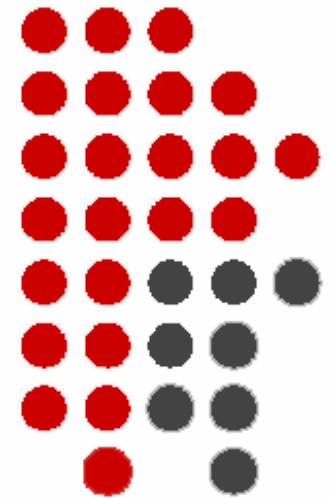


Business Planning that Tells Your Story

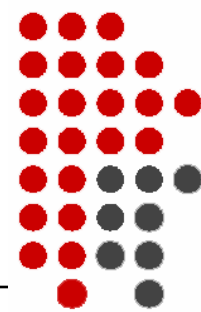
Richard E. Kouri, Ph.D.
Executive Director
BioPharma Management
Initiative
College of Management
North Carolina State University
May 3, 2007





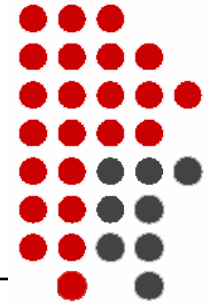
Would you be interested in this company?

- Product is ready for sales within 18 months
- Multiple issued patents on device
- At least 440,000,000 device users per year in US
- Manufacturing cost is <5% of selling price
- No competitor has patented device
- Potential revenues are in the \$300M-\$500M/yr range by 5-8 yrs
- Revenue stream generates an NPV of \$50M-\$150M for an investment of \$1M
- Revenue stream generates an NPV of \$360M-\$1,000M for our consumer healthcare partner
- Management Team has history of exits totaling \$820M



Requirements for a New Venture

| | <u>Value</u> |
|--------------------------|--------------|
| • Idea | 5-25% |
| • Business concept | 25-50% |
| • Value proposition | |
| • Financial proposition | |
| • <u>Management Team</u> | |
| • Capital | 25-50% |



“Pushing” vs. “Pulling”

- We have this cool technology, now how do we package it to get the best deal?
 - Focus is on the technology
- We have this list of stated needs by these big companies or VCs, how do we get our technology to match these needs?
 - Focus is on the customers



Properties of the “Business Concept”

- Is key step in new venture creation
- Is time and resource intensive (esp. people)
- Cannot be started until ideation occurs
- Should be completed prior to raising any capital (most often is not)
- Has to be linked to specific needs of specific customers (almost always is not)

Companies that do it well are successful at the commercialization process



Technology

- Disruptive
- Market size
- Competition
- Differentiation
- Patent protection
- Scientific founders



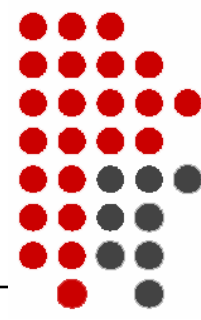
Advisors/Managers

- Experience
- Skills
- Relevance
- Commitment
- Team work
- Honest



Proposed Situation

- We won our SBIR Phase II grant
- We have 18 months before it is completed
- We will complete all our animal studies
 - show POC for our 'drug' for lung cancer
 - ADME/tox profile is excellent
- We can manufacture 'drug'
- We have advisors who can help direct next steps
- We know we need more money

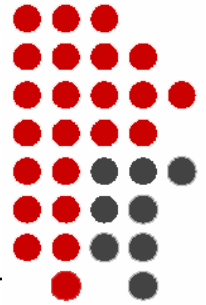


Potential Sources for Money

- More grants
- Loans
- Strategic partners
- Angels
- Venture capital
- Public offering

How do we choose?

First Step



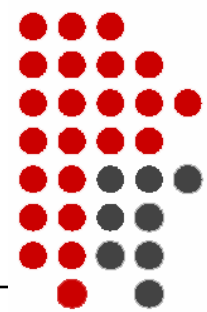
Write Business Plan

- a must for financing
- imperative for team alignment



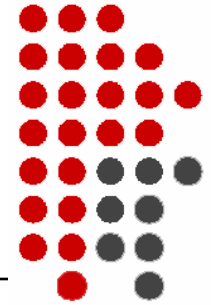
Put it on paper; Executive Summary

- Business description for product or service
- Target market
- Distinguish from competition
- Management team
- Summary of key financials
- Funding requirements
- Projected revenues and EBITDA



