Pressmeddelande den 14 juni 2015

Kvartalets informationsbrev till aktieägarna från Protein Sciences

Protein Sciences Corporation (Protein Sciences) har distribuerat ett informationsbrev till sina aktieägare (”Shareholder Letter June 2015”). Protein Sciences har godkänt att Mertiva offentliggör detta informationsbrev. Informationsbrevet innehåller en redogörelse för de viktigaste händelserna i bolaget samt oreviderade siffror för första kvartalet 2015 och är bifogat till detta pressmeddelande.

Informationsbrevet innehåller även pressmeddelanden, vilka tidigare publicerats på Protein Sciences hemsida.

Protein Sciences avser att distribuera informationsbrev kvartalsvis till sina aktieägare. När Mertiva erhåller 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 NGMs 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.

Protein Sciences CORPORATION

June 2015

To Our Shareholders:

The second quarter was a good one for your company. Of significance, the FDA awarded Flublok® 12 years exclusivity at the end of May (see attached press release). Flublok is the first vaccine awarded this very important status, demonstrating that Flublok is a unique and game changing influenza vaccine. The determination of regulatory exclusivity means that FDA cannot approve any product similar to Flublok before January 16, 2025.

We are well on our way to achieving the goals set out for the year in our previous letter. As expected, we received FDA licensure of our Pearl River manufacturing facility and of MassBiologics as a fill/finish contractor in May. This expands our commercial manufacturing capacity of Flublok® by four-fold and allows us to meet our commitment to BARDA to manufacture 50 million doses of Panblok within six months of declaration of a pandemic. The clinical studies of our quadrivalent formulation of Flublok are complete, and top-line results are expected in late June. These studies compare Flublok to a licensed egg-based quadrivalent influenza vaccine. Our Phase 3 clinical study of Panblok will begin enrollment in July.

Flublok: Flublok pre-booking has grown modestly since last year. It will be available at Target Pharmacies across the United States in 2015 - Target has pre-ordered 45,000 doses of Flublok with the potential to increase the order to 100,000 doses. Joining Target as national access points are Wal-Mart, Publix, Price Chopper, various other TOPCO Brands, and Rite Aid (will have at least one box of Flublok in all 4,500 stores). We are developing strategies to drive consumer traffic to these retailers to increase sales of Flublok as most will need to be requested by the consumer before the vaccine is stocked. Other large holding companies have elected to perform a geographical introduction of Flublok; for example, Flublok will be available in 200 Kroger pharmacies such as City Market and King Soopers in Colorado. In May we added Henry Schein Medical as a fourth distributor for Flublok. We will continue our Passport Health collaboration that provides access in approximately 200 clinics across the country and to provide vaccination clinics to large employers.

We have received a $500,000 contract from the State of Connecticut to provide Flublok to state agencies, and we have partnered with The Connecticut Association for Healthcare at Home to further increase access to Flublok (see attached press release). The CDC placed orders for approximately 1,000 doses of Flublok with the potential to order up to 300,000 doses, and we expect orders to grow as the flu season gets closer. We are also completing a submission to the Department of Veterans Affairs to be in included on the Federal Supply Schedule.

We hired two experienced sales professionals whose sole focus will be to sell Flublok and leverage our distribution relationships, and we continue to explore innovative ways to market and build demand for Flublok.

Mass immunizing efforts continue to move forward with Health-At-Work booking employer clinics for Connecticut, New York and Massachusetts. The Healthy Choices Mobile Vaccination Clinic initiative continues to grow, and we will use the mobile vaccine clinic to bring Flublok to underprivileged neighborhoods in Connecticut again this flu season. We received a "Shining Star Award" from the Midstate Chamber of Commerce for this partnership with Hunter's Ambulance. We also partnered with Hunter's Ambulance and Hartford Healthcare at Home to widen the opportunity to bill insurance companies. Hartford Healthcare at Home has applied for a grant of approximately $30,000 to allow us to vaccinate individuals who would not otherwise be covered through insurance.

Board of Directors Retreat: The Board met for several days off site to discuss short and long-term strategy for the Company. We agreed that our primary focus should be on growing Flublok sales, reducing manufacturing costs and out-licensing our technology. Our goal for the next 5 years is to increase our market-share to 20% or approximately 30 million doses.

