GILDAN ACTIVEWEAR INC
Form 6-K
August 19, 2003

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# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

# FORM 6-K

**Report of Foreign Issuer**

**Pursuant to Rule 13a-16 or 15d-16 of**
**the Securities Exchange Act of 1934**

For the month of: August 2003 Commission File Number: 1-14830

# GILDAN ACTIVEWEAR INC.

(Name of Registrant)

**725 Montée de Liesse**
**Ville Saint-Laurent, Quebec**
**Canada H4T-1P5**
(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F o Form 40-F ý

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the SEC pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

Yes o No ý

If "Yes" is marked, indicate the file number assigned to the registrant in connection with Rule 12g3-2(b): N/A

**SIGNATURES**

Pursuant to 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.

GILDAN ACTIVEWEAR INC.

Date: August 19, 2003

By: /s/ STÉPHANE LEMAY

Name: Stéphane Lemay
Title: *Vice-President, General Counsel and Corporate Secretary*

**EXHIBIT**

| Exhibit | Description of Exhibit | Page |
|---|---|---|
| 1 | Quarterly Report to Shareholders for the Third Quarter ended July 6, 2003 | |

**EXHIBIT 1**

**Quarterly Report to Shareholders**
**Third quarter ended July 6, 2003**

**MESSAGE TO SHAREHOLDERS**

On behalf of the Board of Directors, I am pleased to provide results for the nine months ended July 6, 2003.

The Company reported all-time record quarterly net earnings of $31.3 million, or $1.05 per diluted share, up respectively 13.0% and 11.7% from $27.7 million or $0.94 per diluted share in the third quarter of fiscal 2002.

As had been reflected in the Company's forecast and guidance for the year, the third quarter of the 2003 fiscal year comprised 14 weeks instead of the normal 13 weeks for a fiscal quarter. The inclusion of an extra week is required in every sixth fiscal year due to the Company's floating year-end date. It is included in the third quarter, which is seasonally the largest sales quarter in the year. Management estimates that the impact of including the extra week in the third quarter of fiscal 2003 was to add approximately $0.06 per diluted share to the EPS for the quarter.

Based on the Company's actual results, including the extra week, the higher net earnings compared to last year were due to increased unit sales and higher gross margins, together with reduced selling, general and administrative expenses and lower interest expense. The positive impact of these factors was largely offset by the lower selling prices and the weaker U.S. dollar, as well as higher depreciation as a result of the Company's recent major capital investment projects and a temporary increase in the effective tax rate in the third quarter. The negative impact of the lower U.S. dollar on the Canadian dollar EPS for the quarter is estimated at approximately $0.35 per share. In U.S. dollars, net earnings for the third quarter amounted to U.S. $21.8 million, or U.S. $0.73 per diluted share, up respectively 23.2% and 21.7% from the third quarter of fiscal 2002.

Sales were a quarterly record of $204.0 million, up 4.2% from $195.7 million in the third quarter of fiscal 2002. The higher sales were due to a 14.0% increase in unit shipments largely offset by the impact of the lower-valued U.S. dollar and lower selling prices. The higher unit sales reflected 11.6% growth in overall industry shipments of T-shirts in the U.S. wholesale distributor market combined with continuing market share increases achieved by Gildan, compared with the third quarter of last year. In spite of capacity constraints, which have prevented the Company from fully capitalizing on the strong demand for its products pending completion of the ramp-up of its new textile capacity expansion, Gildan maintained its market leadership position in the overall T-shirt category, with a share of 28.0%, versus 27.7% a year ago. Gildan continued to achieve significant penetration in the sport shirt segment. Although overall industry shipments in the sport shirt segment through the U.S. distributor channel declined by 13.1%, the Company's market share increased to 19.5% from 13.8% a year ago. Gildan's unit shipments in this category grew by 40.1% compared with the third quarter of fiscal 2002. Gildan's share in the fleece category increased to 12.1%, compared with 11.2% a year ago, while industry demand in this segment declined by 1.8% versus the third quarter of last year. All U.S. market and market share data is based on the S.T.A.R.S. Report produced by ACNielsen Market Decisions.

