COST TO BRING A DRUG TO THE U.S. MARKET

$161 Million - $2.86 Billion*

*Depending on Assumptions

(Google for Details)
COST TO BRING A MEDICAL DEVICE TO THE U.S. MARKET

$31 Million - $94 Million*

(Up to 80% of this cost related to FDA approval)

*Depending on Complexity
FROM IDEA TO MARKET

• DISCIPLINED APPROACH
• PROFOUND INTELLECTUAL CHALLENGE
• SERIAL PROCESS
• EXPERIMENTAL ATTITUDE
• COMMERCIAL OUTLOOK
• REALISTIC EXPECTATIONS
QUESTIONS TO SELF

▪ DO I REALLY WANT TO DO THIS?
▪ DO I HAVE ACCESS TO SOME MONEY?
▪ CAN I PLAY WELL WITH OTHERS?
▪ DOES MY IDEA HAVE SIZEABLE COMMERCIAL POTENTIAL?
▪ WHAT KIND OF HELP DO I NEED?
▪ Legal
▪ Business & Finance
▪ Science & Engineering
PREPARATION (BUSINESS AND FINANCE)

▪ PERSONAL INVESTMENT
▪ ENTITY FORMATION
▪ SHORT, PLAIN LANGUAGE WRITTEN DESCRIPTION
▪ PRO FORMAS & RECORD-KEEPING
▪ GREYBEARD SHEPHERD
▪ KNOWLEDGE OF SECURITIES, IP, & TAX LAW
▪ OWNERSHIP RIGHTS
PREPARATION (TECHNICAL)

- HIRE IP COUNSEL
- CONDUCT IP SEARCH
- GO-NO DECISION
- DOCUMENT STATE-OF-THE-ART
- ID CURRENT AND POTENTIAL COMPETITORS
- YOUR INNOVATION – FEATURES AND BENEFITS
- PERSONAL AND TEAM CREDIBILITY
DOCUMENTS (1)

- SHORT JARGON-FREE SUMMARY OF THE INNOVATION(S)
- 5-YEAR FINANCIAL PROJECTIONS
- BUSINESS PLAN WITH TECHNICAL APPENDIX
- INVESTOR PRESENTATION (PITCH DECK REPREHENSIBLE)
- SHAREHOLDER AGREEMENT
- PATENT ASSIGNMENT
- NON-DISCLOSURE, NON-COMPETITION AGREEMENT
• OPERATING AGREEMENT (FOR LLC’S)
• PRIVATE PLACEMENT MEMORANDUM (WHEN APPROPRIATE)
• EMPLOYMENT CONTRACTS
• THIRD-PARTY CONTRACTS (CONSULTANTS, PARTNERS)
• OPTION AGREEMENTS
• CURRICULUM VITAS
• RELEVANT TECHNICAL PAPERS
ACTIONS

- R & D DESIGN
- PROOF-OF-PRINCIPLE
- PROVISIONAL PATENT FILINGS
- PROTOTYPING AND TESTING
- GO-NO-GO DECISION
- UTILITY PATENT FILINGS
REGULATORY ENVIRONMENT

- FDA & EU REQUIREMENTS
- COSTS
- RISKS AND BENEFITS
- GO-NO-GO DECISION
- STRATEGY DECISION
LICENSING

- COMMON PRACTICE
- STRONG IP POSITION MANDATORY
- HIGHLY COMPETITIVE
- LARGE MARKETS FAVORED
- IND DESIGNATION FAVORED
- REIMBURSEMENT OF PATENT COSTS
- RESEARCH SUPPORT & BENCHMARK PAYMENTS
FINANCING

▪ Acquisition of IP or whole company a remote possibility
▪ Persistence is necessary for fund-raising
▪ Private financing theoretically available
▪ FDA and EU sometimes idiosyncratic
▪ IPO possible but expensive and complex
▪ Management of public company expensive & complex
▪ Management of public company requires PROs
REPRISE

- SKIN IN THE GAME
- CREDIBILITY
- TECHNICAL EXCELLENCE
- RESOURCES
- IP PROTECTION
- RATIONAL BUSINESS MODEL
- EFFECTIVE COMMUNICATION
RECOMMENDATIONS

▪ USE YOUR OWN $ AND NON-DILUTIVE $ FIRST
▪ PROTECT YOUR IP WITH PARANOID FERVOR
▪ MATCH YOUR IP WITH INTERESTS OF LICENSEES/ACQUIRERS
▪ SECURE IND STATUS IF POSSIBLE
▪ RESIST TEMPTATION TO BUILD AND MANAGE AN EMPIRE
▪ USE YOUR CREATIVITY & NEW MONEY TO DO NEXT PROJECT