant effect). Bad exits depart the market while good exits do not. Bad exits may thus be an indicator of industry velocity as new firms enter to take the place of others that have left. This pattern is not observed among biotechnology firms.

We also found evidence of interindustry entry and exit effects. Higher medical device entries, more medical device good exits and bad exits, and higher levels of venture capital financing of medical devices fostered greater entry by biotechnology firms. Additional models (not reported here) show the converse: higher bio-

technology firm entries and higher levels of venture capital financing of biotechnology fostered greater entry by device firms.

■ **Multivariate analysis of market exit.** Estimates from the market exit models are also available in our online Technical Appendix.[21] The results generally support our expectation that the independent variables have opposite associations with good exit and bad exit, and they show that the associations are largely similar across the two technology sectors.

The results also support many of the hypothesized associations. Both biotechnology and medical device firms appeared to suffer from liabilities of adolescence: good exits were associated with firm age in a U-shape relationship, while bad exits were associated with firm age in an inverse U-shape relationship. These patterns may reflect the time pressures that venture capital firms work under to have the company they support go public or be acquired within several years of initial financing. Controlling for age, we found that firm size exhibits similar associations with good and bad exits. A moderate number of executives are associated with good exit, while too many and too few are associated with bad exit.

Access to capital via a larger number of venture capital financing rounds increased the likelihood of both good and bad exit. However, companies had a significantly higher likelihood of good exit when they raised more capital from these investment rounds. The number of financing rounds and level of financing had an inverse U-shape (curvilinear) impact on good exit, which suggests the importance of moderate levels of venture capital investment. The number of investors does not affect exit. The likelihood of good (bad) exit was positively (negatively) associated with the venture capital firm's experience with investing in more companies, the cumulative amount invested, and the fewer the rounds of investment made; most of the effects were not statistically significant, however. As noted above, what appears to matter is not the frequency of venture capital investment but rather the companies themselves and the amounts invested in them.

We also point out a handful of correlates at the firm level that went beyond age, size, and venture capital financing. The likelihood of a good exit was positively associated with the firm's track record of acquiring other firms, its cumulative history of good exits, and the presence of a smaller board. Location in an economic cluster (or "hot spot"), on the other hand, seemed to only reduce the likelihood of a bad exit among biotechnology firms.

At the VEIC level, the specific industry was associated with both good and bad exits, which suggests that the firm's technology plays a large role in its success. High levels of entry within a VEIC were also associated with both good and bad exit. We further found a U-shape relationship between the number of industry competitors and the start-up's likelihood of exit. Initially, firm entry and growth within an industry lowered the risk of good and bad exit; this effect reversed as the industry became more crowded and exit risks increased. These results echo prior research findings that early entrants enjoy legitimacy benefits from having other

firms present, but mortality risks gradually rise as additional entrants increase industry competitiveness.

Discussion

Our analyses suggest that venture capital firms play some role in fostering new firm entry, but they play a more pronounced role in fostering successful firm exit. On the entry side, venture capital financing does not appear to spur new entry directly, but it does spur entry indirectly through its financing of firms in other sectors and its financing of prior entries both within and across sectors. On the exit side, moderate levels of venture capital financing and financing rounds promote successful exits. Successful exits are also fostered by greater levels of venture capital experience with other companies and investments.

These findings are important given the historical trends in venture capital financing of biotech and devices depicted in the exhibits. Venture capital firms have gradually increased the level of their investment in these two sectors over time, sometimes alternating between the two. At the same time, the actual number of companies they finance appears to be somewhat stable, which suggests that these firms are concentrating their growing investments in a fixed number of start-up companies. Our multivariate results suggest that such behavior is associated with good exit and, thus, with technologies that get successfully commercialized.

To be sure, there are other predictors of firm entry and exit in these two sectors. Demographic processes are shaped by a host of firm-level characteristics such as age, size, and the firm's own M&A experience. They are also shaped by several market-level characteristics such as the number of incumbent competitors, the degree of M&A activity within that sector, and the particular technology of that industry. Broader economic trends such as the change in GDP appear to affect entry more than exit.

More broadly, the factors that drive entry and exit in the two sectors appear to be more similar than different. Demographic processes in one sector also appear to influence demographic processes in the other. Policymakers should recognize that these technological sectors are thus linked and interdependent, not only in terms of their financing but also in terms of their competitive conditions. Venture capital firms appear to play an important role in both.

The authors thank the editors and four anonymous reviewers for their helpful comments on an earlier draft.

