



Halteres
Associates

Diagnostics Report

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DIAGNOSTICS: A KEY COMPONENT OF HEALTH SYSTEM STRENGTHENING

The Need for New Approaches to Business Planning and Modeling in Diagnostics

Imagine if there were a master planning tool to support the development of diagnostic systems for use in any disease state in any healthcare setting and any geography. Envision the strategic opportunities for sustainable healthcare improvements such a tool would enable. Is such a planning tool available? Yes - this is what Halteres has achieved with its Diagnostics Business Modeling Initiative and is the subject of this article.

We believe that better diagnostic business plans are needed. Diagnostics is a fragmented, complex and difficult industry, perhaps one of the most difficult market sectors to provide successful and sustainable products to over the long-term. Success requires an understanding of unmet market needs from very diverse customer groups and how best to address them. Success also requires organizational expertise in the biological variations associated with target diseases, assay development, systems development, software and IT expertise, manufacturing processes, regulations, reimbursement, market development and commercialization. Ideally, the business plan takes into account all of these factors and is quantified in the form of a business model.

Diagnostics is a market with few single blockbuster success stories (e.g., HCV, HPV, BNP), usually relying instead on the incremental contributions from panels of assays and instrument system solutions. The model of developing and commercializing individual proprietary testing platforms each offering only one or a few assays is giving way to the demand for well designed, versatile platforms offering multiple assay technologies and/or a broad menu of assays. Next generation diagnostic systems must satisfy a broad distribution of policy makers, funders, global users, needs of public and private healthcare settings, ever growing threats from infectious and chronic diseases, as well as the changing needs of both centralized and decentralized testing locations. At the same time, despite the growing pricing pressures, there is an



expanding need to generate substantial in-field evidence to prove positive outcomes and other beneficial impacts of test use in order to catalyze market uptake.

As a result, we believe that single-product, single-market, diagnostic business models are becoming less tenable. Instead there is a growing understanding that new testing paradigms are needed to address the growing demand for more comprehensive health services across an increasing number of diseases and health conditions in the face of highly scrutinized healthcare spending; customers need to do more with less in more locations. There is a need for developers to understand the continuum of testing needs throughout the entire healthcare ecosystem from the sophisticated laboratory to self-testing schemes and where their technology will fit. The ecosystem definition will require the evaluation of unmet needs, use cases, workflows, local constraints and stakeholder demands for diagnostic data.

Developed with an understanding of this changing diagnostic landscape in mind, the Halteres Business Modeling Initiative involves much more than a standard profit and loss statement. It involves a disciplined approach to identifying and documenting essential elements of a successful diagnostics business. For a business model to be useful it must

