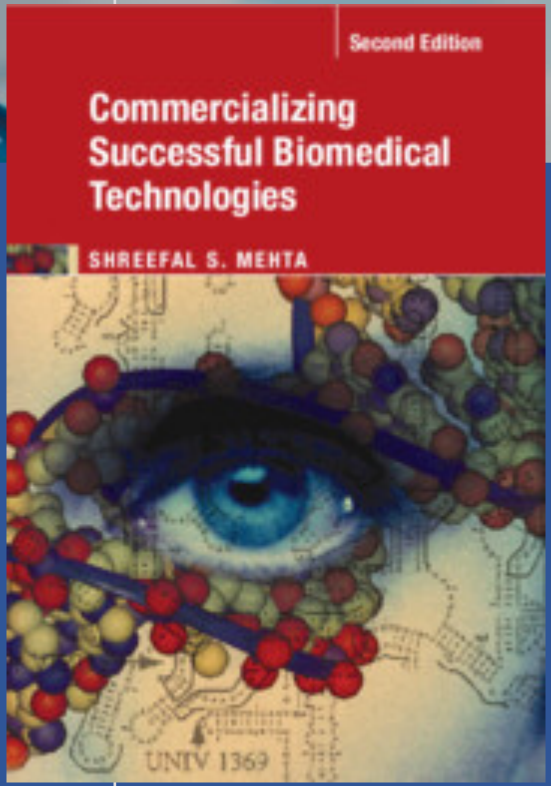
Commercializing Successful Biomedical Technologies 2nd Ed.

Shreefal Mehta



Plan	Position	Pitch	Patent	Product	Pass	Production	Profits
1 Industry context	**2** Market research	**3** Start a business venture	**4** Intellectual property rights	**5** New product development (NPD)	**6** Regulatory plan	**7** Manufacture	**8** Reimbursement

Starting up your company

Shreefal Mehta

Chapter 3

Building the team

- ***Selection at the management level***
  - ✓ Based on gut feeling or chemistry with the people
  - ✓ Logical fit within the gaps in the founders' skills
  - ✓ Fit for the company's future needs
  - ✓ Pitch the concept in business plan competitions to attract co-founders, early hires
- ***Hiring people and assigning roles*** **:**
  - ✓ *on the basis of aptitude, not experience or degrees alone, pays off in a growing company*
  - ✓ *Company grows very quickly - functions and roles are likely to change*
  - ✓ *successful hiring is the fit of that person with the* ***company culture***
- ***Culture is built every day in how the leaders and others act and react.***

Who should be on the team?

If the founders are from technical backgrounds (technopreneur)

attract a co-founder from a different background that

brings experience in building companies and/or Is thinking predominantly from the business or the commercial perspective (market perceiver)

People from different backgrounds should be a part of recruitment strategy at all levels, from board of directors' members to management and staff.

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Board of directors usually include

- ❑ The representatives of the largest shareholders
- ❑ The CEO and possibly other management
- ❑ Independent directors

Primary duty :

- ✓ Fiduciary duty to act on the behalf of ALL shareholders to oversee company
- ✓ The board provides oversight and approves major strategic decisions made by the management team

Early-stage company

- one- or two-member boards are adequate for formal functions
- Recruit investors and independent directors who can give the energy and time to help the startup
- Board directors play an active role in helping with financings or opening doors using their extensive networks, help resolve conflicts in a management team.
- Board Appointments will naturally grow with the company from 1-2 in seed round, to 3-5 in series A and B, and 7 or 9 in Series B/C.

