

Pressmeddelande den 24 september 2015

Kvartalets informationsbrev till aktieägarna från Protein Sciences

Protein Sciences Corporation (Protein Sciences) har distribuerat ett informationsbrev till sina aktieägare ("Shareholder Letter September 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 halvåret 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 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.

Mertiva AB (publ.) Upplandsgatan 67, 113 28 Stockholm, Sverige E-post: info@mertiva.se Org. Nr: 556530-1420



September 2015

To Our Shareholders:

The Company's business remains positive as we head into the 2015/16-influenza season. This quarter we received excellent results from our large clinical trial of Flublok[®] Quadrivalent in comparison to a traditional egg-based inactivated quadrivalent vaccine in adults 50 years and older. The study showed that people vaccinated with Flublok were ~45% less likely to get confirmed flu than people that received the traditional vaccine. Protection against the dangerous H3N2 virus was even better – more than 50% better than the egg-based vaccine. No other influenza vaccine has ever shown superiority results like these.

In June, we hosted our quarterly Board of Directors meeting and our annual shareholder meeting at our Pearl River facility. Following the shareholder meeting, we held a press conference where we were joined by BARDA officials and local political and economic development leaders to announce the FDA approval of the facility, the top line results from our recent clinical trials and the FDA's grant of 12 years exclusivity for Flublok. You can view the complete press conference at the following link: <u>https://www.youtube.com/watch?t=2&v=8CFZMXYhixc</u>.

In August, we convened a meeting in New York City of Key Opinion Leaders in the influenza field. The experts discussed the clinical data from our most recent Flublok study, strategies for building awareness, future directions for Flublok and new product opportunities. Overall, the participants were very enthusiastic about Flublok and agreed that its purity and superior efficacy are true game changers. Priorities are being placed on publishing the paper on the quadrivalent clinical study in a leading medical journal and creating strong messaging for various audiences. We have implemented a radio campaign in selected cities to drive pull-through of Flublok at stores in which it is stocked.

We had commitments in place to produce approximately 1.2 million doses of Flublok this year (12 lots at Hospira and 6 lots at MassBio) and are on track to successfully complete production of projected materials. One lot (~25,000 doses) will be provided to our Mexican partners, Liomont, whose application for licensure of Flublok was accepted by Mexican authorities. Approval is expected later this fall.

The Board of Directors approved the promotion of Mireli Fino to Senior Vice President of Manufacturing and Tim Fields to Senior Vice President of Quality. Mireli and Tim have both made very significant contributions to the Company, most recently playing a major role in securing FDA licensure of the Pearl River facility.

Flublok: Pre-booking has concluded with approximately 160,000 doses pre-booked (this includes a 90,000 dose order from Target; approximately 10,000 from TOPCO Supermarkets; and hospitals nationwide). In-season sales have begun and we expect these to be filled primarily by independent pharmacies, doctor's offices, our clinic initiatives and re-orders from stores carrying our vaccine. Our contracts with the Connecticut State Government and the CDC also allow for the purchase of over 300,000 doses of Flublok. Flublok will be available at Passport Health Clinics

and other national access points. It will also be widely available at regional supermarkets and independent pharmacies including, Roundys and Mariano's in the Chicago area, Brookshires in Texas and Price Chopper in the Northeast.

We are focusing our efforts on all of our access points to drive pull-through of the product. This includes furnishing marketing and promotional materials and development and implementation of a carefully targeted radio campaign in collaboration with iHeart Media. We are running a national advertising campaign this fall directed at independent pharmacies in partnership with the National Community Pharmacists Association (NCPA) as we have found independent pharmacies to be strong proponents of Flublok. In addition, we are attending several pharmacy and healthcare professional annual meetings.

We continue to develop and leverage our relationships with our four distributors: FFF Enterprises, McKesson, Cardinal Health and Henry Schein. We have met with them in person, conducted comprehensive training of their sales teams on the advantages of Flublok and how to position it in the marketplace and we are working with them to develop creative approaches to drive demand for the product. We have also become licensed to direct ship from our facilities in Connecticut.

