



Pressmeddelande den 15 december 2016

## Informationsbrev till aktieägarna från Protein Sciences

*Protein Sciences Corporation (Protein Sciences) har distribuerat ett informationsbrev till sina aktieägare. Protein Sciences har godkänt att Mertiva offentliggör detta informationsbrev. Informationsbrevet innehåller en redogörelse för de viktigaste händelserna i bolaget och finns att läsa nedan.*

Protein Sciences har beslutat att man framöver inte vill låta publicera sina oreviderade kvartalssiffror, varför kvartalssiffror alltså inte ingår i pressmeddelandet denna gång. För pressmeddelanden från Protein Sciences som publicerats under perioden hänvisas till Protein Sciences hemsida; <http://www.proteinsciences.com>.

Protein Sciences har sagt att man avser att distribuera informationsbrev kvartalsvis till sina aktieägare och de har godkänt att Mertiva publicerar dessa i detta format. När ett informationsbrev kommer avser Mertiva att lägga ut det via pressmeddelande och hemsidan så snart som möjligt.

### För ytterligare information, vänligen kontakta:

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### Om Mertiva

Mertiva AB är ett investeringsföretag som i huvudsak består av innehav i Protein Sciences Corporation och Mercodia AB.

Mertiva-aktien är listad på NGM:s handelsplats Nordic MTF (kortnamn: MERT MTF).

Mer information finns på [www.mertiva.se](http://www.mertiva.se).

*Denna information offentliggörs enligt lagen om värdepappersmarknaden, lagen om handel med finansiella instrument eller krav ställda i noteringsavtal.*



**Protein Sciences**  
CORPORATION

December 2016

**To Our Shareholders:**

It is officially flu season and we have been focused on increasing awareness and driving even more demand for Flublok®.

In October, we joined our Mexican partner Liomont and its sales team for the official launch of Flublok in Mexico. Liomont has partnered with Pfizer to help promote Flublok in Mexico and they have already secured commitments from several large companies to use Flublok exclusively for their employees. Liomont's next goal is to expand sales by obtaining a government contract for Flublok.

Also in October, FDA approved the quadrivalent version of Flublok. Flublok Quadrivalent protects against 4 strains of influenza, with the same strains contained in trivalent Flublok and an additional B strain. More importantly, the clinical results from our recent study demonstrating that Flublok Quadrivalent was over 40% better at protecting against cell-culture confirmed flu than an egg-derived quadrivalent vaccine are now included in the package inserts of both the trivalent and quadrivalent vaccines. Flublok Quadrivalent was approved in a pre-filled syringe presentation, the preferred presentation for flu vaccines in the U.S. market.

We produced approximately 900,000 doses of Flublok this year and all lots have been released by FDA. We have sold over 200,000 doses. Planning is underway to determine how much trivalent and quadrivalent vaccine will be produced for the 2017/18 season. We are working closely with our fill/finish partners to establish firm dates that will enable us to come to the market even earlier in 2017.

We conducted a successful rights offering that raised about \$3.5M from shareholders, Board members and the entire Management team. We are grateful for the commitment of our shareholders and the confidence they have shown in the Company.

We continue to work with our advisors to secure a marketing and sales partner. Discussions continue to be slower than anticipated but we expect to be able to provide further updates in the next few weeks.

**Flublok:** Flublok sales have exceeded the amount sold at this time last year. We continue to work closely with our distributors to increase in season sales. We are shipping directly to distributors, strategic distribution centers and to customers resulting in savings to the Company and more efficient delivery of the product to the customer.

The Flublok Finder online locator tool that was developed this year has been effective in providing our customers access to the product. Over 1,000 pharmacy locations including more than 600 Walmart and 250 Rite Aid locations nationwide are listed on the Flublok Finder and more locations are being added each week. We have also benefitted from the tenacity of our Senior Business Development Director for Flublok based in Florida. She has been successful in expanding our geographical footprint by getting Flublok into new pharmacy chains, resolving issues for consumers who have encountered challenges in getting the product, and creating awareness within cancer centers nationwide. Our plan is to add more



regional business development ambassadors because experience has convinced us that this is the most effective way to market Flublok.

We launched a social media campaign (#ShowMeTheVial) that will raise money for health based charities and further increase the awareness of Flublok. Recipients of Flublok are asked to post a picture with the Flublok vial or getting vaccinated with Flublok on Facebook, Twitter or Instagram. For each post, the Company will donate \$1 to a health based charity. The American Heart Association, Go Red initiative was chosen as our first recipient.

We are again posting vaccination events of prominent leaders in government and business on our Facebook page and using Twitter to promote those events and relevant influenza topics. Some notable Flublok recipients in Connecticut include: Senator Richard Blumenthal, Congresswoman Rosa DeLauro, Governor Dannel Malloy, Secretary of State Denise Merrill, State Senator Dante Bartolomeo, Commissioner of the Department of Economic and Community Development, Catherine Smith, CEO of the Middlesex Chamber of Commerce Larry McHugh and media personalities, Jocelyn Maminta and Renee DiNino.

