ORIGINAL RESEARCH

Postmortems on diagnostic testing start-ups: reports of commercial successes and failures and the case of the Zombie life science company

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ABSTRACT

Background From 2014 to 2017, more than 1000 diagnostic companies were launched, securing more than US$10 billion in investment.

Methods We performed an in-depth exploration of 28 diagnostic companies to differentiate successful and failed startups, plus a third 'Zombie' state where companies have achieved financial solvency but without long-term viability.

Results From these data, we created a five-phase, 13-item framework indicating the corporate health of a diagnostic company as it progresses from conception to commercialisation. We found 6 successful companies, 14 failures and 8 Zombies. On a scale of 0–26 points (two points per item), successful companies averaged 24.5 points (range 22–26), failures averaged 4.5 (range 0–16) and Zombies averaged 12.3 (range 3–23) ($p<0.001$). To determine if there was any predictivity to this framework, we looked at only the first two phases (concept and feasibility/planning) of progress and found a distinct gradient in success potential based solely on these first two phases.

Conclusion Our five-phase framework generated a score that could predict diagnostic companies more likely to successfully and sustainably enter the market from those more likely to fail.

INTRODUCTION

A boon in new diagnostic tests over the past decade is adding important new insights into disease mechanisms and uncovering opportunities to use novel therapeutics that reduce disease burden and save lives. These diagnostic tests reveal more information about our genes, the proteins they express and where they act thereby moving care from the bench to the bedside in remarkable ways making it possible to treat patients more effectively and earlier in their disease processes.[1] Diagnostic companies, especially those with pharmaceutical alliances are at the forefront of this trend towards precision medicine.[2] Notwithstanding there is an unmet need: clinicians need better and more sophisticate diagnostics to keep pace with our advancing understanding of disease pathology.

Between 2014 and 2017, about 250 diagnostic companies a year were launched, each aspiring to bring new tests into the clinical realm.[3] Bringing a new diagnostic test successfully to the bedside or examination room requires a blend of scientific creativity, technical proficiency and business acumen with coverage, reimbursement and regulatory savvy. Among the hundreds of companies that are launched there are only a few successes that make it to market, compared with many more that end as failures. Others appear to live on for a long time, existing in a Zombie-like state characterised by short-term sustainability that ultimately devolves into long-term failure.

The scores of diagnostic technology companies that fail along the way do so for a myriad of reasons,[4 5] including an inability to identify a clear market need; insurmountable technical barriers; corporate leadership challenges; regulatory hurdles; inadequate commercialisation efforts and, often, lack of clinical utility evidence showing that the test changes physician behaviour in a way that improves patient outcomes.[4–6] In short,

for the few companies that get it right, there is a legion of companies that have struggled and failed.

Previous publications have assessed success of life science diagnostic companies using qualitative and quantitative criteria to define success, but only in specific settings. The qualitative studies examined molecular diagnostics in cancer by looking at stakeholder agreement on definitions, understanding of the clinical setting by the developers[7–11] or trial through a regulatory lens[12] and quantitative factors examining the strength of clinical validation data. However, we found no works that were more generalisable or proposed an evaluation framework.

In an ideal construct, the impact of a new diagnostic test on patient care would determine its market success. Companies would simply traverse a well-marked path from bench to bedside allocating the necessary resources behind high-impact tests while simultaneously recognising and abandoning low-impact technologies at the earliest possible stage of the journey. Given the range of obstacles along the path, however, it stands to reason that there are good technologies, with strong scientific validity and clinical utility, that never make it to patients; there are also poor technologies that continue to attract time and money despite low probability of impact on patient care.

What, then, are the critical passages that every diagnostic company should navigate if they are to be successful and avoid failure? Viewed from a deterministic perspective, what lessons can be learnt by systematically examining a cohort of successful and failed diagnostic products?

We set out to better understand these lessons by reviewing the experiences of 28 companies we either worked with or know in sufficient detail to analyse. What we found was interesting: Some companies succeeded, some failed quickly and others persisted in what we describe as a 'Zombie' state, failing slowly over several years. We compare the journies of these three archetypes to identify the common success criteria to replicate and the pitfalls to avoid.

