



Pressmeddelande den 17 augusti 2016

Informationsbrev till aktieägarna från Protein Sciences

Protein Sciences Corporation (Protein Sciences) har distribuerat ett informationsbrev till sina aktieägare ("Shareholder Letter Q2 2016"). Protein Sciences har godkänt att Mertiva offentliggör detta informationsbrev. Informationsbrevet innehåller en redogörelse för de viktigaste händelserna i bolaget, samt oreviderade siffror för det första halvåret 2016 och finns att läsa nedan.

För pressmeddelanden som publicerats under perioden hänvisas till Protein Sciences hemsida;
<http://www.proteinsciences.com>.

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

För ytterligare information, vänligen kontakta:

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.



August 2016

To Our Shareholders:

It has been another productive quarter for your Company. Over that period, we reported several key events that have had a positive impact on our business. Most important, FDA extended the shelf life for Flublok® to 9 months from the date of final manufacture, increasing the previous shelf life by 3 months. FDA also approved our 2016/17 formulation for Flublok. This year it mandated two new components for trivalent vaccines. These factors - longer shelf life and early FDA approval of the 2016/17 formulation put us on track to distribute product earlier this season than before.

We are pleased to advise that we finally received the BARDA stockpile contract. The maximum value of this contract is \$564 million over five years: a three-year base period and two one-year option periods. The contract begins August 22 and we will immediately negotiate with BARDA which items will be funded and when. We do anticipate that funding will at least be adequate to support the operating expenses of our Pearl River facility and balance off the seasonality of our Flublok income but that the maximum funding will be achieved only if a pandemic occurs.

We have been working with our distributors to finalize Flublok returns and close out the 2015 season, a process that is almost complete. Preliminary results indicate that of the nearly 700,000 doses that were shipped, our actual sales were slightly below 150,000 doses. As we mentioned in our previous letter, this was largely due to the acquisition of Target by CVS during the season that made that distribution channel ineffective and our inability to ship product direct to customers in various states, a problem that has been eliminated. Although this year's sales exceeded last year's sales, they were well below our expectation.

The Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommended against the use of live attenuated influenza vaccine (LAIV), marketed as FluMist®, for the 2016/17 flu season, making reimbursement of FluMist by insurance companies uncertain. This decision was made based on data from 2013-16 that showed poor effectiveness of the LAIV vaccine. This presents a possible opportunity for Flublok as FluMist was used in people with egg-allergy as the ovalbumin content is ~1,000-fold lower than other egg-derived vaccines. We have contacted our distributors and customers to remind them of our recent 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 and informed them that our product is available to fill the gap created by ACIP's decision.

We hired an experienced business development professional who will focus on developing sales in the States of Florida and Missouri that are potentially large markets for Flublok.

We continue to work with our advisors to identify a marketing and sales partner who will be able to accelerate awareness of Flublok in medical groups we are unable to reach effectively and increase sales.

Flublok: The number of Flublok doses pre-booked exceeds the amount last year. In 2016, we will produce 900,000 doses and will only use MassBio for fill/finish for our 2016/17 campaign, resulting in substantial cost savings and decreased cost of goods.

We continue to work with our distributors to identify creative ways to increase sales. Representatives from McKesson, our largest distributor, recently visited the Company. We identified additional strategies to increase awareness and sales of Flublok and are evaluating other marketing efforts.

We will also work with the CDC and the State of Connecticut to increase pull through on the contracts that we have been awarded. We are set up to ship directly from our Meriden facility that will help to ensure more timely delivery to our customers.

Our mass immunization initiative to offer workplace and community Flublok clinics in Connecticut and surrounding states continues to expand. Health-At-Work(HAW) (www.health-at-work.net) is a partnership with physicians from Velocity Urgent Care, a full service vaccination provider that allows employers to customize vaccination clinics for their employees. Multiple clinics have already been scheduled and we expect to exceed the number of HAW doses administered last year.

The Healthy Choices mobile vaccination collaboration with Hunters Ambulance, various nursing organizations, HealthMed Urgent Care and Health Mart pharmacies has already published a calendar of clinics for the 2016/17 season and continues to explore additional opportunities and partnerships. They too have set a very ambitious goal to double the number of doses administered and expand the geographic reach of the mobile vaccination program.

Clinical: Clinical activities over the past quarter have focused largely on responding in a timely fashion to FDA's Requests for Information about our BLA for Flublok Quadrivalent that is under review. The requests have been reasonable and relatively easy to respond to, and approval is on track for October this year. In addition, we have been discussing with partners in Latin America a possible collaboration on a Phase 3 study of Flublok Quadrivalent in a pediatric population that is important for many developing markets. The costs associated with the FDA's expectations for this study have compelled us to consider creative ways to conduct a study that will support approval in all jurisdictions of the Americas and Europe.