The Healthy Choices Mobile Vaccination collaboration with Hunters Ambulance, Hartford Healthcare at Home, HealthMed Urgent Care and Health Mart pharmacies has gained significant momentum this year. Over 3,200 doses have been administered representing an increase of 45% over last year. Requests for the Mobile unit continue to come in.

**Clinical Trials/Regulatory:** We had a productive meeting with the FDA on August 30 to discuss our plans for a bioreactor feed strategy that will increase our yields from each harvest. We were able to negotiate a reduced number of process validation lots required for BLA submission to implement this change.

We were also able to obtain a waiver of our FY'16 FDA Product and Establishment User Fees, saving the company \$438,000. We expect to receive another waiver shortly of FY'17 FDA User Fees for \$354,000.

**Manufacturing:** The Manufacturing Operations Team met the target of producing 900,000 Flublok doses for the 2016/2017 influenza season. Product was ready for distribution one week earlier than the previous season.

In mid-August, the Pearl River team transitioned to post commercial operations starting with our annual preventive maintenance shutdown. This year we streamlined several production areas by removing unnecessary equipment and implementing cost reduction measures and low-cost energy saving upgrades. We also started the technology transfer activities to scale-up the Fed-Batch process for production of Flublok. The Fed Batch process is expected to increase our yields and nearly double the number of doses each 2,000 L bioreactor can deliver. However, unexpected setbacks in equipment readiness will delay introduction of these improvements until the 2018/19 manufacturing campaign.

Our Meriden Operations Team continued working on pilot operations and clinical supply. The Team completed technology transfer, scale-up and production of GMP material for our Zika vaccine program in late July. The team then switched to perform formulation and filling of rHA produced at Unigen, the production facility of our Japanese licensee, into trivalent vaccine to support our FDA application for receiving FDA licensure of the 2x21,000-L scale facility and demonstrate stability. We will return to Zika operations in late Fall with complete sterile filling qualification and production of clinical materials for our Phase 1 clinical study. We will end the year producing GMP material for our collaborator, BioArctic – we are making a component of a product entering clinical trials to reverse spinal cord injuries.



**BARDA/PD:** We obtained a no cost extension for our previous BARDA contract to complete the follow-up of our H7 Panblok® Phase 2 study. We have also received our first task order under the new BARDA Stockpile contract under which we will produce three working virus banks, three research lots and a GMP lot. This will generate approximately \$2-3 million in revenue to the Company. Work has begun on producing an H5N8 antigen.

To secure non-dilutive funding for our Influenza program development, we submitted three Partnership RO1 grant applications in collaboration with EpiVax (structure optimization of H7 HA for the development of influenza pandemic vaccine), AVATAR (development of universal flu vaccine) and Florian Krammer, Mount Sinai Medical School, (enhancing the immunogenicity of influenza vaccine by adding neuraminidase (NA) to the influenza vaccine).

We undertook a custom project with one of our major Research Antigens customers involving production of multiple NA antigens.

**Zika:** We completed the process development activities for our initial Zika vaccine candidate and performed our first GMP manufacturing run successfully in July. Immunogenicity studies in mice have been conducted and the samples are under analysis. Initial data show a robust response to our vaccine.

We had a pre-IND meeting with the FDA about our Zika vaccine development program on September 20. We received approval to submit of an Investigational New Drug (IND) application with interim rabbit toxicology data, allowing us to submit the IND in January 2017. We will be able to begin our Phase 1 clinical study shortly thereafter.

NIH has agreed to fund the rabbit toxicology study. In addition, we have submitted a Partnership R01 grant application to NIH in collaboration with Immunova (an Argentinean company) and University of Brisbane, Australia to support further development work. The proposed grant period is 5 years (\$750K direct cost/year).

**Collaborations:** This quarter we celebrated the official launch of Flublok in Mexico with our licensee, Laboratorios Liomont. Liomont purchased 50,000 doses of Flublok from us. The doses were successfully exported to Mexico and released for sale by the Mexican regulatory agency (COFEPRIS). In preparation of the launch, Liomont invited members of the Mexican press to our Pearl River, NY location to introduce Flublok, and we provided tours of our manufacturing facility. Video coverage of the tour is available at <https://youtu.be/CymUoE2pall>. Liomont is working in partnership with Pfizer to promote Flublok in Mexico.

We continue to work with our various Flublok licensees to obtain Flublok registrations in other countries, initiate technology transfer and create an international market for Flublok. Flublok approval in Japan has been slow but our Japanese partner, UMN Pharma, has informed us that the Japanese regulatory agency, PMDA, will initiate the final step in the review process in December. UMN anticipates approval in early 2017 that will entitle us to a significant milestone payment.

We are conducting a second GMP campaign to produce recombinant FGF1 for our long-standing partner BioArctic. BioArctic will use this material in Phase 1 clinical studies for the treatment of spinal cord injury.

Cordially,

Manon M.J. Cox  
President & CEO

Daniel D. Adams  
Executive Chairman