Our mass immunization initiative to offer workplace and community Flublok clinics in Connecticut and the surrounding regions is off to a great start. Health-At-Work (<u>www.health-at-work.net</u>) is a partnership with physicians from Velocity Urgent Care that is a full service vaccination provider that allows employers to customize vaccination clinics for their employees. We hosted three breakfast events on site and partnered with Goodwin College on a fourth breakfast event to promote Flublok to local employers and generate clinics for Health-at-Work. Those efforts have yielded increased interest and repeat and new business.

The Healthy Choices Mobile Vaccination collaboration with Hunters Ambulance, Hartford Healthcare at Home and the Meriden Housing Authority has a new name: FastVax! A bus has been wrapped to showcase Flublok and the logos of each of the partners. We added Hancock Pharmacy as a partner in the initiative that will further increase our opportunity to bill insurance companies. The initiative is growing and the community's response has been great.

Clinical Trials: Our large clinical trials of Flublok Quadrivalent were completed in late May and the data are now available. PSC12 assessed the protective efficacy of Flublok Quadrivalent in comparison to a licensed, inactivated egg-grown quadrivalent vaccine in ~9,000 adults 50 years of age and older. This trial was designed to support full, traditional approval (as opposed to accelerated approval) of trivalent Flublok in this age group and to support traditional approval of the quadrivalent vaccine in older adults. The exciting news is that the study met all endpoints and that Flublok demonstrated superiority over the traditional vaccine. People that received Flublok were ~45% less likely to get flu than those that received the egg-grown vaccine. Moreover, the 2014-2015 flu season was a particularly severe one caused largely by the H3N2 strain that is often responsible for severe complications from influenza. Flublok recipients were >50% less likely to get H3N2 influenza than the egg-grown vaccine recipients. These data have been accepted for presentation at the American Society for Microbiology's Interscience

Conference of Antimicrobial Agents and Chemotherapy (ICAAC) (the largest infectious diseases meeting in the world annually) in September.

The other clinical trial, PSC16, studied the safety and immunogenicity of Flublok Quadrivalent in 1,350 adults 18-49 years of age. The results of this trial will support approval of the quadrivalent formulation in the younger adult age group, for whom Flublok already has full, traditional approval. The results were positive and contribute to the provision of a consistent "story" of the significant improvement that Flublok brings to the armamentarium of influenza vaccines.

We are preparing to conduct a large post-marketing study this season with Kaiser Permanente to satisfy FDA commitments. This study that will include approximately 50,000 subjects is expected to generate important health outcome data.

Manufacturing: The manufacturing teams in Pearl River and Meriden continued production of Flublok drug substance during the second quarter. We experienced higher than expected productivity that offset production delays that occurred in the first quarter. This allowed us to maintain a 10-day cadence in Pearl River and slow down the projected staff growth for 2015. With the early start in 2014, we were able to begin filling drug product at MassBio and Hospira in mid-July.

This quarter we initiated two new projects in manufacturing in parallel with commercial Flublok production. The first project allows us to increase the number of times we can reuse one of our most expensive reagents and, therefore, reduce the cost of producing Flublok. We received FDA approval for this change. The second project supports our Pandemic Vaccine. The Meriden team successfully implemented a new aseptic filling team and completed production of vials for the Pandemic clinical trial PSC26. This allowed PSC26 to be fully enrolled in August 2015.

BARDA: We are pleased to report continued progress on the milestones that were established under the second option of the BARDA contract that extends through December 2015.

- Milestone 11D-2: Perform a clinical study to support Emergency Use Authorization (EUA) of Panblok in case of an influenza pandemic. Status: Patient enrollment for Stage 1 was completed on August 4th.
- Milestone 11D-3a and b: Approval of seasonal Flublok Quadrivalent Status: Completed necessary clinical trials; met criteria for primary endpoint of noninferiority and exploratory endpoint of superiority.

BARDA Stock Pile Contract: We anticipate award of a new contract from BARDA relating to stock piling: however, award of this contract has been delayed until January 2016.

