



Pressmeddelande den 1 januari 2015

Kvartalets informationsbrev till aktieägarna från Protein Sciences

Protein Sciences Corporation (Protein Sciences) har distribuerat ett informationsbrev till sina aktieägare ("Shareholder Letter December 2014"). Protein Sciences har godkänt att Mertiva offentliggör detta informationsbrev. Informationsbrevet innehåller en redogörelse för de viktigaste händelserna i bolaget, samt oreviderade siffror för de första 9 månaderna 2014 och är bifogat till detta pressmeddelande.

Informationsbrevet innehåller även ett antal pressmeddelanden, vilka sedan tidigare funnits publicerade på Protein Sciences hemsida.

Protein Sciences avser att distribuera informationsbrev kvartalsvis till sina aktieägare. Om Mertiva får sådana informationsbrev avser Mertiva publicera dessa.

För ytterligare information, vänligen kontakta:

Andreas Bergsten, VD Mertiva AB
info@mertiva.se
070-5673670

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.

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

December 2014

To Our Shareholders:

The Company has been in the spotlight this quarter in the midst of the flu season and a surging Ebola outbreak. Development of our Ebola vaccine drew a lot of attention in early October, which was quickly followed by the long awaited FDA approval of Flublok® in adults 50 years and older. Clinical trials for Flublok Quadrivalent that protects against four strains of influenza have been initiated in two age groups (adults ≥50 years old and 18-49 year olds) and enrollment in both studies is complete. We submitted a supplemental BLA (sBLA) for licensure of the Pearl River manufacturing facility in the beginning of November and expect approval in early March 2015. We also welcomed a new addition to our executive leadership team in October: Dr. Xiaomi Tong joined us as Senior Vice President and Chief Technology Officer.

Flublok: Flublok sales continue to increase as we move through the flu season, although they remain lower than anticipated. Our primary impediment was the later than expected approval for use in people 50 years and above. Over 30% of the nation's hospitals have ordered Flublok, up from ~25% last year. We also saw increased sales to physician's offices, health departments and independent pharmacies.

We are very pleased to report that on October 29th we received FDA approval of Flublok for adults 50 years and older, and, as a result, Flublok is now approved for all adults 18 years and older (see attached press release). Following approval, we held a press conference that was well attended by the media. CT State Senator Danté Bartolomeo and State Representative Buddy Altobello attended and received Flublok vaccinations – many other politicians were scheduled to attend and get vaccinated but had to be present at an election event hosting Michelle Obama in New Haven to support Governor Malloy. U.S. Representative Elizabeth Esty published a congratulatory statement following the approval (see attached). Unfortunately most people in the older age range had already been vaccinated by the end of October and, therefore, it is unlikely we will see a major impact in sales this year based on the expanded age range. However the approval opens up a new market that we expect will positively impact sales next year.

In response to the CDC's recently issued advisory warning that flu vaccines may be ineffective this season because a new strain of H3N2 influenza is circulating that is not matched to the vaccines, we issued a press release reminding the public of Flublok's benefits and that the 3x antigen content of Flublok may offer protection this season when traditional flu vaccines may not (see attached). This message was heard by our officials and on December 23rd, the U.S. Senators from CT, Chris Murphy and Richard Blumenthal, held a joint press conference at Protein Sciences urging the CDC to purchase Flublok and make it more widely available. Both the Senators and two of our U.S. Representatives from CT, Elizabeth Esty and Rosa DeLauro, sent publicized letters to the CDC emphasizing this point and the importance of Flublok (see attached). U.S. Representative Nita Lowey who represents Pearl River sent a similar letter. We are hopeful that this support will spur the CDC into action.

Pharmacies remain a target outlet for Flublok and, in October, we sponsored and attended the New England Pharmacists Convention that brought together independent and large chain pharmacists from across the region. Our Flublok booth was a popular attraction and drew attention from both pharmacists and distributors interested in carrying the vaccine next year. We will use this momentum as a starting point as we begin to engage with the large chain pharmacies and distributors about purchasing Flublok for the 2015/16 season. We are working to expand our distribution network to

include distributors who deal exclusively with major retail pharmacy chains. Flublok was also offered to more than 80,000 members of the American Pharmacists Association through an email blast in mid November.