Some practical dos and don’ts about working with boards:

- Discuss and confirm the time commitment and availability of a director
- For a startup with no revenues, the remuneration of the director should only be in equity
- Structured meetings with agendas
- Structure the agenda so that most important strategic issues are presented at the beginning of the meeting
- Promote two-way dialogue – reporting from management team to board and gathering feedback from board members
- Ad hoc calls of the CEO with individual board members between meetings builds understanding and trust
- Diversity of thought and background

Advisory board members

✓ Research scientists or medical physicians are best added to the scientific advisory board, where they do not have fiduciary responsibility

✓ A board of advisors can be formed to show the support of important names in the field and add credibility or bring specific relationships to the young company

The startup company

There must be a clear designation of the duties and responsibilities so that there is accountability for goals and objectives

Team

- Hire people smarter than yourself and demand accountability
- Give these smart people resources and freedom
- The main element for success in a startup is the team
- Maintaining trust and mutual respect must be a key part of the cultural values of the company and management team

Role of a leader

- Who is the voice and face of the company to current and potential stakeholders
- Role that is needed from the beginning - role of head of science or product development, or technology
- Eg: Many life sciences companies have just two management-level roles – CEO+CSO – for many years while the company is carrying out prolonged R&D

Tips for building startup teams and assigning roles

- Do specifically assign roles and responsibilities, even if it seems too formal for 3 people company
- Do follow through on accountability
- One person functionally responsible for the task should lead, be making the final decisions, and be responsible for the outcome
- When a decision is made after due consideration for inputs, the decision needs to respected by the other management team members
- Do build a culture of trust
- when the company is struggling, keep roles and responsibilities steady unless it is clear that someone is overwhelmed or incapable or has consistently shown poor judgement

Role of the CEO

- A company needs a figurehead “talking head” at the helm, even for a “flat” organization
- CEO is answerable to the board and ultimately to the investors
- The CEO communicates the vision of the company, lays out a path to the next milestone, sets up the strategy, organizes responsibilities, and assigns tasks, building a cohesive culture
- Hires strong second-in-command people with specific expertise and skills in functional areas
- As the company grows, the CEO needs to continue to build and reinforce the culture of the company, coordinate goals, communicate the vision to all stakeholders

The Business Plan

- Lays out the vision for the company, with a set of signposts and milestones
- Explains why the world is better with the launch of that new venture
- Describes how it plans to grow, make money and become profitable.

Components of Biz Plan

I. Executive summary 1-2 pages

II. Slide deck - business plan

III. Pro forma financial statements for 1-2 years into the future

IV. Biodata of the key-founders

V. Second slide deck for technical data

VI. Technical documents or patents to be reviewed in due diligence

"In preparing for battle, I have always found that plans are useless, but planning is indispensable."

A saying often ascribed to President Dwight D. Eisenhower

Process of planning has great value for any startup team

Business plan cont..

- Majority of the successful companies that have raised financing from venture capital pivoted to a different business model
- The success of a startup company hinges on the founding management team, and experienced investors

Base for building the business plan

1. **A commercialization plan**, which defines the market need, the development pathway to build and launch the product/service, and an associated budget and resources
2. **A financial plan** that lays out a strategy to raise financing and meet budgetary needs

Business Plan Contents

- ✓ People (bios)
- ✓ Need and market
- ✓ Competition
- ✓ Path to market
- ✓ Product/service
- ✓ Business model
- ✓ Milestone based funding and use of funds
- ✓ Valuation/liquidity

Stepping Stones To The Business Plan

The commercialization plan

- ***The output of the commercialization plan***

  I. A recognition of key milestones for the company

  II. A critical path outline for product development to market with the time and resources (budget, staffing, functions, headcount, etc.)