Collaborations: We attended the BIO 2015 International Convention in Philadelphia in June where we had multiple productive meetings centered around our platform technology and license opportunities. The companies we met with ranged in size and were interested in either licensing our cell line for development of new products or licensing Flublok for new

territories. We also had a Flublok exhibit where we created broad awareness and generated vaccine sales leads.

Liomont, our Flublok licensee in Mexico, submitted its application for licensure of Flublok in Mexico to the Mexican regulatory authorities. Approval is expected this fall. Liomont is purchasing one lot of Flublok this season to test market in Mexico following licensure. We will receive a milestone payment when the vaccine is approved.

Progress continues to be made in Japan as our Flublok licensee, UMN Pharma, which is partnered with Astellas, works with Japanese regulatory authorities to secure licensure. The license application has been submitted and approval is expected later this year. We will receive a significant milestone payment upon licensure.

Our SBIR grant from the National Cancer Institute that funds development work on the production of vault nanoparticles for treatment of lung cancer in collaboration with UCLA and Vault Nano, Inc. was funded for a second year. Process development work is nearing completion and material will soon be produced for preclinical testing.

We were also awarded a Phase I SBIR grant sponsored by the Department of Defense for development of an adenovirus vaccine.

Financial Results: For the six months ended June 30, 2015 revenues increased 37% to \$19.4 million from \$14.2 million in 2014. This increase reflects an increase in the contribution from our BARDA contract that accounted for approximately 89% of revenues, up from 73% in the comparable period in 2014 primarily as a result of the initiation of two large clinical trials that are funded by BARDA. Product sales increased 28% to \$723,000 but our Collaborative Agreements and Technology Licenses that together accounted for 7% of revenues were down 21% and 79%, respectively to \$1 million and \$398,000, respectively. As a reminder, revenues from Collaborative Agreements and Technology Licenses are based on success in product development by our customers and, therefore, significantly increase or decrease on a quarterly basis. Operating expenses increased by 74% to \$19.6 million from \$11.3 million in 2014 primarily because of clinical trial expenses covered under the BARDA contract. We had an operating and net loss before tax expense and benefit of \$250,000 and \$245,000, respectively, compared to an operating and net profit before tax expense and benefit of \$2.9 million in 2014. The difference results primarily from the sale of a portion of the UMN Pharma shares we own in 2014. Cash and receivables net of payables were \$9.8 million - \$625,000 less than at the end of Q1 and \$7.7 million less than at the end of 2014 – reflecting the seasonal impact of our flu business where almost all expenses are incurred in Qs 1, 2 and 3 and most revenues received in Q4 and the following Q1. Now that we are manufacturing for commercial sale the impact is much clearer than in previous years. We closed a \$10 million banking working capital line to assist in covering seasonal cash flow shortfall.

We continue to be highly dependent on support from our BARDA contract. We do expect to become less dependent on BARDA as we build Flublok sales and secure royalties from licenses, collaborative agreements and other government grants.

Cordially,

Mainon Cor

Manon M.J. Cox President & CEO

Daniel D. Adams Executive Chairman

Protein Sciences Corporation Balance Sheets (Unaudited)

	 June 30, 2015	D	ecember 31, 2014
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	\$ 5,193,526	\$	5,818,164
Short term investment	3,446,206		3,630,057
BARDA funds receivable including unbilled of \$823,839			
and \$4,738,666, respectively	6,175,597		13,428,471
Accounts receivable including unbilled of \$52,961 and \$245,818,			
respectively and net of allowance for doubtful accounts of \$50,000	400 694		2 270 502
and \$50,000, respectively Inventory	400,684 6,893,402		2,279,502 2,207,079
Deferred tax asset	3,168,463		2,974,473
Other current assets	584,860		927,319
Total current assets	 25,862,740		31,265,065
	25,002,740		31,205,005
PROPERTY, PLANT AND EQUIPMENT Net	3,811,047		4,020,026
Long term deferred tax asset	4,960,017		4,960,017
Restricted cash	638,258		638,258
Other assets	384,681		350,859
TOTAL ASSETS	\$ 35,656,742	\$	41,234,225
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Accounts payable	\$ 5,394,555	\$	7,627,970
Accrued expenses	2,483,491		4,904,104
Deferred revenue, current portion	598,779		1,076,578
Other current liabilities	 147,290		147,290
Total current liabilities	 8,624,116		13,755,942
LONG TERM LIABILITIES:			
Deferred revenue	717,166		956,555
Other liabilities	 270,032		343,677
Total long term liabilities	 987,198		1,300,232
TOTAL LIABILITIES	 9,611,314		15,056,175
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			
June 30, 2015 and December 31, 2014, respectively	77,607		77,549
Additional paid-in capital	63,691,497		63,519,642
Accumulated other comprehensive income, net of tax	487,716		641,955
Accumulated deficit	 (38,211,391)		(38,061,095)
Total stockholders' equity	 26,045,428		26,178,051
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 35,656,742	\$	41,234,225

