



# Pharmaceutical Case Competition 2008



## Team 2: Lifeline Consulting

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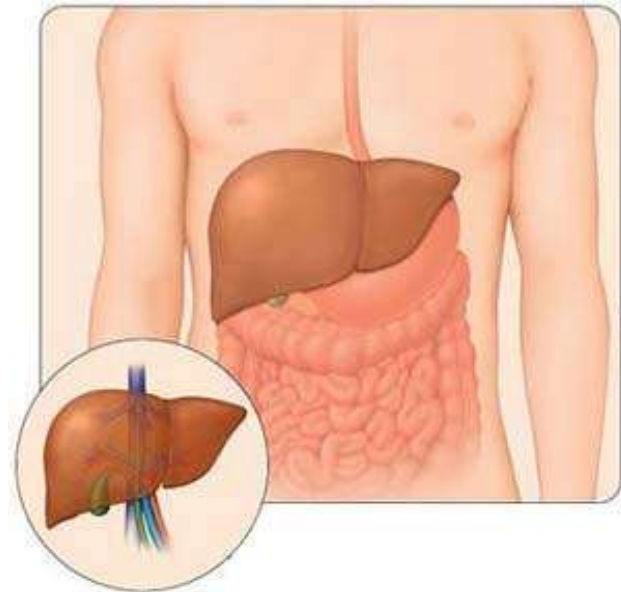
**November 14, 2008**



# HCV: The Silent Epidemic

	HIV	HCV
<b>Prevalence</b>	1,000,000	4,000,000
<b>Incidence</b>	56,000	37,000
<b>Mortality</b>	20,000	10,000
<b>Major route of transmission</b>	Sexual contact (84%)	IV Drug (60%) Sexual contact (15%)

- Leading cause of chronic liver disease (40%)
- Leading indication for adult liver transplantation (43%)
- **No Vaccine available for HCV**
- **Need for more effective drugs against most prevalent genotype**



# HCV Drug Targets

## Current Available Therapy

### *Interferon*

- Cytokine immune-booster
- Initiates response to viral dsRNA

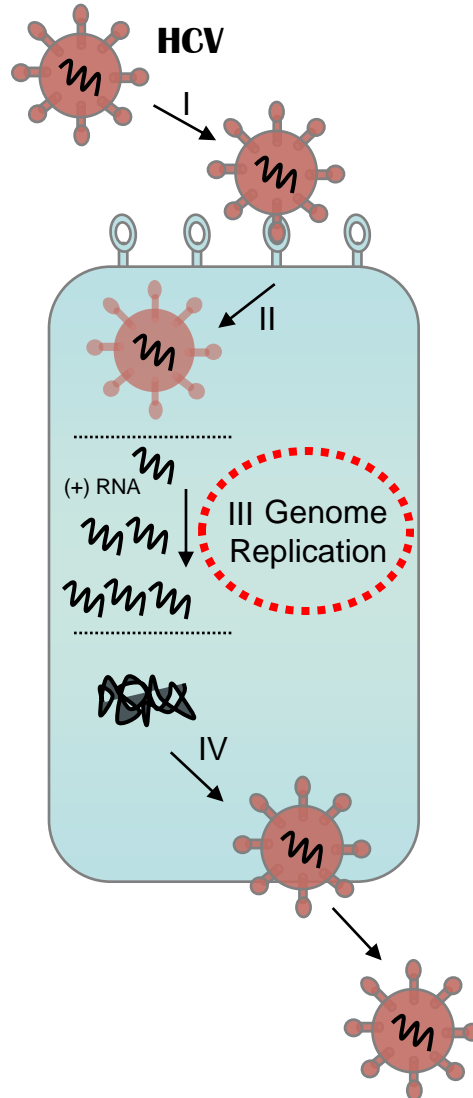
### *Ribavirin*

- Purine nucleoside analog
- Induces viral hypermutation
- Initiates T-cell activation

