



Pressmeddelande den 27 april 2016

## Informationsbrev till aktieägarna från Protein Sciences

*Protein Sciences Corporation (Protein Sciences) har distribuerat ett informationsbrev till sina aktieägare ("Shareholder Letter April 2016"). Protein Sciences har godkänt att Mertiva offentliggör detta informationsbrev. Informationsbrevet innehåller en redogörelse för de viktigaste händelserna i bolaget, samt oreviderade siffror för 2015 och finns att läsa nedan.*

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

Protein Sciences har sagt att man avser att distribuera informationsbrev kvartalsvis till sina aktieägare och de har godkänt att Mertiva publicerar dessa i detta format.

Med anledning av att detta kvartalsbrev skickats ut senare i relation till kvartalsslutet än föregående kvartalsbrev, så vill Mertiva upplysa om att vi inte kan kontrollera när Protein Sciences skickar sina informationsbrev och att vi inte vet detta på förhand. Protein Sciences är ett privat bolag och de har ingen officiell finansiell kalender eller liknande, utan de skickar information när de själva vill och har möjlighet. Mertiva uppskattar mycket att Protein Sciences har börjat distribuera informationsbrev och att Mertiva får publicera dem, men vi har inte möjlighet att kräva detta av dem eller att kräva att informationsbreven ska skickas vid någon specifik tidpunkt. När ett informationsbrev kommer, så kommer vi även fortsättningsvis att lägga ut det via pressmeddelande och hemsidan, så snart som möjligt.

### 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](http://www.mertiva.se).

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



April 2016

**To Our Shareholders:**

The 2015/16 flu season is winding down and we are rigorously assessing our progress and planning for the 2016/17 flu season. We manufactured 1.2 million doses of Flublok® for the 2015/16 season and all lots were released by FDA. This marks an important milestone for the Company as we have established ourselves as a reliable supplier with early FDA release (August). We shipped 600,000 doses through increased distribution channels with the addition of three new distributors and shipped product directly from our Meriden facility. Unfortunately, failure of the flu to circulate reduced the demand for flu vaccine for the industry. In addition, while Flublok sales exceeded the amount sold last year, they fell well below our expectations in part because of the poor flu season and in part because of the introduction and widening acceptance of quadrivalent flu vaccines in prefilled syringes. We are processing returns from our distributors and total actual sales for the season should be confirmed by the end of April.

We licensed Flublok and Panblok® for the Brazil market to Orygen Biotecnologia SA, a joint venture between the Brazilian pharmaceutical companies Eurofarma Laboratórios SA and Biolab Sanus Farmaceutica Ltda. We will initially manufacture Flublok for this market and will receive significant licensing and milestone payments. Brazil is experiencing a severe outbreak of H1N1 swine flu that has killed almost twice as many people over the past three months as it did in all of 2015, according to Brazil's Health Ministry, evidencing the need for effective influenza prevention.

The Company and our "Plug and Play" platform technology received national media attention when the Zika virus was declared a public health emergency of international concern by the World Health Organization. In addition, our unique approach to funding the Zika vaccine through an international consortium received wide publicity and interest from funding agencies here and abroad. Our Zika vaccine program, whose speed and safety is unmatched in the industry, is particularly attractive to organizations and governments especially in Latin America but also other parts of the world.

We submitted a Supplemental BLA (sBLA) to the FDA for approval of Flublok Quadrivalent. This sBLA also included a request for approval of our partner, Adimmune, in Taiwan as an additional fill/finish site for Flublok to increase capacity and offer presentation in pre-filled syringes. The FDA inspected Adimmune at the end of March and it appears that the inspection went well. We are also evaluating additional fill/finish facilities in other locations. Quadrivalent flu vaccines in pre-filled syringes are the direction in which the industry is moving. In addition, we have applied for an increased Flublok shelf life of nine months or one year to enable us to produce product early in the season without the risk of expiration prior to use.

We submitted for publication in a leading medical journal the data from our pivotal post-marketing trial of Flublok Quadrivalent in ~9,000 adults 50 years of age and older that confirmed the superior protective efficacy of Flublok over a conventional egg-derived inactivated vaccine. We are taking advantage of every opportunity to share these results.

