DOR BIOPHARMA INC
Form 10QSB
November 14, 2006

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-QSB

(X) QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the Quarterly Period Ended September 30, 2006

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from _____ to _____

Commission File No. 1-14778

DOR BIOPHARMA, INC.
(Exact name of small business issuer as specified in its charter)

DELAWARE	**41-1505029**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1101 Brickell Ave., Suite 701-S Miami, FL	**33131**
(Address of principal executive offices)	(Zip Code)

(786) 425-3848
(Issuer's telephone number, including area code)

Check whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes x No o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

At November 10, 2006, 68,778,401 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

Transitional Small Business Disclosure Format (check one): Yes [ ] No [X]

Table of Contents

PART I. - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

DOR BioPharma, Inc.
Consolidated Balance Sheet
September 30, 2006
(Unaudited)

Assets		
Current assets:		
Cash and cash equivalents	**$**	**589,601**
Grants receivable		**407,564**
Prepaid expenses		**96,868**
Total current assets		**1,094,033**
Office and laboratory equipment, net		**33,370**
Intangible assets, net		**1,080,353**
Total assets	$	**2,207,756**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$	**1,713,281**
Accrued compensation		**100,229**
Total current liabilities		**1,813,510**
Shareholders' equity:		
Common stock, $.001 par value. Authorized 150,000,000		
shares; 68,687,664 issued and outstanding		**68,687**
Additional paid-in capital		**91,312,807**
Accumulated deficit		**(90,987,248)**
Total shareholders' equity		**394,246**
Total liabilities and shareholders' equity	$	**2,207,756**

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Operations
For the three months ended September 30,
(Unaudited)

		2006		2005
Revenues:	**$**	**117,982**	$	733,892
Cost of revenues		**(70,147)**		(545,812)
Gross profit		**47,835**		188,080
Operating expenses:				
Research and development		**761,276**		964,398
General and administrative		**660,085**		441,489
Total operating expenses		**1,421,361**		1,405,887
Loss from operations		**(1,373,526)**		(1,217,807)
Other income (expense):				
Interest and other income		**10,104**		19,989
Interest expense		**(2,106)**		39,567
Total other income (expense)		**7,998**		59,556
Net loss	$	**(1,365,528)**	$	(1,158,251)
Basic and diluted net loss per share	$	**(0.02)**	$	(0.02)
Basic and diluted weighted average common shares outstanding		**68,533,689**		49,399,734

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Operations
For the nine months ended September 30,
(Unaudited)

		2006		2005
Revenues:	**$**	**1,644,393**	$	2,270,135
Cost of revenues		**(1,198,403)**		(1,465,664)
Gross profit		**445,990**		804,471
Operating expenses:				
Research and development		**3,821,255**		2,431,289
Purchased in-process research and development		981,819		-
General and administrative		**2,099,608**		1,207,297
Total operating expenses		**6,902,682**		3,638,586
Loss from operations		**(6,456,692)**		(2,834,115)
Other income (expense):				
Interest and other income		**39,282**		68,588
Interest expense		**(2,106)**		36,549
Total other income (expense)		**37,176**		105,137
Net loss	$	**(6,419,516)**	$	(2,728,978)
Basic and diluted net loss per share	$	**(0.10)**	$	(0.06)
Basic and diluted weighted average common shares outstanding		**62,062,667**		49,399,734

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Cash Flows
For the nine months ended September 30,
(Unaudited)

	2006	2005
Operating activities:		
Net loss	**$ (6,419,516)**	$ (2,728,978)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	**148,913**	170,915
Non-cash stock compensation	**655,552**	(284,855)
Non-cash stock purchase of in-process research and development	**981,819**	-
Impairment expense for intangibles	**816,300**	-
Change in operating assets and liabilities:		
Grants receivable	**156,766**	352,302
Prepaid expenses	**41,926**	(151,790)
Accounts payable	**77,545**	(965,518)
Accrued royalties	**(60,000)**	-
Accrued compensation	**(48,535)**	-
Total adjustments	**2,770,286**	(878,946)
Net cash used by operating activities	**(3,649,230)**	(3,607,924)
Investing activities:		
Acquisition of intangible assets	**(228,668)**	(313,592)
Purchases of equipment	**(2,552)**	(11,191)
Net cash used by investing activities	**(231,220)**	(324,783)
Financing activities:		
Net proceeds from sale of common stock	**3,535,029**	3,549,593
Proceeds from exercise of stock options	**113,320**	-
Repayment of amounts due under line of credit or note payable	**-**	(115,948)
Net cash provided by financing activities	**3,648,349**	3,433,645
Net increase (decrease) in cash and cash equivalents	**(232,101)**	(499,062)
Cash and cash equivalents at beginning of period	**821,702**	2,332,190
Cash and cash equivalents at end of period	**$ 589,601**	$ 1,833,128
Non-cash transactions:		
Non-cash stock payment to an institutional investor	**$ 220,374**	-
Cash paid for interest	**-**	$ 41,865

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

DOR BioPharma, Inc. ("DOR" or "Company") is a research and development biopharmaceutical company incorporated in 1987, focused on the development of biotherapeutic products and biodefense vaccines intended for areas of unmet medical need. DOR's biotherapeutic business segment focuses on the development and regulatory approval of orBec®, which is intended to treat gastrointestinal Graft-versus-Host disease. In addition, the Company has several other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs. DOR's biodefense business segment consists of the development of RiVax™, DOR's vaccine against ricin toxin and BT-VACC™, DOR's vaccine against botulinum toxin. DOR's biodefense segment focuses on converting biodefense vaccine programs from early stage development to advanced development and manufacturing.

