



Pressmeddelande den 18 februari 2014

## Information kring Mertivas innehav Protein Sciences

*Mertiva har kontaktat Protein Sciences styrelse och ledning och ställt ett antal frågor om verksamheten. Svaren på dessa frågor redovisas i detta pressmeddelande. Protein Sciences årsredovisning för 2012 finns bifogad till detta pressmeddelande samt tillgänglig i pressmeddelande på Mertivas hemsida.*

Mertiva har fått en del frågor kring aktieinnehavet i det amerikanska bolaget Protein Sciences.

Protein Sciences har hittills framförallt varit ett forskningsbolag och de intäkter bolaget har haft har varit statliga bidrag (BARDA) samt ersättning från samarbetsavtal, vilka är av engångskaraktär, varför dessa intäkter inte säger mycket om framtiden. De siffror som finns tillgängliga är från 2012. Nu har bolaget gått in i en ny fas, då vaccinet Flublok nyligen lanserats på den amerikanska marknaden, och det är därför av intresse att veta vad bolaget tror om framtiden och om den förväntade försäljningen.

Mertiva är bara aktieägare och har ingen insyn i Protein Sciences verksamhet. Mertiva har dock kontaktat Protein Sciences och ställt ett antal frågor om verksamheten, baserade på de frågor som Mertiva själva fått från aktieägare. Protein Sciences styrelse och ledning har svarat på dessa frågor, samt godkänt att informationen publiceras på Mertivas hemsida tillsammans med den senaste årsredovisningen från 2012.

Frågorna till Protein Sciences styrelse och ledning gav följande information:

- Protein Sciences estimat för totala intäkter 2013 är omkring 40 miljoner USD. Av detta är 65-70% BARDA-finansiering.
- Under influensasäsongen 2013/2014 förväntar de sig att sälja cirka 35 000 doser av Flublok.
- De svårigheter som de har stött på under det första året på marknaden har varit följande:
  - ✓ Begränsat åldersspann. Bolaget har bara FDA godkännande för gruppen 18-49 år för Flublok. De förväntar sig dock få godkännande för gruppen 50+ senare under 2014.
  - ✓ De var sena till marknaden. Detta då de inte hade tillräcklig erfarenhet av FDAs årliga godkännandeprocess för influensavaccin. De kunde skicka de första vaccinen först i mitten av november. För influensasäsongen 2014/2015 förväntar de sig att skicka de första vaccinen i september.
  - ✓ Osäkerhet angående ersättning i Medicaresystemet: Flublok har en unik CPT-kod, emellertid blev denna kod funktionell först i januari 2014.
  - ✓ Kort utgångsdatum på vaccinet. Utgångsdatumet på Flublok är i dagsläget 4 månader efter produktion. De har ansökt om att få detta förlängt till 6 månader och förväntar sig få detta godkänt under 2014.
  - ✓ Tillgänglighet. Tiden var för kort för att finna effektiva distributionskanaler.





- Protein Sciences förväntar sig godkännande för gruppen 50+ i Q3/Q4 2014. Det fanns tidigare förhoppningar om att få detta redan under Q1 2014, vilket visade sig inte vara möjligt. Anledningen till förseningen är dels att det interna arbetet med att sammanställa material tog längre tid än förväntat och dels att de trodde att FDA skulle påskynda processen genom en snabbutredning. FDA har dock meddelat att de behandlar ärendet med normal handläggningstid, vilket innebär att processen tar cirka 10 månader.
- Bolagets estimat för influensasäsongen 2014/2015 är i dagsläget 250 000 doser. Detta klarar de att producera i sin produktionsanläggning i Meriden. De räknar med att så småningom få FDA-godkännande för sin andra produktionsanläggning i Pearl River. När de får det har de kapacitet att producera 2,5 - 5,0 miljoner doser.
- För influensasäsongen 2014/2015 räknar de med att behålla priset 32 USD/dos.
- Vad gäller internationell agenda för Flublok, så finns idag ett licensavtal i Japan med UMN Pharma. Protein Sciences utvärderar att söka godkännande för Flublok i EU, Canada och Australien. De har emellertid beslutat sig för att primärt bygga marknaderna i US och Japan. Att söka godkännande för marknaderna i Kina, Korea, Taiwan, Hong Kong och Singapore ligger i händerna hos UMN Pharma, licenstagaren i Japan.
- Statlig finansiering från BARDA har varit den huvudsakliga inkomstkällan under de senaste åren. Vad gäller BARDA-finansiering i framtiden, så förväntar sig bolaget att BARDA-intäkterna kommer att minska som andel av de totala intäkterna i takt med att Flublok-försäljning och milestone-betalningar från licenstagare ökar. "Option period 1" under deras BARDA-avtal har förlängts till att fortsätta t.o.m. mars 2014 och den resterande budgeten är 14 miljoner USD. De förväntar sig att BARDA godkänner "Option period 2" med början i Q2 2014 och slut i slutet av 2015 och med en ytterligare budget på runt 50 miljoner USD. Denna finansiering kommer användas för att stödja utvecklingen av produktionsanläggningen i Pearl River och kliniska försök med Flublok.