## Standard of Care

- 24 or 48 weeks
- Injectable PEG-IFN co-therapy with oral ribavirin

*< 50% effective against Genotype I HCV*



## HCV-908

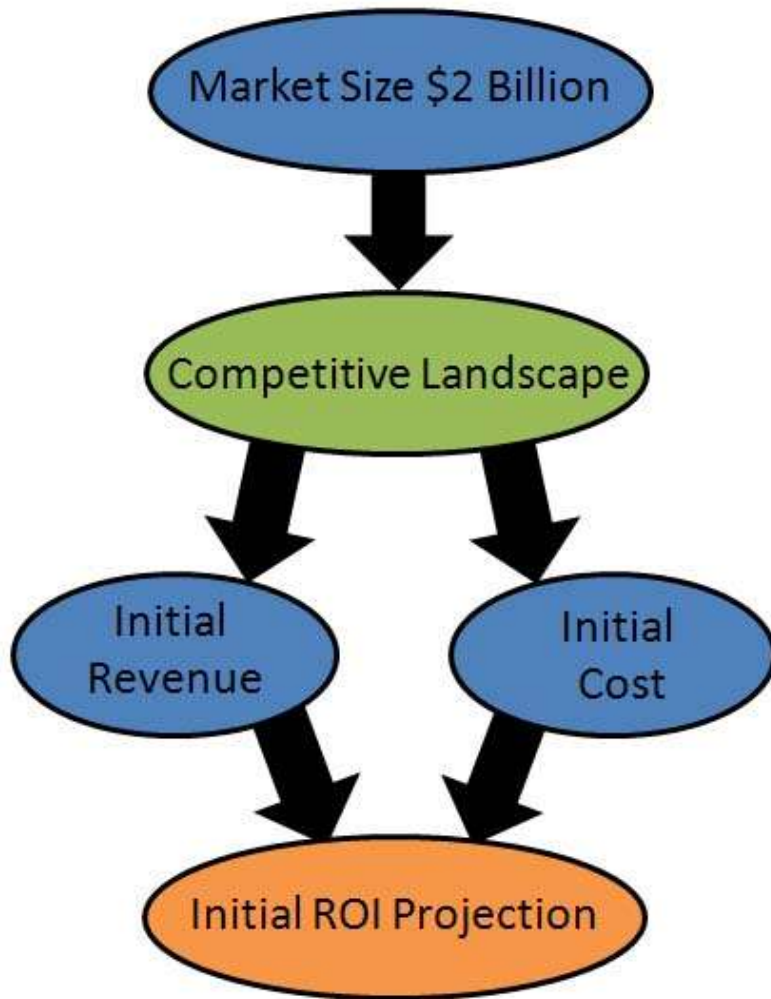
- Inhibitor of HCV RNA-dependent RNA polymerase (RdRP)
- Directly targets ability of virus to replicate

## Phase II Results

- Incidence of viral resistance in small fraction
- HD-developed genetic screen to avoid treating resistant strains

