Suggestions for Contents of a Business Plan
Medical Device Start-up

Table of Contents

I. Executive Summary
   • Overview of the business concept
   • Short background on industry/market
   • Short description of first products, what is proprietary, strategy, competition
   • Brief summary of what you need to do to get there (i.e. reg approvals, clinical trials, etc.)
   • Business model; how you will make money
   • Financing – what have you already raised, how much you need this round
   • Management team, brief bio

Should be no more than 3-4 pages. You may want to send this ahead of full plan to gauge interest before revealing the whole plan.

II. Disease State
   • If appropriate, clinical background of the disease/problem you are addressing; what are the current options for diagnosis/treatment; target patient characterization

III. Market Size and Opportunity
   • Describe and “segment” the market
   • Market size numbers, both in total $, and # of procedures, geographics (US & worldwide), projections (list reference sources)
   • Competitor discussion, market shares if relevant, strengths/weaknesses, pricing
   • Nature of the sale, distribution channels
   • Current reimbursement, economics of business

IV. The “New Company” Product and Procedure
   • Description of initial product(s) in detail, future product ideas briefly
   • How far along is product and what evidence of feasibility/performance do you have now
   • Company expertise or proprietary technology
   • Clear description of why it is unique, what problem it solves, why and who would buy it, and why other people can’t do it
   • If possible, specific economics showing value added (i.e. cost effectiveness) to customer
   • What changes must the user, referral chain or health care provider make to have this product/procedure be adopted (i.e. training issues, referral pattern changes, changes in physician specialist providing the therapy, payment changes) and how are you going to get them to do it.
V. Clinical and Regulatory
- Regulatory path needed (IDE, 510K, NDA, CE with or without clinicals, etc.)
- Expected time frame
- Nature of clinical trial, approximate expected number of patients, follow-up time, what are end points, what do you need to prove for FDA/CE mark, what clinical data do you need to provide for market acceptance beyond regulatory requirements

VI. Intellectual Property
Patents applied for, status, etc.
Agreements on any licenses, royalty, etc.
Who has patents close to yours and why you think you are free to operate

VII. Key Personnel
Management team and bios, previous relevant experience and successes (include company names)
What key positions are yet to be filled, who are candidates, timing
Scientific Advisory Board, Board of Directors, other key personnel affiliations (i.e. attorneys, accountants, etc.)

VIII. Current Status and Funding Needs
- Accomplishments to date of company overall (including organization, product development, animal trials, etc.)
- Amount of funding being raised, type of investors you are seeking
- Financing history and current investors (a capitalization table showing the pre/post for each series and what % of ownership each major owner or group of investors has, and the employee options pool is very helpful)
- What activities will the funds raised be used for (time line, rough budget)
- Key accomplishments anticipated before the next funding event
- How much funding total will you need to get to self-funding or liquidity, timing, what is likely liquidity event

IX. Pro-Forma Financial Projections
- Revenue projections as % of market
- P & L projections for company along with funding needs
- Pricing and margins expected on products, discussion of variables if appropriate

X. Footnotes and References
- Pertinent clinical articles
- Renderings or photos of the product or other visual aids
- Market info references used for projections