**För ytterligare information, vänligen kontakta:**

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**Om Mertiva**

Mertiva AB (tidigare Diamyd Medical) består i huvudsak av en kassa samt innehav i Protein Sciences Corporation och Mercodia AB.

Mertiva-aktien (tidigare Diamyd Medical) är listad på NGM:s handelsplats Nordic MTF (kortnamn: MERT MTF) fr.o.m. 29 juli 2013 och var tidigare noterad på Nasdaq OMX Small Cap-lista i Stockholm (ticker: MERT).

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.*

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# Protein Sciences Corporation

Financial Statements as of and for the  
Years Ended December 31, 2012 and 2011, and  
Independent Auditors' Report



**PROTEIN SCIENCES CORPORATION**

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## INDEPENDENT AUDITORS' REPORT

To the Board of Directors of  
Protein Sciences Corporation  
Meriden, Connecticut

We have audited the accompanying financial statements of Protein Sciences Corporation (the "Company"), which comprise the balance sheets as of December 31, 2012 and 2011, and the related statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes to the financial statements.

### **Management's Responsibility for the Financial Statements**

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

### **Auditors' Responsibility**

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Company's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.



**Opinion**

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Protein Sciences Corporation as of December 31, 2012 and 2011, and the results of its operations and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

A handwritten signature in black ink that reads "Deloitte & Touche LLP". The signature is written in a cursive, flowing style.

August 9, 2013



**PROTEIN SCIENCES CORPORATION**  
**BALANCE SHEETS**  
**AS OF DECEMBER 31, 2012 AND 2011**

	<b>2012</b>	<b>2011</b>
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 9,980,564	\$ 2,921,661
BARDA funds receivable — including unbilled of \$1,218,734 and \$1,562,122, respectively	2,427,477	3,471,943
Accounts receivable — including unbilled of \$339,319 and \$89,669, respectively and net of allowance for doubtful accounts of \$50,000 and \$60,000, respectively	771,766	361,729
Deferred tax asset	1,178,722	7,473,284
Other current assets	<u>1,287,485</u>	<u>1,146,530</u>
Total current assets	15,646,014	15,375,147
PROPERTY, PLANT AND EQUIPMENT — Net	5,500,813	4,736,465
Long term deferred tax asset	9,897,047	8,523,268
Restricted cash	638,478	-
Other assets	<u>27,150</u>	<u>34,954</u>
TOTAL ASSETS	<u>\$ 31,709,502</u>	<u>\$ 28,669,834</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
CURRENT LIABILITIES:		
Deferred revenue, current portion	3,962,338	4,494,454
Accounts payable	1,692,944	2,023,032
Accrued expenses	1,424,135	787,562
Current portion of capital lease obligations	<u>2,497</u>	<u>139,819</u>
Total current liabilities	<u>7,081,914</u>	<u>7,444,867</u>
LONG TERM LIABILITIES		
Deferred revenue	3,877,703	7,234,293
Other liabilities	340,845	-
Capital lease obligations - less current portion	<u>-</u>	<u>2,497</u>
	<u>4,218,548</u>	<u>7,236,790</u>
COMMITMENTS AND CONTINGENCIES (Notes 6, 7 & 8)		
STOCKHOLDERS' EQUITY:		
Common Stock, \$.001 par value, 150,000,000 shares authorized; 76,618,695 and 75,770,194 outstanding in 2012 and 2011, respectively	76,619	75,770
Additional paid-in capital	62,507,021	62,059,237
Accumulated deficit	<u>(42,174,600)</u>	<u>(48,146,830)</u>
Total stockholders' equity	<u>20,409,040</u>	<u>13,988,177</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 31,709,502</u>	<u>\$ 28,669,834</u>

See notes to financial statements.



**PROTEIN SCIENCES CORPORATION**  
**STATEMENTS OF OPERATIONS**  
**FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011**

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	<b>2012</b>	<b>2011</b>
REVENUES:		
BARDA contract	\$ 17,632,459	\$ 15,571,002
Collaborative agreements	8,373,816	4,554,142
Technology licenses	3,603,424	3,361,570
Product sales	<u>1,861,722</u>	<u>2,526,807</u>
Total revenues	<u>31,471,421</u>	<u>26,013,521</u>
OPERATING EXPENSES:		
Research and development	15,947,572	12,372,240
General and administrative	<u>4,219,078</u>	<u>4,206,525</u>
Total operating expenses	<u>20,166,650</u>	<u>16,578,765</u>
INCOME FROM OPERATIONS	11,304,771	9,434,756
OTHER (INCOME) EXPENSE:		
Interest expense	4,963	52,985
Interest income	<u>(44,313)</u>	<u>(11,529)</u>
Total other (income) expense	<u>(39,350)</u>	<u>41,456</u>
Income before tax (expense) benefit	11,344,121	9,393,300
Tax (expense) benefit	<u>(5,371,891)</u>	<u>8,065,740</u>
NET INCOME	<u>\$ 5,972,230</u>	<u>\$ 17,459,040</u>

See notes to financial statements.