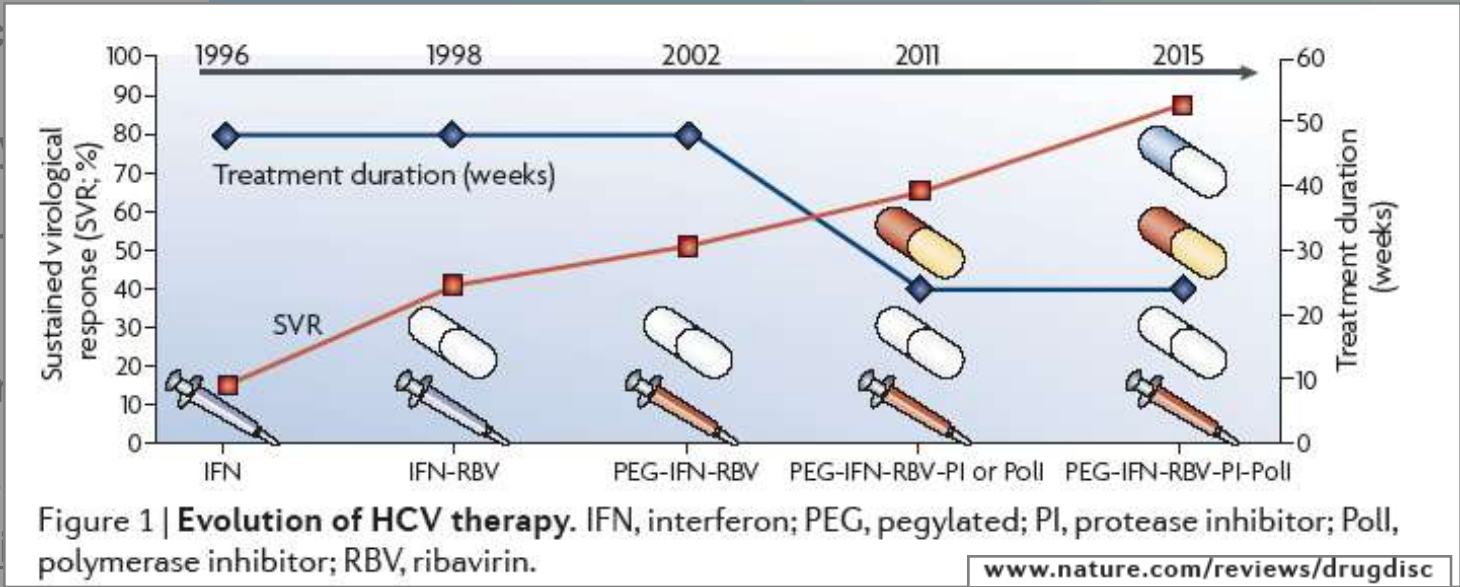
*Very effective against Genotype I HCV*

# Market Analysis

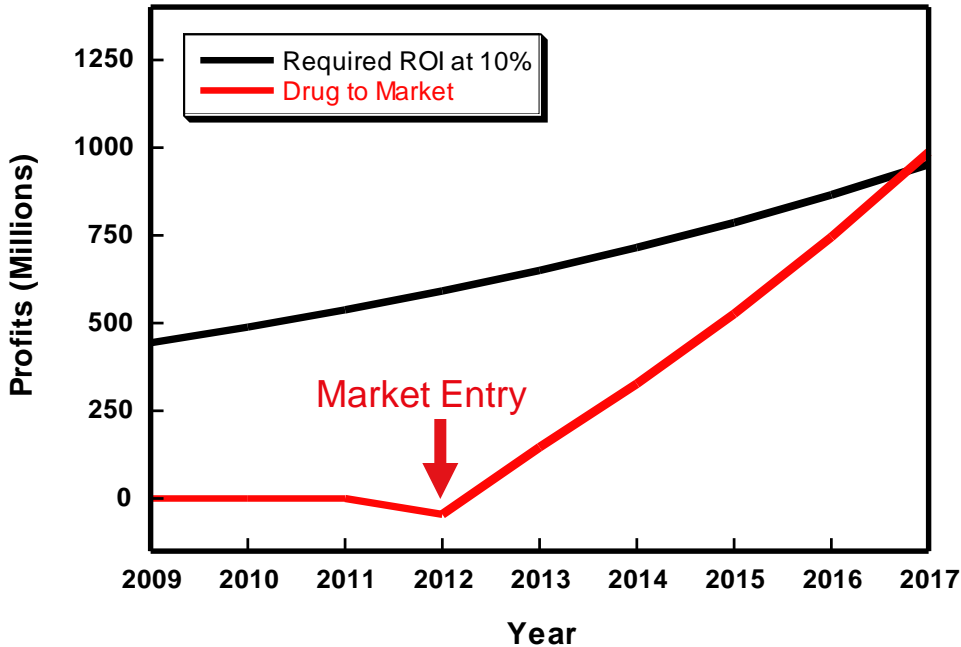


# Competitive Landscape

Pipeline Drug	Pre-Clinical	Phase I	Phase II	Phase III	Filed
<u>Polymerase Inhibitors</u>					
HCV-908 (HD)	➔				
R-1626 (Roche)					
HCV-796 (Wyeth)					
Valopicitibir (Novartis)					
HCV NS5B Inhibitor (ViroChem)					
<u>Protease Inhibitors</u>					
Telaprevir (Vertex)	➔				
Boceprevir (Schering)	➔				



