



“What Investors Really Want To See In Your Business Plan”

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Zero Stage Capital

- Zero Stage Capital founded 1981
- Six investment professionals
- \$350 million under management
- Invest across technologies and stages
- U.S. northeast corridor focus

Like everything else, the life sciences are different

- Pharmaceuticals/biopharmaceuticals; medtech (devices/instruments and reagents); diagnostics – human and veterinary
- Long, expensive, complicated development cycle if used in humans/for human disease diagnosis or treatment
- Competitive advantage relies heavily on IP
- Complicated and lengthy regulatory review process
- Third party reimbursement (public/private)
- (FI_CO business model may be very capital intensive with high operating costs)

Cover letter/e-mail: ≤ 2 pages

- “X (e.g., a prominent VC) suggested that I contact you...”
- Who you are and a little personal history (where you’ve been)
- What this is about (e.g., raising Series A for X purpose)
- Brief overview: technology origin, utility, customer need (i.e., problem being solved), market opportunity...
- Status of development/commercialization
- “I’ll contact you the week of X to introduce myself and confirm your receipt”...
 - Then call that week – get a meeting; if no interest, get \geq two names(!)
- Attachments: executive summary, business plan, a press release or published article

The (life sciences) business plan

- Purpose:
 - A primer – provides “technical” (science, technology, market segment) background for the non-expert
 - To provide a detailed operating plan – your “road map”
 - To demonstrate you are: knowledgeable, thoughtful, sophisticated
 - To get a meeting – to demonstrate your passion...
- General layout:
 - Use graphics for clarity and simplicity
 - Executive summary – the “hook”
 - Corpus – details to follow
 - Appendices – detailed financials, literature, PR, patents

Life sciences business plan: corpus

- Background/Overview
- Market opportunity
- Science and technology
- Product description and commercialization plan
- Intellectual property
- Business model (including reimbursement)
- Competition
- Management team/BoD/SAB
- Financials/Use of proceeds

Life sciences business plan: corpus

Background/Overview – tell your *story* here...

- Tell me: your history – “Based on ground-breaking research from the lab of Dr. X, Nobel Laureate...”
- Enlighten me: what is the problem that your product/technology solves?; the need that it fulfills?; the desire it creates?
- Show me: that the market that your product serves is worth pursuing (size, accessibility,...)
- Help me: understand why you think your product/technology, development plan, and team will succeed

Life sciences business plan: corpus

Market opportunity

- Who is/are the customer(s)?
- How many are there?
- What are they buying now?
- What are they (patient or insurer) paying...will they pay your price? More?
- Not all diabetics use insulin, not all back pain requires disk replacement: define the applicable – not the aggregate – population
- Applicable population X ASP = relevant total market

Life sciences business plan: corpus

Science

- Therapeutics and diagnostics (human and veterinary)
 - Definition/epidemiology/biological basis/clinical manifestations and natural history/diagnosis/treatment alternatives and outcomes
- Research tool
 - Specifics of biological systems being explored and physiochemical measurements being made
- Technology
 - Description and explanation of how it works
 - Applicability to diagnosis/treatment or R&D needs
 - Validation - in vitro/in vivo/clinical data/beta tests/sales

Life sciences business plan: corpus

Product description and commercialization plan

- Detail of *specific* product(s) under development
- Status of research – Proof of principle?
- Development pathway: pre-clinical, clinical, regulatory requirements
 - Pre-clinical data – GLP data?
 - Basic design of human clinical trials
 - Any FDA contact yet?
 - Outsourcing?
- If regulated product, upon approval what will the “label” read?

Life sciences business plan: corpus

Intellectual Property

- Patents/applications: numbers, dates of filing or issuance
- “U.S. and foreign counterparts...”
- Types of claims:
 - Composition of matter
 - Methods of use
 - Manufacturing processes
- Assignee(s)/licensee(s)/sublicensee(s)
 - Exclusivity, field(s) of use, territories
- Know-how, trademarks, copyrights

Life sciences business plan: corpus

Business model and reimbursement

- FI_CO, virtual, or something in between?
 - Most VC don't like spending equity dollars on bricks and mortar or "re-creating wheels"
 - Make/do only what you have to; bring it inside if you can't find it or manage it on the outside
- Third party reimbursement is: complicated, time consuming and levels are uncertain
 - Medicare/Medicaid/private carrier/self-insured
 - CPT codes (AMA) describe physician procedures; procedure reimbursement is different than product reimbursement
 - Expert help is available

Life sciences business plan: corpus

Competition

- Competing technologies
- Competing companies
- Explain, then compare and contrast succinctly

Life sciences business plan: corpus

Management, Directors, Advisors

- Senior management (“team”)
 - The “No (or interim) CEO conundrum”
- Keep board small: pre-VC = 3-5
 - Look for independent directors with relevant industry experience early
 - Scientific/academic founder as director or observer (SAB chair, too)
- SAB more than “window dressing”
- Management, BoD, SAB will evolve – right team for tasks at hand and the proximate stage

Life sciences business plan: corpus

Financials

- Five year financials are of interest; the next 18-24 months are key
- Worth spending time on revenue build-outs and timing of major expenses (e.g., GLP toxicology studies, clinical material manufacture,...)
- It's the assumptions I'm focusing on
- Use of Proceeds
- Milestones achieved with this round of financing need to "build value" (i.e., potential for an up round!)
- With very early stage companies, I can see out about 18-24 months...so I focus on milestones that I can commit to achieving during that timeframe
- You are raising money to get to certain meaningful milestones – not "enough money for 18-24 months"...