**PROTEIN SCIENCES CORPORATION**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
**FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011**

	Common Stock		Additional Paid-In Capital		Accumulated Deficit	Total
	Shares	Amount				
BALANCE — January 1, 2011	72,173,194	\$ 72,173	\$ 60,083,070	\$ (65,605,870)	\$ (5,450,627)	
Exercise of stock options	125,000	125	35,625		35,750	
Share-based compensation	472,000	472	235,209		235,681	
Conversion of rent payable into common shares	3,000,000	3,000	1,705,333		1,708,333	
Net income				17,459,040	17,459,040	
BALANCE — December 31, 2011	75,770,194	75,770	62,059,237	(48,146,830)	13,988,177	
Exercise of stock options	651,000	651	196,599		197,250	
Share-based compensation	197,501	198	251,185		251,383	
Net income				5,972,230	5,972,230	
BALANCE — December 31, 2012	76,618,695	\$ 76,619	\$ 62,507,021	\$ (42,174,600)	\$ 20,409,040	

See notes to financial statements.



**PROTEIN SCIENCES CORPORATION**  
**STATEMENTS OF CASH FLOWS**  
**FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011**

	<b>2012</b>	<b>2011</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income	\$ 5,972,230	\$ 17,459,040
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,563,064	818,417
Share-based compensation	251,383	235,681
Loss on disposal of assets	-	39,816
Deferred taxes	4,920,783	(7,972,677)
Changes in operating assets and liabilities:		
Accounts receivable	(410,037)	79,606
BARDA funds receivable	1,044,466	1,168,726
Restricted cash	(638,478)	-
Other assets	(133,151)	(161,332)
Accounts payable and accrued expenses	306,488	(2,016,698)
Other liabilities	340,842	-
Federal income tax payable	-	(310,300)
Deferred revenue	<u>(3,888,706)</u>	<u>(1,608,982)</u>
Net cash provided by operating activities	<u>9,328,884</u>	<u>7,731,297</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	<u>(2,327,412)</u>	<u>(1,390,148)</u>
Net cash used in investing activities	<u>(2,327,412)</u>	<u>(1,390,148)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	197,250	35,750
Payments for cash redemptions due stockholders	-	(4,461,371)
Payments recorded on notes payable to officers	-	(180,730)
Payments of capital lease obligations	<u>(139,819)</u>	<u>(270,867)</u>
Net cash provided by (used in) financing activities	<u>57,431</u>	<u>(4,877,218)</u>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>7,058,903</b>	<b>1,463,931</b>
<b>CASH AND CASH EQUIVALENTS — Beginning of year</b>	<b><u>2,921,661</u></b>	<b><u>1,457,730</u></b>
<b>CASH AND CASH EQUIVALENTS — End of year</b>	<b><u>\$ 9,980,564</u></b>	<b><u>\$ 2,921,661</u></b>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	<u>\$ 4,963</u>	<u>\$ 420,799</u>
Cash paid, net of taxes received	<u>\$ 218,747</u>	<u>\$ 215,497</u>
<b>SUPPLEMENTAL DISCLOSURE OF NONCASH FINANCING ACTIVITIES:</b>		
Non-cash conversion of accrued rent to common shares	<u>\$ -</u>	<u>\$ 1,708,333</u>

See notes to financial statements.



## PROTEIN SCIENCES CORPORATION

### NOTES TO FINANCIAL STATEMENTS

#### AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011

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##### 1. BUSINESS

Protein Sciences Corporation (the “Company”) uses its proprietary baculovirus expression vector system (BEVS) to produce proteins in its proprietary non-mammalian cells (*expresSF+*<sup>®</sup>). The Company’s lead product is Flublok<sup>®</sup>, a recombinant protein based influenza vaccine, which received licensure from the Food and Drug Administration (FDA) on January 16, 2013. In December 2012, the Company leased an 83,000 square foot facility for the large-scale production of Flublok.

The United States Government [the Department of Health and Human Services (DHHS) Biomedical Advanced Research and Development Authority (BARDA)] has recognized that recombinant influenza vaccines are essential to combat biological threats like pandemic influenza, and therefore issued a multi-phase contract totaling approximately \$147 million in June 2009 to the Company to support the further development of its recombinant influenza vaccines. The initial option period budget was approximately \$34 million. BARDA exercised its option to continue the contract for an additional two years during the second quarter of 2011 with a budget of approximately \$47 million. The Company realized \$17.6 and \$15.6 million of the budget during 2012 and 2011, respectively. In May 2013, BARDA extended the option period to the end of 2013 with an additional budget of \$15 million. BARDA has released approximately \$96 million of the awarded \$147 million budget leaving approximately \$51 million for the final option period. The Company expects that the BARDA contract will provide adequate resources to support further development of and its manufacturing infrastructure for its influenza vaccines. Therefore the Company does not anticipate the need for additional financing to fund its working capital requirements, obtain regulatory approvals, or establish manufacturing, sales and marketing capabilities through the foreseeable future.