# Initial ROI Projection



## Assumptions

- 75% success rate entering Phase III to market
- Leading drug obtains 100% penetration into current S.O.C. market
- Standard distribution through sales reps
- 10% Opportunity cost of Phase III investment
- Cumulative profits invested at 10%
- Stable market size at 80,000 treated
- Standard antiviral manufacturing cost

### Year 1

- 4 competitors have equal chance to become leading drug

### Years 2 - 5

- 5 competitors have equal chance to become leading drug

Treatment	Attain SVR	Insurance Provider Value of Therapy
S.O.C. (IFN + Ribavirin)	45%	\$25,000
S.O.C. + HCV-908	65%	\$36,111
<b>HCV-908 Market Price</b>		<b>\$11,111</b>

# Profitable Awareness

***Unmet need: 37% diagnosed, 5% treated***

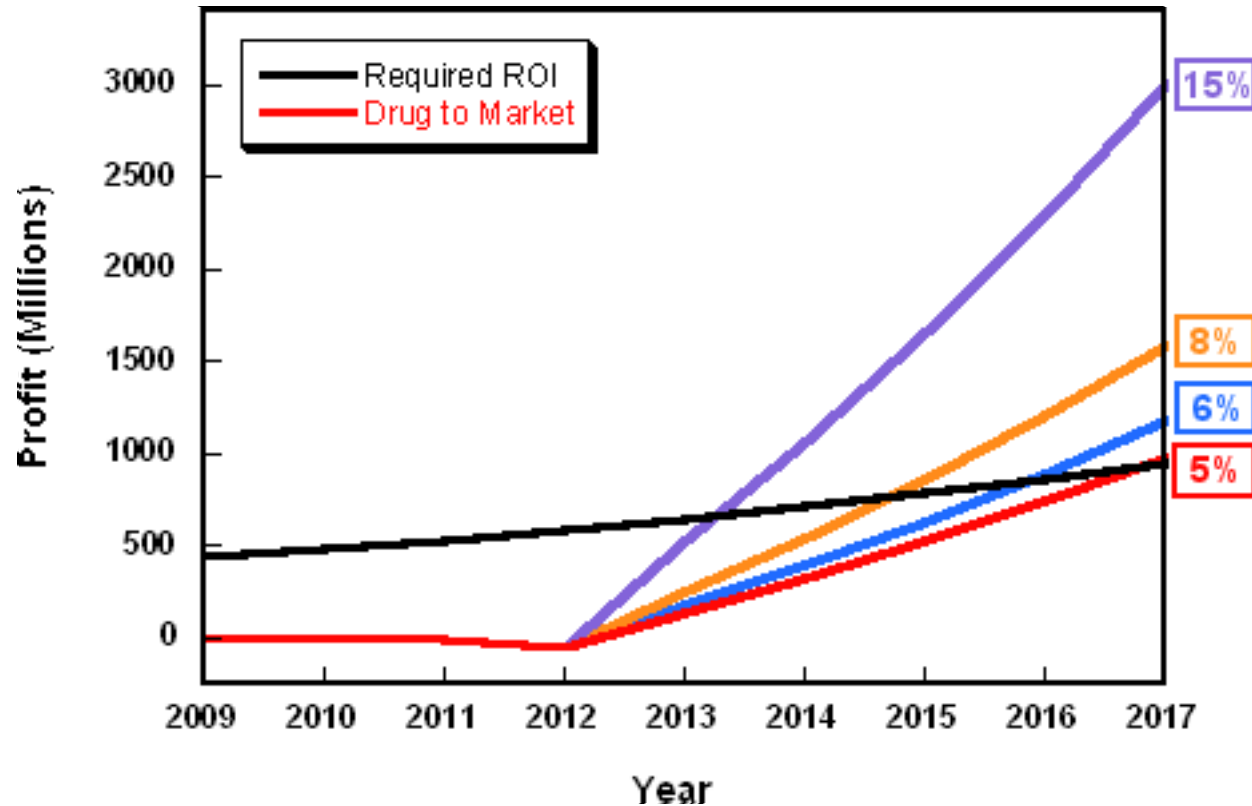
***1.9% HCV-infected population is treated***

How to access untreated population?

