Halteres Associates

Diagnostics Report
January 2018

by
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Why Do Diagnostics Companies Fail?

Over the last decade, we have had the opportunity to work with many diagnostics companies (over 150 startups and small to mid-sized companies, many large multinational manufacturers, and clinical labs) and their investors (angels, venture capitalists, granting agencies, NGOs, and strategics). In that period, several diagnostics companies that initially appeared to be on a path to success ultimately failed. Recently, the Bill & Melinda Gates Foundation asked Halteres to conduct a study to help them understand why diagnostics companies fail. For that purpose, we identified 28 diagnostics companies at various stages of growth to include in our study. We also sought out and interviewed a number of experts from the investment community, management teams from successful and failed diagnostics companies, and our Halteres Associates, most of whom have direct experience in several diagnostics companies, from startups to multinationals, at all levels within their organizations. We were delighted by the eagerness of all those we contacted to participate. There were many insights shared that we have attempted to summarize here. The materials are presented with the permission from the Gates Foundation and are contained in a report available on our website.

The 28 diagnostics companies were classified into one of three groups. The first group was “Successes,” defined as those companies that had reached commercial sustainability. There were 6 companies in this category, some of which were decades old while others were started less than 10 years ago. Larger companies ultimately acquired 4 of the 6 Successes, 2 of which were start-ups less than 15 years ago. Two of these 4 acquisitions occurred after the completion of the study reported here. The second group was “Failures,” which contained 15 companies that were either out of business entirely or whose assets were sold for small sums. The third group was referred to as “Zombies,” to indicate companies that we felt were likely to eventually fail. We apologize for not sharing the company names, but we do not wish to sway opinions about any of these companies.

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In order to compare and contrast the diagnostics companies, we defined a series of phases of growth to objectively describe each company (table below).

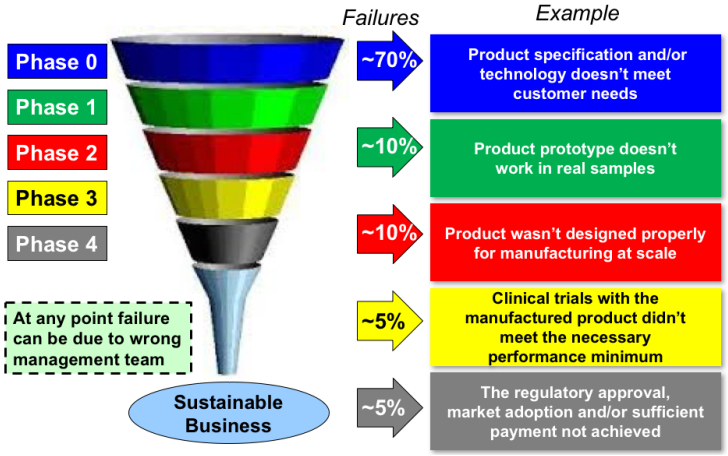
Diagnostics Company Growth Phases: 0 to 4

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

Specific scores were developed for each company for each phase and for each specific item in the three boxed comments associated with each. The scores for each unidentified company are available on our website. The breakdown for the scores for the group of companies categorized as Failures were as shown in figure (right).

For the Failures, many of the problems occurred early in the Phase 0 activities. For most of the companies included as Phase 0 failures, either: 1) the technology was developed by clever people without a clearly defined market opportunity (6 of 8) or; 2) a market opportunity was clearly defined but the technology simply failed to provide adequate performance (2 of 8). The other 7 of the 15 Failures had troubles at other points along the way. Two did not have experienced management

Where the Failure Companies Failed



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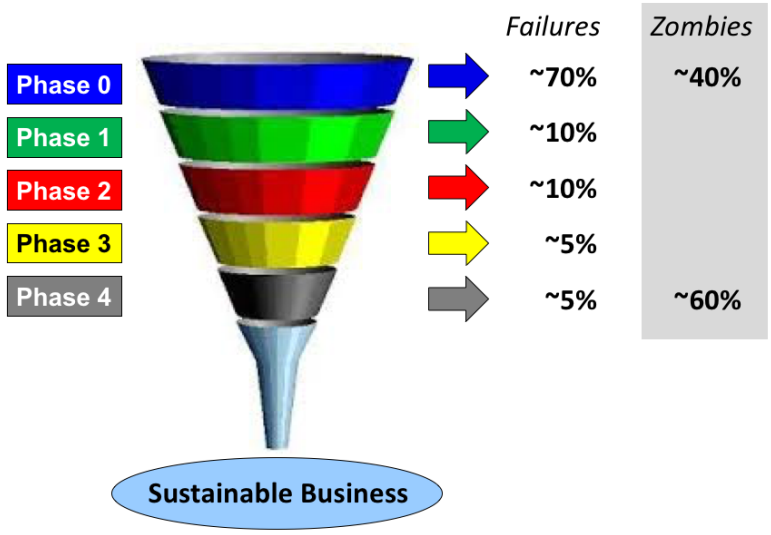
teams that could execute the product plan. One had a working prototype that could not be manufactured at an acceptable COGS. Two failed large clinical studies needed to support robust reimbursement. One could not convince third-party payers of their proposed value proposition and was therefore denied coverage and payment.