- From this timeline of cash and resource needs, a financial plan can be built up

The financial plan

- Gives investors information about the capital investment
- Correlates the funding schedule and budget to key milestones
- Describes quantitatively the business model by which the company will earn revenues and reach profitability
- The amount of capital needed over time to get the company to the point of break-even

Bottom-up plan

✓ Each milestone is practically reviewed from the basic steps

✓ As a basis for the business plan is much more credible to investors

Identify the assumptions :

✓ identify assumptions that need to be addressed for each milestone to be met

Investor Perspective

An investor will have the following questions when reviewing the business plan:

- Specific market need - is it a big enough market, and one that is growing?
- How much further investment is needed and when could the investor get their capital and profits back
- The potential return to the investor
- How is the proposed solution unique and competitive in the market and is there a moat defending the market access ?
- Experience and background of the founders or management team
- Multiple chances (e.g. Products in different therapeutic areas) to get revenues from a product or service to the market
- Does business model strategy adequately mitigate the perceived risks?
- What are the underlying key assumptions that are needed to be fulfilled for this business to be successful?
- Patent strategy ?

Typical business models for drug, device

Drug innovators :

- License their innovative product idea to the large pharma companies at appropriate stage
- If successful in fund raising, take advanced products to market

Device innovator companies :

- Licensing to one of the top device companies
- Build a sales team in a specific market and commercialize

Innovator diagnostic companies :

- Can nonexclusively license their technology to several large diagnostic companies
- Gain early revenues by launching the test as a laboratory developed test (LDT) and establish a level of reimbursement from payers
- Target a niche market with a unique biomarker or test format and build sizeable revenues for the company while establishing its new platform
- Channel other tests through the same platform to grow its market.

Business models – Life science companies

The dominant business models that have emerged in the biopharma industry are:

1. Vertical model

- has a product focus with vertical integration over the whole value chain to discover, develop, and market a single technology e.g. large pharma
- Biotechnology and device companies focus on research, and work in a "short vertical" model, where the product prototype (having achieved proof of concept in human) is sold or partnered out to a commercial partner
- High-risk, High return on investment

2. Horizontal platform model

- Operate at a specific location in the value chain
- Sell a broadly applicable product/service across various sectors or industries such as human, agricultural or industrial
- Existing within this type of business model are service companies like contract manufacturing and clinical research organizations (CMO/CROs) that obtain a comprehensive fee for their service and have no plans to develop an FDA-regulated product on their own
- A few horizontal platform cos built up rapidly on partnership revenues with their broad technology and brought in products to become vertically integrated businesses

Business models – contd

3. Hybrid model I – tools to product development

- Occupies a horizontal and vertical position over the value chain
- Starts with a horizontal business model to make money quickly and then builds therapeutic pipeline to vertically integrate for higher value

4. Hybrid model II – services backward-integrating to discovery

- Shared risk models, where the services company takes on a performance risk and gets incentives based on success or develop their own internal R&D product pipeline

5. Venture capital–led, incubated virtual company

- The VC groups hire experienced pharma mid-career executives and run companies virtually or with a small, shared lab footprint and majority outside contracted work
- Validate new target or drug platform at low cost
- Proved to be financially successful for the venture investors and the founders

Practical tips on presenting the business plan

- Prepare different versions of the business plan presentation for different investor types
- Technical presentations are prepared separately for confidential discussions
- Financial statements (budgets) for the first 18 to 24 months should be presented in monthly or quarterly layout
- Identify assumptions behind the projections and flesh out the path to scaling the business
- Bring focus on the benefits of the product in first few meetings
- A go-to-market strategy is critical - include any validation from prospective customers.

- Competition must be addressed credibly – present alternatives and competitors
- Experienced board of directors or advisors can help reduce the perception of inexperience
- Do not propose a valuation for the company unless a lead investor has invested
- Use a private placement memorandum (PPM) to bring in angel investors. This is typically useful when reaching out to many diverse angel investors or crowd funding platforms
- Hire a lawyer to review the term sheet from the investors before agreeing to terms. It is also advisable to have a securities lawyer review the PPM

Distributing equity

- Founders should have an open discussion on distributing founding equity
- **Share equity evenly** or **split the founding equity** based on perceived contributions
- Important to put all members on a vesting schedule
- Time based or a combination of time based and milestone-based vesting
- Early sale of equity to founders should be undertaken with guidance from legal counsel and business advisors, so that appropriate board and shareholder approvals can be correctly put in place in the company records