The Company is also developing proprietary vaccines for other viruses such as SARS. The Company further manufactures and sells research antigens and under the service contracts of its GeneXpress<sup>®</sup> program develops protein-based products for customers.

The Company has devoted substantially all of its efforts to product development. Since inception, the Company has funded its operations through development contracts, product sales, license fees, the issuance of equity securities, investor notes, bank borrowings, and equipment and building financings.

There can be no assurance that adequate patent protection for the Company’s technology will be obtained and maintained or that any products developed will be commercially viable. The Company operates in an environment of rapid changes in technology and substantial competition from pharmaceutical and biotechnology companies and is dependent upon the services of its employees and its consultants.

##### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**Basis of Presentation** — The Company’s financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP).

**Use of Estimates** — The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported



amounts of revenues and expenses during the reporting period. Actual results could differ materially from these estimates.

**Cash and Cash Equivalents** — The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. The Company maintains its excess cash in a “sweep” interest bearing account linked to its checking account.

**Restricted Cash** — The Company designates any cash that is not readily available for immediate use due to legal requirements as restricted. As part of the December 2012 lease of the New York facility, the Company is required to hold approximately \$640,000 in restricted cash supporting a letter of credit for the duration of the five year lease (see Note 6).

**Accounts Receivable and Allowance for Doubtful Accounts** — Accounts receivable is stated at its estimated net realizable value. The Company provides for an allowance for potentially uncollectible accounts receivable based on management’s assessment of the customers’ financial condition, general economic and industry conditions and past experience. Accounts receivable are charged to the allowance when deemed uncollectible. The Company records a receivable for unbilled revenues, which are representative of revenues earned as of yearend based on actual resources utilized and work performed under research grants and contracts and the BARDA contract in advance of billing dates.

**Significant Customers and Concentration of Credit Risk** — In the normal course of business the Company grants credit to customers for which it does not require collateral based on an evaluation of their financial condition. The Company reviews its trade receivable balances at least bi-monthly for collectability and/or whenever events and circumstances indicate that the carrying amount may not be collectible and provides currently for any potentially unrealizable amounts. In 2012 and 2011, two customers/contractors represented approximately 87% and 88%, respectively, of revenues from collaborative agreements and technology licenses. At December 31, 2012, four customers/contractors represented 87% of gross trade accounts receivable. At December 31, 2011, three customers/contractors represented 93% of gross trade accounts receivable.

**Property, Plant and Equipment** — Property, plant and equipment, including assets recorded under capital leases, are stated at cost. Construction in process relates to the preparation of the large scale manufacturing facility. Depreciation and amortization are computed using the straight-line method over the shorter of the estimated useful lives or term of the lease of the related assets. For depreciation, the Company employs a half-year convention, whereby in the first and last years of an asset’s useful life a half-year of depreciation is recorded.

	Useful Lives
Land	Indefinite
Buildings and improvements	11–20 years
Laboratory and pilot production equipment	7 years
Machinery and other equipment	3–7 years
Furniture and fixtures	5–7 years

Expenditures for maintenance and repairs that do not improve or extend the useful lives of the respective assets are expensed as incurred.



**Impairment of Long-Lived Assets** — Long-lived assets including property, plant and equipment are reviewed for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable by applying a recoverability test based on projections of future cash flows. There were no impairments recorded during the years ended December 31, 2012 or 2011.

**Revenue Recognition** — The Company generally recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is both fixed and determinable, and collectability is probable. In accordance with Accounting Standard Codification (ASC) 605-25, the Company evaluates revenue from arrangements with multiple deliverables to determine whether the deliverables represent one or more units of accounting. A delivered item is considered a separate unit of accounting if the following separation criteria are met: (1) the delivered item has stand-alone value to the customer and (2) if the arrangement includes a general right of return relative to the delivered item, the delivery of undelivered items is probable and substantially in the Company's control. The relevant revenue recognition accounting policy is then applied to each unit of accounting.

The Company has historically generated revenue from the following activities:

*Collaborative agreements.* Revenue is earned under cost reimbursable and fixed price contracts. Direct contract costs are expensed as incurred. Under cost reimbursable contracts, the Company is reimbursed for allowable costs and paid a fixed fee. Revenue on cost reimbursable contracts is recognized as costs are incurred plus the associated fee earned. Revenue for fixed price arrangements are recognized under the proportional performance method based upon the ratio of costs incurred to achieve contract milestones to total estimated cost. Losses on contracts, if any, are recognized in the period in which they become known. The majority of the Company's unbilled revenue at December 31, 2012 represents research funding earned based on actual resources utilized under the Company's various research and development contracts, specifically from the BARDA contract.

