

BioForward Meeting

6 May 2009



Quintessence | Biosciences

Innovative Science

***Effective* Medicine**

Innovative Science *Effective* Medicine



- Translating EVade™ Ribonuclease technology into therapeutic products

Product Pipeline

Cancer	Stage					
	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	
EVade™ RNase, Single agent	■	■	■	■	■	
EVade™ RNase, Combination	■	■	■			
PK Enhanced EVade™ RNase	■	■	■			
Targeted EVade™ RNase	■	■				

Federal Government Resources

- Small Business Innovation Research (SBIR) enacted in 1982
- Small Business Technology Transfer (STTR) enacted in 1992
- Grants and Contracts

Year	Agency	Phase 1 Awards	Phase 1 Dollars	Phase 2 Awards	Phase 2 Dollars	Total Awards	Total Dollars
2008	All	48	\$7,679,986	23	\$18,851,330	71	\$26,531,316
2008	HHS	27	\$5,786,213	8	\$10,206,468	35	\$15,992,681

SBIR/STTR Funding

- Dept of Agriculture
- Dept of Commerce
- Dept of Defense
 - Air Force Office of Sponsored Research (AFOSR),
 - Office of Naval Research (ONR),
 - Army Research Office (ARO)
 - Defense Advance Research Projects Agency (DARPA)
 - US Army Medical Research & Materiel Command, which oversees the Congressionally Directed Medical Research Programs (CDMRP)
 - Army Corps of Engineers
 - National Security Agency (NSA)
- Dept of Education
- Dept of Energy
- Dept of Health and Human Services
 - Center for Disease Control
 - National Institutes of Health
- Dept of Homeland Security
- Dept of Transportation
- Environmental Protection Agency
- National Aeronautics and Space Administration
- National Science Foundation

Examples of Other Opportunities

- Examples:
 - U.S. Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD) grant awards to support clinical trials on the safety and effectiveness of products for rare diseases and conditions.
 - NIH Clinical Trial Planning (R34) or Implementation (U01) Grant Application

Drug Development Pathway



Discovery

Non-clinical Testing

Laboratory and Animal Testing

Phase I

Tens of healthy volunteers

First in human (General effects)

Phase II

Tens to hundreds of patients

Proof of concept (some efficacy)

Phase III

Hundreds to thousand of patients

Confirm benefit to patients

FDA Review/Approval

Time



Pharma & Biotech Industry – Impact of Federal Legislation



- Patent Reform
- SBIR Reauthorization
- Capital Formation Tax Incentives
- Healthcare reform
- Comparative Effectiveness
- Follow-On Biologics
- FDA Appropriations



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