As an example of how we are creating further awareness and access to Flublok, we teamed up with Passport Health and Uber, a rideshare organization, to launch a one-day public health initiative in November. On November 18th UberHEALTH announced that anyone in Chicago could use the Uber app and request Flublok using his/her smart phone. A driver carrying a Passport Health nurse then personally delivered and administered Flublok to up to 10 people per request. You can read more about the event here: <http://www.passporthealthusa.com/2014/11/flublok-at-your-door-passport-health-and-uber-are-at-it-again/>. Overall, it was a successful event that generated meaningful publicity reflected by the large spike in traffic to our web and social media sites that day.

Clinical Trials: Two Phase 3 clinical trials of Flublok Quadrivalent sponsored by BARDA were initiated in late October and the enrollment rates were impressively rapid. In just under a week, the trials were more than halfway enrolled and are now fully enrolled.

PSC12 is a large trial in adults 50 years of age and older intended to demonstrate the protective efficacy of Flublok Quadrivalent in preventing influenza disease. The trial enrolled just over 9,000 participants at sites across the U.S. The efficacy of Flublok Quadrivalent is being compared to that of a licensed conventional egg-based inactivated quadrivalent vaccine.

PSC16 is a trial in adults 18-49 years of age intended to demonstrate that Flublok Quadrivalent elicits satisfactory immune responses for all four influenza proteins. The trial enrolled 1,350 adults across the U.S. and will compare Flublok Quadrivalent to a licensed conventional egg-based inactivated quadrivalent vaccine.

Pearl River: We made significant progress in Pearl River and completed drug substance process validation and drug substance comparability to product manufactured in Meriden. In November, we submitted the sBLA for licensure of the facility. We expect to receive approval in approximately four months, in time to produce Flublok for commercial sale for the 2015/16 season.

During a recent BARDA site visit, the team commented that they were very pleased both with our progress in Pearl River and the rapid enrollment rate of our ongoing clinical trials. As you know BARDA is an important ally whose support is both financially and politically significant.

Ebola Vaccine: In the wake of the Ebola outbreak in West Africa and beyond, we are working with the U.S. government on the development of an Ebola vaccine. A vaccine for Ebola is more readily made using recombinant technology, as traditional vaccine manufacturing would require growth of Ebola virus, which would be very dangerous. Our BEVS platform is therefore ideally suited for this task.

Several years ago we had begun the process of making an Ebola vaccine as a subcontractor on a grant issued by the National Institutes of Health (NIH). That project had been put on hold due to a lack of government funding. However, because of that early work and inherent advantages of our platform technology, we have been able to respond quickly to the crisis.

Our Ebola vaccine is based on recombinant Ebola glycoprotein (GP), the major surface antigen of the Ebola virus. Antibodies against GP are known to confer protection against the disease in non-human

primates. We have produced Ebola GP and will provide it to the NIH by the end of December. This protein will be used in animal immunogenicity and challenge studies. At the same time, we have produced GMP material that could potentially be used in people if warranted by the state of the outbreak. We are in discussions with various regulatory and health agencies about providing funding and will not proceed further without that.

Our Ebola vaccine development has generated national attention. News stories have been published across the country, and in October, U.S. Congresswoman Rosa DeLauro held a press conference at Protein Sciences emphasizing the need for the U.S. government to support such work. In addition, the recent emphasis on Ebola is encouraging more research to be conducted on the disease, and we are planning to add Ebola GP to our Research Antigens offerings to cater to this need.

Rabies Vaccine: We are continuing to develop our rabies vaccine. Similar to our Ebola vaccine, the rabies vaccine is based on the surface glycoprotein of the rabies virus that has been shown to be immunogenic in mice. We developed a process to produce and purify recombinant rabies glycoprotein and are initiating immunogenicity studies with our collaborators at Erasmus University in The Netherlands. These studies will be followed by challenge studies in animals later next year.

Additional Antigen Production: This fall we manufactured H7 rHA for our upcoming Panblok® clinical study that is supported by BARDA. Purification was performed at the 1L, 4L, 50L, 450L and 2,000L scale with consistent results and generated the highest yields of rHA to date.

We are also in the process of manufacturing antigens for two different customer projects. Two production runs of GAD (glutamic acid decarboxylase) protein are being manufactured at the 450L scale in Meriden for our partner Diamyd Medical, and two production runs of VLP are being manufactured in our Meriden pilot plant (40L scale) for one of our Japanese customers. Both projects are progressing smoothly and on time.

