

## Marketing and Startups

*This article regards innovations and startup companies in Life Sciences.*

New ideas, technologies, procedures and products can be devised in a variety of ways. Most are created by professionals (be it a physician, therapist, nurse, technologist, engineer, scientist, technician or pharmacist) who are facing or experiencing wastefulness, inefficiencies or problems in their daily routines.

What can “trigger” an idea for a new product?

- High-risk procedure, like radiation risk, invasiveness, unacceptable morbidity and mortality rate
- Costly product and/or consumables
- Too expensive treatment procedure; this can be as a result of the procedure’s complexity or duration, and/or the number of staff, facilities and ancillary products needed
- Too invasive treatment procedure and/or general anesthesia needed, requiring a too long recovery time
- Inferior or inadequate product specificity and/or sensitivity
- Outcome of procedure that does not or hardly improves a patient’s health status (recovery, “back to work” moment, QLY – Quality Life Years)
- Susceptibility to errors
- Poor reliability, such as malfunctions, frequent repairs, lack of spare parts and/or service support
- Too difficult or complex to use and/or to master/learn
- Outdated technology
- Poor manufacturer/supplier support

Most innovations are based on own experience and creating an idea and subsequent product as a solution to a known, experienced problem. Other innovations originate from manufacturers that improve an existing product, or revise or expand the product’s applications or treatment procedures.

Before an idea can be converted into a product, the market needs, requirements and potentials must be researched and evaluated, the first task of Marketing. While the product is being developed based on market and user feedback, Marketing will develop the regulatory, reimbursement, clinical trials and marketing strategies, determine sales objectives and tactics, and create training programs and MarCom materials. Based on market introduction priorities, Marketing will establish a distribution network. The eventual product launch will be managed by Marketing. Marketing is an on-going process that oversees customer and public (press) relations, continuously updates promotional and training materials, identifies and reports encountered problems or needs, and recommends upgrades and changes to the product and in the Business Plan. In order to convert an innovation into a real product and eventually bring it to market, there is only one way to do so successfully: Marketing.

Marketing is the core of a company, an amalgamation of activities that can either break or make a company. Only Marketing can determine the viability of an innovative idea, help design the resultant product, launch it, and keep track of its use. Without Marketing a company is doomed. Business schools use a plethora of case studies chronicling the debacles and demise of companies that neglected Marketing.

The biggest and most vital mistake of a company, any company, is to ignore Marketing or give Marketing a supporting instead of a leading role. The second mistake is to elevate sales (revenues) above anything in the company. Correct, revenues allow a company to pay its bills, accomplish its financial survival, and determine its ultimate success. But what won’t work (and never has) is to go straight from product development to sales, without the “Marketing Steps” described herein. Selling an unfinished and unproven product to the odd geek, gullible acquaintance, or early adaptor will not evolve the startup into a profitable enterprise. People and companies have tried selling without Marketing, but failed in the long run.

### Rule of thumb

Sales do NOT drive revenues: Marketing drives the entire product and business development process with revenues as end result. Most, if not all funds for new product development or a startup company should be allocated to Marketing and R&D, with ideally an investment ratio Marketing-to-R&D of 2:1. There is nothing to manufacture, nothing to organize, nobody else to hire or engage except for Marketing and Engineering experts, with Marketing driving Engineering and the design and production process, based on market, regulatory, reimbursement and potential user feedback. Most, if not all, successful companies have launched new products using this focus and allocation of funds. More than 90% of failed startups\* went belly up because they spent nothing or virtually nothing on Marketing, trying to push the sale of unproven, unwanted and unfinished products to uninterested users in unverified markets.

*\* this includes companies that did not have sufficient funds for Marketing and companies that saw no need to spend enough on Marketing*

Marketing consists of 2 parts, with each part split into 3 stages – something few people realize.

Part I, Upstream Marketing involves Market Research, Market Intelligence, Market Understanding, Market Validation and Market Acceptance.

Part II, Downstream Marketing involves Training, Design of Marketing Materials, Strategic Planning, Tactical Sales Planning, Distribution Channels, Marketing Communications and Customer Relations Management.

### **Part I – Stage 1: Needs Research**

“Is there a need for the product? Is it a must-have or just a nice-to-have?”

Needs Research must be performed before a product, even a prototype, has been developed. As a result of this Needs Research, the product must be designed based on those needs.

Users are looking for benefits. People don't buy features, they buy benefits, advantages that offer them something better, faster, easier, safer, more reliable, stronger, smaller, lighter and/or less expensive.