We have been working with our advisors to identify a marketing and sales partner who will be able to accelerate awareness of Flublok particularly in physicians who are difficult for us to reach.

**Flublok:** Our distributors did not achieve the level of pull through of the product that they had projected and the returns have been significant. We are working with them to secure more favorable terms for the upcoming season and strategies to market the product more effectively. Based on our experience last season, we decided to reduce the number of doses produced from 1.2 million to 900,000 and will only use MassBio for fill/finish in our 2016/17 campaign. We have strongly encouraged our customers to pre-book as we will strive to limit production to match pre-booked orders as much as possible taking into consideration commitments we had to make to MassBio.

Working through distributors is necessary for some customers, but we can reduce costs and offer better pricing to customers if we ship direct. Shipping direct requires us to register in almost all states, an arduous task that is largely complete and will pay dividends in the future.

Medical reimbursement remains excellent with almost all insurance plans whereas reimbursement in the pharmacy sector varies by insurance plan. We continue to make progress in managed care organizations and contracted pharmacy rates by providing clinical data to substantiate higher reimbursement and ensure proper coding.

Our mass immunization initiative to offer workplace and community Flublok clinics in Connecticut and surrounding states continued to expand. Health-At-Work ([www.health-at-work.net](http://www.health-at-work.net)) 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. Health-At-Work was successful in increasing the number of Flublok doses administered this year and they are actively pursuing additional contracts for clinics in 2016.

The Healthy Choices mobile vaccination collaboration with Hunters Ambulance, Hartford Healthcare at Home, HealthMed Urgent Care and Health Mart pharmacies has been actively marketing its services to a wider number of communities. The goal for 2016 is to build on this year's success and double the amount of Flublok administered this year.

**Clinical Trials:** The clinical team has been responding to FDA questions on our Quadrivalent sBLA submission (a good sign that things are progressing at FDA) and prepared a manuscript describing our pivotal clinical efficacy trial in adults 50 years of age and older (PSC12). Dr. Wayne Hachey presented this data at a recent National Advisory Committee on Immunization Practices CDC meeting in Atlanta. The data was also presented by Dr. Lisa Dunkle at the Annual Conference on Vaccine Research sponsored by the National Foundation for Infectious Diseases this month. We further shared the data with national pharmacy chains, managed care organizations and

independent pharmacists and expect that wide dissemination of the information will positively impact orders and sales for the 2016/17 flu season.

We are also preparing plans for a pediatric efficacy study that will be a joint project with our Mexican partners, Laboratorios Liomont S.A. de C.V., in this coming season.

**Manufacturing:** The Manufacturing Operations Team is producing active ingredients for the 2016/17 commercial Flublok season. Late last year we began building inventory in Pearl River and Meriden of the H1 A/California antigen. Producing one of the more likely antigens to be retained in the vaccine composition in advance is standard practice in the influenza manufacturing industry. Production of new antigens occurs after the official strain selection is made. Our goal is to have FDA released product three weeks earlier this coming season, which is significant to retail pharmacies. The 2016/17 strain selection occurred in late February and was consistent with our in-house expert prediction. As a result, we are well positioned for successful commercial production: we produced the required inventory of H1 A/California; verified the process for the H3 A/Hong Kong at pilot scale (450L process); and completed development supporting yield improvements for the B B/Brisbane antigen. Commercial production of H3 and B antigens is ongoing from March to July.

We began transitioning our Meriden manufacturing team from commercial production operations to clinical production, contract manufacturing and product pipeline support. This transition is part of our plan to reduce commercial manufacturing costs as commercial operations solidify in our larger scale Pearl River facility and we implement our supply agreement with UMN Pharma.

We are also preparing for the post commercial season in Pearl River. We began the technology transfer activities required to implement the Fed-Batch process for production of rHA that will increase our yield at least two-fold. This yield improvement is critical to achieving our production - above five million doses - and cost of goods targets. We plan to execute process validation as soon as the commercial campaign is completed.

**Product Development:** We completed our Phase 1 Small Business Innovation Research (SBIR) grant from the Department of Defense to develop a next-generation adenovirus vaccine and are in discussions for Phase 2/3 SBIR support that should bring a much higher level of funding.