Clinical Trials: Our large clinical trials of Flublok Quadrivalent have been completed, and the data are being analyzed. Because of the severity of the 2014-2015 influenza season that was partly due to the appearance of a new, drifted strain of H3N2, our clinical efficacy trial (PSC12) in older adults (≥50 years) has sufficient cases of laboratory-confirmed influenza cases to demonstrate non-inferiority (the primary endpoint of the trial) and receive full traditional approval of Flublok Quadrivalent in this population. Because the egg-derived vaccines performed so poorly (according to the CDC ~19% effective overall and only about 10% effective in the vulnerable elderly population), we are optimistic that the trial may also demonstrate superiority of Flublok Quadrivalent over the licensed egg-grown vaccine and show that the problem of egg drift[1] that occurs in egg-based vaccine manufacturing can be avoided using recombinant technology (Flublok is the only licensed flu vaccine that uses this modern technology). This will clearly demonstrate the advantages of our system.

The smaller PSC16 clinical study, intended to demonstrate the immunogenicity of Flublok Quadrivalent in young adults (18-49 years), collected all of the necessary data to support approval of the quadrivalent product in that population.

We plan to submit an application for traditional approval for all adults 18 years of age and older in the early fall.

Manufacturing: Our Pearl River manufacturing site and fill/finish contractor MassBiologics were approved by FDA for production of Flublok and pandemic influenza vaccines and fill/finish, respectively, on May 12, 2015. This approval is the culmination of a tremendous team effort and demonstrates the dedication of our employees to meet our strategic goals. Furthermore, it confirms our maturity as a biotech manufacturing company and our readiness to pursue a robust Flublok product life cycle and strategic production plan. The support of BARDA was essential in making this happen.

The manufacturing teams in Pearl River and Meriden are executing the upcoming season's production campaign accumulating Flublok drug substance and completing testing and documentation to release and ship these to MassBiologics and Hospira for fill/finish. We are on schedule to produce bulk drug substance for 12-15 lots of Flublok in Meriden and 6-8 lots in Pearl River for a total of about 1.2 million doses and plan to release the first lots in August.

We are also preparing to validate the manufacture of the quadrivalent vaccine formulation and pre-filled syringes in addition to single dose vials. These two targets are critically important to our portfolio and are the next steps as Flublok enters the product maturity cycle.

Lastly, we received FDA approval for an important change to our license - the number of approved uses for chromatography resins. This approval will reduce the cost of goods and ensure the viability of our manufacturing strategy. FDA also granted us 12 years exclusivity for Flublok (see attached press release) that we believe will prevent other companies developing flu vaccines using recombinant technology from securing registration for many years.

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[1] Egg drift refers to changes that result in the influenza viruses when grown in eggs. Sometimes, as has happened in the last two years, the changes can make the vaccine very ineffective as discussed in this report. We are the only manufacturer that does not use eggs or live flu viruses.

BARDA: In the second option period that extends through December 2015, the BARDA contract has three new milestones (D1-3) and two milestones remaining from the previous option period (C2-3). It is an exciting time for us and BARDA since our accomplishments are their success. The milestones and our accomplishments are:

a) Milestone D1: Approval of the Pearl River manufacturing facility for commercial production of drug substances.
   Status: Facility is approved, and we have started commercial production.
b) Milestone D2: Perform clinical study with H7 recombinant hemagglutinin to support Emergency Use Authorization (EUA) of Panblok in case of influenza pandemic.
   Status: The clinical study PSC26 to support the EUA for Panblok will start in July 2015
c) Milestone D3: Approval of seasonal Flublok quadrivalent formulation in adults ≥18 years of age.
   Status: Two clinical studies (PSC12 and PSC16) to achieve this milestone are complete, and the data will be available later this month.
d) Milestone C2: Approval of Flublok indication in older adults.
   Status: FDA approved Flublok for older adults in October, 2014.
e) Milestone C3: Approval of Flublok indication for children and adolescents.
   Status: The clinical study for Flublok indication in adolescents is complete, and the Clinical Study Report has been submitted to CBER.

Two additional BARDA contracts for alternative delivery of influenza vaccines and pandemic stockpiling are in the negotiation phase, and a Small Business Innovation Research (SBIR) grant from the Department of Defense for an Adenovirus vaccine is expected to be awarded soon.

Ebola vaccine: Our Ebola vaccine was tested in four monkeys in a challenge study in collaboration with NIH. Although all 4 survived longer after challenge than the unvaccinated control animals, all monkeys became sick and were euthanized. Preliminary analysis of the serum from the monkeys indicates that two produced anti-Ebola antibodies in response to the vaccine. Additional work on this project is dependent on financial support.