New Customer Projects: In September we signed an agreement with biotech start-up Vault Nano to manufacture a new, protein-based treatment for non-small cell lung cancer. The product is comprised of a vault nanoparticle encapsulating the CCL21 chemokine. Vault nanoparticles were discovered and are being characterized by Dr. Leonard Rome at UCLA, who is one of the founders of Vault Nano and a collaborator on this project. We were awarded a ~\$1 million grant over two years (\$669,156 in year 1) from the National Cancer Institute through the Small Business Innovation Research (SBIR) program to support this work (see attached press release).

We also entered into an agreement this fall with a new customer to produce recombinant adeno-associated viruses (rAAVs) that have gene therapy applications. We previously produced rAAVs for gene therapy in collaboration with the National Institutes of Health that demonstrated the utility of our BEVS platform to produce these vectors.

In December we extended our agreement with BioArctic and will manufacture additional clinical-grade fibroblast growth factor (FGF1) for them next summer. The FGF1 we produce is inserted into a biodegradable device that comprises a surgical treatment BioArctic is evaluating for complete spinal cord injury.

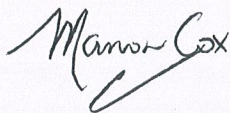
Financial Results: For the nine months ended September 30, 2014 revenues decreased 28% to \$22.8 million from \$31.9 million in Q3 2013. This reflects a reduced contribution from our BARDA contract

due to the timing of spending on clinical trials that accounted for approximately 68% of revenues and a 22% reduction in our Collaborative Agreements, Technology Licenses and Product Sales that together accounted for 32% of revenues. As a reminder, revenues from Collaborative Agreements are based on success in product development by our customers and, therefore, will significantly fluctuate on a quarterly basis. Operating expenses decreased by 32% to \$18.7 million from \$27.6 million in Q3 2013 primarily because of a reduction in BARDA supported clinical trial expenses. Our operating profit was \$4.2 million in line with Q3 2013. Net income was \$2.7 million compared to \$7.4 million in Q3 2013. The difference was caused primarily by a \$3.1 million gain from selling a portion of the UMN stock we own in 2013 and application of the non-cash tax benefit. Cash and receivables after deducting payables were \$15.4 million compared to \$14.2 million in Q3 2013. It is important to remember that the flu vaccine business is seasonal with almost all expenses being incurred in Q's 1, 2 and 3 and almost all revenues being received in Q4.

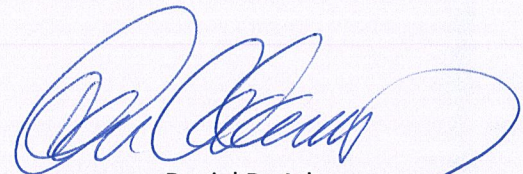
We continue to be highly dependent on BARDA support as a result of a contract that was secured and extended through the end of 2015. We expect to reduce our dependency on BARDA support as we build Flublok sales and secure royalties from licenses and collaborative agreements. We are building the Flublok brand responsibly without taking "bet the company" financial risks.

New Addition: In October we welcomed Dr. Xiaomi Tong to our leadership team as Senior Vice President and Chief Technology Officer (see attached press release). Dr. Tong has extensive experience in biopharmaceutical product development, manufacturing and commercialization. She joins us from Emergent BioSolutions Corporation where she held multiple roles including Vice President of Advanced Development and Manufacturing, Vice President of Regulatory Affairs, and Principal Investigator for Emergent's Centers for Innovation in Advanced Development and Manufacturing - a public-private partnership with the U.S. Department of Health and Human Services responsible for developing and manufacturing vaccines and other medical countermeasures. Prior thereto Xiaomi worked with Sanofi Pasteur on various aspects of their influenza business.

