



**BIO Investor Forum  
San Francisco, CA  
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## LigoCyte's mission:

- Focus on GI and respiratory indications
  - expertise in immunology and virology development
- Emphasize vaccine development in commercially attractive infectious disease markets
  - Proprietary virus-like particle (VLP) core technologies established
  - VLP vaccines against norovirus, influenza and RSV
- Use partners to co-develop non-core targets
  - Biogen Idec CD103 mAb partnership for chronic inflammatory diseases

## Company Structure:

- Private company, staff of 42
- Founded in 1998
- Located in Bozeman, Montana
- Shareholders include:



• GlaxoSmithKline



• Forward Ventures



• Novartis VF



• Fidelity Biosciences



• MedImmune Ventures



• JAFECO



• MC Life Sciences Ventures



• Athenian Venture Partners

# *LigoCyte Value Milestones Planned in 2010*

## Norovirus Vaccines

- Norovirus nasal monovalent vaccine safety and immunogenicity data in hand
- Data in hand for norovirus vaccine protection against live virus challenge
- Data in hand for norovirus bivalent intramuscular safety and immunogenicity
- IND and enrolment for norovirus bivalent nasal vaccine safety and immunogenicity study

## Respiratory Syncytial Virus Vaccines

- RSV vaccine protection data in animal models
- Development and scale-up underway

## Antibody Program

- Disease model data for CD103 mAb

## Vaccine Market:

- Expanded from \$7B in 2004 to \$20B in 2008
  - Revenue growth from new products
  - Future growth includes expansion to world markets
    - Wyeth's (Pfizer's) Prevnar® '09 forecast is \$3B in pediatric market alone, one-third of which is US sales.
- 85% of market currently controlled by Merck, Sanofi Pasteur, GSK, Novartis, Wyeth (Pfizer)
  - Major emphasis on pipeline development via external relationships
  - Other companies growing into the space: AZ-MedImmune, Crucell, Intercell
- Few small, clinical-stage infectious disease vaccine companies to feed future growth

### Prized Acquisition

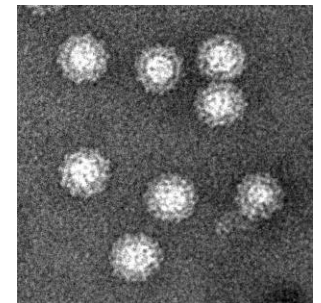
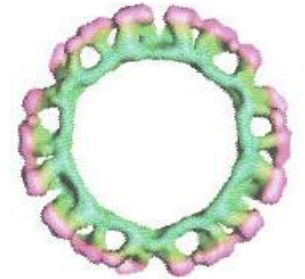
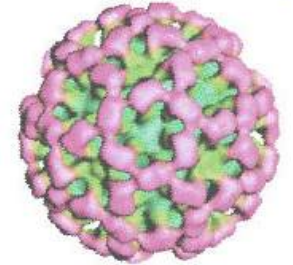
Sales of Wyeth's Prevnar vaccine, in billions



Source: the company

# VLP Vaccines

- Proven successful scientifically and commercially
  - Merck's Gardasil and GSK's Cervarix HPV vaccines
  - Hepatitis B vaccines
- Larger, more immunogenic than subunit proteins
  - Drives antiviral immune responses
- VLP structure assures presentation of conformationally-correct epitopes
  - Leads to higher quality immune responses against viral antigens
  - Cell expression of enveloped antigens on VLPs avoids difficulty with subunit expression



Norovirus VLPs

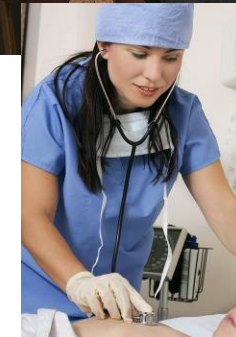
# The Norovirus Problem

- The most common cause of extreme vomiting, diarrhea and dehydration worldwide
- CDC estimates 200,000 deaths in children under 5 worldwide (similar to rotavirus)
  - 900,000 pediatric clinic visits annually in developed countries
  - 64,000 pediatric hospitalizations
- Notable mortality in the elderly and vulnerable populations
- Strikes wherever people congregate:
  - Nursing homes, hospitals, schools, military, cruise ships
- Epidemiology increasingly supporting argument for widespread immunization campaign
  - Big problem, spread rapidly through communities
  - No therapeutic interventions or vaccines available