During the quarter ended September 30, 2006, the Company had one customer, the U.S. Federal Government. All revenues were generated from two U.S. Federal Government Grants. As of September 30, 2006 all outstanding receivables were from the U.S. Federal Government, National Institutes of Health and the Food and Drug Administration ("Government").

2. Summary of Significant Accounting Policies

Basis of Presentation

These unaudited interim consolidated financial statements of DOR BioPharma, Inc. ("we" or "us") were prepared under the rules and regulations for reporting on Form 10-QSB. Accordingly, we omitted some information and note disclosures normally accompanying the annual financial statements. You should read these interim financial statements and notes in conjunction with our audited consolidated financial statements and their notes included in our annual report on Form 10-KSB for the year ended December 31, 2005. In the Company's opinion, the consolidated financial statements include all adjustments necessary for a fair statement of the results of operations, financial position and cash flows for the interim periods. All adjustments were of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results for the full fiscal year.

Grants Receivable

Receivables consist of unbilled amounts due from grants from the Government that were billed in the month subsequent to period end. The Company considers accounts receivable to be fully collectible; accordingly, no allowance for doubtful accounts has been established. If accounts become uncollectible, the balances will be charged to operations at the time the determination is made.

Intangible Assets

Intangible assets consist of patent costs, principally legal fees, and, upon application for the patent, are capitalized and amortized on a straight-line basis over the shorter of the estimated useful life of the patent or the regulatory life. The Company capitalizes legal costs incurred for work designed to protect, preserve, maintain and extend the lives of the patents.

Impairment of Long-Lived Assets

Office and laboratory equipment and intangible assets are evaluated and reviewed for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets or the business to which such assets relate. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

The Company recorded an impairment expense of $816,300 for the SRI MicroVAX Technology for the quarter ended June 30, 2006. The Company deemed that this intangible did not fit the current portfolio of products under development.

Stock Based Compensation

The Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R, “Share-Based Payment,” effective January 1, 2006, which requires companies to record compensation expense for stock options issued to employees or non-employee directors at an amount determined by the fair value of options. SFAS No. 123R is effective for annual periods beginning after December 15, 2005.

The Company has adopted SFAS No. 123R using the “modified prospective application” and therefore financial statements from periods ending prior to January 1, 2006 have not been restated. As a result of adopting SFAS No. 123R, the Company’s net loss for the three months and nine months ended September 30, 2006 was $207,218 and $482,394, respectively, higher than if it had continued to account for share-based compensation under APB No. 25. Basic and diluted earnings per share for the three and nine months ended September 30, 2006 would not have changed if the Company had not adopted SFAS No. 123R.

The fair value of each option grant at the quarter ended September 30, 2006 is estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option’s vesting periods. 2,500,000 stock options were granted for the three months ended September 30, 2006 and 4,360,000 stock options were granted for the nine months ended September 30, 2006.

Pro forma information, assuming the Company had accounted for its employee and director stock options granted under the fair value method prescribed by SFAS No. 123R for the nine months ended September 30, 2005 is presented below:

Net Loss applicable to common shareholders	
As reported	$(2,728,978)
Add stock-based employee compensation expense related to stock options determined under fair value method	(340,237)
Pro forma net loss according to SFAS 123	$ (3,069,215)
Net loss per share:	
As reported, basic and diluted	$ (0.06)
Pro forma, basic and diluted	$ (0.06)

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.39 and $0.29 for 2006 and 2005, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 116% and 120% in 2006 and 2005, respectively and average risk-free interest rates in 2006 and 2005 of 3.99% and 3.96%, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and Emerging Issues Task Force ("EITF") 96-18, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest.

Net Loss Per Share

In accordance with accounting principles generally accepted in the United States, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during respective periods (excluding shares that are not yet issued). The effect of stock options and warrants is antidilutive for all periods prescribed. There were options to purchase approximately 12.8 million and 10.2 million shares of the Company's common stock outstanding at September 30, 2006, and 2005, respectively.

3. Liquidity and Management's Plan

The Company has incurred continuing losses since its inception in 1987. At September 30, 2006, the Company had negative working capital of $ 719,477, a net loss of $ 6,419,516 and was delinquent in payment of some of its obligations. The Company expects to sustain additional losses over the next 12 months. The Company's ability to raise additional funding may be compromised should the Food and Drug Administration deny approval of orBec® for sale in the United States.