They are interested in:

- Better and reproducible clinical results
- Less invasive, faster and safer treatments
- Reliable, highly specific and durable products
- Lower costs
- Ease of use / easy to learn
- Dependable support and after-sales service

Needs Research can uncover:

- Important clinical problems
- Inferior or unacceptable clinical outcomes
- Error-prone procedures
- Bottlenecks
- Inefficiencies
- Waste of staff, time and money
- Excessive paperwork

Upon completion of this stage it can be determined if the innovation can potentially solve certain clinical challenges and problems that inflict significant medical and/or financial burdens.

But, is there a market?

### **Part I – Stage 2: Proof of Market**

“If nobody is interested in the new idea, nobody wants to use it, and nobody wants to pay for it, what is the logic of going ahead spending money on product design and development, if one will end up with dead meat?” Proof has to be delivered, demonstrating that there is a viable Market for the innovative product. This entails real-life Market Research: not the purchase of off-the-shelf, often costly, unspecific market research reports.

Proof of Market is driven by the results of the Needs Research. Market Research starts by determining whom the target users are and what the specific product applications can potentially be. It requires developing questionnaires, setting goals and expectations of the Market Research's outcome. It consists of a complex series of collecting facts from real users in face-to-face meetings and interviews, and by observing daily routines and treatment procedures. Besides actual users, also providers (hospitals), regulatory bodies, payers (insurance companies, reimbursement coverage), medical societies and KOL's must be included in this Market Research stage.

Obtained data then need to be analyzed and evaluated in order to segment, size and validate the potential markets, to determine market trends, opportunities and threats, to analyze the competition, and to establish the requirements of and interaction between all parties involved. A good Proof of Market Research should answer: “Does it make sense, and is it worth the effort, time and money to make a product out of the idea, something that people need, want to buy and are willing to pay for?”

### **Part I – Stage 3: Proof of Concept**

If at this stage the light is still Green, one or more prototypes can be produced, making sure that they will incorporate specifications and designs that can meet the market needs, wants and requirements. This includes the knowledge obtained how the product must be categorized, on what parameters it will eventually obtain regulatory approval, and if there will be reimbursement coverage for its purchase or use.

The most important detail to know at this stage is whether the product will be considered:

- (a) A totally new product or technology, or
- (b) Identical to an existing product, or
- (c) Similar to an existing product with slight adaptations or modifications, or
- (d) A product with a new application or use (a.k.a. 'label').

Knowing the product's classification, its applications and limitations can make a huge difference in the time it will take and the amount it will cost to obtain approval and reimbursement coverage.

Also in this stage Marketing takes the lead. It advises and supports R&D in matching the design and development of the product to all of the above requirements. Marketing can now develop regulatory, reimbursement and clinical trials strategies, making sure that the clinical trial designs and protocols will be producing evidence to conform to regulatory, reimbursement and market requirements. Too often clinical studies are performed without considering these requirements, resulting in the necessity to set up new (costly) clinical trials.

In the meantime R&D performs in-house tests, trials and benchmarking on the prototypes, and subsequently designs the first functional models of the product. After the approval of the first production model, no modifications can be made during the clinical trials, since this first model and the results of the clinical trials will also be used in the regulatory and reimbursement procedures.

Marketing meanwhile negotiates with identified medical centers and lead investigators the clinical trials plan, and liaises with the company's specialists the implementation of that plan. Clinical trials should evidence the product's safety, efficacy, and cost effectiveness, and that it will improve the patient's Quality Life Years.

The outcome of this vital stage will validate the product's viability and its future profitability and ROI.

### **The Moment of the Big Decision.**

This is the time and moment of the Big Decision. Based on market and customer feedback:

- can a viable product be developed that will be beneficial for users and the manufacturer, or
- does the idea need to be modified, or
- is the feedback so convincing that the idea better be trashed?

This is the toughest moment in time for every enthusiastic inventor and startup company. With the Green light to move forward, from here onwards all attention must be given to product and business development, the next stages where Marketing plays a major role.

### **Inter alia: "The Business Plan"**

Generating a Business Plan starts right at the beginning of the Upstream Marketing Process. Its "Market & Competitive Intelligence" chapter will be based on the results of the Needs Research and the obtained Market Research data. The "Problems & Solutions" chapter will be the rationalization of the very existence of the product in question (and for many startups, the whole company's existence), and the eventual success of its Marketing strategies. The Business Plan will determine the company's objectives and strategies, and what human, financial and material resources are needed in achieving those objectives using those strategies.

A Business Plan describes the markets and practices the company will serve, but it is also a working tool that functions as the company's operational manual, a road map that is regularly updated as time goes by, enabling Marketing to keep strategies that work, eliminate those that don't, and change objectives as the business evolves. A Business Plan develops as the product advances towards market acceptance and has proven to be able to satisfy customer needs. The practical part of the plan describes the allocation of resources, preparing for problems, responding to market opportunities, manufacturing, distribution, staffing, training, MarCom, development and growth, funding and financial matters.