*BARDA contract.* In June 2009, the Company was awarded an approximately \$147 million multiple phase contract by BARDA to support further development and licensure of Flublok and Panblok<sup>®</sup>, the pandemic influenza version of Flublok. This contract will support further development and licensure of Flublok in all populations and the development and manufacturing of Panblok. The Company expects that the BARDA contract will provide adequate resources to support product development of its influenza vaccines at least through Q4 2013. Contract revenue is recorded when there is reasonable assurance that the Company has complied with the conditions of the contract and funding will be received for qualifying expenses.

*Technology licenses.* The Company recognizes upfront license payments as revenue upon delivery of the license only if the license has standalone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations are accounted for separately as performed. However, if the license is considered to either (i) not have standalone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement is accounted for as a single unit of accounting, and the upfront license payments are recognized as revenue over the estimated period of when the Company's performance obligations are performed.

When the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue related to upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. The Company recognizes revenue using the



proportionate performance method provided that it can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Under the proportionate performance method, periodic revenue related to upfront license payments is recognized as the percentage of actual effort expended in that period to total effort expected for all of the Company's performance obligations under the arrangement.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company expects to complete the related performance obligations. In the event that a change in estimate occurs, it is accounted for prospectively.

*Product sales.* Revenues from product sales are generated from supply agreements for the manufacturing of clinical trial material and sales of research proteins and are recognized upon shipment.

**Research and Development** — Research and development costs are expensed as incurred. They include costs associated with revenues from research grants and contracts and product sales. They also include direct costs for salaries, employee benefits, manufacturing, subcontractors, including clinical research organizations (CRO's) and clinical sites, facility-related expenses and depreciation.

**Patent Costs** — The Company records the costs of obtaining and maintaining patents and licensed technology as general and administrative expenses.

**Income Taxes** — The Company accounts for income taxes in accordance with ASC 740 — *Income Taxes*. This requires the Company to recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements and tax returns. Under this method, deferred tax assets and liabilities are measured based on the difference between the financial statement carrying amounts and the respective tax basis of assets and liabilities and net operating loss carryforwards available for tax reporting purposes, using the applicable tax rates for the years in which the differences are expected to be recovered or settled. The effect of changes in income tax rates is recognized in earnings in the period in which the change occurs. A valuation allowance is recorded to reduce deferred tax assets to an amount that represents management's best estimate of the amount of such deferred tax assets that more likely than not will be realized.

If the Company considers that a tax position is "more-likely-than-not" of being sustained upon audit, based solely on the technical merits of the position, it recognizes the tax benefit. The tax benefit is measured as the largest amount that is more than 50% likely to be realized upon ultimate settlement. Uncertain tax positions are classified as current only when the Company expects to pay such liabilities within the next twelve months. Interest and penalties, if any, are recorded in the provision for income taxes in the Company's statements of operations and are classified on the balance sheets with the related liability for unrecognized tax benefits. The Company has recorded a \$160,000 liability related to an uncertain tax position as of December 31, 2012. There were no uncertain tax positions as of December 31, 2011.

**Share-Based Compensation** — The Company accounts for stock options in accordance with ASC 718 — *Share Based Payments*. This requires that the cost resulting from all share-based payment transactions be recognized in the financial statements. This topic establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair value based measurement method in accounting for share-based payment transactions with employees except for equity instruments held by employee stock ownership plans. This method includes estimates and judgments pertaining to term, volatility, risk free interest rates, dividend yields and forfeiture rates.



**Recent Accounting Pronouncements** — In June 2011, the FASB issued ASU 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*, which revises the manner in which entities present comprehensive income in their financial statements. The new guidance removes the presentation options in ASC 220 and requires entities to report components of comprehensive income in either (a) a continuous statement of comprehensive income or (b) two separate but consecutive statements. The ASU does not change the items that must be reported in other comprehensive income. The amendments are effective for fiscal years ending after December 15, 2012, and annual periods thereafter. The adoption of this ASU did not have a material impact on the Company's financial statements.

In December 2011, the FASB issued ASU No. 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 ("ASU 2011-12")*. ASU 2011-12 defers the presentation of the reclassification adjustments in the income statement but does not defer the presentation of the reclassification adjustments in other comprehensive income. The adoption of this ASU did not have a material impact on the Company's financial statements.

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income ("ASU 2013-02")* to improve the reporting of reclassifications out of Accumulated Other Comprehensive Income ("AOCI"). ASU 2013-12 does not change the current requirements for reporting net income or other comprehensive income in the financial statements. Under ASU 2013-02, an entity is required to provide information about the amounts reclassified out of AOCI by component. In addition, an entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of AOCI by the respective line items of net income, but only if the amount reclassified is required under U.S. GAAP to be reclassified in its entirety in the same reporting period. For amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. The adoption of ASU 2013-02 is effective prospectively for the Company for annual and interim periods beginning January 1, 2014. The Company does not expect that the adoption of this update will have a material effect on its financial statements.