Collaborations: Liomont, our Flublok licensee in Mexico, had two successful meetings with Mexican regulatory authorities in early April and late May after which they received the green light to submit an application for licensure. Liomont remains on track to submit its application this month and receive approval later in the summer. We will receive a milestone payment upon licensure.

We have begun the process of licensure by FDA of the UNIGEN Flublok manufacturing facility in Japan as we explore the possibility of sourcing Flublok from there. The UNIGEN facility has two 21,000L bioreactors and the capacity to add six more and is where our partner, UMN Pharma that is partnered with Astellas, manufactures Flublok for the Japanese market. Sourcing Flublok from Japan will allow us to provide more doses to the U.S. market as the demand for Flublok increases and at lower cost due to economies of scale.

We signed an agreement with a new company to conduct a proof of concept study for development of a protein-based therapeutic. Based on the results, the company may elect to engage in a full product development campaign.

We continue to attract interest from companies developing recombinant adeno-associated vector (rAAV)-based gene therapies to license our cell line for rAAV product development. Our cell line has significant value in the rAAV field because it is used to manufacture uniQure's Glybera®, the only approved gene therapy in the Western world. This approval greatly simplifies the path to approval for other products that use our technology.

We published two papers. The first entitled *"The baculovirus expression vector system: A commercial manufacturing platform for viral vaccines and gene therapy vectors"* reviews the utility of the BEVS platform for manufacturing vaccines and gene therapy vectors. It was published in *Biotechnology Journal*, and an abstract can be found at http://onlinelibrary.wiley.com/doi/10.1002/biot.201400438/abstract. The second entitled "*Dissolved carbon dioxide determines the productivity of a recombinant hemagglutinin component of an influenza vaccine produced by insect cells*" describes the effect of carbon dioxide on the production of recombinant hemagglutinin in our cells. It was published in *Biotechnology and Bioengineering,* and an abstract can be found at http://www.ncbi.nlm.nih.gov/pubmed/25943562.

Financial Results: For the three months ended March 31, 2015 revenues increased 57% to $11.0 million from $7.0 million in Q1 2014. This reflects an 87% increase in payments from BARDA, which accounted for approximately 91% of revenue, due to funding of large clinical trials and activities associated with securing licensure of the Pearl River facility. Revenue from Collaborative Agreements increased 57% to $611,000 while Technology Licenses decreased 83% to $174,000 because no milestone payments were received. As a reminder, revenues from Collaborative Agreements and Technology Licenses are based on development decisions by our customers and the achievement of milestones and, therefore, significantly increase or decrease on a quarterly basis. Operating expenses increased 136% to $12.0 million from $5.1 million in Q1 2014 primarily because of expenses associated with our clinical trials and Pearl River licensing expenses. We had an operating and net loss of $982,000 and $597,000, respectively, compared with an operating and net profit of $1.9 million in 2014. It is important to remember that the flu vaccine business is seasonal with almost all expenses being incurred in Qs 1, 2 and 3 and most revenues being received in Q4 and the following Q1. Now that we are manufacturing for commercial sale the impact is much clearer than in previous years. Cash and receivables net of payables were $10.6 million - $2.0 million less than in Q1 2013 – reflecting the same seasonal impact. We have secured a commitment from a bank for a working capital line to cover any seasonal shortfall.

We continue to be highly dependent on BARDA support as a result of a contract that was secured and extended because of the excellence of our technology and the people who implement it. Over time, we expect to be less dependent on BARDA support even with the approval of Option Period 2 as we build Flublok sales and secure royalties from license and collaborative agreements.

The audit of our 2014 financial statements is proceeding on schedule and will be available in mid-June.

Cordially,

Manon M.J. Cox
President & CEO

Daniel D. Adams
Executive Chairman

Protein Sciences Corporation
Balance Sheets
(Unaudited)

