The Company: Protein Sciences
Manufacturing Vaccines for Over 30 Years

Only American owned and based influenza company

Meriden, CT
(FDA licensed)

Pearl River, NY
(FDA licensed)
Flublok

- First recombinant influenza vaccine
- Manufacturing platform allows us to match wild type influenza strain rather than an egg adapted strain
- Can produce vaccine in one month should a strain change be needed

Wayne: We may need to remove the third bullet point. I will forward you a comment from Maryna E.
Flublok

- Licensed for those 18 years and older
- Trivalent
- Three times more antigen than standard dose
- No preservatives, egg products, gelatin, antibiotics, or formaldehyde
- Shelf life 6 months
Projected Availability

- Available August/September 2015
- Production up to 1.5 M doses depending on demand
- Distributors: FFF, McKesson, Cardinal Health; Henry Schein
In Development

- Quadrivalent formulation
  - Expected 2016-17 season

- Pediatric Approval
  - Expected 2017-18 season

- Extended Shelf Life
  - Data supporting 1 year shelf life ready for submission

- Room Temperature Stable Product
  - Modification of non-immunogenic portion of HA antigen permits storage at temperatures over 90°F for over 6 months
Recombinant pandemic influenza vaccines are projected to be available much sooner than those produced with egg-based technology.

Projected Availability of Recombinant Vaccines: 60M doses in 6 mos. (2M doses a week)

Availability of Egg-Based Vaccines: 12-16 weeks

First batch of 2009 H1N1 pandemic vaccine:
- Harvested 4 days after pandemic declaration
- Released for clinical study ~ 30 days thereafter

Adapted from R. Robinson’s presentation to FDA’s VRBPAC on February 29, 2012
Flublok

- Is an FDA approved influenza vaccine approved for individuals 18 years of age and above
- Is the only vaccine that is egg, gelatin, mercury, antibiotic, and formaldehyde free
- Is the only vaccine recommended by the ACIP for egg allergic individuals
- Is the only vaccine that matches the wild type virus
- Has three times the active ingredient
- Clinical trials suggest greater seroprotection in individuals over 65
- Is the only vaccine platform capable of providing early protection against emerging pandemic strains