METHODS

We performed a qualitative analysis on 28 diagnostic companies to determine, sort, and explore the characteristics that distinguished successful companies from companies that either failed or companies that persisted precariously balanced between success and failure, which we identify as 'Zombies.' These 28 companies, whose names are not disclosed herein, were drawn from a pool of more than 200 companies of similar size, with similar diverse stages of development and also working in the novel diagnostic space. They were non-randomly chosen based on our ability to gain intimate, working knowledge of the internal processes within each company, details usually unavailable to the public. Our data were gleaned from: (1) long-time investors in the healthcare diagnostics space; (2) management-level and C-suite executives who worked at these companies and (3) consultants hired to guide these companies through startup and growth phases. Three authors (MR, RMT and MU) conducted the structured interviews. Our conclusions herein were only possible because we had deep inside access to the company histories.

Time frame

The initial determining data were collected and evaluated between July and December 2015; company status of the Zombies was subsequently tracked through May 2019.

Outcomes

We defined 'success' as bringing a product to market and sustaining sales for at least 3 years and 'failure' as abandonment of efforts by a company to bring a test into the marketplace or stopping all sales of a product that had reached the market. 'Zombies' were defined as companies that, despite having product(s) on the market, we believed were destined to fail due to looming problems that we preidentified in other companies that ultimately failed.

Framework

To describe and understand successes versus failures, we created an encompassing framework that designates five phases a diagnostic company progresses through to bring a product into clinical practice (refer to figure 1 for a summary of each phase). These designations were developed over more than 15 years of observations of what does and does not work for more than 100 companies and their investors that were clients of Halteres Associates. These companies ranged from diagnostics startups to multinational companies. The criteria were refined over time and vetted with many chief executive officers (CEOs), venture capitalists and non-governmental organizations (NGOs) that make investments in diagnostics companies.

Phase 0: design Phase-concept: In the concept phase, no actual research or development activity is taking place, and generally no funds are being raised. Founders and other principals are identifying whether a promising technology could be developed with specifications that meet an identified unmet clinical need. The intended use of the technology is or should be defined here and, importantly, the market size, the competitive and intellectual property landscape and/or a price that warrants further investment. Additionally, the concept needs to address a specific unmet need, and voice of the customer (the intended audience) needs to be understood. A target product profile is developed at this time. The design or concept phase usually begins before a company is formally established or personnel are hired. Typically, the successful output from Phase 0 is a set of corporate slides or a business plan describing the product or services, a target product profile, assessment of the market opportunity, financial requirements and the planned path to success. These materials are used to raise funds.

Phase 0	Design Phase — Concept	Clearly defined Intended Use for actionable intervention decision and has market size large enough to support investment	Performance (Sens /Spec/ Repro) specifications fill an unmet need	Customer needs are understood (Voice of the Customer)
Phase 1	Feasibility and Planning	Experienced leadership/employee team capable of addressing business/tech challenges	All inventions have been completed to achieve final product/scale/COGs targets	Menu strength (one product vs. multiple). Company has back up plan in event of failure
Phase 2	Design and Development	Disciplined development processes (Design Control, Quality System)	Supply chain process, COGs targets, capital needs. Product designed for manufacturability	Robust IP, freedom to operate
Phase 3	Validation and Launch Readiness	Established manufacturing and design control processes	Clinical studies supporting regulatory approval AND commercial/ reimbursement strategy	Market entry strategy in place, specific initial customers identified
Phase 4	Commercialization	Complete plans for commercial positioning and targeted launch	Reimbursement and/or payment strategy with clear objectives, budget and timelines. Partners identified	Operations robust and stable enough to transfer to sustaining operations. Have sufficient cash planed to profitability or liquidation

Figure 1 Diagnostics company growth phases. COG, Cost of Goods; IP, Intellectual Property.

Phase 1: feasibility and planning. In this phase, entrepreneurs expand on the initial planning by creating product requirements that satisfy the unmet need. This phase marks the beginning of the process of finding and building an experienced leadership team to create or tune the technology, reagents and/or software to meet target requirements. A prototype product that achieves product targets is available, and other avenues of diversification to improve menu strength have been explored in the event the initial concept fails. Success would be measured by the fit of the prototype to the market opportunity and the likelihood that it can be developed for manufacturing at the scale and cost required for success in the marketplace.