Cordially,



Manon M.J. Cox
President & CEO



Daniel D. Adams
Executive Chairman

Protein Sciences Corporation
Balance Sheets
(Unaudited)

	September 30, 2014	December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 7,505,420	\$ 4,936,355
Short term investment	4,597,887	4,323,771
BARDA funds receivable -- including unbilled of \$1,663,634 and \$3,834,701, respectively	3,015,031	5,098,194
Accounts receivable -- including unbilled of \$0 and \$1,067,473, respectively and net of allowance for doubtful accounts of \$50,000 and \$50,000, respectively	1,184,039	2,319,022
Inventory	5,251,644	1,807,028
Deferred tax asset	1,575,149	3,311,661
Other current assets	565,143	624,958
Total current assets	23,694,313	22,420,989
 PROPERTY, PLANT AND EQUIPMENT -- Net	 5,187,739	 6,265,254
 Long term deferred tax asset	 4,979,616	 4,979,616
Restricted cash	638,258	638,258
Other assets	9,453	13,642
 TOTAL ASSETS	 <u>\$ 34,509,379</u>	 <u>\$ 34,317,759</u>
 LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Deferred revenue, current portion	\$ 2,672,706	\$ 3,570,232
Accounts payable	948,612	2,525,018
Accrued expenses	1,842,709	2,043,658
Other current liabilities	147,291	439,038
Total current liabilities	5,611,317	8,577,946
 LONG TERM LIABILITIES:		
Deferred revenue	634,909	499,951
Other liabilities	380,500	490,968
Total long term liabilities	1,015,408	990,919
 COMMITMENTS AND CONTINGENCIES	 -	 -
 STOCKHOLDERS' EQUITY		
Common Stock, \$0.001 par value; 150,000,000 shares authorized; 77,521,602 and 77,512,769 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	77,521	77,513
Additional paid-in capital	63,460,563	63,210,458
Accumulated other comprehensive income, net of tax	1,231,226	1,070,861
Accumulated deficit	(36,886,656)	(39,609,938)
Total stockholders' equity	27,882,654	24,748,894
 TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	 <u>\$ 34,509,379</u>	 <u>\$ 34,317,759</u>

Protein Sciences Corporation
Statements of Operations
(Unaudited)

	Nine Months Ending September 30,			2014 % of
	2014	2013	% Change	Revenue
REVENUES:				
BARDA contract	\$ 15,582,030	\$ 22,589,358	-31%	68.3%
Collaborative agreements	2,176,988	4,230,469	-49%	9.5%
Technology licenses	2,756,814	3,658,293	-25%	12.1%
Product sales	2,311,189	1,407,452	64%	10.1%
Total revenues	22,827,021	31,885,572	-28%	100.0%
OPERATING EXPENSES:				
Research and development	13,932,499	24,170,697	-42%	61.0%
Cost of goods sold	808,579	-		
General and administrative	3,931,426	3,468,899	13%	17.2%
Total operating expenses	18,672,504	27,639,596	-32%	81.8%
INCOME FROM OPERATIONS	4,154,517	4,245,976	-2%	18.2%
(INCOME) OTHER EXPENSE:				
Interest expense	124	1,142	-89%	0.0%
Interest income	(7,855)	(11,594)	-32%	0.0%
Other income/expense	1,321	(3,153,150)		
Total other (income) expense	(6,410)	(3,163,602)	-100%	0.0%
Net income before tax expense and benefit	4,160,926	7,409,578	-44%	18.2%
Tax (expense) benefit	(1,437,645)	(45,478)	3061%	-6.3%
Net Income	\$ 2,723,282	\$ 7,364,100	-63%	11.9%

Protein Sciences Corporation
Statements of Cash Flow
(Unaudited)

	Nine Months Ending September 30,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 2,723,282	\$ 7,364,100
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,211,858	2,096,032
Share-based compensation	246,906	307,802
Loss on disposal of assets	189	-
Deferred taxes	1,736,512	-
Changes in operating assets and liabilities:		
Inventory	(3,444,616)	(2,730,082)
Accounts receivable	1,134,983	(1,905,763)
BARDA funds receivable	2,083,163	(2,933,274)
Restricted cash	-	-
Other assets	69,004	265,051
Accounts payable and accrued expenses	(1,777,355)	(658,986)
Other liabilities	(402,215)	527,790
Deferred accounts	(762,567)	(2,576,294)
Net cash provided by operating activities	<u>2,819,144</u>	<u>(243,623)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of investments	(118,753)	(2,579,484)
Purchases of property and equipment	<u>(134,532)</u>	<u>(1,958,766)</u>
Net cash used in investing activities	<u>(253,285)</u>	<u>(4,538,250)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	3,206	308,174
Payments of capital lease obligations	<u>-</u>	<u>(2,497)</u>
Net cash used in financing activities	<u>3,206</u>	<u>305,677</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,569,065	(4,476,196)
CASH AND CASH EQUIVALENTS - Beginning of period	<u>4,936,355</u>	<u>9,980,564</u>
CASH AND CASH EQUIVALENTS - End of period	<u>\$ 7,505,420</u>	<u>\$ 5,504,368</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	\$ 124	\$ 627
Cash paid for taxes	\$ 106,582	\$ 45,478