NOTES

1. See, for example, Congressional Budget Office, *Technological Change and the Growth of Health Care Spending* (Washington: CBO, 2008); D.M. Cutler, *Your Money or Your Life: Strong Medicine for America's Health Care System* (New York: Oxford University Press, 2004); M. Platzer, *Patient Capital: How Venture Capital Investment Drives Revolutionary Medical Innovation* (Arlington, Va.: National Venture Capital Association, 2007); Global Insight, *Venture Impact: The Economic Importance of Venture Capital Backed Companies to the U.S. Economy* (Arlington, Va.: NVCA, 2006); K. Kruger, "The Medical Device Sector," in *The Business of Healthcare Innovation*, ed. L.R. Burns (Cambridge: Cambridge University Press, 2005), 271–321; and C. Pfeffer, "The Biotechnology

Sector—Therapeutics," in ibid., 103–189.

2. F.M. Scherer and D. Ross, *Industrial Market Structure and Economic Performance*, 3d ed. (Boston: Houghton Mifflin, 1990); and Z. Acs and D. Audretsch, "Innovation in Large and Small Firms—An Empirical Analysis," *American Economic Review* 78, no. 4 (1988): 678–690.
3. The different exits are not mutually exclusive. As noted above, some firms that enter the public market via an IPO can be subsequently acquired by a larger incumbent. Nevertheless, researchers commonly dichotomize the different types of exits into two classes: unsuccessful versus successful. Other labels for these categories are involuntary versus voluntary exit and destruction versus retention of organizational capabilities.
4. Platzer, *Patient Capital.*
5. Milken Institute, *Biopharmaceutical Industry Contributions to State and U.S. Economies* (Washington: Milken Institute, 2004).
6. AdvaMed, *The Medical Technology Industry At A Glance* (Washington: Advanced Medical Technology Association, 2004), 14, Chart 3.2.
7. The private sources include venture capital firms, corporate venture capital, specialty venture capital, business angels, incubators, private equity and hedge funds, private placements via merchant or investment banks, private investment in public equity (PIPEs), stock warrant off-balance sheet R&D financing (SWORDs), convertible and asset-based debt, and government-funded Small Business Innovative Research (SBIR) grants. Pfeffer, "The Biotechnology Sector"; and Kruger, "The Medical Device Sector."
8. The authors thank David Cassak, managing partner, Windhover Information, and Windhover Publications for this information.
9. Many of these differences are discussed by Pfeffer, "The Biotechnology Sector"; and Kruger, "The Medical Device Sector."
10. Much of the theory and evidence is summarized in literature reviews. See, for example, J. Baum and T. Amburgey, "Organizational Ecology," in *Companion to Organizations*, ed. J. Baum (Oxford: Blackwell, 2002), 304–326; and L. Berchicci and C. Tucci, "Entrepreneurship, Technology, and Schumpeterian Innovation: Entrants and Incumbents," in *The Oxford Handbook of Entrepreneurship*, ed. M. Casson et al. (Oxford: Oxford University Press, 2006), 332–350.
11. The result is an inverse-U-shape relationship: too few entries suggest that the area is not a legitimate investment, while too many entries suggest that there is too much competition.
12. To investigate these different patterns, and to control for the confounding effects of firm size, prediction models typically include age, size, and their squared terms.
13. In the case of venture capital–funded companies, they can also stem from the firm's ultimate failure to resolve product development problems.
14. The VentureXpert database is cosponsored by PricewaterhouseCoopers, Venture Economics (a division of Thomson Financial), and the National Venture Capital Association.
15. The VEICs (industry codes) for biotechnology firms are 4110, 4120, and 4130; the VEIC codes for medical devices are 5210, 5220, 5230, 5240, and 5299. The description of the types of technologies represented within each VEIC is given in Table 2 in the Technical Appendix, online at http://content.healthaffairs.org/cgi/content/full/hlthaff.28.1.w76/DC2.
16. When only the exit date was missing, we estimated the year of exit as three years after the last observed company activity: for example, round of venture capital financing, acquisition, or IPO. When the founding date was missing, we estimated the year of market entry as three years prior to their first company activity. These estimates were based on the observed timing of entry and exit among companies for which these data were available.
17. Table 1 in the Technical Appendix (see Note 15) presents the descriptive statistics for all of the variables included in our entry models.
18. Table 2 in the Technical Appendix (see Note 15) presents the summary statistics for all of the variables included in our exit models.
19. David Cassak, personal communication, November 2007.
20. See Table 3 in the Technical Appendix, as in Note 15.
21. See Table 4 in the Technical Appendix, as in Note 15.