We completed negotiations for the stockpile contract with BARDA and expect contract award shortly. The execution of this contract has been delayed from its original target date of September 2015 to January 2016 and most recently April. The funds will support product development of vaccines to combat influenza viruses of pandemic interest and manufacturing of such vaccines.

The small scale purification process for the Zika virus E protein has been completed and we are scaling up the process to support production of the “protective” E protein for pre-clinical and clinical studies. We plan to submit a grant application to the National Institute of Allergy and Infectious Diseases (NIAID) for Zika Virus Vaccine Development within the next 30 days.

We submitted several other grants to BARDA, NIAID and the Gates Foundation to fund new and existing vaccine development programs. These include programs for:

- FluNhanse™ (recombinant neuraminidase (NA) - supplemented influenza vaccine) - Submitted to BARDA
- Development of a recombinant human rabies vaccine – under review at NIAID
- Phase 2 SBIR for developing a chlamydia vaccine in collaboration with our partners at UCLA and Vault Nano – submitted to NIH

**Collaborations:** We signed an agreement with Sinergium Biotech S.A., an Argentinean company, which included an up-front payment that will partially fund our Zika vaccine program and give Sinergium access to the vaccine for Argentina and potentially other Latin American countries. We are also in discussions with one of the large government-affiliated vaccine manufacturers in Brazil that is interested in co-developing the vaccine for that market. Several other companies in the Americas, Middle East and Asia have also expressed interest in the program and we are expecting to sign additional funding agreements soon. The Zika outbreak, following close on the heels of the Ebola epidemic last year, has reinforced a growing interest in our technology platform by many countries and we are in discussions with multiple parties that are interested in establishing domestic manufacturing facilities based on that technology.

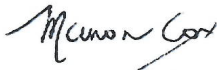
Beyond Zika, work with our collaborators continues to go well. Merck has renewed its research license to our SF+ cell line for another year and Liomont has notified us of its interest to expand their Flublok and Panblok licenses to include additional territories in Latin America. The Pfizer team has expressed satisfaction with our work under our Services Agreement and remarked that our baculovirus is significantly more stable and therefore better than an internal comparator they recently acquired.

**Financial Results (Unaudited):** For the year ended December 31, 2015 revenues decreased 32% to \$31.7 million from \$46.6 million in 2014. This decrease reflects a decrease in the contribution from our BARDA contract that accounted for approximately 69% of revenues, down from 79% in 2014 primarily as a result of the completion of two large clinical trials and the end of support for our Pearl River facility post licensure by FDA that were funded by BARDA. Product sales increased 53% to \$5.6 million from \$3.7 million in 2014 and our Collaborative Agreements and Technology Licenses that together accounted for 13% of revenues were up 23% and down 78%, respectively to \$3.4 million and \$747,000. 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 from period to period. Operating expenses increased by 3% to \$46.0 million from \$44.6 million in 2014 primarily because of our assuming the cost of operating the Pearl River facility that BARDA ceased to fund post FDA licensure. We had an operating and net loss before tax expense and benefit of about \$14.4 million compared to an operating and net profit before tax expense and benefit of about \$2.0 million in 2014. The difference results primarily from the sale of a portion of the UMN Pharma shares we owned in 2014 and the incorporation of the Pearl River operating costs in our operating expenses. Cash and receivables net of payables were \$0.5 million compared to \$17.5 million in 2014 reflecting the cost of manufacturing Flublok. We closed a \$10 million bank working capital line to cover

seasonal cash flow shortfall. In addition, we have added to cash through sale of the remaining UMN stock for over \$3 million, licensing additional territories for Flublok and securing funding for the Zika project.