Protein Sciences Corporation
Statements of Comprehensive Income
(Unaudited)

	Nine Months Ending September 30,	
	2014	2013
Net Income	<u>\$ 2,723,282</u>	<u>7,364,100</u>
Other comprehensive income:		
Net change in unrealized gain in investments	<u>\$ 27,882,654</u>	<u>24,748,894</u>
Total Comprehensive Income	<u>\$ 30,605,935</u>	<u>\$ 32,112,994</u>

Flublok® Influenza Vaccine Now Approved for Adults Ages 18 and Older

For Immediate Release

October 30, 2014

Contact:

Manon Cox, President & CEO

Phone: (203) 686-0800 ext. 308

Meriden, CT — [Protein Sciences Corporation](#) announced today that the U.S. FDA has approved [Flublok influenza vaccine](#) for all adults aged 18 years and older, granting approval for use in people 50 and older under the accelerated approval of biological products regulations, 21 CFR 601.40-46. Flublok is the only licensed flu vaccine that is made using modern recombinant technology and the only flu vaccine that is 100% egg-free and highly purified. It also contains three times more active ingredients than traditional flu vaccines. The expanded age indication means Flublok is now available for everyone over 50 who have been waiting patiently to receive his or her vaccine.

Lisa Dunkle, MD, Chief Medical Officer of Protein Sciences said, “Older adults are known to be at high risk for contracting and developing complications from influenza.” She continued, “Flublok has been shown to induce high antibody levels in seniors.”

“We are excited with this approval,” said Dr. Manon Cox, MBA, President and CEO of Protein Sciences. “We set out to develop a better vaccine for the older population by increasing the amount of active ingredients in the vaccine. People of all ages have been calling and asking for Flublok and now it is terrific to be able to (finally) tell them that the product is approved for all adults. Flublok is a modern vaccine with particular benefits to individuals who want (need) to avoid exposure to egg proteins, gelatin, latex, formaldehyde or antibiotics as Flublok is free of all of these unnecessary and avoidable components.”

Earlier this year the FDA approved a shelf life extension for Flublok to 6 months.

Flublok is available at Passport Health locations nationwide and select pharmacies, clinics and doctor’s offices. A list of locations can be found at www.flublok.com.

Healthcare professionals seeking Flublok should contact FFF Enterprises at 800-843-7477 or online at www.myfluvaccine.com. FFF Enterprises will begin shipment immediately or delivery dates can be specified.

About Protein Sciences

Protein Sciences specializes in vaccine development and protein production. Our mission is our inspiration: to save lives and improve health through the creation of innovative vaccines and biopharmaceuticals.

Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was approved by FDA in January 2013. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an infectious influenza virus or antibiotics in manufacturing. Flublok is highly purified and does not contain any preservatives (e.g., thimerosal, a mercury derivative), egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines (3x45mcg hemagglutinin protein versus 3x15mcg hemagglutinin protein). Flublok is a perfect copy of the virus coat and is not subject to the egg-adapted mutations associated with low vaccine effectiveness (see [Skowronski et al. \(2014\) PLOS ONE 9\(3\), e92153](#)).

Healthcare professionals can order Flublok by contacting FFF Enterprises at 800-843-7477.

Learn more at www.proteinsciences.com and www.flublok.com.

Flublok Safety Information

Flublok is approved for people 18 and older to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection. Headache, fatigue or muscle ache may occur.

Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine.

Vaccination with Flublok may not protect all individuals. Clinical effectiveness in adults 50 and older is based on the immune response elicited by Flublok and not on demonstration of decreased influenza disease.

Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

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Congresswoman Elizabeth H. Esty
CONNECTICUT'S 5TH DISTRICT

FOR IMMEDIATE RELEASE

October 30, 2014

Contact: Courtney Chandler, 860-223-8412

**Rep. Elizabeth Esty Statement on the Expanded Label Approval of
Protein Sciences' Flublok Vaccine**

MERIDEN, CT – Today, Rep. Elizabeth Esty (CT-5) released the following statement congratulating Protein Sciences on the expanded label approval of the Flublok vaccine for adults 50 years and older.