Management's plan to generate positive cash flows either from operations or financing includes the following:

- The Company is currently seeking sources of additional funding, which could involve debt or equity financing.
- The Company plans to continue seeking grant funds from governmental sources. In September 2006, the Company received two grants totaling approximately $5,300,000 to support the development of its BioDefense vaccine programs.
- The Company is exploring outlicensing opportunities for orBec® both in the US and Europe and for its BioDefense programs.
- In January 2006, the Company entered into a $6,000,000, 15 month equity financing agreement with Fusion Capital to fund operations into the second quarter of 2007. This agreement provides for the sale of $20,000 of common stock per working day (the amount can be increased if the stock price is greater than $0.40). The stock price must be greater than $0.12 in order to use the financing agreement. Pursuant to the terms of our April 2006 private placement, we may not sell any additional shares to Fusion Capital without the prior consent of our lead investor until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the NDA for orBec® or (ii) the date the FDA responds to the NDA for orBec®. The Company filed its NDA for orBec® on September 21, 2006 with the FDA. The Company expects an initial response as to its acceptance of the filing and whether it will be granted priority review from the FDA by mid to late November 2006.
- The Company believes that if there were no other sources of financing and it is not able to utilize the funding from the investment banking organization, reductions or discontinued operations of several of the Company's programs may be required. If this should occur, the Company believes it could continue to operate over the next eight quarters at a reduced level and only continue with the existing NIH grant projects.

There is no assurance that the Company will be able to successfully implement its plan or will be able to generate cash flows from either operations, partnerships, or from equity financings.

4. Intangible Assets

The following is a summary of intangible assets which consists of licenses and patents:

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
September 30, 2006	10.1	$ 1,762,338	$ 681,985	$ 1,080,353
December 31, 2005	10.2	$ 2,605,472	$ 802,452	$ 1,803,020

Amortization expense was $45,000 and $45,785 for the quarters ended September 30, 2006 and September 30, 2005, respectively. Amortization expense was $135,000 and $151,927 for the nine months ended September 30, 2006 and September 30, 2005, respectively.

Based on the balance of the intangibles at September 30, 2006, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Amount
2006	$ 145,000
2007	115,000
2008	115,000
2009	115,000
2010	115,000

License fees and royalty payments are expensed annually.

5. Grants Receivable

In the first quarter of 2006, the Company recorded grant revenues for the RiVax™ Grant in the amount of $759,850 of which $175,350 was to reimburse overhead. At March 31, 2006, the Company had completed the work necessary to reach the milestone but had not processed the filings required for payment. As of the date of this report the filing has been completed and the funds have been collected.

6. Shareholders' Equity

During the nine month period ended September 30, 2006, the Company issued 367,460 shares of common stock as payment to vendors for consulting services. An expense of $97,180 was recorded which approximated the shares' fair market value on the date of issuance. Additionally, the Company issued 193,413 shares of common stock as part of severance payments to terminated employees. An expense of $75,979 was recorded, which approximated the shares' fair market value on the date of issuance. These shares of common stock issued were covered by the Company's Form S-8 Registration Statement filed with the SEC on December 30, 2005. Also, 504,100 stock options were exercised to purchase shares of common stock which provided proceeds of $113,320.

On May 10, 2006, the Company completed a merger pursuant to which Enteron Pharmaceutical, Inc. ("Enteron"), the common stock of which the Company held 89.13% prior to the merger, was merged into a wholly-owned subsidiary of the Company. Pursuant to this transaction, the Company issued 3,068,183 shares of common stock to the Enteron minority shareholders in exchange for all of the outstanding common stock of Enteron that the Company did not already own. This transaction required the Company to record an expense of $981,819 which was classified as in-process research and development and approximated the shares' fair market value on the date of the merger.

On April 10, 2006, the Company completed the sale of 13,099,964 shares of common stock to institutional and other accredited investors for a purchase price of $3,630,000. The investors also received warrants to purchase 13,099,964 shares of common stock at an exercise price of $0.45 per share. The warrants are exercisable for a period of three years commencing on April 10, 2006. The Company filed a registration statement with the Securities and Exchange Commission and it was declared effective on May 25, 2006.

On January 17, 2006, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). Fusion Capital agreed to purchase on each trading day $20,000 of common stock up to an aggregate of $6,000,000 million over approximately a 15-month period, subject to earlier termination at the Company's discretion. During the three month period ended March 31, 2006, the Company sold 329,540 shares of common stock to Fusion Capital for $125,000 and issued 512,500 shares of common stock as a commitment fee. Pursuant to the terms of the April 2006, private placement, the Company may not access the funds available under the Fusion Capital commitment by selling shares of common stock to Fusion Capital without the prior consent of the lead investor of the prior round of financing until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the NDA for orBec® or (ii) the date the FDA responds to the NDA for orBec®. If and when the Company resumes selling stock to Fusion Capital, it may elect to sell less common stock to Fusion Capital than the daily amount and may increase the daily amount as the market price of the stock increases. The Company may sell shares of common stock to Fusion Capital based upon the future market price of the common stock without any fixed discount. Fusion Capital does not have the right or the obligation to purchase shares of DOR common stock in the event that the price of the common stock is less than $0.12. The Company only has the right to receive $20,000 per trading day under the agreement with Fusion Capital unless the stock price equals or exceeds $0.40, in which case the daily amount may be increased under certain conditions as the price of the common stock increases.