Phase 2: design and development: The hallmark of this next phase is developing disciplined development processes, including formal product development under design control, which are based on the prototype product. Importantly, manufacturability, supply chain and capital needs are all assessed during this phase, and typically, the major risks of product design have been addressed and minimised or eliminated at this stage. Finally, all intellectual property protections are secured. At the end of this phase, the product is ready for commercial manufacture. Success indicates that the product has met the target profile requirements defined in phase 0.

Phase 3: validation and launch readiness: It is in this phase where the company readies for launch of a proven product. This phase includes finalisation of the manufacturing process, initiating clinical studies to support regulatory and reimbursement approval for the diagnostic test, and identification of the marketing strategy and detailing of the customer targets. Metrics of success include manufactured product lots that pass all quality measures, completed clinical studies that met their end points and a detailed market introduction plan.

Phase 4: commercialisation: In the last stage, operations are stabilised, plans for reimbursement/payment and commercial positioning are secured, and key partners are identified. At this point, firms must ensure they have sufficient capital to support operations as they move to sustain their business model. Ongoing success is measured by successful market uptake, reimbursement and meeting financial goals over a sustained period.

Within each phase, through an iterative process, we specified two to three common activities or milestones that emerged across the companies from our interviews and exploration. After collating our findings, companies were scored across each indicator within each phase to determine whether or not the company had succeeded (two points), partially succeeded (one point) or failed (0 points) in each segment. These results were summed for (1) all five phases to generate an overall framework score and (2) phases 0 and 1 for predictive modelling. When companies failed before completing all five phases, unreached segments were scored as failures. We then performed an analysis to determine the scores which delineate successes from Zombies from failures. We also identified the triggering segment during which each company became a Zombie or overtly failed.

Ethics

Proper consideration has been given to all ethics-related issues.

RESULTS

The 28 companies ran the gamut from small startups to whole divisions of multinational biotech firms. Of the 28 companies, there were 6 successes, 14 failures and 8 Zombies (figure 2).

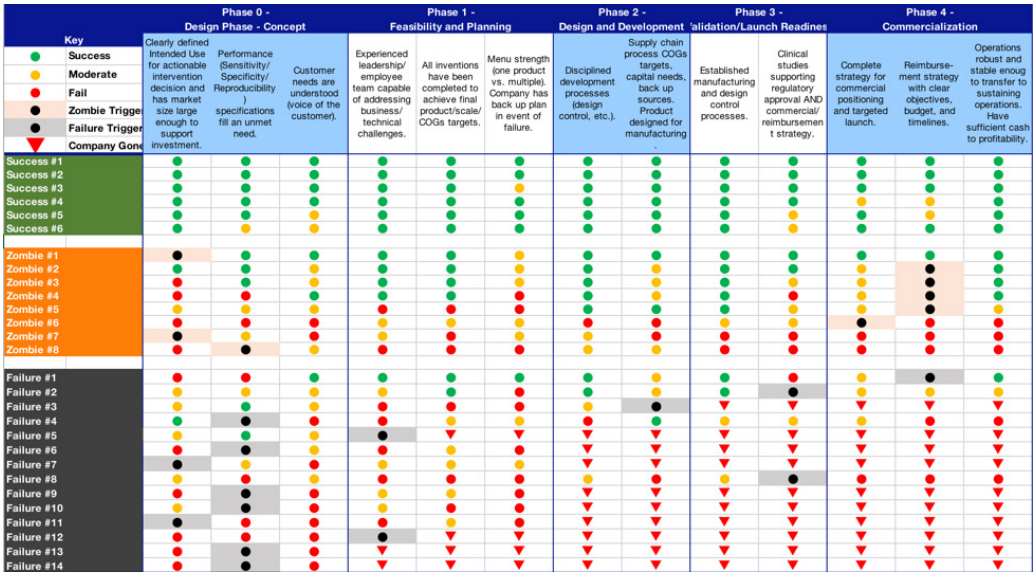

Figure 2 Success metrics results by development phase and subphase. COG, Cost of Goods.

We found that successful companies had an average score of 24.5 (out of 26) and a range of 22–26; Zombies averaged 12.3 (ranging from 3 to 23) and failures averaged 4.5 (range 0–16). The difference in scores by outcome was significant ($p<0.001$) (table 1).