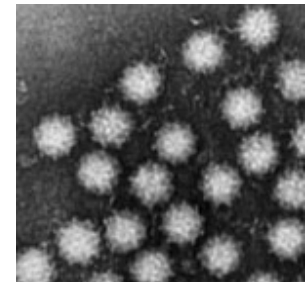
# Norovirus Market Opportunity

- New, emerging market opportunity
- Fits pattern of age-based ACIP recommendation to implement widespread immunization program
  - Pediatric or school entry
  - Elderly over 65 years
- Targetable risk-based groups
  - Health care workers, military, schools, cruise ships, etc.
- New, large markets in vaccines are rare
- LigoCyte has significant IP protection around the target

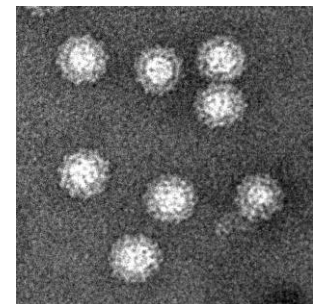


## VLP Vaccine Characteristics

- Non-replicating, virus-like particles
  - Identical to the actual virus capsid
  - Initial formulation is monovalent
  - Bivalent formulation will be commercial product
- Multiple formulations in clinical development
  - Shelf-stable, nasal dry powder for mucosal administration in clinic
  - Intramuscular formulation in tox for 2Q'10 clinical study
- Includes GSK's MPL adjuvant
  - License and commercial supply agreement in place for any norovirus vaccine
  - Transferable to third parties
  - MPL containing vaccines are approved in over 100 countries including the U.S.
- Scalable processes for commercial production



Norovirus



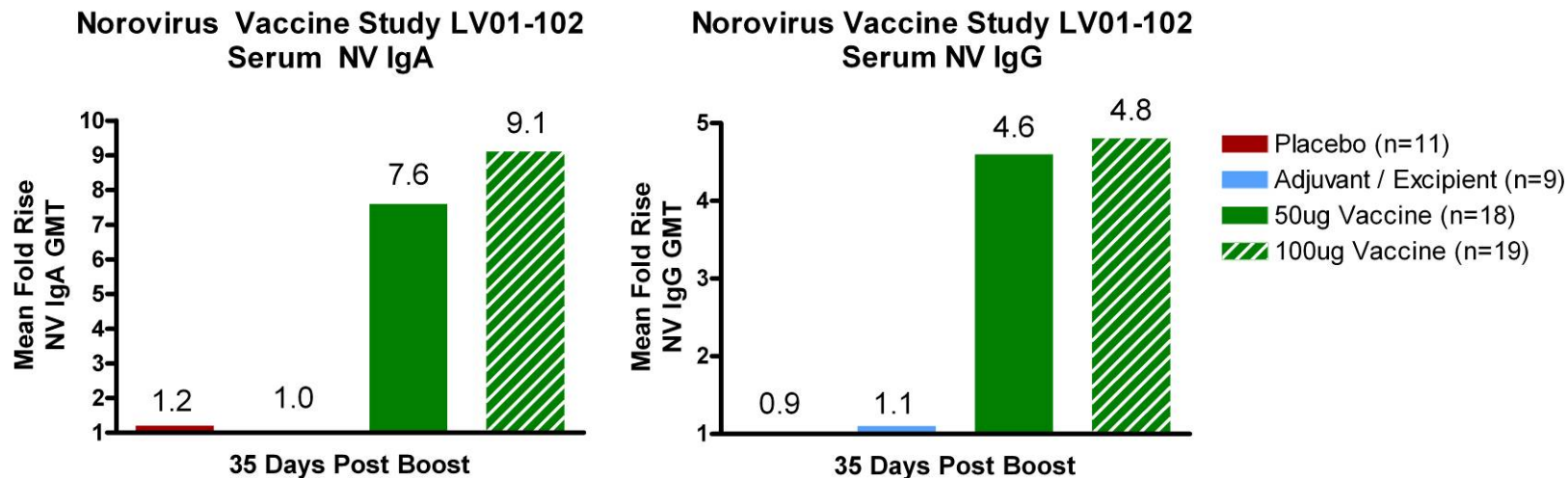
LigoCyte's norovirus VLP vaccine

# *Norovirus Vaccines: Clinical Progress*

## Study Status

- Phase I complete for nasal 5 $\mu$ g, 15 $\mu$ g, 50 $\mu$ g at University of Maryland CVD (n=28)
- Nasal 50 $\mu$ g, 100 $\mu$ g, placebo, vehicle study (n=60) in progress at 4 U.S. sites
  - 56-day safety and immunogenicity completed
- Live virus challenge study for nasal vaccine underway with top line data expected 2Q'10
- Intramuscular bivalent safety and immunogenicity to begin 2Q'10