7. Contingencies

On October 26, 2006, the Company received a summons in a civil case from Michael T. Sember, the Company's former Chief Executive Officer. The complaint claims that the Company breached the employment agreement entered into with Mr. Sember on December 7, 2004, specifically in the payment of his bonus. The Company is currently paying his severance and accrued vacation according to the terms of his employment agreement. Under the terms of this agreement, the Company will pay Mr. Sember $150,000 in severance and $28,383 in vacation over the next six months, which began in August 2006. The Company denies the merit of the claim as it is contrary to what is specifically stated in the agreement. On August 25, 2006, Mr. Sember was dismissed without Just Cause (as such term is defined in the agreement). The Company's position is that, upon termination of Mr. Sember without Just Cause, he was to be paid six months severance, any unpaid bonuses, and any vacation accrued but not taken. The complaint contends that a minimum annual bonus of $100,000 was due. In addition, Mr. Sember is also seeking costs and attorney's fees incurred for this action. The Company denies that it owes Mr. Sember any bonus and will vigorously defend against Mr. Sember's claim that he is entitled to a bonus of $100,000. The Company has not recorded this contingency. Please refer to the employment agreement filed as an exhibit to the 8K filed with the SEC on December 14, 2004.

As of the date of this report, no claim or complaint has been filed by Gastrotech Pharma A/S ("Gastrotech") as to the obligation to pay a break-up fee of $1,000,000. The Company's position is that it does not owe Gastrotech any break-up fee pursuant to not renewing its letter of Intent to acquire Gastrotech.

8. Business Segments

The Company had two active segments for the nine months ended September 30, 2006 and 2005:

	For the three months ended September 30,	
	2006	2005
Revenues		
BioDefense	**$ 71,881**	$ 733,892
BioTherapeutics	**46,101**	-
Total	**$ 117,982**	$ 733,892
Income (Loss) from Operations		
BioDefense	**$ (99,395)**	$ (390,617)
BioTherapeutics	**(624,952)**	(399,842)
Corporate	**(649,179)**	(427,348)
Total	**$ (1,373,526)**	$ (1,217,807)
Amortization and Depreciation Expense		
BioDefense	**$ 38,001**	$ 39,119
BioTherapeutics	**9,001**	9,819
Corporate	**2,002**	3,152
Total	**$ 49,004**	$ 52,090
Identifiable Assets		
BioDefense	**$ 1,140,106**	$ 2,008,034
BioTherapeutics	**377,812**	471,770
Corporate	**689,838**	2,042,203
Total	**$ 2,207,756**	$ 4,552,007

	For the nine months ended September 30,	
	2006	2005
Revenues		
BioDefense	**$ 1,506,092**	$ 2,207,135
BioTherapeutics	**138,301**	-
Total	**$ 1,644,393**	$ 2,207,135
Income (Loss) from Operations		
BioDefense	**$ (1,907,899)**	$ (548,941)
BioTherapeutics	**(3,468,298)**	(991,535)
Corporate	**(1,080,495)**	(1,293,639)
Total	**$ (6,456,692)**	$ (2,834,115)
Amortization and Depreciation Expense		
BioDefense	**$ 112,477**	$ 67,316
BioTherapeutics	**29,478**	94,105
Corporate	**6,955**	9,494
Total	**$ 148,910**	$ 170,915

ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-QSB, and the our audited consolidated financial statements and their notes and other information included in our Annual Report on Form 10-KSB for the year ended December 31, 2005. This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe-harbor created by that Section. Forward-looking statements within this Form 10-QSB are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expression, however, these words are not the exclusive means of identifying such statements. In addition, any statements that refer to expectations projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, including those identified in Exhibit 99.1 "Risk Factors" filed with this Form 10-QSB, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or, circumstances or developments occurring subsequent to the filing of this Form 10-QSB with the SEC or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures the Company makes in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Overview:

Business Overview and Strategy

We are a research and development biopharmaceutical company focused on the development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. We have submitted a New Drug Application, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of gastrointestinal Graft-versus-Host Disease, ("GI GVHD") and have submitted a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicines Evaluation Agency ("EMEA"). Our business strategy is to; (a) prepare for the potential marketing approval of orBec® by the FDA and the EMEA; (b) consider prophylactic use studies of orBec® for the prevention of GI GVHD; (c) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identify a sales and marketing partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (e) secure government funding for each of our biodefense programs through grants, contracts, and procurements; (f) convert our biodefense vaccine programs from early stage development to advanced development and manufacturing; (g) reinitiate development of our other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs as resources permit; and (h) acquire or in-license new clinical-stage compounds for development. We were incorporated in 1987. We maintain two active segments: BioTherapeutics and BioDefense.

We hired Christopher J. Schaber, Ph.D. as Chief Executive Officer on August 29, 2006. Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc. where he was responsible for their operations including all drug development and commercial launch activities. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his B.A. from Western Maryland College, a M.S. in Pharmaceutics from Temple

University School of Pharmacy and a Ph.D. in Phamaceutical Sciences from The Union Graduate School.

orBec®

We filed an NDA on September 21, 2006 for orBec® (oral beclomethasone dipropionate) with the FDA for the treatment of GI GVHD. We also filed the Marketing Authorization Application ("MAA") with the European Medicines Evaluation Agency ("EMEA") on November 3, 2006. We assembled an experienced team of consultants and contractors who worked on all aspects of the NDA preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is completed and these batches are currently undergoing stability testing.