Gross margins were 30.7% in the third quarter, compared with 29.8% in the third quarter of fiscal 2002. The increase in gross margins was primarily due to the significant impact of the Company's recent capital investments, in particular its new low-cost integrated textile manufacturing facility at Rio Nance, Honduras. The resulting reductions in manufacturing and transportation costs, together with more favourable product mix and the impact of lower raw material costs, were largely offset by lower selling prices and by the impact of the weaker U.S. dollar.

Selling, general and administrative expenses for the third quarter were $18.8 million, or 9.2% of sales, compared with $19.6 million, or 10.0% of sales, in the third quarter of last year. Selling, general and administrative expenses in the third quarter of the prior year were unusually high due to the timing of accruing the provision for the results-based management incentive program.

The increase in the tax rate in the third quarter of fiscal 2003, to 12.0% compared with 10.2% in the third quarter of the prior year, was a direct consequence of the significant decline in the U.S. exchange rate during the

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quarter, which generated an unrealized foreign exchange gain from revaluation of long-term debt denominated in U.S. currency within Gildan's Canadian legal entity. Although this gain was fully offset on a pre-tax basis by an exchange loss on the conversion of U.S. working capital held by foreign subsidiaries, a higher proportion of overall income taxes was reflected at the Canadian tax rate in the quarter. The Company expects that the tax rate will revert to a rate that is in line with the recent downward trend, once the value of the U.S. dollar stabilizes.

Net earnings for the first nine months of fiscal 2003 were a record $57.5 million or $1.94 per diluted share, up respectively 22.6% and 21.3% from $46.9 million or $1.60 per diluted share in the first nine months of last year. Diluted EPS for the first nine months of the current year include a $0.04 charge in the second quarter for the closure of Gildan's Montreal sewing plant.

In U.S. dollars, net earnings for the first nine months after the special charge amounted to U.S. $38.9 million, or U.S. $1.31 per diluted share, up respectively 30.7% and 28.4% from the first nine months of fiscal 2002.

The Company continues to be comfortable with its previously announced EPS range for the full 2003 fiscal year of $2.70 $2.80 per diluted share, after reflecting the impact of the special charge for the sewing plant closure. If the value of the U.S. dollar remains at the current level, the company expects the full year EPS to be at the higher end of this range.

In the third quarter, the Company generated $41.4 million of free cash flow, defined as cash flows from operating activities less cash used in investing activities. Included in investing activities for the quarter were capital expenditures amounting to $13.6 million. The Company ended the third quarter with surplus cash reserves of $68.5 million.

We are pleased to have achieved an all-time record performance for quarterly earnings and EPS. We have been able to fully offset the significant impact of the U.S. currency decline by surpassing our targets for manufacturing efficiencies and by exceeding our unit sales growth forecast, in spite of low inventories and capacity constraints. We continue to be excited about the progress and potential of our Rio Nance integrated textile facility, which will provide additional production capacity as well as allow us to significantly further drive down our cost structure, and position us to achieve our sales and EPS growth objectives in 2004.

As of July 31, 2003 there were 23,330,234 Class A subordinate shares and 6,094,000 Class B multiple voting shares issued and outstanding along with 1,011,368 options outstanding.

In keeping with Gildan's ongoing commitment to first-class Corporate governance, Mr. Robert M. Baylis has been appointed effective immediately as Lead Director of the Company's Board of Directors. In this capacity, his responsibilities will include chairing a quarterly private executive session of the six independent Board Members. Mr. Baylis has been a member of Gildan's Board of Directors since 1999. An experienced Corporate Director, Mr. Baylis also sits on the Board of four U.S. public companies as well as various charitable institutions. Prior to becoming a professional director, Mr. Baylis served as Chairman and CEO of Credit Suisse First Boston (Asia).

On behalf of the Board of Directors, I wish to take this opportunity to thank our shareholders for their continued confidence and support.