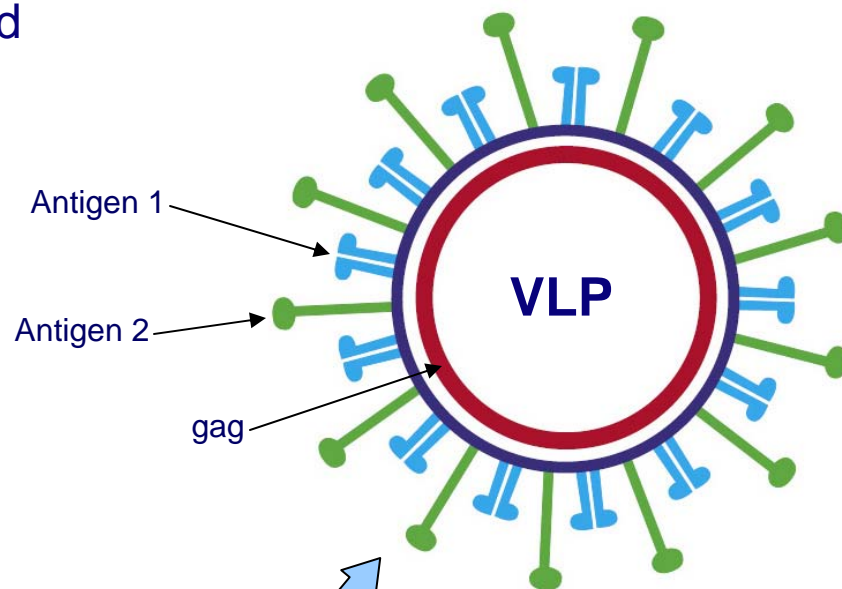
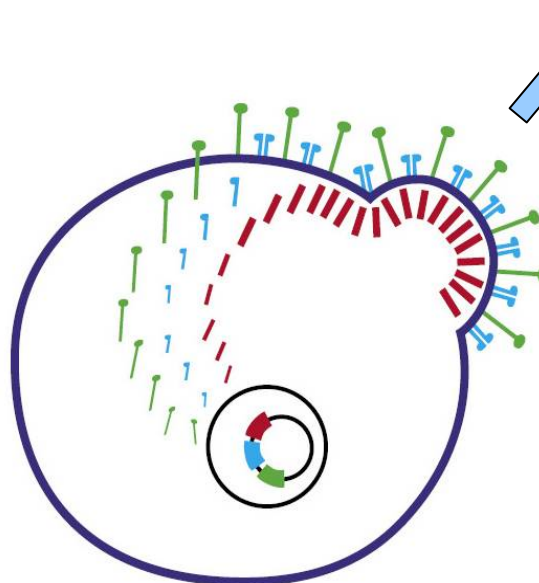
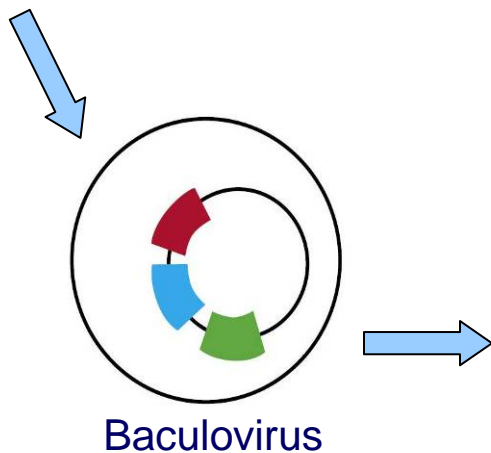
# Nasal Monovalent Norovirus Vaccine Phase I Dose Comparison Study: Prime at day 0, Boost at day 21