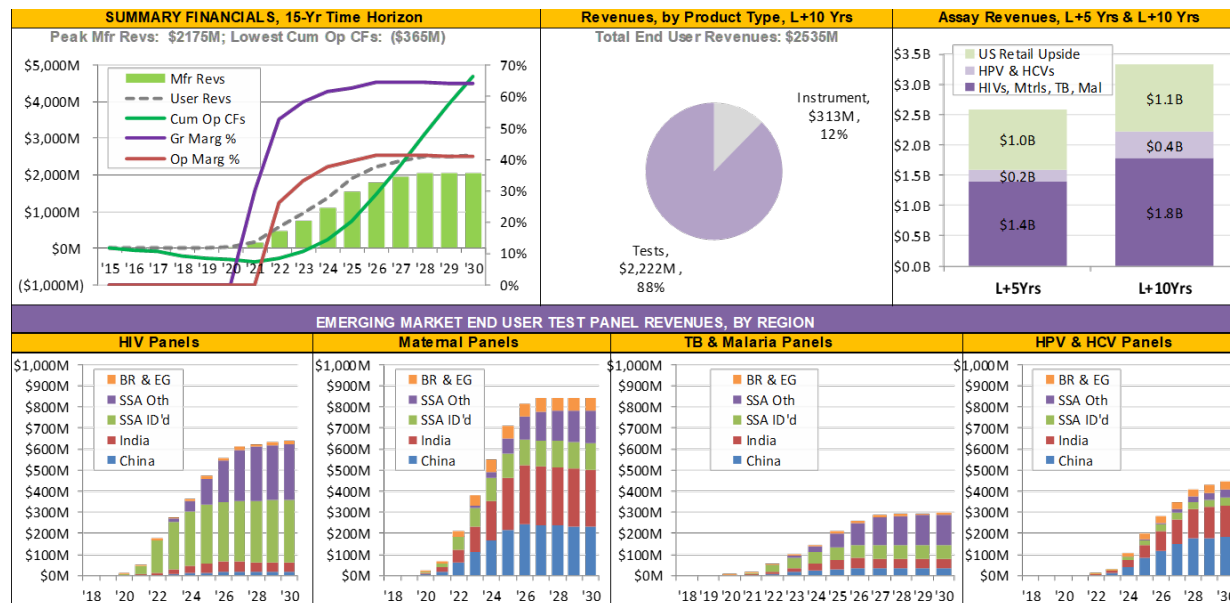
Modifier	Definition
Adoption	How likely is it that a country will adopt the diagnostic test in its national guidelines
Access	What percentage of the target population is likely to have appropriate access to the diagnostic test and/or test data
Adherence	What percentage of the target population using the diagnostic test is likely to adhere to the recommended frequency of testing

be supported by validated, well-accepted, current data sources to allow reasonable and reliable alignment, consistency and comparison of findings across diseases, countries and healthcare settings. The market or revenue side of the model must be anchored by a concise set of assumptions and accommodate country and patient cohort-specific market factors including Adoption, Access and Adherence modifiers (see Table). These market modifiers are essential for determining the estimated percentage of the total addressable market (the TAM) that might be served (the SAM) by the diagnostic tests and/or platform under development with an acceptable level of program risk and time. Often, market strengthening interventions, such as local in-field studies, are required to optimize the SAM, and provisions for those interventions should be included in the business plan. Another important market factor is determining and achieving the required price per test in the target public and private settings. The market-side influencers are rounded out by understanding and accounting for local demand and uptake drivers, market development hurdles, funder, payer and/or procurer demands and logistics needs.

Making up the other half of the business model are the developer's cost-side inputs, including the costs for technology, product, process and market development activities. These cost inputs also include other costs of operation including manufacturing, clinical, regulatory, commercial, legal, general and administrative. Once a pro forma business model has been developed, company-specific plans can be created to better underpin the cost analysis, including delineation of specific use cases and associated product performance requirements; planning for manufacturing scale-up and cost reduction to achieve cost of goods targets; understanding partnering requirements, options and impacts; highlighting business sustainability goals and metrics; and other factors. In short, this exercise encompasses the quantification of the inputs and outputs of a well-crafted business plan.

While lack of familiarity with new emerging markets in many geographic regions makes such modeling difficult for new and smaller companies, Halteres has developed benchmarks useful for business

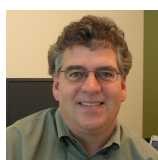
planning and portfolio modeling. Once the assumptions have been agreed to and the market revenue and cost-side inputs verified, various business scenarios can be modeled and compared. These include, for example, market opportunities defined by disease or syndrome, by testing setting (e.g., central lab or Point of Care), by country, by target patient type and other parameters of use in establishing common baselines to drive portfolio development decisions, benchmarking and investments. Done properly, such dashboard outputs will facilitate cross-portfolio comparisons and opportunity assessments for developers, funders, governments, payers, implementers and users (see Example below).



In summary, a well-formulated business plan, backed by sound business modeling, is a cornerstone of efficient and effective development programs and necessary for achieving a successful and sustainable diagnostics business. Please contact Halteres if you are interested in learning more about how the Business Modeling Initiative can help you.



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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.