When we compared the Zombies to the Failures (figure, below), less than half of the Zombies made mistakes in the Phase 0 category. Instead, the problems we identified were mostly in Phase 4, Commercialization. In each case these were companies with senior management with a remarkable ability to find new sources of cash to keep their dream going. However, in our opinion, they were not likely to make it to sustainability. Since the study was completed 2 of the 8 Zombie companies have ceased operations, 1 of which had been selling products for several years. However, 3 other Zombies have managed to raise additional funds.

Where Do Diagnostics Companies Fail Or Become Zombies?



Our study was limited to a relatively small number of diagnostics companies, and the distribution of failure modes could change with a large increase in the number of companies involved. However, we felt that the overall observations and recommendations were not likely to materially change.

In communication with our interviewees and our Halteres team, a number of suggestions were made for assessing the likelihood of success of diagnostics companies. The first group of questions to consider was categorized into the five phases of growth used:

- **Phase 0**
  - Is the intended use statement clear?
  - Is there a clear intervention action informed by the use of the test?
  - Has the voice of the customer been incorporated as part of the initial feasibility assessment?
  - Is there a clear unmet need that could be addressed by the invention?
- **Phase 1**
  - Will all inventions required to initiate product development under design control be finalized at the end of this stage?
  - Does the company have back up plans in the event of failure with this product design?

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- Does the initial feasibility data continue to support the intended use in a demonstrable way?

- **Phase 2**
  - Does the company have a robust development and quality plan in place?
  - Is the product designed for manufacturing at the scale required in the business plan?
  - Are cost of good targets likely to be met?
  - Have all elements of the supply chain been identified, and are plans in place to secure all critical rare reagents and other key materials?
  - Has all intellectual property (IP) been filed?
  - Is there freedom to operate?

- **Phase 3**
  - Have all manufacturing and design control processes been finalized?
  - Has manufacturing at scale been achieved?
  - Is the company using the final manufactured product in its clinical validation studies (NOT PROTOTYPES!)?
  - Is an actionable clinical study plan in place that addresses regulatory and reimbursement requirements?
  - Have marketing/pre-clinical studies been developed with involvement of representative intended users?

- **Phase 4**
  - Is the commercial launch plan complete and achievable?
  - Is the reimbursement plan complete and achievable?
  - Are the company operations robust and reliable?
  - Can the market bear the initial COGS while the company increases manufacturing volumes and market shares or do sufficient market interventions exist to off-set any gaps?
  - Does the company have sufficient cash or plans to acquire it to fund ongoing operations until self-sustainability (or a liquidation event) is achieved?

These questions were based upon the assessment of the Successes and Failures of the companies scored plus our combined knowledge of more than 100 others that were not formerly scored. We had many hours of discussion. These questions can be applicable to companies at any stage of their growth. It is appropriate to consider Phase 0 issues even for a company that has made it to Phase 4. An inability to clearly articulate answers to the questions from earlier phases could be the basis for becoming a Zombie many years ago. Now it's just a matter of time.

From the overall set of interviews and analyses, the following summary of general questions to ask was prepared. We feel that this is a good list of questions for any startup or more mature company to ask themselves before their existing or potential future investors ask them instead.

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- Does the company's team have a thorough understanding of the customer(s), stakeholders and the unmet need the product/technology will satisfy?
- If so, how do they know someone will buy it and at what price? What alternatives exist and how competitive are they now and in the foreseeable future?
- In a startup, there is precious little time for on the job training. Does the team have successful diagnostic company experience (not tools, not pharma, not biotech)? If not, what is the plan to develop a team with the requisite skills in key roles of responsibility?
- Does the team have plans to implement design control and do they have direct experience in developing products under this system? If not, do they plan to bring in this expertise or partner with others who are expert?
- Does the team have the required experience or intentions to partner with others for skills or competencies that are needed for success? Does the company have a strong program management function with management responsibilities?
- Does the product development plan include processes to design for manufacturing?
- Does the team have a realistic and detailed assessment of the timeline to feasibility, product development, manufacturing, and commercial launch?
- Does the company understand the full ecosystem into which they will introduce the product and all the pain points for the users that must be overcome?
- What is the projected return on investment for each type of investor? Is this sufficient to attract the required investment to commercialize the product? If not, what provisions need to be made to ensure all stakeholders have attractive returns to offset the development/commercialization risks?

Although the issues raised appear slanted toward investment opportunities for for-profit entities (e.g., venture capital), the same issues are of concern to sophisticated not-for-profit investors (e.g., NGOs). Although the primary reasons for investment might differ significantly between the two, there is a need for the diagnostics company to become sustainable without the need for constant influxes of cash from both investor types. Even for the wealthiest of charitable foundations that might be inclined to catalyze low- to middle-income diagnostics markets with financial instruments, such as advanced market commitments or purchase price buy downs, there will come a time when they will need to let the company stand alone; these financial instruments are temporary solutions. Fundamentally, some companies are on the path to achieve sustainability and will be future success stories, while others might already be Zombies. Which ones are which? We hope that the observations and recommendations for questions to ask presented in this newsletter will be of help to those of you working in the international diagnostics community. We hope that you all will do good by doing well.

We thank and acknowledge Halteres Associates principal, Mike Richey, for his contribution to the research and analysis for this work.

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Halteres Associates is a bioscience consultancy, and serves as a business, market and strategy advisor in the biotechnology, life sciences, and healthcare information and communications technologies sectors.

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