“This expanded label approval of the Flublok vaccine testifies to Protein Sciences’ cutting-edge leadership in the vaccine industry. This is the first time an egg-free, highly pure flu vaccine will be available for adults over 49, and I’m proud to say it’s developed and manufactured right here in the 5th District. I applaud Protein Sciences and thank the company for their innovation and commitment to keeping our communities healthy.”

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Flublok® Technology Could Solve the Problem of Ineffective Flu Vaccines

For Immediate Release

December 15, 2014

Contact:

Manon Cox, President & CEO

Phone: (203) 686-0800 ext. 308

Meriden, CT — The Centers for Disease Control and Prevention (CDC) recently warned that flu vaccines may be ineffective this season because a new strain of H3N2 influenza virus is circulating that is not included in this year's vaccines. The technology used to make [Protein Sciences' Flublok influenza vaccine](#) could be the solution.

"A drift in influenza virus strain can effectively be addressed by a strong antibody response," said Protein Sciences' President and CEO Dr. Manon Cox. "Flublok contains 3x more antigen than traditional trivalent flu vaccines and induces a stronger antibody response against the influenza A viruses and a comparable response against influenza B viruses. The H3N2 virus is an influenza A virus and therefore we expect similar results to those observed in our 2007/08 clinical study where Flublok was effective against drifted H3N2 viruses."

The manufacturing process for Flublok is significantly faster than egg-based methods and provides an exact match to circulating flu strains unlike traditional manufacturing that changes a virus as it is passaged in eggs.

Dr. Cox added, "If the government deemed it necessary, we could begin manufacturing an H3N2 vaccine that matches the new circulating flu virus immediately and have it ready for release within a few months."

Flublok is still available this season for those seeking the vaccine. Influenza typically peaks in February and the CDC advises that people protect themselves by getting vaccinated. Flublok is FDA approved for all adults 18 and older and is fully reimbursed by Medicare and other insurances.

Healthcare professionals wanting to order Flublok should contact FFF Enterprises at 800-843-7477 or online at www.myfluvaccine.com.

About Protein Sciences

Protein Sciences specializes in vaccine development and protein production. Our mission is our inspiration: to save lives and improve health through the creation of innovative vaccines and biopharmaceuticals.

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Healthcare professionals can order Flublok by contacting FFF Enterprises at 800-843-7477.

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Flublok Safety Information

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Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine.

Vaccination with Flublok may not protect all individuals. Clinical effectiveness in adults 50 and older is based on the immune response elicited by Flublok and not on demonstration of decreased influenza disease.

Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

*Flublok demonstrated a higher antibody response to the A strains during 2 clinical trials in adults ≥50 years old. The B strain antibody response was comparable to traditional trivalent vaccines.

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United States Senate

WASHINGTON, DC 20510

December 23, 2014

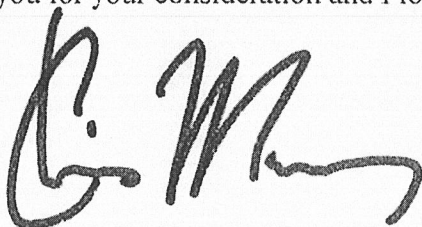
Thomas Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Frieden,

In light of the recent health advisory issued this influenza season, I write to bring your attention to a possible solution to the H3N2 drifted virus and the vaccine's decreased effectiveness. In particular, I would like you to consider increasing distribution of Flublok, the FDA approved vaccine that is both developed and manufactured in Meriden, Connecticut. As you know, this vaccine is developed using influenza's genetic code and contains three times more of the antigen than conventional egg-grown flu vaccines. As such, Flublok provides a stronger immune response against influenza A viruses, and past studies have shown effective immune responses against drifted H3N2 strains.