### 3. PROPERTY, PLANT AND EQUIPMENT

Property, plant, and equipment consists of the following:

	2012	2011
Land	\$ 1,425,000	\$ 1,425,000
Building and improvements	4,292,610	3,765,914
Laboratory and pilot production equipment	5,445,103	4,515,262
Machinery and other equipment	383,598	313,645
Furniture and fixtures	172,877	169,982
Construction in process	<u>773,378</u>	<u></u>
	12,492,566	10,189,803
Accumulated depreciation and amortization	<u>(6,991,753)</u>	<u>(5,453,338)</u>
	<u>\$ 5,500,813</u>	<u>\$ 4,736,465</u>

Depreciation and amortization expense for the years ended December 31, 2012 and 2011 was \$1,563,064 and \$818,417, respectively.

Capital Leases included in the property, plant, and equipment are as follows:

	2012	2011
Land	\$ -	\$ 1,425,000
Building and improvements	-	1,075,000
Laboratory and pilot production equipment	<u>132,877</u>	<u>132,877</u>
	<u>\$ 132,877</u>	<u>\$2,632,877</u>

### 4. OTHER ASSETS

Other assets consist of the following:

	2012	2011
Other current assets		
Prepaid clinical trial expenses	\$ 560,451	\$ -
Inventory	302,098	228,622
Prepaid expenses	188,009	136,755
Other	236,927	412,150
Deposits	<u>-</u>	<u>369,003</u>
Total other current assets	1,287,485	1,146,530
Other assets	<u>27,150</u>	<u>34,954</u>
Total other assets	<u>\$ 1,314,635</u>	<u>\$ 1,181,484</u>



## 5. ACCRUED EXPENSES

Accrued expenses consist of the following:

	2012	2011
Compensation	\$ 399,744	\$ 402,958
Final formulation and packaging	337,939	-
Professional services	240,964	262,721
Deferred rent	98,193	-
Other	<u>347,295</u>	<u>121,883</u>
	<u>\$ 1,424,135</u>	<u>\$ 787,562</u>

## 6. LEASE OBLIGATIONS

The Company had capital lease obligations for land, buildings including improvements and laboratory equipment. On April 5, 2012 the Company exercised its option to acquire its principal operating facility and real estate located at 1000 Research Parkway, Meriden, CT from the Meriden Economic Development Corporation (MEDCO) for \$439,425.

In prior years, MEDCO entered into a lease with the Company relating to its principal operating facility. In connection with the lease, MEDCO obtained approximately \$3,100,000 in financing from the State of Connecticut and the City of Meriden, Connecticut, and MEDCO leased the facility to the Company. The lease required the Company to make monthly payments equal to MEDCO's debt payments plus additional fees, as defined. During the years ended December 31, 2012 and 2011, the Company made payments of \$113,219 and \$277,100, respectively.

Future minimum lease payments including interest as of December 31, 2012 under capital leases are as follows:

2013	<u>\$ 2,508</u>
Total minimum lease payments	2,508
Less amount representing interest	(11)
Less current portion	<u>(2,497)</u>
Net long term portion	<u>\$ -</u>

**Leased Facilities** — In July 2008, the Company entered into a 15 year lease agreement for a building located in Connecticut with rent expense of \$500,000 annually. With the consent of the landlord the Company accrued rather than paid such rent. In 2011 the Company and the landlord agreed to modify the lease such that the Company agreed to pay all amounts owing for rent through June 30, 2011 in common stock with a value of \$500,000 per year. On June 30, 2011 the accrued lease payments were settled with 3,000,000 shares of common stock with a value of \$1,708,333. At the end of year five of the lease, the Company has the option to purchase the property at fair market value. As of the issuance of these financials, the Company has no plans to exercise the option to purchase the property.



In December 2012, the Company entered into a five year lease agreement for a building located in New York with rent expense of \$1,914,773 annually. The lease included base rent abatement for the first five months of the lease. At the end of the five year lease, the Company has the option to extend it an additional five years.

Rent expense was \$647,290 and \$500,000 for the years ended December 31, 2012 and 2011, respectively.

Future minimum lease payments as of December 31, 2012, under the operating leases are as follows:

2013	\$ 1,776,515
2014	2,414,773
2015	2,414,773
2016	2,414,773
2017	2,414,773
Thereafter	<u>3,179,935</u>
Total minimum lease payments	<u>\$ 14,615,542</u>

## 7. STOCK OPTION PLANS

In December 2010, the 2011 Stock Incentive Plan was adopted by the Board of Directors and approved by shareholders in 2012. Options granted under the 2011 Plan can be designated as either nonqualified or incentive stock options and expire not more than ten years from the date of grant. In almost all cases the vesting schedule is set at 34% one year after the date of the grant and 33% on each of the second and third yearly anniversaries of such date. Under the 2011 Plan, a total of 11,000,000 shares of Common Stock were made available for option grants. During 2012 and 2011, 471,000 and 1,335,000 options, respectively, were granted from the 2011 Stock Incentive Plan.