Typically, equity distribution frameworks assign weights to:

1) The significance of the idea or the patent inventor
2) Business knowledge using functions such as who is drawing up the business plan, bringing in investors, etc.
3) Domain expertise such as a chief architect of the product
4) Commitment and risk such as who is keeping their full-time job or joining the company full time
5) Responsibilities such as taking leadership in most items and staying up late worrying about payroll or delivering on planned milestones etc.
6) Additional contributions that may not be returned to the founder

✓ Summarizing the points for each founder gives a percent ratio of allocation of founding equity

✓ The main benefit is promoting discussion and improving founders understanding of each other's motivations.

Doing science for product development

- Goal in commercial product development is to get to technology proof-points as early as possible
- Be able to change directions before running out of money to reach a significant milestone
- In academia, exploration of possibilities and following outliers for new discoveries are suitable actions
- Goal in academia is to gain a publication or to gather data for the next idea for a grant application
- The decision-making process of a researcher, trained with the academic goal of getting grants or publishing, has to shift to a different gestalt in a company
- Moving from scientist to CEO requires different basis for decisions, killing projects early is preferred

Challenges in setting up a new lab

- It may not be easy to set up credit accounts with larger suppliers of bulk materials who also may not sell small quantities
- An incubator can be helpful in extending the relationships or infrastructure of a larger institution to the member startups
- Specialty gases or chemicals sourcing may be difficult or costly to meet regulatory materials handling or disposal requirements.
- Setting up a biological laboratory or animal testing facility requires significant compliance-related administrative activities
- Some universities have formulated guidelines to allow young spin-out companies to contract work back to the lab

Working with academic labs – lessons learned by a startup CEO

- Many academics feel that their contributions are outsized, as their fame or reputation itself is transformational to the young company (in most cases it is not)
- Negotiating with academics on a viable, equitable distribution of equity or gains becomes a very emotional discussion.
- Giving them large chunks of the company may make it impossible to raise financing from savvy investors
- Students run the labs and thus the quality of the labor available for running experiments is highly variable, lacking professional discipline on timings and consistency
- Large pharmaceutical or biotech companies typically give very little credence to academically-generated data and trust the data only if replicated in a professional, commercial laboratory

Setting company culture

- Set a culture for accountability and decision-making processes
- When the company is small, the culture is that of the individuals' own behaviors
- The way people communicate and behave toward one another, their integrity, and approach to problem solving all define the culture
- Make conscious decisions about the culture you want to see in the company and embody those characteristics in your own behavior from day one

Conflict resolution among staff and management team

- Hire a part-time HR manager from a local firm for part time on site availability
- Mandate training for sexual harassment education
- Interpersonal conflicts: best addressed in person rather than with written emails
- Clear corrective actions and follow-up must be laid out in writing
- Tough decision to let a problem person go is usually seen as the best decision even if they are a technical genius
- Growth salves many personnel ills in a startup company

Financing a company

- "If an investor is offering you money – take it!"
- It is prudent to have more cash than you think you need
- The budget has to be built from the ground up

Sourcing of financing to early milestones

Early development activities

Funding sources :
- Existing research grants
- Founders, friends and family, angel-investors
- Early commercialization government grants
- Philanthropic foundations/ venture capital

Product validation stage

Funding sources:
- Venture capital, govt grants, high-net-worth angel-investor

Human clinical testing

Funding sources:
- Venture capital (financial investors)
- Strategic corporate partners.

larger clinical studies, marketing, and manufacturing

Funding sources:
- Public markets
- Private equity
- Venture capital, or corporate partner financing

Valuations

- A major step of completing a financing : pre-money valuation, which is a highly subjective measure
- Common methods
  - ✓ Market comparables
  - ✓ Product valuation taken from licensing or financing transactions
  - ✓ Current value of discounted cash flow calculations from projections of future revenues
  - ✓ Best method to support a targeted valuation is to bring in competing offers (term sheets) from multiple investors or corporate partners
  - ✓ *Usually, a professional investor or a seasoned angel-investor sets the valuation by first offering a term sheet to the company*