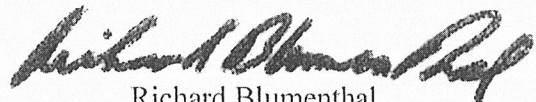
As you have noted, about half of the H3N2 viruses that have been analyzed are different than the H3N2 virus that is included in this year's flu vaccine. Additionally, I understand that the traditional vaccine is less than 10 percent effective against this strain in people over 65 years of age. This could be an incredibly dangerous situation since we know that we tend to have the worst flu seasons, with sometimes twice as many hospitalizations and deaths, when H3 viruses are predominant. For these reasons, I believe Flublok is an even more important weapon in our fight against the disease this season.

The expertise of the Centers for Disease Control and standing in the world is unmatched and I greatly appreciate the work that your agency does to protect our nation from influenza, Ebola and other diseases. Again, I would urge that you consider using Flublok to combat influenza H3N2 drifted viral outbreak. According to Protein Sciences there are approximately 250,000 doses of Flublok available now for individuals most at risk from flu and much more could be developed should a larger production facility be approved in the coming months. Thank you for your consideration and I look forward to your response.



Christopher S. Murphy
United States Senator

Sincerely,



Richard Blumenthal
United States Senator

Congress of the United States
House of Representatives
Washington, DC 20515

December 22, 2014

Tom Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, Georgia 30329-4027

RE: Solicitation # 2014-N-16818

Dear Dr. Frieden,

We write to you on behalf of Protein Sciences Corporation headquartered in Meriden, Connecticut. As you know, Protein Sciences specializes in vaccine development and protein production.

Through their proprietary BEVS protein expression technology, they developed Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease. Flublok was approved by FDA in January 2013. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an infectious influenza virus or antibiotics in manufacturing. Flublok is highly purified and does not contain any preservatives, egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines.

In light of the CDC's recent warning that flu vaccines might be ineffective this season given that the newest strain, H3N2, was not included, we are asking the CDC to consider purchasing the 250,000 doses offered by Protein Sciences through their response to Solicitation # 2014-N-16818. Protein Sciences maintains that because Flublok "contains 3x more antigen than traditional trivalent flu vaccines and induces a stronger antibody response against the influenza A viruses" it is expected that Flublok would be more effective with the H3N2 virus as it is an influenza A virus.

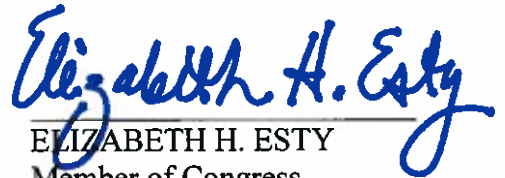
We have worked with Protein Sciences Corporation on a variety of issues and have always been impressed with the dedication and resolve that the company and its leadership have demonstrated in their innovative approach to vaccine development. Protein Sciences is at the forefront of technological advancements in their field. Flublok is the only the only flu vaccine made in America by an American company and only flu vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) for people who have known or suspected egg allergies, regardless of severity.

We believe that upon review of their submission as well as the Flublok product itself, you will find that this product may best serve the CDC's mission during the 2015-2016 flu season. We urge you to give their proposal every possible consideration. Thank you for your time and attention to our comments.

Sincerely,



ROSA L. DeLAURO
Member of Congress



ELIZABETH H. ESTY
Member of Congress



Congresswoman Elizabeth H. Esty
CONNECTICUT'S 5TH DISTRICT

FOR IMMEDIATE RELEASE

September 29, 2014

Contact: Courtney Chandler, 860-223-8412

Rep. Elizabeth Esty Announces \$669,000 Federal Grant for Protein Sciences in Meriden

Department of Health and Human Services Grant will support lung cancer treatment

MERIDEN, CT – Today, Rep. Elizabeth Esty (CT-5) announced that Protein Sciences in Meriden received a \$669,156 grant from the Department of Health and Human Services (HHS). The funding is from the National Cancer Institute through the Small Business Innovation Research (SBIR) program and will be used to support lung cancer treatment.

“Protein Sciences is on the cutting edge of developing innovative healthcare solutions for the 21st century, and it is no surprise that the Department of Health and Human Services awarded this funding,” said Esty. “Last year when I toured their facility, I saw first-hand how Protein Sciences stands as a global leader in the biotech industry, creating jobs here in Connecticut. This grant will allow Protein Sciences to continue to deliver life-saving technologies to effectively treat lung cancer patients and keep our families healthy.”