At December 31, 2012, options for 6,824,000 shares of Common Stock remain available for future grant under the 2011 Plan; no shares are available for future grant under any previous stock option plans.



A summary of stock option activity for the years ended December 31, 2012 and 2011 are as follows:

	Shares	Average Exercise Price
Balance Outstanding — December 31, 2010 (3,345,002 exercisable)	4,975,000	\$ 0.30
Granted	1,335,000	
Exercised	(125,000)	
Cancelled	<u>(65,000)</u>	
Balance Outstanding — December 31, 2011 (3,576,662 exercisable)	<u>6,120,000</u>	\$ 0.35
Granted	471,000	
Exercised	(651,000)	
Cancelled	(149,000)	
Expired	<u>(8,500)</u>	
Balance Outstanding — December 31, 2012 (4,187,650 exercisable)	<u>5,782,500</u>	\$ 0.37

The following table summarizes information about stock options at December 31, 2012:

Options Outstanding			Options Exercisable		
Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Number Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
5,782,500	\$ 0.37	6.63	4,187,650	\$ 0.33	5.78

All options granted by the Company in 2012 under the 2011 Plan and previous plans were granted with exercise prices that approximated the fair value of the Company's common stock as determined by the Company's Board of Directors in conjunction with an independent outside firm.

The Company utilizes the Black-Scholes option pricing model for determining the estimated fair value of awards. Key assumptions for this pricing model include the expected term of the option, stock price volatility, risk-free interest rate, dividend yield, stock price and exercise price. Many of these assumptions are judgmental and sensitive in the determination of compensation expense. Based on these Black-Scholes assumptions, the fair market value of options granted was \$.51 for 2012. In addition, the Company estimates forfeitures when recognizing compensation expense and adjusts forfeiture estimates over the vesting period based on actual or anticipated forfeitures. The Company recognizes share-based compensation expense on a straight-line basis over the requisite service period of the individual grants that is generally the vesting period.

As the Company has been privately-held since inception, there is no specific historical or implied volatility information available. Accordingly, the Company determines volatility based on an average of reported volatility of selected peer companies within the life sciences industry.



The assumptions used to value 2012 option grants are as follows:

Risk free interest rate	0.84 - 1.46%
Expected dividend yield	0.00%
Expected life	6.5 years
Expected volatility	55%

Total unamortized stock compensation cost as of December 31, 2012 and 2011, net of forfeitures was approximately \$362,000 and \$572,000, respectively.

## 8. COMMITMENTS AND CONTINGENCIES

**Flublok and Panblok Japan License** — In August 2006, the Company entered into an arrangement with UMN Pharma (UMN), a Japanese company, to grant UMN an exclusive license to make, use and sell Flublok and Panblok influenza vaccine in Japan (the “License Agreement”). In exchange for granting the license, the Company received an up-front payment of \$5,000,000 and in 2008 an additional \$150,000 to extend certain provisions under the license through 2014. As part of the License Agreement the Company was required to transfer certain technology to the Japanese company. The transfer of technology was completed in 2009 and the Company was paid a total of \$500,000 for such transfer. In addition, the Company was entitled to a royalty of 12% on sales of future products, as defined in the License Agreement.

On October 22, 2010, the License Agreement was amended to allow UMN to transfer specific rights it had been granted to two other Japanese companies. In consideration for entering into the amended agreement, the Company will receive a range from 12% to 16% of amounts received by UMN from sub-licensees upon the occurrence of certain events including the upfront payment paid to UMN from the sub-licensor Japanese company. The Company also agreed to reduce the royalty rate on sales of Flublok and Panblok from 12% to 10%. The Company was paid \$3,920,127 in October 2010 representing its 16% share of an upfront payment to UMN from their development partner and is further entitled to 24% of payments received by UMN from such development partner upon the occurrence of certain other events.

Also on October 22, 2010, the Company further amended the License Agreement to extend such Agreement to include additional territories. In return for the inclusion of these territories, the Company received an upfront payment of \$7,200,000 and became entitled to payments based on the occurrence of certain events and royalties based on sales of Flublok and Panblok.

If UMN does not obtain regulatory approval in Japan by December 2014, the Company may cancel the License Agreement with respect to Japan. Cancellation rights exist with respect to other licensed territories based on failure to receive licensure by certain dates. If UMN obtains regulatory approval in one qualifying market segment in one other territory it has two years to gain regulatory approval in the remaining qualifying market segments. If UMN does not obtain approval in the additional qualifying market segments, the Company may cancel or restrict the License Agreement. The Company accounts for certain of the payments received under this arrangement as revenue over the performance obligations’ period that is through December 2014 and other payments are recognized as received.