Manufacturing: The Pearl River manufacturing team is completing production of drug substance for the 2016/17 commercial Flublok campaign and shipments to our contractor Mass Biologics for fill/finish are in progress. Our process yields were better this year thanks to the work of our development team. We are on target to produce the planned 900,000 doses and have already released product on schedule in early August. Preparations for the post commercial season in Pearl River are fully underway and readiness for Fed-Batch process validation is advancing rapidly. The Fed-Batch process will increase our production yields and enable us to produce up to 5 million doses from this facility per season when the process change is approved. A request for a Type C meeting for implementation of the Fed-Batch process has been submitted to CBER.

Our Meriden manufacturing team is adjusting well to their new focus on pilot operations and new product clinical production. This quarter, the Fed-Batch process was scaled-up in Meriden prior to transfer to Pearl River for commercial production. A strong synergy is developing between the development team and the Meriden manufacturing team with increased integration during the late development and technology transfer activities.

We made significant progress in securing licensure of Unigen's plant in Japan (a joint venture of UMN and IHI Corporation). The Type C meeting with the FDA took place in early April and the Agency agreed to license the facility using product comparability and process validation with some additional work that will be completed this year. The submission is delayed approximately four months pending execution of the additional work and we are working closely with the Unigen team to expedite the work. We do not expect this delay to impact our long term plans.

Quality: The biennial FDA inspection of the Meriden facility occurred from June 8-15. Overall the inspection went well and we received a FDA-483 with 18 observations. The responses to the FDA-483 were submitted at the end of June.

Stability testing of Flublok Quadrivalent in pre-filled syringes continued with completion of the nine-month time point for Process Validation lot QFCA1501 and a four-month time point for Process Validation batches 2 and 3.

Zika: We completed the process development activities for our initial ZIKV vaccine candidate and performed our first cGMP manufacturing run successfully in July. Immunogenicity and toxicology studies in animals are scheduled over the next few months and we plan to initiate a first-in-human trial in the next six to nine months. A pre-IND meeting with FDA is being planned for September and an IND filing shortly thereafter.

We finalized the Founding Members of our Zika vaccine consortium that is supporting development of our Zika vaccine program. Members include Sinergium Biotech (Argentina), UMN Pharma (Japan), Bio-Manguinhos/Fiocruz (Brazil) and Liomont (Mexico). Each member has invested or will invest \$0.5M in the consortium in return for which each will be guaranteed no less than a 10% ownership of the consortium. The initial funding is sufficient to support early vaccine development and get us ready to initiate Phase 1 clinical testing. Additional funding for the program is expected through non-dilutive sources, such as government and foundation grants and contracts. For example, we have submitted proposals to NIH for testing and funding of our program and our partners plan to take a similar approach in their countries. We also plan to submit a Partnership R01 application to NIH for the evaluation of different platforms for the development of a Zika vaccine in collaboration with Inmunova (an Argentinean company) and EpiVax.

BARDA: We have obtained a no cost extension for our current BARDA contract to complete the follow-up of our H7 Panblok® Phase II study. We also had a meeting with BARDA leadership to explore additional areas of collaboration, including ZIKV vaccine development.

Collaborations: This spring we signed an agreement with Al Sawari Medical as the exclusive distributor of Flublok, Panblok and potentially other vaccines to be developed in the future for certain countries in the Middle East and North Africa (MENA) markets, a market that represents about 6% of the total world population. Specifically included are Morocco, Algeria, Tunisia, Libya, Egypt, Lebanon, Jordan, KSA, UAE, Kuwait, Qatar, Bahrain, Oman, Yemen, Iraq, Israel and Turkey. Under the terms of the agreement, Al Sawari will pursue registration of Flublok in all countries and will initially purchase Flublok from us for distribution in the region. We are receiving a multimillion dollar license fee and royalties on certain sales. This agreement dramatically expands the global footprint of Flublok.

We also signed an agreement with Sinergium Biotech, the first partner that joined our Zika vaccine consortium, to license Flublok and Panblok for Argentina. Sinergium has a 20,000 m² state-of-the-art production facility located in Garin, Buenos Aires and manufactures more than 13 million doses of different vaccines, including for seasonal influenza, pneumococcal disease and HPV. As part of the agreement, Sinergium will initially purchase drug substance for Flublok that it will fill/finish for the Argentina market. We are entitled to receive a significant upfront payment and royalties on sales. Sinergium strongly believes in our technology platform and we are exploring additional ways to work together.