Both filings are supported by data from two randomized, double-blinded, placebo controlled clinical trials. The first was a 129 patient pivotal Phase III clinical trial for orBec® conducted at 16 bone marrow/stem cell transplant centers in the U.S. and France. The second trial was a 60 patient Phase II clinical trial conducted at the Fred Hutchinson Cancer Institute. While orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely time to treatment failure through Day 50 (p-value 0.1177), orBec® did achieve statistical significance in other key outcomes such as median time to treatment failure through Day 80 (p-value 0.0226), and most importantly, it demonstrated a statistically significant survival advantage in comparison to placebo. In the pivotal Phase III trial, analysis of patient survival at the pre-specified endpoint of 200 days post-transplant showed a clinically meaningful and statistically significant 66% reduction (p-value 0.0139) in mortality among patients randomized to orBec®. The mortality benefit in favor of orBec® was corroborated earlier this year in a retrospective analysis of the Phase II study in which there was a 55% reduction in mortality at 200 days post transplant. At one year after randomization, there were relatively consistent 51% and 45% reductions in the risk of mortality among patients randomized to orBec® in both the Phase III and Phase II studies, respectively. In the pivotal Phase III trial, a subgroup analysis also revealed that patients dosed with orBec® who had received stem cells from unrelated donors had a 94% reduction in the risk of day-200 mortality.

We anticipate the market potential for orBec® for the treatment of gastrointestinal GVHD to be approximately 70 percent of the more than 10,000 bone marrow and stem cell transplants that occur each year in the U.S.

We have had and are having strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. We may seek a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec®. We also intend to seek a partner for the other potential indications of orBec®. We are also actively considering an alternative strategy of a commercial launch of orBec® by ourselves in the U.S.

RiVax™

The development of RiVax™, our ricin toxin vaccine, has progressed significantly this year. Our academic partner, The University of Texas Southwestern led by Dr. Ellen Vitetta, recently completed a Phase I safety and immunogenicity trial of RiVax™ in human volunteers. The results of the Phase I safety and immunogenicity dose-escalation study indicate that the vaccine is well tolerated and induces antibodies in humans that neutralize ricin toxin. Despite the absence of an adjuvant, antibodies were present in the blood of several volunteers for as long as 127 days after their last vaccination. The functional activity of the antibodies was confirmed by transferring serum globulins from the vaccinated individuals along with active ricin toxin to sensitive mice, which then survived subsequent exposure to ricin toxin. The outcome of the study was recently published in the Proceedings of the National Academy of Sciences. In January of 2005, we entered into a manufacturing and supply agreement for RiVax™ with Cambrex Corporation. We recently announced that Cambrex has successfully achieved the third milestone of our collaboration of fermentation and downstream process development under our development and manufacturing agreement.

On September 29, 2006, we announced that we had been awarded a grant of approximately $4,800,000 from the National Institute of Allergy and Infectious Diseases ("NIAID") over a three year period for the continued development of RiVax™. This is in addition to the $6,433,316 already awarded by the NIAID. This new grant will

fund the development of animal models which will be used to correlate human immune response to the vaccine with protective efficacy in animals. This is necessary for ultimate licensure by the FDA, when human efficacy vaccine trials are not possible. This new grant also supports the further biophysical characterization of the vaccine containing a well-characterized adjuvant that is needed to enhance the immune response to recombinant proteins. These studies will be required to assure that the vaccine is stable and potent over a period of years. A prototype version of RiVax™ has been evaluated in a Phase I clinical trial last year and was shown to be safe and effective, while also inducing ricin neutralizing antibodies as confirmed in subsequent animal studies.

BT-VACC™

Our mucosal botulinum toxin vaccine program has made important strides this year. We are developing a multivalent vaccine against botulinum neurotoxins serotypes A, B and E, which account for almost all human cases of disease. We have identified lead antigens against Serotypes A, B and E consisting of the Hc50 fragment of the botulinum toxin. Our preclinical data to date suggests that a bivalent formulation of serotypes A and B are completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in mice and rats. The animals were given a small quantity of the bivalent combination vaccine containing each of the type A and type B antigens (10 micrograms) three times a day at two week intervals. All of the animals developed equivalent immune responses to A and B types in the serum. Importantly, they were then protected against exposure to each of the native toxin molecules given at 1000 fold the dose that causes lethality. The immune responses were also comparable to the same vaccines when given by intramuscular injection. Typically, vaccines given by mucosal routes are not immunogenic because they do not attach to immune inductive sites. In the case of the combination BT-VACC™, both the A and the B antigens were capable of attaching to cells in the mucosal epithelium and inducing an immune response with similar magnitude to the injected vaccine.

Ongoing studies are focused on serotype E and multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals. Further, we are engaged in formulation work to create a microencapsulated, enterically formulated oral dosage form, which we anticipate will be a more active and stable oral formulation improving immunogenicity and potency. To date much of the preclinical work is being conducted at Thomas Jefferson University under a sponsored research agreement funded by us. We have applied for and intend to continue to apply for research grants and contracts from the U.S. government to continue development of this vaccine. We have also recently entered into a joint development agreement with Dowpharma, a business unit of the Dow Chemical Company. Dowpharma is providing process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC™ using its Pfēnex Expression Technology™, a high yield expression system based on *Pseudomonas fluorescens.* Up to this point we have demonstrated successful high expression of soluble material from all three Hc50 vaccine candidates.