We were highly dependent on support from our BARDA contract in the past but the impact will be much less in 2016 since only about \$3 million remains to be billed under the contract. We do expect to receive a large BARDA stockpiling contract in Q2 2016 but with or without that contract we expect Flublok sales and milestones and royalties from licenses, collaborative agreements and other government grants to make up for the ending BARDA contract. In addition, we are working to secure additional financing so that we can address opportunities created by the licensure of Flublok and the growing acceptance of our platform technology as the way to rapidly and safely

Cordially,



Manon M.J. Cox  
President & CEO



Daniel D. Adams  
Executive Chairman

**Protein Sciences Corporation**  
**Balance Sheets**  
**(Unaudited)**

	December 31,	
	2015	2014
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,120,548	\$ 5,818,164
Short term investment	2,442,551	3,630,057
BARDA funds receivable -- including unbilled of \$239,859 and \$4,738,666, respectively	907,235	13,428,471
Accounts receivable -- including unbilled of \$250,335 and \$245,818, respectively and net of allowance for doubtful accounts of \$150,000 and \$50,000, respectively	3,101,409	2,279,502
Inventory	4,033,249	2,207,079
Deferred tax asset	-	2,974,473
Other current assets	810,616	927,319
Total current assets	12,415,608	31,265,065
PROPERTY, PLANT AND EQUIPMENT -- Net	3,620,975	4,020,026
Long term deferred tax asset	-	4,960,017
Restricted cash	638,258	638,258
Other assets	542,012	350,859
<b>TOTAL ASSETS</b>	<b>\$ 17,216,852</b>	<b>\$ 41,234,225</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
CURRENT LIABILITIES:		
Accounts payable	\$ 7,059,320	\$ 7,627,970
Accrued expenses	2,097,662	4,904,104
Deferred revenue, current portion	667,716	1,076,578
Other current liabilities	147,290	147,290
Total current liabilities	9,971,988	13,755,942
LONG TERM LIABILITIES:		
Deferred revenue	407,175	956,555
Other liabilities	196,387	343,677
Total long term liabilities	603,562	1,300,232
<b>TOTAL LIABILITIES</b>	<b>10,575,550</b>	<b>15,056,175</b>
STOCKHOLDERS' EQUITY		
Common Stock, \$0.001 par value; 150,000,000 shares authorized; 78,415,252 and 77,549,402 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	78,415	77,549
Additional paid-in capital	67,903,773	63,519,642
Accumulated other comprehensive income, net of tax	(320,836)	641,955
Accumulated deficit	(61,020,050)	(38,061,095)
Total stockholders' equity	6,641,302	26,178,051
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 17,216,852</b>	<b>\$ 41,234,225</b>

**Protein Sciences Corporation**  
**Statements of Operations**  
**(Unaudited)**

	Year Ending December 31,		Percent	Percent of
	2015	2014	Change	2015 Revenue
REVENUES:				
BARDA contract	\$ 21,723,078	\$ 36,694,704	-41%	68.8%
Product sales	5,656,016	3,690,850	53%	17.9%
Collaborative agreements	3,444,821	2,790,450	23%	10.9%
Technology licenses	<u>746,978</u>	<u>3,416,047</u>	-78%	2.4%
Total revenues	31,570,893	46,592,051	-32%	100.0%
OPERATING EXPENSES:				
Research and development	31,378,600	32,569,409		
Cost of goods sold	7,992,469	6,807,397		
General and administrative	<u>6,691,857</u>	<u>5,215,128</u>		
Total operating expenses	46,062,926	44,591,934		
(LOSS) INCOME FROM OPERATIONS	(14,492,033)	2,000,117		
(INCOME) OTHER EXPENSE:				
Interest expense				
Interest income	(9,455)	(10,961)		
Other income/expense	<u>(96,097)</u>	<u>20,611</u>		
Total other (income) expense	(105,552)	9,650		
Net income before tax expense and benefit	(14,386,481)	1,990,467		
Tax (expense) benefit	<u>(8,572,474)</u>	<u>(441,624)</u>		
Net (Loss) Income	<u>\$ (22,958,955)</u>	<u>\$ 1,548,843</u>		