In June, we signed an agreement with our long time licensee uniQure, an early adopter of our cell line technology platform, granting them an exclusive license to use our *expresSF+*® cells for the production of all of its rAAV-based human gene therapy products. They use our cell line to produce Glybera®, the first gene therapy product approved in the Western world, and are leaders in the highly competitive gene therapy field. uniQure's exclusive adoption of our technology further substantiates the value and breadth of our platform. Under the terms of the agreement, we received a multimillion dollar upfront payment and are entitled to a significant milestone payment in one year.

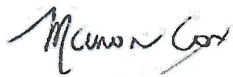
Other News

Dr. Manon Cox co-chaired the Engineering Conferences International Vaccine Technology VI conference in Portugal. She was joined at the conference by co-chair Professor Laura Palomares, our collaborator at the University of Mexico, and Dr. Indresh Srivastava, who heads the Company's Product Development Group.

Financial Results: For the six months ending June 30, 2016 revenues declined 86% to \$2.8 million from \$19.4 million in 2015. This decrease reflects primarily reduction in the contribution from our BARDA contract that accounted for almost 90% of revenues in 2015. This results from the completion of two large clinical trials funded by BARDA and the winding down of the contract. Product sales decreased 35% to \$468,000 and our Collaborative Agreements and Technology Licenses that together accounted for 46% of revenues were down 12% to \$1.3 million. 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 decreased by 65% to \$6.8 million from \$19.6 million in 2015 primarily because of the completion of the two clinical trials. We had an operating and net loss before tax expense and benefit of \$4.0 and \$3.5 million, respectively, compared to an

operating and net loss before tax expense and a benefit of \$249,000 and \$245,000, respectively, in 2015. The difference results primarily from FDA licensure of the Pearl River facility and the consequential end of BARDA funding of our manufacturing costs there. Cash remains low as our operations are funded primarily from our line of credit and continuing revenues from licenses, collaborations and research antigen sales – 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.

Cordially,



Manon M.J. Cox
President & CEO



Daniel D. Adams
Executive Chairman

Protein Sciences Corporation
Balance Sheets
(Unaudited)

	June 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 7,001	\$ 1,120,548
Marketable securities	195,920	2,442,551
Accounts receivable -- including unbilled of \$0 and \$250,335, respectively and net of allowance for doubtful accounts of \$50,000 and \$150,000, respectively	3,794,432	3,101,409
BARDA funds receivable -- including unbilled of \$281,490 and \$239,859, respectively	335,488	907,235
Inventory	10,856,312	4,033,249
Other current assets	755,511	823,879
Total current assets	15,944,664	12,428,870
 PROPERTY, PLANT AND EQUIPMENT -- Net	 3,463,173	 3,620,975
Long term deferred tax asset	16,174,416	16,291,740
Restricted cash	638,258	638,258
Other assets	550,172	542,012
 TOTAL ASSETS	 <u>\$ 36,770,683</u>	 <u>\$ 33,521,855</u>
 LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 4,196,230	\$ 7,059,320
Accrued expenses	1,917,891	2,097,662
Line of credit	3,455,194	-
Deferred revenue, current portion	1,051,763	667,716
Other current liabilities	147,290	147,290
Total current liabilities	10,768,369	9,971,988
 LONG TERM LIABILITIES:		
Deferred revenue	4,875,638	407,175
Deferred tax liability	1,415,564	1,415,564
Notes Payable- Officers	1,150,000	-
Deferred rent	122,742	196,387
Total long term liabilities	7,563,944	2,019,126
 TOTAL LIABILITIES	 <u>18,332,313</u>	 <u>11,991,114</u>
 STOCKHOLDERS' EQUITY		
Common Stock, \$0.001 par value; 150,000,000 shares authorized; 78,415,252 and 78,415,252 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	78,415	78,415
Additional paid-in capital	68,142,286	67,903,773
Accumulated other comprehensive income, net of tax	(118,901)	(334,432)
Accumulated deficit	(49,663,430)	(46,117,015)
Total stockholders' equity	18,438,370	21,530,741
 TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	 <u>\$ 36,770,683</u>	 <u>\$ 33,521,855</u>

Protein Sciences Corporation
Statements of Operations
(Unaudited)