A convincing Business Plan is written from the potential customers' perspectives, to which the company offers answers and solutions. Writing an effectual Business Plan takes time, costs money, and requires expertise.

## Finances

From a financing point of view, the Upstream Marketing Process should ideally be financed from own resources or angel investors. Approaching VC's with a complete and well-designed Business Plan, supported by proven customer demand, needs and acceptance, will increase the company's valuation, making it possible to obtain more funds with a lower dilution than when VC's are approached in a too early stage with just an idea, scarce data, or vague guesstimates of market size, demand and acceptance.

### Part II – Stage 1: Pre-Launch

Before the product can actually be launched, the following issues play a role prior to launch:

- (a) Decisions must be made where (which countries and which medical centers) the product will be introduced. Selling all over the world at once will definitely create problems regarding available human and financial resources. Marketing plays a decisive role here.
- (b) The product must have regulatory approval in these target countries.
- (c) Preferably it should have reimbursement coverage already, or in process of obtaining this.
- (d) Publications in prime medical journals; not white papers, case studies, or publications authored by company paid physicians and scientists, but quality, peer-reviewed articles by key opinion leaders, with statistically significant data and positive results.
- (e) A distribution network must be established. To entice and motivate local partners, a well-outlined plan + budget must be created prior to negotiations as to who does and pays for what, crucial issues when negotiating with strategic partners, distribution companies or other types of local representatives. Marketing will negotiate these relationships and develop the relative matrix of responsibilities and tasks. Optionally, sales and deliveries can be done directly by the company to the end-user (not advisable if the product requires close sales and technical support). Alternatively, if adequate funding is available, a local subsidiary or joint venture company can be established.
- (f) Documentation (user and service manuals, warranties, brochures, etc.) and product (labels, screen language, keyboards, technical requirements, etc.) should be available in the local language and comply with local legislation and requirements. Translations do not need to be perfect yet, until the local partner can proofread and advise on modifications.
- (g) Marketing will develop training programs and organize the training of a local sales force, technical service and/or clinical specialists, as well as of (potential) end-users. At this stage, the company's technical, scientific, medical, engineering, sales, administrative, distribution and other specialist staff (if available) will take over, develop training and other operational materials, give the training itself (if possible – otherwise this needs to be handled by Marketing), and exercise their responsibilities.
- (h) Completion of the distribution agreements and infrastructure, and all sales and service aspects, such as warranties, ordering procedures, delivery and payment terms, packaging and shipping conditions, warehousing and distribution, and the reporting of installations, demonstrations, sales, clinical results, adverse reactions, malfunctions, replacements, returns, etc.

### Part II – Stage 2: The Launch

Adequately funded and with all issues outlined in Stage 4 finalized, the actual launch can begin. Marketing will be responsible globally and assist local representative companies with:

- (a) Creating brand awareness
- (b) Product demonstrations, road shows and workshops
- (c) Presence at medical conferences and exhibitions
- (d) Design of printed materials, such as brochures, posters, mailings
- (e) Content for websites and press releases
- (f) PR
- (g) CRM

### Part II – Stage 3: Sales & Growth

With Sales taking full responsibility for the selling process, Marketing remains in touch with the market, evaluating customer acceptance and satisfaction, assessing new needs and possible product improvements, and investigating how to convert non-users into clients. Marketing will perform continual SWOT analyses and update the Business Plan accordingly. The road to continuous success and growth is by having Marketing establish close relationships with client-users and KOL's in order to always be ahead of competition, and offer healthcare providers the newest and most advanced products that offer a plethora of proven benefits.