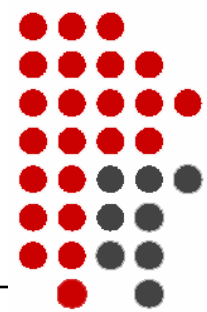
Business Plan

- Introduction
- Statement of Market Opportunity
- Statement of Solution/Offering
- Competition
- Marketing
- Management
- Financials
- Milestones



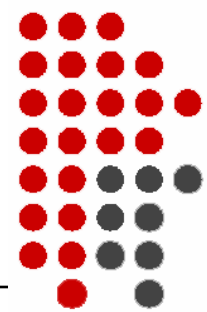
Introduction

- Founding date, progress, and founders
- Products or services
- State of development
- Key financials, capitalization
- Vision for the company
- Potential exits



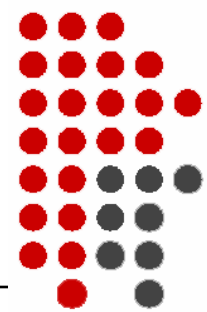
Market Opportunity

- Market segment; historic and predicted growth rate
- Market segmentation strategy
- Critical product characteristics
- Customer description



The Product or Service

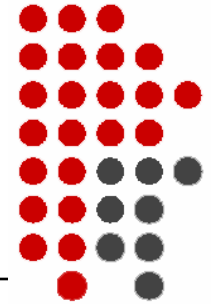
- Clear, full description of product or service
- Intellectual property protection
- Long term profitability protection
- Product differentiation strategy



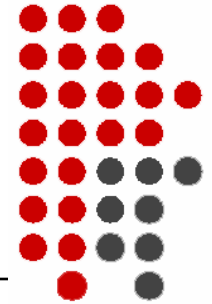
Competition

- Identify main competitors; strengths, weaknesses and market share
- Realistic analysis
- Principal competitive factors
- Closest substitute

Marketing

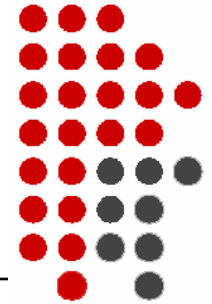


- Branding
- Distribution channel
- Pricing strategy
- Promotion



Management

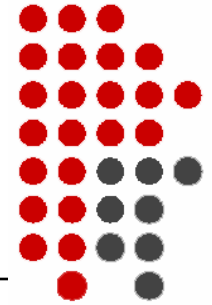
- Key managers
- Honest assessment of strengths and weaknesses
- Plan to complete management structure
- Management incentives for success



Financials

- Current financial statement
- 3 years past; 5-10 year forward
- Assumptions
- Capitalization chart
- Milestones reached tied to cash flow

Example of a Conclusion from Business Plan

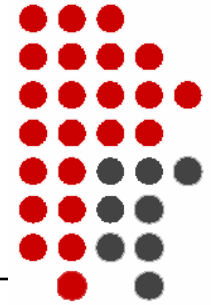


We need to raise \$3M from VCs



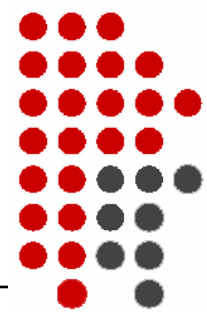
Characteristics of VC Providers

| | Professional Venture Capitalist (VC) | Business Angel (BA) | Corporate Venture Capitalist (CVC) |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Source of funds | <ul style="list-style-type: none"> ● Investing funds of outside limited partners | <ul style="list-style-type: none"> ● Investing their own money | <ul style="list-style-type: none"> ● Investing corporate funds |
| Legal form | <ul style="list-style-type: none"> ● General partnership | <ul style="list-style-type: none"> ● Private individual | <ul style="list-style-type: none"> ● Subsidiary of a large firm |
| Typical size of investment | <ul style="list-style-type: none"> ● \$2–10M | <ul style="list-style-type: none"> ● \$50–100K | <ul style="list-style-type: none"> ● \$2–20M |
| Financing stages | <ul style="list-style-type: none"> ● All stages | <ul style="list-style-type: none"> ● Seed & Startup | <ul style="list-style-type: none"> ● All stages, later preferred |
| Geographic proximity Preferences | <ul style="list-style-type: none"> ● Close proximity is preferred | <ul style="list-style-type: none"> ● Very close proximity is preferred | <ul style="list-style-type: none"> ● Proximity less important |
| Motive for the investment | <ul style="list-style-type: none"> ● Equity growth only | <ul style="list-style-type: none"> ● Equity growth and personal | <ul style="list-style-type: none"> ● Strategic and equity growth |
| Investment criteria | <ul style="list-style-type: none"> ● Growth prospects ● Great management | <ul style="list-style-type: none"> ● Growth and mentoring prospects | <ul style="list-style-type: none"> ● Strategic value and 'fit' |
| Finding investors Reaching agreement | <ul style="list-style-type: none"> ● Easy to find ● Lengthy and extensive due diligence | <ul style="list-style-type: none"> ● Hard to find ● Relatively quick to reach agreement when 'fit' | <ul style="list-style-type: none"> ● Few but easy to find ● Hard to meet 'fit' requirements |
| Reporting requirements | <ul style="list-style-type: none"> ● Regularly timed reporting requirements ● Financially focused | <ul style="list-style-type: none"> ● Varies by individual ● Generally light | <ul style="list-style-type: none"> ● Regularly timed reporting requirements ● Strategically focused |
| Involvement level Method | <ul style="list-style-type: none"> ● Moderate ● Board membership direct or through syndicate | <ul style="list-style-type: none"> ● Low to extremely high, informal | <ul style="list-style-type: none"> ● Low to moderate ● Informal or board |
| Exit planning Method | <ul style="list-style-type: none"> ● Planned ● IPO/trade sale | <ul style="list-style-type: none"> ● Often unplanned ● Trade sale | <ul style="list-style-type: none"> ● Often unplanned ● Acquisition/trade sale/IPO |