On September 29, 2006, we announced that we had been awarded a Small Business Innovation Research ("SBIR") grant of approximately $500,000 from the National Institute of Allergy and Infectious Diseases ("NIAID") over a one year period for further work to combine antigens from different serotypes of botulinum toxin for a prototype multivalent vaccine. The grant funding will support further work in characterizing antigen formulations that induce protective immunity to the three most common botulinum toxin types that may be encountered naturally or in the form of a bioweapon. This work will continue the research conducted by Dr. Lance Simpson and colleagues at Thomas Jefferson University, who originally showed that recombinant non-toxic segments of the botulinum toxin can be given by the oral as well as the intranasal route to induce a strong protective immune response in animals. This observation forms the basis for development of an oral or intranasal vaccine for botulinum toxin that can be used in humans. Currently, the recombinant vaccines under development are given by intramuscular injections. The alternate route provides a self administration option, which will bypass the requirement for needles and personnel to administer the vaccine.

Oraprine™

Oraprine™ is an oral suspension of azathioprine, which we believe may be bioequivalent to the oral azathioprine tablet currently marketed in the United States as Imuran®. We acquired the azathioprine drug (Oraprine™) as a result of the merger of Endorex and CTD in November 2001. Also acquired were patent applications licensed from Dr. Joel Epstein of the University of Washington. We conducted a Phase I bioequivalence trial following a trial conducted by Dr. Epstein that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from graft versus host disease. Azathioprine is one of the most widely used immunosuppressive medications in clinical medicine. Azathioprine is commonly prescribed to organ transplant patients to decrease their natural defense mechanisms to foreign bodies (such as the transplanted organ). The decrease in the patient's immune system increases

the chances of preventing rejection of the transplanted organ in the patient. Oraprine™ may provide a convenient dosage form for patients who have difficulty swallowing pills or tablets, such as children.

LPM™ - Leuprolide

LPM™ - Leuprolide is an oral dosage formulation of the peptide drug leuprolide, a hormone-based drug that is among the leading drugs used to treat endometriosis and prostate cancer, which utilizes a novel drug delivery system composed of safe and well characterized ingredients to enhance intestinal absorption. The LPM™ system incorporates biocompatible lipids and polymers and is potentially useful for a wide variety of molecular structures of water-soluble drugs, particularly those based on peptides. Although both small molecules and large molecules can be incorporated into our system, there is a molecular size cutoff for a commercially viable oral bioavailability enhancement, and this system is most effective with hydrophilic drugs/peptides below 5,000 Daltons in molecular weight. Utilizing a simple and scaleable manufacturing process, aqueous solutions of peptides can be incorporated into lipid-polymer mixtures forming stable micelles.

LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs

We were developing two lipid-based systems, LPE™ and PLP™, to support the oral delivery of small molecules of water insoluble drugs. Such drugs include most kinds of cancer chemotherapeutics currently delivered intravenously. The LPE™ system is in the form of an emulsion or an emulsion pre-concentrate incorporating lipids, polymers and co-solvents. We have filed for patent applications on the use of perillyl alcohol as a solvent, surfactant and absorption enhancer for lipophilic compounds. The polymers used in these formulations can either be commercially available or proprietary polymerized lipids and lipid analogs.

Material Letter of Intent - Acquisition of Gastrotech Pharma

On October 28, 2005, we entered into a binding letter of intent to acquire Gastrotech Pharma A/S ("Gastrotech"), a private Danish biotechnology company developing therapeutics based on gastrointestinal peptide hormones to treat gastrointestinal and cancer diseases and conditions. The October 28, 2005 letter of intent with Gastrotech, as amended on December 29, 2005, expired in accordance with its terms on January 15, 2005 without being extended or renewed by us. Additionally, on January 26, 2006 we notified Gastrotech Pharma that we would not be renewing the letter of intent. The breakup fee of $1,000,000 is only payable if a party breaches the terms of the letter of intent or terminates the letter of intent. In accordance with SFAS No. 5, we disclosed a potential liability in that Gastrotech advised us that if we were not willing to comply with the terms of the Letter of Intent, we would be in material breach of our obligations and would be obligated to pay Gastrotech the break up fee of $1,000,000. However, pursuant to SFAS No. 5, paragraph 33b, we have not recorded a loss provision because we do not believe there will be any monetary damages since there is no pending litigation, we cannot reasonably determine the amount of loss, and we do not believe we have any liability to Gastrotech for allowing the letter of intent to expire. In addition, we have not recorded an accrual for the potential loss, because we do not believe as described in item 8(a) and 8(b) of SFAS No. 5 that any loss has not been confirmed, nor has any outcome or judgment occurred. Moreover, we do not feel that it is probable that a liability has been incurred. Perhaps more importantly, Gastrotech has not brought any legal action against us. No potential loss is estimatable at this time.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. We evaluate these estimates and judgments on an on-going basis.

Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent costs. We make this judgment based on whether the technology has alternative future uses, as defined in SFAS 2, "Accounting for Research and Development Costs". We capitalize and amortize our intangibles over a period of 11 to 16 years. We capitalize payments made to legal firms that are engaged in filing and protecting our rights to our intellectual property and rights for our current products in both the domestic and international markets.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets.