Protein Sciences Corporation Statements of Operations (Unaudited)

	Six Months End 2015	ing Ju	ne 30, 2014	Percent Change	2015 Percent of Revenue
REVENUES:				Ŭ	
BARDA contract	\$ 17,252,242	\$	10,419,271	66%	88.9%
Collaborative agreements	1,023,077		1,299,835	-21%	5.3%
Technology licenses	398,189		1,881,362	-79%	2.1%
Product sales	 723,265		563,780	28%	3.7%
Total revenues	19,396,772		14,164,249	37%	100.0%
OPERATING EXPENSES:					
Research and development	16,540,216		8,734,522	89%	85.3%
Cost of goods sold	291,855		151,450	93%	1.5%
General and administrative	2,814,178		2,399,328	17%	14.5%
Total operating expenses	 19,646,249		11,285,300	74%	101.3%
INCOME FROM OPERATIONS	(249,477)		2,878,949	-109%	-1.3%
(INCOME) OTHER EXPENSE:					
Interest expense	-		125	0%	0.0%
Interest income	(6,203)		(4,673)	33%	0.0%
Other income/expense	 1,286		1,182		
Total other (income) expense	(4,917)		(3,366)	46%	0.0%
Net income before tax expense and benefit	(244,560)		2,882,314	-108%	-1.3%
Tax (expense) benefit	 94,263		221,620	0%	0.5%
Net Income	\$ (150,297)	\$	3,103,934	-105%	-0.8%

Protein Sciences Corporation Statements of Cash Flow (Unaudited)

	Six Month	ns Ending June 30 2015	0,	2014
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net income	\$	(150,297)	\$	3,103,934
Adjustments to reconcile net income to net cash	Ŷ	(100,201)	Ŷ	0,100,001
provided by operating activities:				
Realized gain on short term investment		-		-
Depreciation and amortization		287,492		754,864
Share-based compensation		157,538		161,791
Tax Impact on unrealized loss on S/T investment Excess tax benefit from stock compensation		29,612 -		-
Loss on disposal of assets		1,494		-
Deferred taxes		(193,991)		-
Changes in operating assets and liabilities:				
Inventory		(4,686,323)		(2,694,000)
Accounts receivable		1,878,818		1,109,107
BARDA funds receivable		7,252,874		1,832,263
Restricted cash		-		-
Other assets		308,637		(46,770)
Accounts payable and accrued expenses		(4,654,027)		(1,841,746)
Other liabilities Deferred accounts		(73,645)		(365,394)
Delened accounts		(717,188)	·	(366,460)
Net cash (used in) provided by operating activities		(559,006)		1,647,589
CASH FLOWS FROM INVESTING ACTIVITIES:				
Proceed from sale of short term investment		-		-
Purchase of investments		-		-
Purchases of property and equipment		(80,007)		(145,997)
		<u> </u>		
Net cash (used in) investing activities		(80,007)		(145,997)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from exercise of stock options		14,375		457
Payments of capital lease obligations		-		-
Net cash (used in) provided by financing activities		14,375		457
NET INCREASE IN CASH AND CASH EQUIVALENTS		(624,638)		1,502,049
CASH AND CASH EQUIVALENTS - Beginning of period		5,818,164		4,936,355
CASH AND CASH EQUIVALENTS - End of period	\$	5,193,526	\$	6,438,404
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION Cash paid for interest Cash paid for taxes	l: \$ \$	- 51,115	\$ \$	124 70,129