- Investment terms are not only to be negotiated on the company pre-money valuation price/share
- But also on other terms such as “preferred participating” or “liquidation preference,”
- Consider other terms in the investment offer along with the non-quantitative benefits that the particular investor may bring in
- Taking a lower valuation : help with long-term success, including successful next round financing.
- A company may give away up to 20% of the company equity in the first seed round and about 15% to 30% in the next round of funding.
- The main challenge for biomedical companies is that the risk versus value equation is quite high until completion of human clinical testing, hence there is usually a strong drive to source nondilutive financing in early rounds

Selecting your investors

- Multiple investors should be approached in parallel
- Focus on investors who take the lead
- A company should also carry out due diligence on the investors by speaking to CEOs of other companies in the investor's portfolio
- Getting to know the working style of the person who will potentially be appointed to the board of the company
- Strategy of the venture fund is important to align with the company's stage

Non dilutive funding sources

- Startups in biomedical technology face unique financing challenges.
- Risk remains until very late in development - human testing and regulatory gateways
- Non-dilutive funding is best to meet cash needs:
  - Service revenues
  - Grants
  - Philanthropic venture institutes
  - Strategic partners
  - A type of debt financing : venture debt.
    - ✓ Offered by specialized financing companies right after a venture financing event
    - ✓ Low-interest loan securitized by the new capital infusion to extend the runway

Operating a Startup - Meetings

- *The frequency and method of meetings set the pulse of an organization*
- Help to organize the flow of information and decision making

Types of meetings

1. Daily operations coordination meeting

- ✓ standing check-in-only, 5- to 15-minute
- ✓ Held with each team or team leader
- ✓ Every morning without long discussions
- ✓ Report in on activities for the day and the previous day

2. Weekly management review meeting

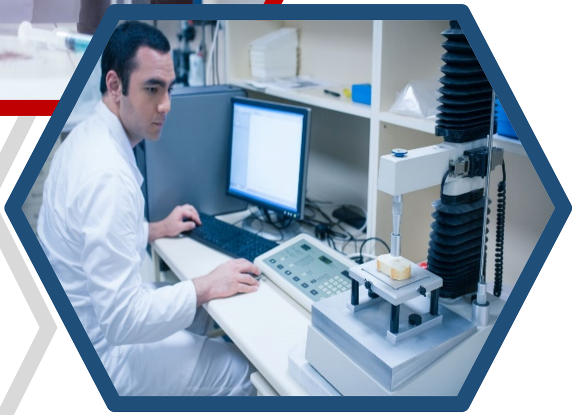
- ✓ With only team leaders or upper management
- ✓ Discuss and resolve tactical issues and lay out priorities for the next week

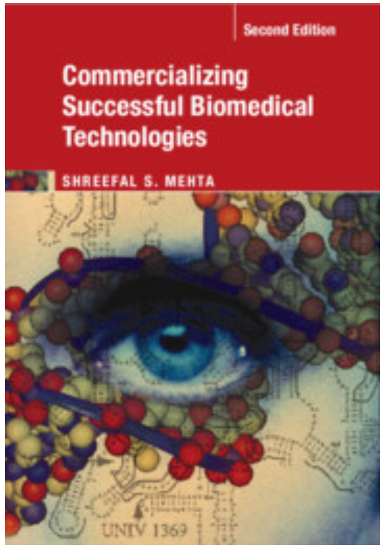
3. Monthly strategy review meeting

- ✓ With management and may include advisors and board members as pertinent

4. Quarterly or monthly all-hands-on-deck meeting

- ✓ With review of deliverables, overview of the progress toward quarterly or annual goals of the company www.shreefalmehta.com/csbtbook





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