Maximizing Value for Company

- Getting VC funds
 - Secure a good referral
 - Write a good business plan
 - Be prepared for meeting
 - Don't (over) shop/ don't (over) rely
 - Be honest, but sell
 - Have patience



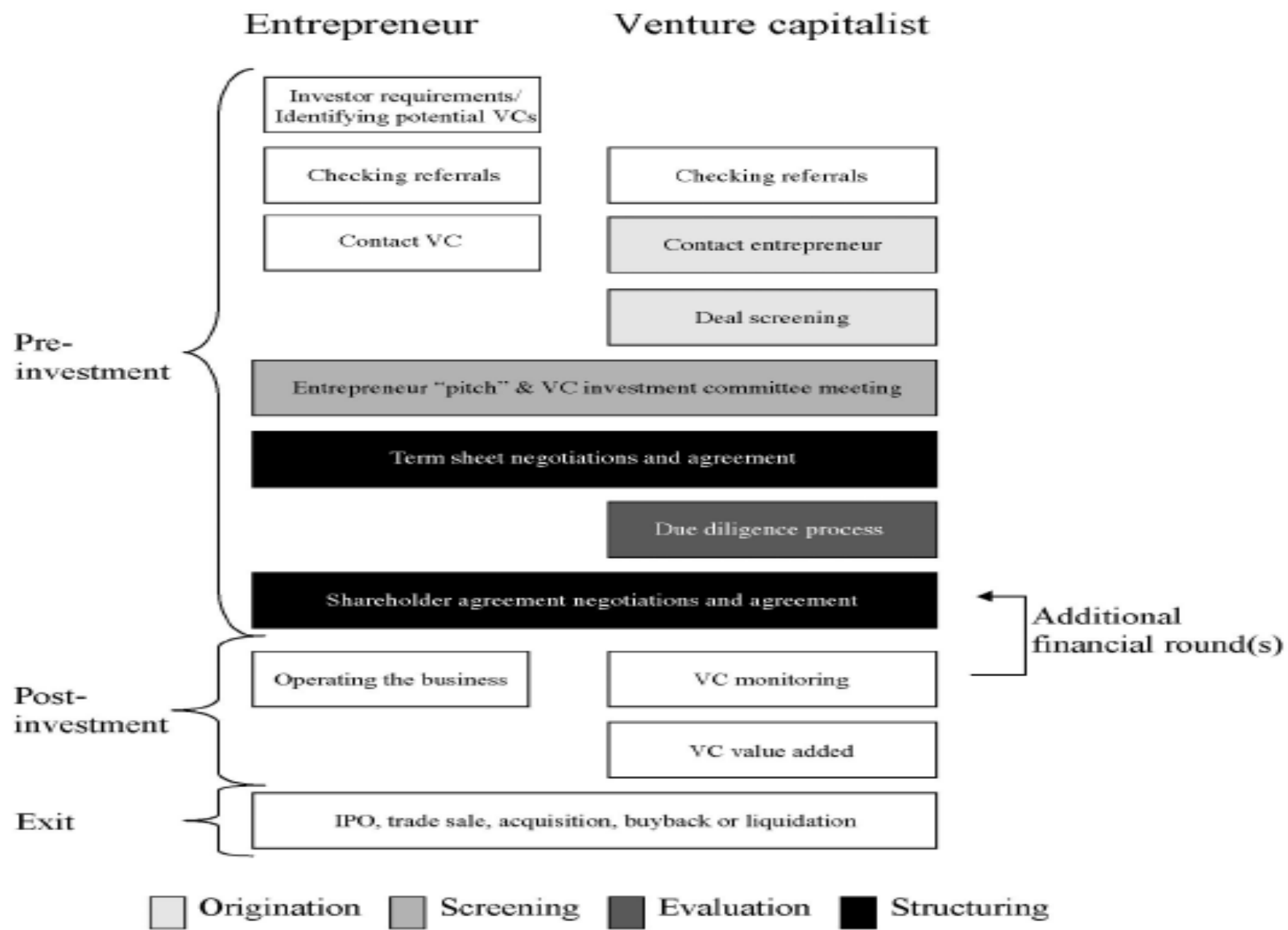
Maximizing Value for Company (cont'd)