Protein Sciences Corporation Statements of Comprehensive Income (Unaudited)

Six I	Months Ending June 30, 2015 2014			
	2015	2014		
Net Income	<u>\$ (150,297</u>)	3,103,934		
Other comprehensive income: Net change in unrealized gain in investments	<u>\$ (154,239</u>)	52,280		
Total Comprehensive Income	<u>\$ (304,537)</u>	<u>\$ 3,156,214</u>		



Flublok[®] Influenza Vaccine is now Nationwide The Pure Choice for Adults 18 and Older

For Immediate Release September 22, 2015

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

Meriden, CT — <u>Protein Sciences Corporation</u> announced today that <u>Flublok Influenza Vaccine</u>, that was shown to provide better protection against the flu than a traditional flu vaccine in a recent clinical study, is now available nationwide. Not only does Flublok work well, it is the only flu vaccine that is free of all of the following undesirable ingredients: formaldehyde, antibiotics, gluten, gelatin, egg protein, latex, thimerosal and other preservatives. This makes it the pure choice for flu protection for adults 18 and older.

Getting Flublok has never been easier. National retailers Target and Walmart are offering Flublok. Flublok is also available in many regional supermarkets and independent pharmacies, including Mariano's and Roundy's in the Chicago area, Brookshire's in Texas, and Price Chopper in the Northeast. Passport Health Clinics will once again offer Flublok at its sites nationwide. Passport patients can even book their vaccines online.

"We are pleased to partner with leading pharmacies to greatly expand access to our vaccine," said Manon Cox, President and CEO of Protein Sciences Corporation. "Anyone over 18 years of age will be able to walk into Target, Mariano's, Roundy's or Brookshire's nationwide and receive Flublok. At other stores, people are encouraged to call the pharmacy in advance to make sure Flublok is in stock when they come in for vaccination. Nearly all insurance providers cover Flublok so most people can get Flublok free of charge."

Flublok has found special appeal among health conscious individuals that prefer its purity and its popularity is growing among people focused on better protection. In a recent clinical study of the quadrivalent version of Flublok in approximately 9,000 adults 50 years and older, Flublok recipients were 43% less likely to develop culture confirmed influenza than people who received a licensed quadrivalent egg-based influenza vaccine.

For more information about Flublok and where to get it, please visit <u>www.flublok.com</u>.

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 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
- Henry Schein: 1-800-772-4346 <u>www.henryschein.com</u>

Learn more at <u>www.proteinsciences.com</u> and <u>www.flublok.com</u>.

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.

###



Protein Sciences Promotes Vice Presidents Mireli Fino and Tim Fields to Senior Vice President

For Immediate Release July 10, 2015 Contact:

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

Meriden, CT — <u>Protein Sciences Corporation</u> announced that the Board of Directors has approved the promotion of Mireli Fino, Vice President, Manufacturing Operations to Senior Vice President, Manufacturing Operations and Tim Fields, Vice President, Quality to Senior Vice President, Quality.



Ms. Fino joined Protein Sciences in 2012 as VP, Manufacturing Operations. She came from Wyeth (now Pfizer) where she spent 20 years in various roles in vaccine development and commercial manufacturing. Most recently, she served as Director Manufacturing Sciences and Technology - Drug Substance. She played a key role in the successful development and launch of *Prevnar13*® pneumococcal 13-valent conjugate vaccine, considered one of the most complex biologics licensed to date. In addition, Ms. Fino led global initiatives implementing process and yield improvements based on the successful applications of risk management and Quality by Design (QbD) and Process Analytical Technology (PAT) concepts. She has a B.S. in Biochemical Engineering from the University of Aguascalientes in Mexico.



Tim Fields joined Protein Sciences in 2010 as Director of Compliance and Training. Subsequently, he served as Senior Director of Quality Operations before becoming VP of Quality and Validation in 2011. He has more than 30 years of experience in the pharmaceutical industry, including more than 13 years at Pfizer and 16 years as a GMP compliance consultant. Mr. Fields has experience in a variety of compliance areas, including quality systems, validation, aseptic processing, computerized system validation, GMP training, 21CFR Part 11, document management and auditing. He is a member of PDA and ISPE and is on the editorial review board for the *Journal of Validation* and *Journal of GXP Compliance*. Previously, he was a member of DIA, RAPS and ASQC and was an adjunct instructor at the Community College of Rhode Island. He has a B.A. in Biology from Indiana University and an M.A. in Life Sciences from Indiana State University.