Overall, successful companies had clear criteria successes across each of the five phases, from conception in phase 0 to commercialisation in phase 4. While the prevalence of success criteria could be expected, given the ultimate outcome of these products, it was notable that there were very few exceptions to these criteria and the scores. Two companies were successful across all criteria. The most interesting successes were companies #5 and #6, which succeeded in bringing a product to market without completely fulfilling 3 of the 13 criteria. Other, partially successful phases among the successes, were found in every phase, indicating that no single phase required complete criteria success for product launch.

By contrast, all but one of the failures did not successfully fulfil all criteria in at least two phases. Companies failed or found only moderate success across every criterion in which their successful counterparts succeeded. The first two failure cases are the only ones that succeeded across more than one criterion, notably Failure #1, which foreshadowed its by failing in phase 0, but succeeded at all phase 2 criteria before ultimately failing short in phase 4, reaching a failure trigger point tied to securing coverage and reimbursement. The company and its investors actually believed they had succeeded in phase 0 at the time. Often, failures happened within the first 3 years, but five of the failures had been incorporated for more than 7 years, all the while continuing to raise money and hold investors' attention.

Through our interviews, we uncovered that seven failures were due to founders believing that they had product concepts that customers would want without actually conducting 'voice of the customer' studies (phase 0 criterion). Even though these companies gained some understanding of market needs over time, ultimately their tests did not adequately address unmet need. Another company, failure #6, which also failed in phase 0, successfully assessed customer needs, but could not achieve adequate test performance specifications to meet clinical requirements. Three of the failed companies (#9, #13 and #14) were unable to overcome problems with the basic technologies they used for the prototype product.

The 'Zombie' companies display a diverse set of successful and failed criteria. Some, like Zombie #1 and #2, appear to be quite similar to successful companies across the early phases, but we predicted that they would fail in phase 4. For Zombie #1, the size of the market appeared too small to sustain the company, while we felt Zombie #2 was likely to fail due to the level of reimbursement possible. Both remain in business today. Others, like Zombies #7 and #8, have looked like failed companies since phase 0, but have continued to obtain sufficient funding to stay alive for years.

Timelines for entry into a Zombie state also varied. Some of the Zombie companies we investigated have been in business for more than a decade, while some

Table 1 Comparison of segment success by company type

Company type	Mean	SD	Range	P value
Failure	4.5	4.9	(0–16)	<0.001
Zombie	12.3	7.1	(3–23)	
Success	24.5	1.3	(23–26)	

Framework scores were calculated based on +2 for complete success, +1 for moderate success and 0 for failure in each of the 13 indicators of the framework, with a possible maximum of 26 points.

Table 2 Phase 0–1 growth score and outcome likelihood.

Phase 0–1 Framework Score	Likelihood of outcome		
	Failure, %	Zombie, %	Success, %
0	94.5	5.2	0.3
1	90.4	9.1	0.5
2	83.8	15.3	0.9
3	73.8	24.6	1.6
4	60.6	36.5	3.0
5	45.6	49.1	5.3
6	31.4	59.3	9.3
7	20.0	64.2	15.8
8	12.0	62.4	25.6
9	6.9	54.4	38.7
10	3.9	42.5	53.6
11	2.2	29.9	67.9
12	1.2	19.3	79.5

Shaded areas are the most likely outcome based on phase 0 and 1 total point score.

reached their Zombie state in less than 5 years. Subsequent to our 2015 data collection, we continued to monitor the progress of the Zombies; since that time, five of the eight have left the diagnostics business (#4-#8), and three of those five companies have gone out of business altogether (#4, #5 and #8).

To better understand if our findings predicted success or failure, we combined the phase 0 and 1 scores to see if this produced a predictive score. Using our scoring methodology, we found Successful companies scored 11.3 (out of 12) with a range of 10–12, Zombies 5.4 (range 1–10), and Failures 2.8 (range 0–8). We performed an ordered logit on company phase 0–1 scores and found the differences to be significant ($p<0.001$). We then calculated the predicted likelihood of success, failure or Zombie status based on each point scored (table 2). We found a linear relationship between phase 0 and 1 combined score and commercial success. A score of 0 of 12 was most predictive of failure, a score of 12 of 12 was most predictive of success and a score of 7 of 12 was most predictive of Zombie status. In fact, for mid-range scores of 5–9 of 12, Zombie status was the most likely outcome.

