H1N1 “SWINE FLU” VACCINE

We are hard at work on a vaccine for the H1N1 “swine flu” version of our seasonal influenza vaccine called FluBlok® that is in the final stages of the approval process at FDA. We have obtained the H1N1 virus sequence and an H1N1 virus from CDC (we uniquely don't need the live virus itself - just the sequence and a killed virus), have cloned the relevant gene and are preparing the materials we will need to begin scaling up our manufacturing process - will be completed by mid-late May 2009. The go/no go decision on manufacturing will be made at that time. If it is a go, we can be manufacturing 20,000 to 30,000 doses of H1N1 vaccine per week by early to mid-June 2009. By way of comparison, the CDC has announced that the H1 virus does not grow well in eggs and therefore the seed strain will not be available to licensed manufacturers - all licensed flu vaccines are made in eggs - until the end of May at the earliest. From the time of availability of the seed strain, a vaccine will not be available for months or, depending on how well the strain grows in eggs, as late as the spring of 2010.

Can we really manufacture a vaccine as we say? In 1998, we responded to an urgent request from NIH to make a vaccine against the Hong Kong Bird Flu. Even at that early stage of the Company and our patented technology we were able to deliver 1,700 doses (NIH ordered 1,000) in eight weeks (something everyone said was impossible). FDA approved the vaccine (now called PanBlok®) immediately for “compassionate use” and about 200 researchers and first responders were vaccinated. Can we scale up? Yes - we know this because a big pharmaceutical company licensed our patented technology to produce a veterinary vaccine that is being manufactured in our cell line at the 2,000L scale and is selling the vaccine worldwide. 2,000L is our proposed scale for commercial production - which should allow us to produce up to 60 million doses of seasonal vaccine per year or up 500 million doses of pandemic flu vaccine. We would have to switch briefly from producing the seasonal vaccine to make the H1N1 vaccine but will do it if the crisis has legs. We have been in direct contact with CDC, who despite being extremely busy, have provided us with additional materials to assist us in the preparation of a vaccine.

We can take advantage of a special SOPP at FDA to secure approval of PanBlok now that a health emergency has been declared by the U.S. Department of Health and Human Services. FDA already has told NIH that they have no safety concerns with our vaccine. We would have to switch briefly from producing the seasonal vaccine to make the H1N1 vaccine but will do it if the crisis has legs.

We have a long standing collaboration with one of the top scientists in Mexico who has direct access to the most senior officials in Mexico. They have offered to make available to us a large scale biologics manufacturing facility in Mexico that will work well for us. We should be able to crank out about millions doses of vaccine at this facility by the end of the year. Manon Cox, our Chief Operating Officer and Chief Scientist, will be visiting Mexico on May 4 and 5 to begin the technology transfer process. Our technology already has been transferred to Japan where our licensee is in clinical trials with PanBlok and discussions for technology transfer to other countries are underway.