**Other Litigation** — The Company is not a party to any litigation where the Company believes, based on its examination of such matters, its ultimate costs with respect to such matters, if any, will not have a material adverse effect on its business, financial condition, results of operations, or cash flows.



## 9. INCOME TAXES

The provision (benefit) for income taxes consists of the following:

	2012	2011
Current		
Federal	\$ 418,710	\$ (93,063)
State and local	32,398	-
	<u>451,108</u>	<u>(93,063)</u>
Deferred		
Federal	4,251,043	(6,661,256)
State and local	669,740	(1,311,421)
	<u>4,920,783</u>	<u>(7,972,677)</u>
Total	<u>\$ 5,371,891</u>	<u>\$ (8,065,740)</u>

At December 31, 2012 and 2011 the Company has available federal net operating loss carryforwards of approximately \$16,628,000 and \$24,580,000, respectively and state net operating loss carryforwards of approximately \$3,183,000 and \$11,673,000, respectively which have begun to expire and have various expiration dates through 2028. The Tax Reform Act of 1986 contains certain provisions that may limit the Company's ability to utilize net operating loss carryforwards in any given year if certain events occur, including cumulative changes in ownership interests in excess of 50% over a three-year period. The Company performed a study pursuant to Section 382 of the Internal Revenue Code of ownership changes dating back to 1994 and determined no transactions resulted in a 50% change in ownership over a three year period. As a result, the amount of the net operating losses that may be utilized annually to offset taxable income and tax liability is not limited pursuant to Section 382.

At December 31, 2012 and 2011 the Company has available federal research and development credit carryforwards of approximately \$716,000 and \$1,450,000, respectively, which have begun to expire and have various expiration dates through 2031.

Deferred tax assets consist of the following:

	2012	2011
Deferred tax assets		
Federal	\$ 8,878,882	\$ 13,129,925
State and local	2,196,887	2,866,627
	<u>11,075,769</u>	<u>15,996,552</u>
Valuation allowance	-	-
Total	<u>\$ 11,075,769</u>	<u>\$ 15,996,552</u>



	December 31, 2012		December 31, 2011	
	Current	Long Term	Current	Long Term
Deferred tax assets:				
Deferred revenue	\$ 1,106,001	\$ 1,062,629	\$ 1,075,120	\$ 2,923,251
Net operating loss carryforwards	-	5,975,146	6,316,857	2,855,056
Tax credits	-	2,134,822	-	2,347,302
Fixed assets	-	726,553	-	349,750
Stock compensation	-	319,764	-	370,159
Other	72,721	-	81,307	-
Deferred tax liability:				
Cancellation of indebtedness income	-	(321,867)	-	(322,250)
Deferred tax assets, net	<u>\$ 1,178,722</u>	<u>\$ 9,897,047</u>	<u>\$ 7,473,284</u>	<u>\$ 8,523,268</u>

The Company performed an evaluation in 2012, and determined that based on all available evidence, positive and negative, including the Company's income over the past three years and expected future profitability, that all of its deferred tax assets were more likely than not to be realized through future earnings, as of December 31, 2012 and 2011.

The Company has approximately \$160,000 of uncertain tax positions requiring recognition under ASC 740-10. The Company does not expect this balance to significantly increase or decrease in the next 12 months. The Company is subject to U.S. Federal and Connecticut income tax. The Company has not been audited by the U.S. Internal Revenue Service or any states in connection with income taxes. The tax years from 1995 through 2008 remain open to examination by the U.S. Internal Revenue Service up to the amount of the net operating losses and through 2012 without limitation. The tax years from 2001 through 2008 remain open to examination by the state authorities up to the amount of the net operating losses and through 2012 without limitation.

The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense.

## 10. SUBSEQUENT EVENTS

Under *ASU Amendments to Certain Recognition and Disclosure Requirements* (ASU No. 2010-09), the Company is required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. We have evaluated events and transactions that occurred after December 31, 2012 through the issuance of these financial statements.

On January 16, 2013, the Company received approval from the U.S. Food and Drug Administration of Flublok, the world's first recombinant protein-based seasonal influenza vaccine. Flublok was approved for the prevention of seasonal influenza in people 18 through 49 years of age.

On May 2, 2013, the Company signed a modification to the original BARDA contract. The contract was increased \$15 million to a total of approximately \$96 million and the expiration date was extended to December 31, 2013. This modification further supports the transition from development to large scale manufacturing.



On May 7, 2013, the Company exercised a warrant to purchase 225,000 shares of UMN for approximately \$3.9 million and immediately sold 79,000 of such shares to realize net proceeds of approximately \$4.5 million.

On June 25, 2013, the Company was notified by the Connecticut Department of Revenue Services that it will be performing an audit of the 2009, 2010 and 2011 Connecticut income tax returns in August of 2013.

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