We next examined the triggering events, gleaned from the expert interviews, which we define as a major problem unfixable with time, effort or money, which had driven the failures out of business or, in our opinion, would drive Zombies to become failures. Triggering events put the non-successful companies into the failure or Zombie category (black circles in figure 2). All of the Zombies and even some of the failures were able to carry on beyond the triggering event. Our interviews attributed this fact primarily to the presence of willing investors, but all the failures reached a point where they no longer continued operations or pursued funding.

Triggering events for failure occur in all five phases of growth, but 57% of failures occur in Phase 0 and a large majority of those are the technical inability for their product to fill an unmet need (see figure 2). Eight of the 14 failures never completed phase 1. Our interviewees reported that these companies had an overly optimistic view of their technology's capabilities.

The actual and anticipated triggers for Zombies were notably clustered—63% of the triggers came in the commercialisation phase and the remainder occurred in phase 0–1 conception. Of the five companies that triggered Zombie status in commercialisation, four did not have a clear reimbursement strategy and failed to answer in a timely manner one essential question: 'Have we demonstrated the clinical utility of our product in a rigorous scientific way?' For three of the five Zombie companies that would leave the diagnostic business between 2015 and 2019, we had already identified the likeliest triggering events in phase 4.

DISCUSSION

Ideally, successful diagnostic tests enter into clinical practice because they improve patient care at an affordable price. A diagnostic test would achieve commercial viability only on reaching a prescribed set of enumerated milestones confirming its scientific validity and clinical utility. Failure at any step along this journey would lead to cessation of further scientific investigation and investors withdrawing their funds. However, as we found, sometimes the event that leads to eventual failure goes unnoticed by companies and their investors for years.

From more than 200 diagnostic companies, this study examined the fates of 28. The selected companies represent a reasonable and diverse set of small to large diagnostics companies, with most successes and all failures being startups and with Zombies including both startups and later-stage companies. Although a larger sample would self-evidently have improved the generalisability of the study, we felt we had insufficient knowledge of the excluded companies to be confident in their inclusion. We completed a qualitative analysis on these 28 selected diagnostic companies using a five-phase framework consisting of 2–3 criteria in each phase, 13 in all, that ranged from product design through development and commercialisation. The categorisation of diagnostic companies, the lessons learnt and our ability to predict their ultimate outcome may be helpful for members of the diagnostics community including scientists, investors and diagnostics company employees.

Our framework generated a score that could have been used to predict the six products that would go on to successfully and sustainably enter the market from the 14 diagnostic companies that went on to fail. The most interesting group from our analysis were a set of eight companies with scores that did not indicate success at the time we assessed them and that were

categorised in a Zombie state. As of the initial writing of this report, in long-term follow-up, five out of eight identified Zombie companies left the diagnostics business or went out of business altogether. Today, only one of the eight Zombies have continued in business since our initial 2015 findings. Zombie companies often continued in business, sometimes for as long as a decade, avoiding the repercussions of a cataclysm (trigger event) that would otherwise have signalled their corporate demise much earlier, sometimes for as long as a decade, and staggered along never achieving the milestones needed to generate return on their investment and commercial success. Zombie #1 (figure 2) had good leadership who was able to attract investments to avoid the first pitfall, and they were able to expand their portfolio and gain coverage in multiple products to avoid the second. It is worth noting that this company, of all the Zombie companies, was the most similar to successful companies in our framework.

Companies that succeeded, succeeded at every phase, satisfying each criterion sufficiently. Ten of the 14 failures never accomplished all the criteria within a given phase, and only one completed phase 2. These 'category failures' should discourage others, who choose to use this framework, from moving forward until they solve the underlying criterion flaw. The failures were typically heralded by a trigger event, such as a misunderstanding of the actual unmet market need or the inability to attain an adequate test performance. The data underscores that companies fail in a number of different ways but that failures were most commonly identified in phase 0 or 1 by using this simple scoring model. Among the phase 0 and 1 failures, the single most common single criterion, by far, was hubris that the technology addressed a specific unmet clinical need by a technology visionarywho thought what they had would work far better than it actually did. The failure to build an experienced leadership team was not as common as perhaps expected but it was the critical failure in 2 of our 14 cases. In all, 9 of the 14 companies failing in phase 0 or 1, lead to the withdrawal of investor support within the first 5 years.

