

ENET

November 15, 2016



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

DOCUMENTS (2)

- 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