"Mireli and Tim have played critical leadership roles within the organization most recently to secure FDA licensure of the Pearl River manufacturing facility," said Manon Cox, President and CEO of Protein Sciences.

"Licensure of this facility allows us to scale up our commercial manufacturing of Flublok[®] five-fold. I am delighted that the Board has recognized their extraordinary contributions."

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 <u>Skowronski et al. (2014) PLOS ONE 9(3), e92153</u>).

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

- FFF Enterprises: 800-843-7477 <u>www.myfluvaccine.com</u>
- Cardinal Health: 866-677-4844 http://www.cardinal.com/us/en/SPD/Ordering
- McKesson: 877-MCK-4FLU mms.mckesson.com
- Henry Schein Medical: 800-772-4346 <u>www.henryschein.com/flu</u>

Learn more at <u>www.proteinsciences.com</u> and <u>www.flublok.com</u>.

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 of trivalent Flublok in adults 50 and older is based on the immune response elicited by trivalent Flublok and not on demonstration of decreased influenza disease.

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

*Trivalent 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.

###



New Clinical Study of Flublok[®] Influenza Vaccine Shows That Groundbreaking Flublok Is More Effective Than the Traditional Flu Shot

For Immediate Release June 25, 2015

Contact:

Courtney Goodwin Communications Associate Phone: (203) 592-7584

Meriden, CT —<u>Protein Sciences Corporation</u> announced today topline data showing that Flublok® Quadrivalent – the quadrivalent version of FDA-approved trivalent <u>Flublok® influenza</u> <u>vaccine</u> – outperformed a traditional influenza vaccine last season and was better at preventing the flu. The company presented the results of a clinical trial comparing Flublok Quadrivalent to a traditional egg-based quadrivalent inactivated vaccine. The data demonstrate superior performance of Flublok based on a significantly lower number of people contracting the flu after vaccination with Flublok Quadrivalent.

In this study of approximately 9,000 subjects aged 50 and older, half received Flublok Quadrivalent influenza vaccine and half received quadrivalent inactivated influenza vaccine produced in eggs. The results show that 31% more people were protected by Flublok than by the egg-derived vaccine.

"This study points out the advantages of using modern technology to overcome problems with traditional influenza vaccine manufacturing," said Manon Cox, President and CEO of Protein Sciences. "Ten years ago we had the first evidence in clinical trial PSC01 that more antigen was beneficial even for healthy adults. Today with support from the Biomedical Advanced Research and Development Authority (BARDA) we were able to show statistically significant better performance than traditional egg-produced vaccines."

Flublok is the only flu vaccine made without the use of eggs and therefore is not subject to the mutations that are sometimes introduced into the vaccine during the process of egg adaptation that can cause the traditional vaccines to be ineffective (see <u>Skowronski et al. (2014) PLOS ONE</u> <u>9(3), e92153</u>). Flublok contains three times more active ingredients than traditional vaccines (3 or 4x45mcg hemagglutinin protein versus 3 or 4x15mcg hemagglutinin protein for trivalent or quadrivalent vaccine, respectively) and produced significantly higher immune responses to the A strains of influenza (especially H3N2) in the Flublok Quadrivalent study.* Flublok is highly purified and does not contain influenza virus, antibiotics, formaldehyde, preservatives, latex, gluten or gelatin unlike other flu vaccines.

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.

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.

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
- Henry Schein Medical: 800-772-4346 www.henryschein.com/flu

Learn more at <u>www.proteinsciences.com</u> and <u>www.flublok.com</u>.

Flublok Safety Information

Trivalent 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 of trivalent Flublok in adults 50 and older is based on the immune response elicited by trivalent Flublok and not on demonstration of decreased influenza disease.

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

*Trivalent 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.