- Both 50ug and 100ug induce strong serum IgA and IgG responses
- Higher serum immune responses for 100ug dose
- IgA seroconversion was 79% for 100ug and 72% for 50ug
- FDA clearance to proceed with challenge study using 100ug dose
- No serious adverse events associated with vaccine

# Chimeric Enveloped VLP Technology

- Supports VLP vaccines for enveloped viruses including influenza and RSV
- Core and antigens co-expressed in cells

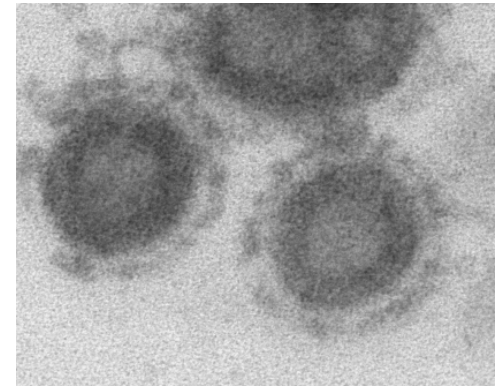


## Insect Cell Expression

- Antigens traffic to lipid rafts on cell surface
- Gag protein buds out at lipid rafts to form VLPs

## *Influenza Vaccines*

- LigoCyte's product profile is a vaccine that is more immunogenic in the elderly and offers broad protection if strains are mismatched
- Data supports intramuscular formulation without adjuvant
- Confirmed superior immunogenicity in industry-standard animal models



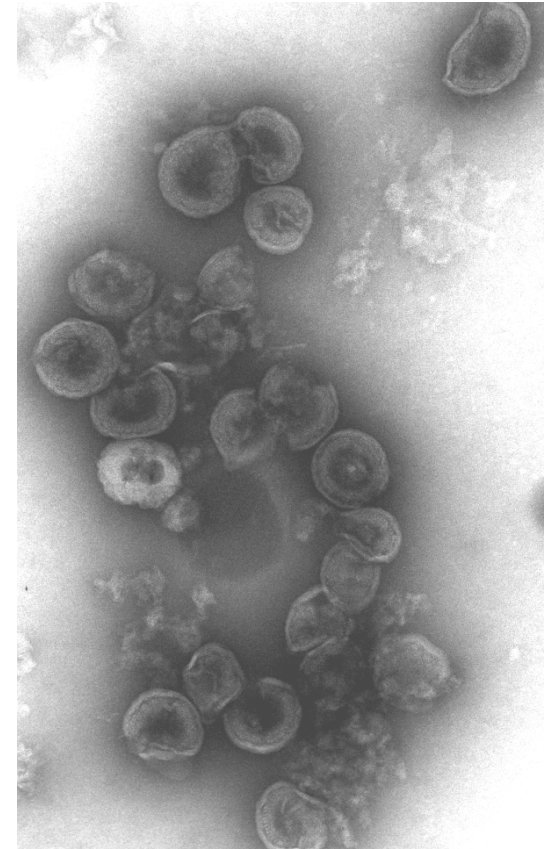
LigoCyte's influenza VLP vaccine

## *LigoCyte Progress on Influenza VLP Vaccines*

- High immunogenicity and broad cross-protection with influenza HA VLP vaccines in mice and ferrets
  - Outperforms current trivalent inactivated vaccine (TIV)
  - Better performance in both matched and drifted strains
  - Consistent results with seasonal and pandemic avian influenza strains
- Intend to partner technology in competitive influenza space rather than invest in clinical development

# Respiratory Syncytial Virus (RSV) Vaccines

- Significant market demand for safe and effective vaccine
  - 10,000 deaths per year in US in older adults
  - Leading cause of lower respiratory infections in infants and children
- Difficult virus to work with, but excellent fit for VLP approach
- Confirmed neutralizing activity with first candidate VLP vaccine in mice
  - Lead selection underway
  - Clinical development planned for 2011



*LigoCyte's RSV VLP Vaccine*

- Only clinical-stage norovirus vaccine in the world
  - Human proof of concept due by mid 2010
  - Large emerging market opportunity in rapidly growing vaccine space
  - Dominant IP position in the field
- Exciting core technology developed for other VLP vaccines
  - Building a pipeline of commercially relevant products
- Valuable therapeutic mAb asset
- Experienced management team, great investors



*Yellowstone National Park, near Bozeman, Montana*

**LIGOCYTE<sup>®</sup>**  
**PHARMACEUTICALS, INC.**