	Six Months Ending June 30,		Percent	Percent of
	2016	2015	Change	2016 Revenue
REVENUES:				
BARDA contract	\$ 1,068,385	\$ 17,252,242	-94%	38.3%
Product sales	468,298	723,265	-35%	16.8%
Collaborative agreements	1,002,760	1,023,077	-2%	35.9%
Technology licenses	<u>249,990</u>	<u>398,189</u>	-37%	9.0%
Total revenues	2,789,433	19,396,773	-86%	100.0%
OPERATING EXPENSES:				
Research and development	3,927,070	16,815,400	-77%	140.8%
Cost of goods sold	182,582	16,671	995%	6.5%
General and administrative	<u>2,678,937</u>	<u>2,814,178</u>	-5%	96.0%
Total operating expenses	6,788,589	19,646,249	-65%	243.4%
INCOME FROM OPERATIONS*	(3,999,156)	(249,476)		
(INCOME) OTHER EXPENSE:				
Interest expense	14,151	-		
Interest income	(953)	(6,203)		
Other income/expense	<u>(465,938)</u>	<u>1,286</u>		
Total other (income) expense	(452,740)	(4,917)		
Net income before tax expense and benefit	(3,546,416)	(244,559)		
Tax (expense) benefit	<u>-</u>	<u>94,263</u>		
Net Income	<u>\$ (3,546,416)</u>	<u>\$ (150,296)</u>		

* Please note that our financial statements will be adjusted over the next few months to more accurately reflect our changing business. We are discussing the reclassification of certain scrap expenses - historically reported under research and development - with our auditors.

Protein Sciences Corporation
Statements of Cash Flow
(Unaudited)

	Six Months Ending June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ (3,546,416)	\$ (150,297)
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	251,821	287,492
Loss on disposal of assets		1,494
Share-based compensation	238,513	157,538
Realized gain on sale of investments	(466,371)	-
Tax impact on unrealized loss on S/T investment	349,047	29,612
Deferred taxes	117,324	(193,991)
Changes in operating assets and liabilities:		
Inventory	(6,823,063)	(4,686,323)
Accounts receivable	(693,023)	1,878,818
BARDA funds receivable	571,747	7,252,874
Other assets	60,208	308,637
Accounts payable and accrued expenses	(3,042,861)	(4,654,027)
Other liabilities	(73,645)	(73,645)
Deferred accounts	4,852,510	(717,188)
Net cash (used in) provided by operating activities	<u>(8,204,210)</u>	<u>(559,006)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Sale of investments	2,579,486	-
Purchases of property and equipment	(94,019)	(80,007)
Net cash (used in) investing activities	<u>2,485,467</u>	<u>(80,007)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Line of Credit	3,455,196	
Notes Payable to Officer	1,150,000	
Proceeds from exercise of stock options	-	14,375
Net cash (used in) provided by financing activities	<u>4,605,196</u>	<u>14,375</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	(1,113,547)	(624,638)
CASH AND CASH EQUIVALENTS - Beginning of period	<u>1,120,548</u>	<u>5,818,164</u>
CASH AND CASH EQUIVALENTS - End of period	<u>\$ 7,001</u>	<u>\$ 5,193,526</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for taxes	\$ 35,000	\$ 51,115
Cash paid for interest	\$ 14,151	\$ -

Protein Sciences Corporation
Statements of Comprehensive Income
(Unaudited)

	Six Months Ending June 30,	
	2016	2015
Net Income	\$ <u>(3,546,416)</u>	<u>(150,296)</u>
Other comprehensive income:		
Net change in unrealized gain (loss) in investments	\$ <u>(51,240)</u>	<u>(154,239)</u>
Total Comprehensive Income	\$ <u><u>(3,597,656)</u></u>	<u><u>\$ (304,536)</u></u>

Protein Sciences Corporation
Statement of Stockholders' Equity
For the Six Months Ended June 30, 2016

	Common Stock		Additional	Accumulated	Accumulated	
	Shares	Amount	Paid-In	Deficit	Comprehensive	Total
			Capital		Income	
BALANCE - December 31, 2014	77,549,402	77,549	63,519,642	(38,061,095)	641,955	26,178,051
Issuance of common stock	800,000	800	3,999,200			4,000,000
Exercise of stock options	65,850	66	20,584			20,650
Share-based compensation			364,347			364,347
Unrealized gain on investments, net of tax					(976,389)	(976,389)
Net income				(8,055,919)		(8,055,919)
BALANCE - December 31, 2015	78,415,252	78,415	67,903,773	(46,117,015)	(334,434)	21,530,741
Exercise of stock options						-
Share-based compensation			238,514			238,514
Change in OCI due to investment sales					266,773	266,773
Unrealized gain on investments, net of tax					(51,240)	(51,240)
Net income				(3,546,415)		(3,546,415)
BALANCE - June 30, 2016	78,415,252	78,415	68,142,286	(49,663,430)	(118,901)	18,438,372