Arguably, late Zombie failures are the most challenging for developers, investors and even payers. These Zombies persist for different reasons along every phase of our continuum. The most common of these is the failure to launch a viable coverage and reimbursement strategy. We and others have pointed this out in other studies.[4 13 14] Collecting high-quality clinical utility data is a requisite for coverage and reimbursement from payers.[15] Too often clinical utility data are begun too late, are non-experimental or take too long at too much cost. Simply put: generating clinical utility has to be started early and probably often to avoid this late cataclysm.

Per the logit score analysis, a phase 0–1 score between 6 and 9 (inclusive) predicted a >50% chance of ending up in the Zombie state. Thus, another regular cause for zombiedom is the failure to achieve the intended use—a criterion that characterised 8 trigger events in the 14 failed companies. Zombie scores have very little overlap with scores of successful companies but quite a bit of overlap with the scores of companies that fail outright. After a company carefully vets the phase 0–1 criteria, these results suggest that founders, leaders and investors have to place an even higher premium on pursuing achievable reimbursement strategies and clinical utility studies much earlier as they make critical decisions about financial and temporal resources needed to go to market.

Although we have our doubts, longer-term follow-up would help reveal whether any of the remaining three Zombie companies would awake from their slumber. Our 3-year follow-up showed that most Zombies will fail. Interestingly, lack of experienced leadership was only identified as a triggering event for 2 of the 14 failed companies, but was a success criterion for all of the successful companies. This confirms the intuition that experienced leadership is necessary but not sufficient to push a company to success.

The management literature provides another perspective on our work where the research focuses on entrepreneurship, organisational, and management conditions for successful entrepreneurial endeavours.[16–18] One such analysis identified three factors affecting new company survival: size disadvantage; research and technical innovation and industry growth.[16] While the first factor is not covered in our study there is a clear overlap in our phase 0 metrics of ideation and determination of market size for a new product. Another insight from the management literature points out that the conceptualisations of failure and survival may not always capture the entire range of company performance.[19] Still, other literature focuses on elements of (1) financing and (2) leadership across the growth continuum for life science companies. This is similar to our own findings, where we also found a positive relationship between the amount of financing that a life science company has received and success.[20–22] However, as we have also shown here, this correlation does not always hold true when some investors provide capital long after a Zombie company should have been left to fail. Other researchers have speculated that certain angel and venture investors are categorically different and may be more immune to capital shortfalls or believe they have a selection framework that can identify companies that are more likely to succeed.[23]

There are some additional important limitations to this analysis. Of an estimated 200 companies of similar size and development stage, the 28 companies presented in this study represent a small sample of the total available tool. Moreover, these were companies known to us, and thus a sampling bias cannot be ruled out. The three interview sources, while providing the

backbone for the information herein, were not exhaustive, allowing for unobserved heterogeneity to come into play. Nevertheless, our interviews uncovered enough similarities across company stories to allow for common themes, a framework and metrics. Finally, the development and weighting of the framework were based on the sample we had available and may not be reliable. For this study, we weighted all indicators equally. It is possible that a larger sample would have suggested that we modify or even remove certain indicators or phases, add additional indicators, or develop a more weighted schema. For this, more extensive additional research would need to be performed.

For the successes and failures, we knew the outcomes before we categorised them—for the Zombie companies, however, we did not and we found that the model and the scoring criteria were particularly helpful in predicting five of the eight companies that fell out of Zombie land into the Failure category. This analysis, we want to underscore, is not a study of the technologies; it is an analysis of companies that succeeded or failed.

CONCLUSION

To maximise the likelihood of success, diagnostic companies—even ones with powerful new technologies—must successfully navigate through a series of phases. The six successful companies in this study all navigated our 5-phase, 13-criteria process, while the 14 failed companies did not. In fact, most failures failed in many of the 13 criteria. Zombie companies accomplish some but not all of these criteria, but based on long-term follow-up, appear destined to fail as well.

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