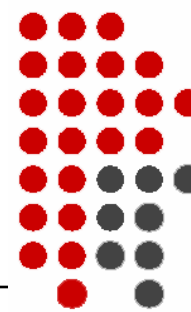
- Get the right VC
 - Complementary skills
 - Commitment
 - Trusting relationship
- Obtain the right amount of money
- Structure a fair deal



Typical VC Investment Criteria

- **Technology**
 - At the intersection of technologies — synthesis rather than invention is needed but disruptive in its application
 - Well-protected and differentiated
- **Market**
 - Unmet customer needs in large and growing markets
 - Basis for building competitive advantage
 - Opportunity to achieve market leadership
- **Management**
 - Creative approach to business
 - Relevant market or industry experience
 - Demonstrated vision
- **Superior financial returns**
 - Multiple potential exit options
 - Able to show 10x return in 5 years
 - Reasonable valuation





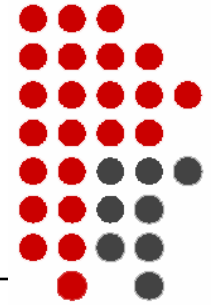
Linking Funds to Value Creation Steps

- Can be achieved in 3 years or less
- Require level of funds that 'match' value created
- Path to reaching goals is logical/believable (no 'leaps of faith' required)



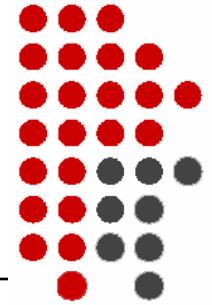
Examples of Value Creation Steps

- Drug Milestones
 - IND approval
 - Through Phase I and into Phase II
 - Through Phase III
 - NDA approval
- Device Milestones
 - 510(k) approval
 - Begin/complete OUS trials
 - PMA approval
- Diagnostics Milestones
 - Categorization of 510(k) IVD (i.e. moderate or high)



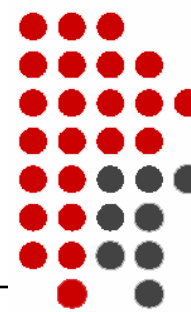
Business Strategy from Plan

- Raise \$3M to take drug for lung cancer through Phase Ia and Ib
 - Time requirement is 24 months
- ID/prioritize prospective partners
 - Time requirement is 30 months (6 months post step above)



Complete Deal with Big Pharma Partner

- Pro forma deal structure
 - \$20M upfront
 - \$10M investment for 20% equity
 - \$150M in milestone payments
 - 1.5% royalty



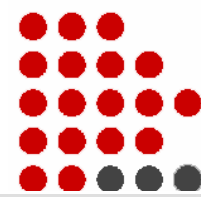
Example of Expectations

- VC perspective
 - Deal values company at <\$50M
 - VCs expect a return of ~\$20M for \$4M investment in a 36 month period
 - Need 40% of company for \$4M
- Company perspective
 - Deal values company at >\$75M
 - VCs should get a return of \$7.5M for \$3M investment in a 30 month period
 - Should sell 10% of company for \$3M



Would you be interested in this company?

- Product is ready for sales within 18 months
- Multiple issued patents on device
- At least 440,000,000 device users per year in US
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Patent protection

FIGURE 1

NCE stands for New Chemical Entity, which is FDA parlance for a new drug; IND stands for Investigation New Drug application, which must be filed with the FDA prior to the commencement of clinical trials in humans; NDA stands for New Drug Application, which is filed with the FDA upon completion of human clinical trials.