## Red Flags

- The inventor is totally in love with his/her invention, and convinced it is the best thing since sliced bread, the ultimate solution to problems in his/her own line of work, without paying serious attention to the world around him/her.
- The founder starts a company with own or family money, appoints him/herself as CEO, and hires family members and friends in various VP position, all or most with no or little marketing experience.
- The CEO is steadfast that Marketing is a “luxury” and not needed, being only interested in Sales.
- The founder objects to in the industry acceptable ownership dilutions when serious financing needs are on the table, insisting on maintaining at least a majority shareholding after investment.
- Funds are spent on prototypes of the new product, or, in the worst-case scenario, on the “final” product, solely based on the inventor’s recommendations and dictates.
- Funds are spent on travels around the world, rubbing shoulders with KOL’s, visiting major international medical conferences, distributing and collecting business cards, merely building a database of names.
- Friends and colleagues are appointed as company advisors, and are invited (and paid) to speak highly of this great innovation at conferences in faraway places, in the press and media interviews.
- KOL’s, often (semi-) retired professors or board members of medical societies, without any or little hands-on user experience are listed as “reference users”, and also used as well-paid speakers.
- No or very few advisors or reference users have shown any commitment to purchase or recommend the purchase of the new product once it is ready.
- A small clinical trial is carried out by a colleague or related physician, the CEO self and/or the people involved in the product’s development, with the intent to produce clinical evidence and the successful use of the new product (prototype). The results may be published as a white paper or in a non-prime medical journal. Such publications are not considered useful, if not designed to meet regulatory, reimbursement and marketing demands. Moreover, studies are only of value if the conclusions are statistically significant, achieve the set objectives and expectations, and are published in peer-reviewed, major medical journals.
- Sales targets and financial projections are based on general off-the-shelf market research data that describe total global markets, but that do not address identified target markets, users and applications. Something like: *“The global market for X reached \$2.5b in 2009, and is expected to double to \$5b by 2015. Conservatively we expect to obtain 1% market share or \$50m in sales by 2015 with our new product.”*
- Lacking regulatory strategies, having no clue how regulatory authorities will classify the new product, which applications have a chance to be approved, what clinical evidence is required, what the regulatory process will cost, and when approval can be expected.
- Lacking reimbursement strategies, having no clue how insurance companies and government agencies will approve coverage of the new product or its use, which applications have a chance to be approved, what clinical evidence (trials) is required, what the application process will cost, and when approval and reimbursement codes can be expected.
- Lacking clinical trials strategies in a manner that will allow usage of the clinical studies’ results for the regulatory and reimbursement procedures, and later for marketing uses.
- Lacking distribution strategies, often expecting that distributors commit to minimum purchases up-front, and that they will spend their own money, time and staff for the marketing and sale of the new product. Distributors are not interested in a new product without clear-cut proof of market needs, market potentials, reliable clinical evidence, and foremost a sense of partnership with the manufacturer, specifically who does and pays for what. Distributors won’t pay out of their own pocket for issues such as applying for regulatory approval and reimbursement codes, setting up and running clinical trials, showing the new product at exhibitions, running workshops and training programs, translating and printing manuals and printed materials, PR, press releases, warehousing and distribution, unless they have a sense of a partnership and fair sharing of expenses and revenues. Identifying, evaluating and negotiating with potential distributors are intensive and elaborate tasks.
- Last, but not least: unwillingness to spend money on Marketing, or expecting Marketing assignments by external consultants to be done for free.

*“Because the purpose of business is to create a customer, the business enterprise has two--and only two--basic functions: marketing and innovation. Marketing and innovation produce results; all the rest are costs. Marketing is the distinguishing, unique function of the business.” Peter F. Drucker*

## Important Facts

A typical Venture Capital professional receives on average 300 Business Plans a year. Just 150 pass the first selection, and about 100 survive a more precise reading. Approximately 50 proponents are then invited for a presentation and discussions. About 25 usually survive a next selection, and about 15 will be thoroughly interrogated and undergo due diligence. 8-10 will then go through a vigorous and comprehensive assessment. In the end, 3-4 startups will receive their funding, though usually not the amount of investment requested, with the odd exception. In order to belong to that last 1% it is of the utmost importance to be prepared, know the business, the users, the markets, the needs and requirements, and foremost, convey a watertight analysis that the new product has clear-cut and proven benefits, rendering the startup an attractive and attainable ROI.

The decision speed (the time between first Business Plan submission and the Green light for an investment) varies immensely, ranging from 2 till 12 months. Also the preferred exit strategies vary, with most VC's demanding a fast exit (3-5 years), with a few expecting to be in it for the longer term. This not always depends on the VC, but also on the completeness of the startup's Business Plan (especially market and user knowledge), supportive facts and clinical evidence, and the type of product. Large capital equipment, BioTech and Pharmaceuticals usually take far longer to obtain approval, reimbursement coverage and profitable sales levels, than consumables and small devices.

Narratives about the greatness of the inventor and advisors, a purported uniqueness and aggrandizement of the invention, big sales figures, huge market potentials, snowballing market shares, uncorroborated market research data, and a poorly written off-the-shelf business plan will not get past the first selection.

## GlobalStrategists

..... has the experience and expertise to take charge of the complete Marketing Process, both the Upstream and Downstream Marketing Stages. In addition we are experienced in composing, writing and implementing Marketing and Business Plans. Invite us for a presentation of our capabilities and a discussion about your needs. With our global network of consulting partners and strategic partners we can deliver a complete range of Marketing, Product and Business Development services and advice.

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