Research and Development Costs

Research and Development costs are charged to expense when incurred and includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries and employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense (IPR&D) represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition. Similar to many cost-reimbursable grants, these governmental grants are typically subject to audit and adjustment by the government.

Revenue Recognition

We recognize revenue from Government grants. These revenues are recorded in the period in which they are earned. The consideration we receive is based upon a cost plus Facilities and Administrative (F&A) rate that provides funding for overhead expenses. . All of our revenues are from government grants which are based upon subcontractor costs and internal costs covered by the grant, plus F&A rate that provides funding for overhead expenses. We record revenue only when we are billed for subcontractor expenses or when we incur internal expenses that are covered by the grant. We bill the government for these costs, typically once a month.

Material Changes in Results of Operations

We are a research and development company. The 2006 revenues and associated expenses were from an NIH Grant which we received in September 2004 and for an FDA grant which we received in September 2005. The NIH grant was associated with our ricin vaccine. The original amount of the NIH grant was $5,173,298. This was increased on May 6, 2005, to $6,433,316. The increase of $1,260,018 was awarded based on a new renegotiated F&A rate with the NIH. Part of this increase was attributed to the NIH reimbursement for overhead expenses for 2004 in the amount of $285,891 in the second quarter of 2005. This new rate provided a fixed rate for facilities and administrative costs (overhead expenditures) that is applied against all costs associated with the grant awarded. The FDA grant was awarded on September 23, 2005, for the "Oral BDP for the Treatment of GI GVHD." We began recognizing revenue for this grant in the fourth quarter of 2005. The total amount of the one-year grant is $318,750.

For the three months ended September 30, 2006, our revenues were $117,982 as compared to $733,982 in the three months ended September 30, 2005 a decrease of $615,910, or 84%. For the nine months ended September 30, 2006, we had revenues of $1,644,393 as compared to $2,270,135 for the same period in 2005, a decrease of $625,742, or 28%. Our progress on the grant had exceeded the original schedule, accelerating the milestone revenues that were recorded in the first quarter of 2006. However, this accelerated pace slowed in the second quarter as the next milestone approached. In addition, the 2005 revenues includes $285,891 that was attributed to the NIH reimbursement for overhead expenses for 2004 but which was received in the second quarter of 2005. We also incurred expenses related to that revenue in the three months ended September 30, 2006 and 2005 of $70,147 and $545,812, respectively, an increase of $475,665, or 87%. These costs relate to payments made to subcontractors and universities in connection with the grants.

Although we have a gross profit, it is due to the increase in the F&A rate and to the FDA grant. The gross profit for the three months ended September 30, 2006 was $47,835 as compared to $188,080 in the three months ended September 30, 2005 a decrease of $140,245, or 75%. The gross profit for the nine months ended September 30, 2006 was $445,990 as compared to $804,471 in the nine months ended September 30, 2005 a decrease of $358,481, or 45%. This decrease is in part attributed to reimbursement of $285,891 from the NIH for overhead expenses for 2004 in the second quarter of 2005.

For the three months ended September 30, 2006, we had a net loss of $1,373,528 as compared to a $1,158,251 net loss for the three months ended September 30, 2005 an increase of $207,277, or 18%. For the nine months ended September 30, 2006 we had a net loss of $6,419,516 as compared to a $2,728,978 net loss for the nine months ended September 30, 2005 an increase of $3,690,538, or 135%. This increase is primarily attributed to the increased regulatory and filing consultant costs associated with the preparation of the NDA filing for orBec®, the in-process research and development expense of $981,819 for acquiring all of the outstanding common stock of Enteron that the Company did not already own, and an impairment expense for intangibles of $816,300.

Research and development expenditures decreased $203,122, or 21%, to $761,276 for the three months ended September 30, 2006 as compared to $964,398 for the corresponding period ended September 30, 2005. Research and development expenditures increased $1,389,966, or 57%, to $3,821,255, for the nine months ended September 30, 2006 as compared to $2,431,289 for the corresponding period ended June 30, 2005. This increase is due to the increased regulatory and filing consultant costs associated with the preparation and completion of the NDA filing for orBec® and the impairment expense for intangibles of $816,300.

In-process research and development expenditures were $981,819 as compared to zero for the nine months ended September 30, 2006 an increase of 100% for the same period ended September 30, 2005. This was due to the purchase acquisition of all of the outstanding common stock of Enteron that the Company did not already own.

General and administrative expenses increased $218,596, or 50%, to $660,085 for the three months ended September 30, 2006, as compared to $441,489 for the corresponding period ended September 30, 2005. General and administrative expenses increased $892,311, or 74%, to $2,099,608 for the nine months ended September 30, 2006, as compared to $1,207,297 for the corresponding period ended September 30, 2005. This increase was primarily attributed to a recovery of $284,855 in 2005 from reported income in 2004 for the variable accounting treatment of options granted to new employees under the stock option plan that exceeded the number of allowed stock options under the plan. The increase was also due to stock option expense of $482,394 for stock options vested and issued in the nine month period ending September 30, 2006 under the new accounting treatment under SFAS No. 123R. Additionally, we had non-recurring acquisition costs of approximately $116,000 associated with the unconsummated acquisition of Gastrotech Pharma A/S.