	March 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 10,663,120	$ 5,818,164
Short term investment	3,829,003	3,630,057
BARDA funds receivable -- including unbilled of $2,220,784 and $4,738,666, respectively	5,459,672	13,428,471
Accounts receivable -- including unbilled of $62,141 and $245,818, respectively and net of allowance for doubtful accounts of $50,000 and $50,000, respectively	1,039,323	2,279,502
Inventory	3,808,198	2,207,079
Deferred tax asset	3,305,434	2,974,473
Other current assets	454,380	927,319
Total current assets	28,559,130	31,265,065
PROPERTY, PLANT AND EQUIPMENT -- Net	3,901,449	4,020,026
Long term deferred tax asset	4,960,017	4,960,017
Restricted cash	638,258	638,258
Other assets	350,152	350,859
TOTAL ASSETS	$ 38,409,006	$ 41,234,225
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Deferred revenue, current portion	$ 908,779	$ 1,076,578
Accounts payable	5,968,551	7,627,970
Accrued expenses	4,427,282	4,904,103
Other current liabilities	147,290	147,290
Total current liabilities	11,451,902	13,755,942
LONG TERM LIABILITIES:		
Deferred revenue	880,960	956,555
Other liabilities	306,855	343,677
Total long term liabilities	1,187,814	1,300,232
COMMITMENTS AND CONTINGENCIES	-	-
STOCKHOLDERS' EQUITY		
Common Stock, $0.001 par value; 150,000,000 shares authorized; 77,606,902 and 77,549,402 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	77,607	77,549
Additional paid-in capital	63,628,482	63,519,642
Accumulated other comprehensive income, net of tax	721,222	641,955
Accumulated deficit	(38,658,021)	(38,061,095)
Total stockholders' equity	25,769,290	26,178,051
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 38,409,006	$ 41,234,225

Protein Sciences Corporation
Statements of Operations
(Unaudited)

	Three Months Ending March 31, 2015	2014	% Change	2015 % of Revenue
REVENUES:				
BARDA contract	$ 9,949,857	$ 5,313,052	87%	90.6%
Collaborative agreements	611,385	389,457	57%	5.6%
Technology licenses	174,395	1,036,926	-83%	1.6%
Product sales	250,700	263,724	-5%	2.3%
Total revenues	10,986,336	7,003,161	57%	100.0%
OPERATING EXPENSES:				
Research and development	10,508,482	3,582,379	193%	95.7%
Cost of goods sold	16,607	218,700	-92%	0.2%
General and administrative	1,442,980	1,264,470	14%	13.1%
Total operating expenses	11,968,068	5,065,549	136%	108.9%
INCOME FROM OPERATIONS	(981,732)	1,937,611	-151%	-8.9%
(INCOME) OTHER EXPENSE:				
Interest expense	-	124	0%	0.0%
Interest income	(3,165)	(1,987)	59%	0.0%
Other income/expense	-	1,182		
Total other (income) expense	(3,165)	(681)	365%	0.0%
Net income before tax expense and benefit	(978,567)	1,938,292	-150%	-8.9%
Tax (expense) benefit	381,640	(50,079)	0%	3.5%
Net Income	$ (596,927)	$ 1,888,214	-132%	-5.4%

Protein Sciences Corporation
Statements of Cash Flow
(Unaudited)

	Three Months Ending March 31, 2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ (596,927)	$ 1,888,214
Adjustments to reconcile net income to net cash provided by operating activities:		
Realized gain on short term investment	-	-
Depreciation and amortization	142,664	330,435
Share-based compensation	94,523	82,418
Tax Impact on unrealized loss on S/T investment	(119,680)	
Excess tax benefit from stock compensation	-	-
Loss on disposal of assets	-	-
Deferred taxes	(330,961)	-
Changes in operating assets and liabilities:		
Inventory	(1,601,119)	(1,500,000)
Accounts receivable	1,240,179	950,324
BARDA funds receivable	7,968,799	442,731
Restricted cash	-	-
Other assets	247,620	(188,313)
Accounts payable and accrued expenses	(1,910,214)	(1,301,936)
Other liabilities	(36,822)	(36,823)
Deferred accounts	(243,394)	328,050
Net cash provided by operating activities	4,854,668	995,100
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceed from sale of short term investment	-	-
Purchase of investments	-	-
Purchases of property and equipment	(24,087)	(14,210)
Net cash used in investing activities	(24,087)	(14,210)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	14,375	457
Payments of capital lease obligations	-	-
Net cash used in financing activities	14,375	457
NET INCREASE IN CASH AND CASH EQUIVALENTS	4,844,956	981,347
CASH AND CASH EQUIVALENTS - Beginning of period	5,818,164	4,936,355
CASH AND CASH EQUIVALENTS - End of period	$ 10,663,120	$ 5,917,702
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ -	$ 124
Cash paid for taxes	$ 50,000	$ 50,079

Protein Sciences Corporation
Statements of Comprehensive Income
(Unaudited)

	Three Months Ending March 31, 2015	2014
Net Income	$ (596,927)	1,888,214
Other comprehensive income:		
Net change in unrealized gain in investments	$ 79,267	499,348
Total Comprehensive Income	$ (517,660)	$ 2,387,562

Protein Sciences and the CT Association for Healthcare at Home Will Provide Flublok® to Connecticut Home Health and Hospice Agencies

For Immediate Release
April 30, 2015

Contact:
Courtney Goodwin
Communications Associate
Phone: (203) 686-0800 ext. 301

Meriden, CT —Protein Sciences Corporation along with The Connecticut Association for Healthcare at Home (CTH@H) announced a new partnership today that will bring Flublok® influenza vaccine to home health and hospice agencies across the state. As a new affinity partner of CTH@H, Protein Sciences will make Flublok available to CTH@H member agencies for the 2015/16 flu season.