**Protein Sciences Corporation**  
**Statements of Cash Flow**  
**(Unaudited)**

	Year Ending December 31,	
	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net (Loss) Income	\$ (22,958,955)	\$ 1,548,843
Adjustments to reconcile net income to net cash provided by operating activities:		
Provision for inventory reserve	5,671,594	5,428,485
Depreciation and amortization	548,951	2,441,085
Share-based compensation	364,347	296,947
Bad debt expense	100,000	1,931
Loss on disposal of assets	1,495	17,896
Deferred taxes	8,159,206	621,595
Changes in operating assets and liabilities:		
Inventory	(7,497,764)	(5,828,536)
Accounts receivable	(921,907)	37,589
BARDA funds receivable	12,521,236	(8,330,277)
Other assets	(88,009)	(639,578)
Accounts payable and accrued expenses	(3,375,092)	7,963,398
Other liabilities	(147,290)	(439,039)
Deferred accounts	(958,242)	(2,037,050)
Net cash (used in) provided by operating activities	<u>(8,580,430)</u>	<u>1,083,289</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	<u>(137,836)</u>	<u>(213,753)</u>
Net cash (used in) investing activities	<u>(137,836)</u>	<u>(213,753)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from sale of common stock	4,000,000	-
Proceeds from exercise of stock options	<u>20,650</u>	<u>12,273</u>
Net cash (used in) provided by financing activities	<u>4,020,650</u>	<u>12,273</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	(4,697,616)	881,809
CASH AND CASH EQUIVALENTS - Beginning of period	<u>5,818,164</u>	<u>4,936,355</u>
CASH AND CASH EQUIVALENTS - End of period	<u>\$ 1,120,548</u>	<u>\$ 5,818,164</u>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ -	\$ -
Cash paid for taxes	\$ 72,430	\$ 81,672

**Protein Sciences Corporation**  
**Statements of Comprehensive Income**  
**(Unaudited)**

	Year Ending December 31,	
	2015	2014
Net (Loss) Income	<u>\$ (22,958,955)</u>	<u>1,548,843</u>
Other comprehensive income:		
Net change in unrealized gain in investments	<u>\$ (962,791)</u>	<u>(428,906)</u>
Total Comprehensive (Loss) Income	<u>\$ (23,921,746)</u>	<u>\$ 1,119,937</u>



## Protein Sciences and Orygen Biotecnologia Announce Agreement to License Flublok® Influenza Vaccine for Brazil

---

### **For Immediate Release**

April 12, 2016

### **Contact:**

Courtney A. Reis

Communications Associate

Phone: (203) 686-0800 ext. 301

**Connecticut, USA and São Paulo, Brazil** — [Protein Sciences Corporation](#) and Orygen Biotecnologia SA, a joint venture between the Brazilian pharmaceutical companies Eurofarma Laboratórios SA and Biolab Sanus Farmaceutica Ltda, announced today that they have agreed on the terms of a licensing partnership that grants Orygen an exclusive license to [Flublok® influenza vaccine](#) for the Brazilian market. Brazil is experiencing a severe outbreak of H1N1 swine flu that has killed almost twice as many people over the past three months as it did in all of 2015, according to Brazil's Health Ministry, evidencing the need for effective influenza prevention. Flublok is the world's first recombinant influenza vaccine that has been shown in a recent large field trial to provide significantly better protection against the flu than a traditional, egg-based influenza vaccine. Under the terms of the agreement, Orygen will seek regulatory approval for and will market Flublok in Brazil. Protein Sciences will manufacture Flublok and will receive significant license and commercial milestone payments.

Andrew Simpson, Scientific Director of Orygen said, "Flublok represents an advance in the performance and quality of an influenza vaccine that will be a welcome addition in Brazil. We admire this achievement of Protein Sciences and are very pleased to be their partner in bringing Flublok to the Brazilian people."

Manon Cox, President and CEO of Protein Sciences said, "Our partnership with Orygen gives way for Flublok to enter the Southern Hemisphere, which has an opposite flu season from the Northern Hemisphere, and thereby opens up a second sales cycle for the vaccine." She added, "Orygen is a young but highly professional company with founders that have deep roots in pharmaceuticals. We expect our relationship will have long-lasting benefits."

### **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.

### **About Orygen**

Orygen is a Brazilian biopharmaceutical company focused the development, manufacture and marketing of therapeutic monoclonal antibodies and vaccines for disorders that affect Brazil and other emerging economies.

**About Flublok**

Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was approved by the U.S. 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](#)).