- Patient-based - *37% diagnosed*
  - Increase diagnosis through patient awareness
  - Current infected population asymptomatic, potentially indifferent
  - ***Low expectation to achieve required ROI***
- Physician-based - *5% treatment*
  - Less experienced MDs treat 77% less than experienced MDs  
(*Hepatology*, 2007, 46(6):1741-9.)
  - ***Reasonable expectation to achieve required ROI***

# Physician-Based Marketing

## Increase Treatment Rate Improves Profit



- Intensive \$10 million annual non-branded awareness campaign
- 50 major cities, keynote experienced hepatologists
- Evidenced-based training on diagnosis and treatment of HCV

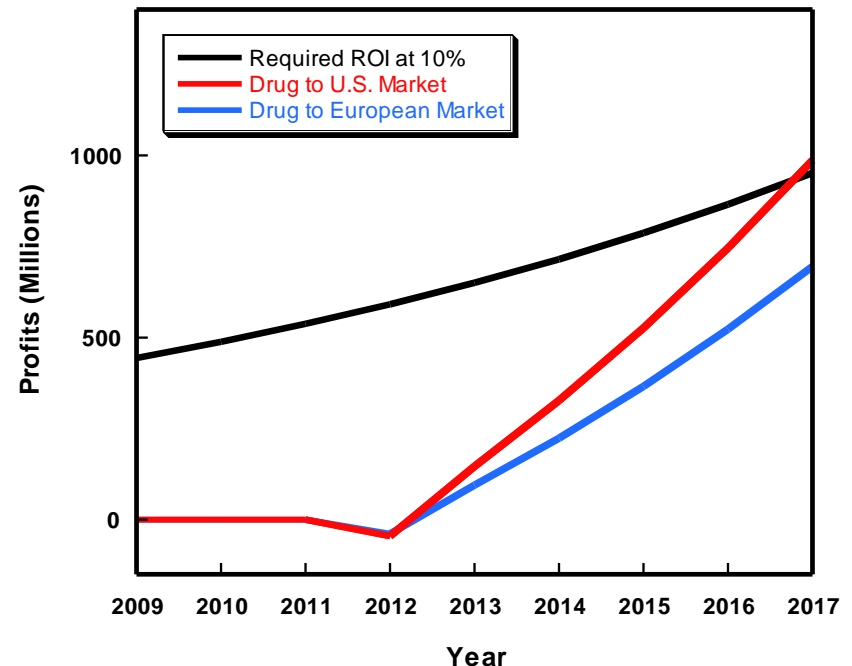
# Alternative Markets

2012 HCV Market Predictions		
	# of People	Market Value
U.S.	4 million	\$2 billion
Europe	6 million	\$1.3 billion
India	8.5 million	\$0.17 billion
China	46 million	\$0.15 billion

India and China have a minimal projected market value compared to the US and Europe.

## European Market Analysis

- Similar treatment rates and cost per patient
- Fails to meet required ROI by 2017



# Recommendation

- HD should enter Phase III trials with HCV-908
- Market Strategy
  - Focus on U.S. market
  - Target physician education to increase treatment rates
    - Sponsor nationwide, non-branded, educational conferences
    - Utilize experienced hepatologists to deliver treatment guidelines
- Projected Profit at 2017: \$2.61 billion
- Future Considerations
  - Continually monitor international growth opportunities
  - Combination therapy partnership

# Patient-Based Marketing

## Increase Diagnosis Improves Profit