"The Connecticut Association for Home Healthcare is the united voice for home and community-based care delivery in the state. This partnership brings new opportunities to create awareness for Flublok from a ground-up perspective," said Manon Cox, President and CEO of Protein Sciences Corporation. "Entering into an affinity partnership with CTH@H is an exciting opportunity to inform and engage the community-based workforce about Flublok and its unique features for their patients."

"Ensuring that Connecticut's 20,000 home health and hospice agency employees have access to the Flublok vaccine for both their patient population as well as for themselves is a positive step toward the goal of limiting exposure and spread of the flu," said Deborah Hoyt, President and CEO of the Connecticut Association for Healthcare at Home. "Home health workers are on the front line in terms of reaching the most vulnerable patients – the frail, homebound and disabled - making this new relationship with Protein Sciences a strategic step toward improving population health in Connecticut.

For more information about Flublok, please visit www.flublok.com.

For more information about The Connecticut Association for Healthcare at Home, please visit www.cthealthcareathome.org

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 wishing to pre-order Flublok should contact one of the following distributors:

- FFF Enterprises: 800-843-7477 www.myfluvaccine.com
- Cardinal Health: 866-677-4844 http://www.cardinal.com/us/en/SPD/Ordering
- McKesson: 877-MCK-4FLU mms.mckesson.com

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.

*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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Protein Sciences New York Facility Receives FDA Licensure to Manufacture Flublok®

For Immediate Release
May 13, 2015

Contact:
Courtney Goodwin
Communications Associate
Phone: (203) 686-0800 ext. 301

Meriden, CT —Protein Sciences Corporation announced that on May 12, 2015 the U.S. Food and Drug Administration (FDA) licensed its Pearl River, NY manufacturing facility for the commercial manufacturing of Flublok® influenza vaccine. Flublok is the world's first licensed influenza vaccine made using modern recombinant technology.

"The approval of our Pearl River facility accelerates the growth of Protein Sciences and Flublok," said Manon Cox, President and CEO. "We will be able to manufacture Flublok at four times the scale compared to our Connecticut facility. This milestone enables us to substantially increase the availability of Flublok this year and in the future."

"Approval of the Pearl River facility has been our passion since we acquired the facility from Pfizer at the end of 2012," said Mireli Fino, Vice President of Manufacturing Operations. "It has been very rewarding to work with our dedicated Pearl River team that was able to manufacture the first batch of Flublok within 100 days and to now achieve FDA licensure. We look forward to the new opportunities licensure presents."

This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, Department of Health and Human Services, under Contract No. HHSO100200900106C.

For more information about Flublok, please visit www.flublok.com.

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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).

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- McKesson: 877-MCK-4FLU mms.mckesson.com

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Flublok Safety Information

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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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FDA Grants 12 Year Exclusivity to Flublok® Influenza Vaccine

For Immediate Release
June 3, 2015

Contact:
Clifton McPherson
VP Corporate Communications
Phone: (203) 599-6064 ext. 116

Meriden, CT —Protein Sciences Corporation announced that in a rare move, the FDA is granting exclusivity to Flublok for a period of 12 years. Flublok is the first vaccine awarded this very important status, demonstrating Flublok as a unique and game changing influenza vaccine.

The US FDA determination of regulatory exclusivity means that no product similar to Flublok can be approved by US FDA before January 16, 2025.

"The FDA's designation prevents a generic product maker from capitalizing on the hard work of our team," said Manon Cox, President and CEO of Protein Sciences Corporation. "We are delighted that the FDA recognizes Flublok as a singular innovation in the prevention of an important and often deadly disease caused by the influenza virus."

"I am honored to be representing Protein Sciences Corporation for nearly twenty years on matters of legal exclusivity," said Tom Kowalski, Esq., Shareholder with Vedder Price, P.C. "This biologics regulatory exclusivity is only the third of such exclusivities granted by the US FDA under the Affordable Care Act, and the only one for an influenza vaccine."

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