Learn more at [www.proteinsciences.com](http://www.proteinsciences.com) and [www.flublok.com](http://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](http://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 Corporation, Sinergium Biotech and Mundo Sano Announce Zika Vaccine Partnership

---

**For Immediate Release**

April 19, 2016

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

**Connecticut, USA and Buenos Aires, Argentina** — [Protein Sciences Corporation](#) (headquarters: Meriden, CT, USA), manufacturer of [Flublok® influenza vaccine](#), [Sinergium Biotech](#) (headquarters: Buenos Aires, Argentina) and [Mundo Sano](#), a private foundation with activities in Argentina, Spain and Africa, announced today that they have entered into an agreement to become members of a consortium that will jointly develop a Zika virus vaccine to combat the recent outbreak of Zika that is wreaking havoc in Latin America and spreading to other continents. Under the terms of the agreement, Sinergium will pay an upfront fee to fund the development and manufacture of the vaccine being produced at Protein Sciences using Protein Sciences' proprietary technology. In return, Sinergium will receive manufacturing and commercial rights to the vaccine in Argentina and other countries to be determined. The companies also said they are in active discussions with additional strategic partners worldwide that could strengthen and rapidly advance the development program.

The vaccine being developed is based on production of recombinant variations of the E protein from the Zika virus. Similar vaccine candidates produced at Protein Sciences against West Nile Virus and Japanese Encephalitis Virus, which are close relatives of the Zika virus, have previously been shown to neutralize their respective viruses in preclinical studies. Protein Sciences' technology is well known for its speed and safety, as it is used to manufacture the FDA-approved Flublok influenza vaccine and has been recognized by the U.S. government as the only approved technology that can respond to a pandemic influenza outbreak in time. The technology is plug-and-play, removing potential regulatory and safety hurdles that can dramatically delay novel vaccine development time lines.

Manon Cox, President and CEO of Protein Sciences said, "We are very pleased to partner with Sinergium Biotech and Mundo Sano on our Zika vaccine. Their focus on vaccine development and manufacturing make them a natural fit for the adoption of our technology." She added, "We initiated Zika vaccine development in February and are rapidly advancing vaccine candidates to the clinic. Sinergium's proximity to the heart of the outbreak opens up channels of support that would otherwise be inaccessible."

Alejandro Gil, President and CEO of Sinergium Biotech added, “This is an important step for our country to prevent Zika and an important step for our company that is committed to developing safely and rapidly different vaccines for the public health. We are also very enthusiastic to cooperate with Protein Sciences. Their great scientific technology and quality standards led to previous approvals of their influenza products in markets including FDA.”

Silvia Gold, President of Mundo Sano Foundation said, “After more than 20 years working in the prevention of neglected diseases, and specifically the vector-transmitted ones, we are also very happy to be part of this consortium opening the opportunity of having a vaccine after WHO declared an imperative need of it.”

#### **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.

#### **About Flublok**

Flublok, the world’s first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was initially approved by the U.S. FDA in January 2013 and the age range was expanded to make Flublok available to everyone over 18 years of age in October 2014. The FDA has accepted for filing and is reviewing Flublok Quadrivalent. 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](#)).

#### **About Sinergium**

Sinergium Biotech is an Argentinean biotech company focused on the development, manufacturing and marketing of different vaccines. Through a model of different strategic alliances with local and international partners, the know-how of new technologies was transferred into Argentina assuring a local supply of strategic products. Sinergium Biotech owns a 20,000 sqm production facility located in Garin, Buenos Aires, Argentina, with state-of-the-art technology aligned with the highest quality standards. Sinergium Biotech is currently manufacturing more than 13 million doses of different vaccines, including for seasonal influenza, pneumococcal and HPV.

#### **About Mundo Sano**

Mundo Sano Foundation was created in 1993, aiming to promote and create better conditions to improve the health of those exposed to *neglected diseases*. It works in increasing awareness, prevention, diagnosis and long-term treatment of communities affected in strategic locations of Argentina, Spain and Africa. It has created partnerships with authorities, universities, renowned

scientists, civil societies, private partners and international organizations. Its community actions and investigations contribute to scientific knowledge. Learn more at [www.mundosano.org](http://www.mundosano.org).

**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](http://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.

###