“We are gratified to be awarded this contract to help develop a novel approach to treating patients with lung cancer,” said Dan Adams, Executive Chairman and Global Head of Business Development at Protein Sciences. “We are collaborating with UCLA and Vault Nano Inc., developers of the vault approach to targeted cell delivery, and using our proprietary baculovirus technology to manufacture recombinant vaults that will deliver a potent chemokine to tumors.

“Elizabeth Esty has been a strong supporter of our company and its proprietary technology that can transform the vaccine business with products such as Flublok and vaults. She has been a leader in promoting groundbreaking Connecticut technologies such as ours in Washington, and we greatly appreciate her help,” said Dan Adams.

The National Cancer Institute is one of eleven agencies in the U.S Department of Health and Human Services. The Small Business Administration coordinates the SBIR program with other

agencies to incentivize commercialization and encourage small businesses to engage in research and development.

Founded in 1983, Protein Sciences in Meriden develops vaccines and biopharmaceuticals for the prevention and treatment of a variety of diseases.

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Xiaomi Tong, Ph.D. Joins Protein Sciences as Senior Vice President & Chief Technology Officer

For Immediate Release

October 23, 2014

Phone: (203) 686-0800 ext. 308

Contact:

Manon Cox, President & CEO

Meriden, CT—[Protein Sciences Corporation](#) announced today that Xiaomi Tong, Ph.D. has joined the Company as Senior Vice President and Chief Technology Officer. Xiaomi will be responsible for Process Development, Product Realization, Regulatory and Clinical, with special emphasis on the Company's Ebola vaccine program.

Xiaomi has extensive experience in biopharmaceutical product development, manufacturing and commercialization. Previously, she served as Vice President of Advanced Development and Manufacturing at Emergent BioSolutions Corporation and Principal Investigator for Emergent's Centers for Innovation in Advanced Development and Manufacturing (CIADM), a public-private partnership with the U.S. Department of Health and Human Services responsible for developing and manufacturing vaccines and other medical countermeasures against pandemic influenza, and biological, chemical, radiological and nuclear threats. She also served as Vice President of Regulatory Affairs, responsible for the development and implementation of global regulatory strategies. Prior to joining Emergent, Xiaomi served as Senior Regulatory Affairs Representative at DynPort Vaccine Company and Product Team Leader and Manufacturing Manager at Aventis Pasteur (now Sanofi Pasteur) of the commercial viral vaccines (influenza vaccine, yellow fever vaccine and mumps skin test antigen). She received her Ph.D. in Bioengineering from University of Utah and her bachelor's degree in Biomedical Engineering from Shanghai Jiao Tong University.



Xiaomi Tong, Ph.D.

Dr. Manon Cox, MBA, President and CEO of Protein Sciences said, "It is a great pleasure to welcome Xiaomi to our senior management team." She added, "Xiaomi brings us a wealth of knowledge in areas that are critical to our continued growth into a major player in the vaccine industry."

About Protein Sciences

Protein Sciences is a vaccine development and protein production company that is dedicated to saving lives and improving health through the creation of innovative vaccines and biopharmaceuticals.

Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was approved by FDA in January 2013. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an infectious influenza virus or antibiotics in manufacturing. Flublok is highly purified and does not contain any preservatives (e.g., thimerosal, a mercury derivative), egg proteins, gelatin or latex. In addition, Flublok is triple the strength of conventional influenza vaccines. Flublok is a perfect copy of the virus coat and is not subject to the egg-adapted mutations associated with low vaccine effectiveness (see [Skowronski et al. \(2014\) PLOS ONE 9\(3\), e92153](#)). We have filed for FDA approval of Flublok for ages 50 and above and expect to receive approval in time for the 2014/15 influenza season.

Healthcare professionals can order Flublok by contacting FFF Enterprises at 800-843-7477 or ASD Specialty Healthcare at 866-281-4FLU.

Learn more at www.proteinsciences.com and www.Flublok.com.

Flublok Safety Information

Flublok is approved for people 18-49 years old to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection. Other side effects may occur and include fatigue, headache and muscle aches.

Flublok should not be administered to anyone with a severe allergic reaction (e.g., anaphylaxis) to any vaccine component.

Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) within 6 weeks of receipt of a previous dose of influenza vaccine. If you notice any other problems or symptoms following vaccination, please contact your healthcare professional immediately. Vaccination with Flublok may not protect all individuals.

Please see the complete Package Insert available at www.Flublok.com or call 203-686-0800 for more information.

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