Interest income for the three months ended September 30, 2006, was $10,104 as compared to $19,989 for the three months ended September 30, 2005, representing a decrease of $9,885, or 49%. Interest income for the nine months ended September 30, 2006, was $39,282 as compared to $68,588 for the nine months ended September 30, 2005, representing a decrease of $29,306, or 43%. This decrease was primarily due to a lower interest bearing cash balances in 2006 as compared to 2005.

Interest expense for the three months ended September 30, 2006, was $2,106 as compared to a $39,567 credit for the three months ended September 30, 2005, a decrease of $41,673, or 105%. Interest expense for the nine months ended September 30, 2006, was $2,106 as compared to a $36,549 credit for the nine months ended September 30, 2005, a decrease of $38,655, or 106%. This decrease was due to recovery of interest because of an agreement reached with a pharmaceutical company for settlement of a note payable. This agreement required a payment of $41,865 in lieu of the $83,729 of interest we had accrued.

FINANCIAL CONDITION:

As of September 30, 2006, we had cash and cash equivalents of $589,601 as compared to $821,702 as of December 31, 2005, and a negative working capital of $719,477 as compared to negative working capital of $319,675 as of December 31, 2005 representing a decrease of $399,803. For the nine months ended September 30, 2006, our cash used in operating activities was $3,649,230, compared to $3,607,924 for the nine months ended September 30, 2005.

We expect our research and development expenditures for the next twelve months, to range from approximately $800,000 to $3,500,000 under existing product development agreements and license agreements pursuant to letters of intent and option agreements. We anticipate grant revenues for the next twelve months to offset research and development expenses of our ricin vaccine in the amount of approximately $4,000,000 with $1,500,000 contributing towards our overhead expenses.

The following summarizes our contractual obligations at September 30, 2006, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligations	Year 2006	Year 2007	Year 2008
Non-cancelable obligations (1)	$ 17,100	$ 33,703	$ -
TOTALS	**$ 17,100**	**$ 33,703**	**$ -**

(1) On August 7, 2006 we signed a 10 month lease at a new location.

On April 10, 2006, we completed the sale of 13,099,964 shares of our common stock to institutional and other accredited investors for a purchase price of $3,630,000. The investors also received warrants to purchase an aggregate of 13,099,964 shares of our common stock at an exercise price of $0.45 per share. The warrants are exercisable for a period of three years commencing on April 10, 2006. We filed a registration statement with the Securities and Exchange Commission covering the shares of common stock issued and issuable pursuant to the exercise of the warrants, and it was declared effective on May 25, 2006.

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC. Fusion has agreed to purchase on each trading day $20,000 of our common stock up to an aggregate of $6,000,000 million over approximately a 15-month period, subject to earlier termination at our discretion. We have sold 329,540 shares of common stock to Fusion Capital. Pursuant to the terms of our April 2006 private placement, we may not access the funds available under the Fusion Capital commitment by selling our shares of common stock to Fusion Capital without the prior consent of the lead investor in our prior round of financing until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the NDA for orBec® or (ii) the date the FDA responds to the NDA for orBec®. The FDA application has been filed. If and when we resume selling stock to Fusion Capital, we may elect to sell less of our common stock to Fusion Capital than the daily amount and we may increase the daily amount as the market price of our stock increases. We will sell our shares of common stock to Fusion Capital based upon the future market price of the common stock without any fixed discount. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than $0.12. We only have the right to receive $20,000 per trading day under the agreement with Fusion Capital unless our stock price equals or exceeds $0.40, in which case the daily amount may be increased under certain conditions as the price of our common stock increases.

Based on our current rate of cash outflows, we believe that we will have to augment our cash position to meet our anticipated cash needs for working capital and capital expenditures to continue to operate all of our current programs. We can however reduce our operations and continue to operate our biodefense programs pursuant to the Grants

through the next eight quarters. If we obtain additional funds through the issuance of equity or equity-linked securities, shareholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. The terms of any debt financing may contain restrictive covenants which may limit our ability to pursue certain courses of action. We may not be able to obtain such financing on acceptable terms or at all. If we are unable to obtain financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities, respond to competitive pressures or continue our operations.

ITEM 3 - CONTROLS AND PROCEDURES

Our Chief Executive Officer and our Chief Financial Officer (the "Certifying Officers") are responsible for establishing and maintaining disclosure controls and procedures. Such officers have concluded (based upon their evaluations of these controls and procedures as of the end of the period covered by this report) that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in this report is accumulated and communicated to management, including the Certifying Officers as appropriate, to allow timely decisions regarding required disclosure.

The Certifying Officers have also indicated that there were no significant changes in our internal controls over financial reporting or other factors that could significantly affect such controls subsequent to the date of their evaluation, and there were no significant deficiencies and material weaknesses.

Our management, including the Certifying Officers, does not expect that our disclosure controls or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any systems of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of these inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

PART II - OTHER INFORMATION.

ITEM 4 - EXHIBITS

31.1 Certification of Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
31.2 Certification of Principal Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2 Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1 Risk Factors

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DOR BIOPHARMA, INC.

November 14, 2006 by /s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer

November 14, 2006 by /s/ Evan Myrianthopoulos
Evan Myrianthopoulos
Chief Financial Officer