H. Greg Chamandy
Chairman of the Board and
Chief Executive Officer

**GILDAN ACTIVEWEAR INC.**

**CONSOLIDATED BALANCE SHEETS**

**(in thousands of Canadian dollars)**

| | July 6, 2003 | September 29, 2002 | June 30, 2002 |
|---|---|---|---|
| | (unaudited) | (audited) | (unaudited) |
| Current assets: | | | |
| Cash and cash equivalents | $ 68,507 | $ 70,905 | $ 24,580 |
| Accounts receivable | 101,678 | 87,746 | 104,513 |
| Inventories | 125,876 | 112,971 | 138,082 |
| Prepaid expenses and deposits | 5,985 | 3,657 | 5,317 |
| Future income taxes | 4,155 | 5,028 | 6,095 |
| | 306,201 | 280,307 | 278,587 |
| Fixed assets | 235,740 | 209,247 | 190,626 |
| Other assets | 4,776 | 7,085 | 4,763 |
| Total assets | $ 546,717 | $ 496,639 | $ 473,976 |
| Current liabilities: | | | |
| Accounts payable and accrued liabilities | $ 82,938 | $ 82,168 | $ 79,499 |
| Income taxes payable | 5,429 | 3,063 | 4,445 |
| Current portion of long-term debt | 27,347 | 6,249 | 6,807 |
| | 115,714 | 91,480 | 90,751 |
| Long-term debt | 74,661 | 114,866 | 116,234 |
| Future income taxes | 23,889 | 20,385 | 18,129 |
| Shareholders' equity: | | | |
| Share capital (note 3) | 109,962 | 104,925 | 103,444 |
| Contributed surplus | 323 | 323 | 323 |
| Retained earnings | 222,168 | 164,660 | 145,095 |
| | 332,453 | 269,908 | 248,862 |
| Total liabilities and shareholders' equity | $ 546,717 | $ 496,639 | $ 473,976 |

See accompanying notes to interim consolidated financial statements.

**GILDAN ACTIVEWEAR INC.**

**CONSOLIDATED STATEMENTS OF EARNINGS**

**(In thousands of Canadian dollars, except per share data)**

| | Three months ended | | Nine months ended | |
|---|---|---|---|---|
| | July 6, 2003 | June 30, 2002 | July 6, 2003 | June 30, 2002 |
| | (unaudited) | (unaudited) | (unaudited) | (unaudited) |
| Sales | $ 204,047 | $ 195,725 | $ 479,375 | $ 440,739 |
| Cost of sales | 141,368 | 137,455 | 335,429 | 316,988 |
| Gross margin | 62,679 | 58,270 | 143,946 | 123,751 |
| Selling, general and administrative expenses | 18,825 | 19,572 | 55,336 | 48,421 |
| Earnings before interest, income taxes, depreciation and amortization | 43,854 | 38,698 | 88,610 | 75,330 |
| Depreciation and amortization | 5,871 | 4,604 | 17,028 | 12,696 |
| Interest expense | 2,471 | 3,234 | 7,357 | 10,378 |
| Earnings before income taxes | 35,512 | 30,860 | 64,225 | 52,256 |
| Income taxes | 4,260 | 3,137 | 6,717 | 5,330 |
| Net earnings | $ 31,252 | $ 27,723 | $ 57,508 | $ 46,926 |
| Basic EPS (note 4) | $ 1.06 | $ 0.97 | $ 1.97 | $ 1.65 |
| Diluted EPS (note 4) | $ 1.05 | $ 0.94 | $ 1.94 | $ 1.60 |

**CONSOLIDATED STATEMENTS OF RETAINED EARNINGS**

**(In thousands of Canadian dollars)**

| | Three months ended | | Nine months ended | |
|---|---|---|---|---|
| | July 6, 2003 | June 30, 2002 | July 6, 2003 | June 30, 2002 |
| | (unaudited) | (unaudited) | (unaudited) | (unaudited) |
| Retained earnings, beginning of the period | $ 190,916 | $ 117,372 | $ 164,660 | $ 98,169 |
| Net earnings | 31,252 | 27,723 | 57,508 | 46,926 |
| Retained earnings, end of the period | $ 222,168 | $ 145,095 | $ 222,168 | $ 145,095 |

See accompanying notes to interim consolidated financial statements.

**GILDAN ACTIVEWEAR INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(In thousands of Canadian dollars)**

| | Three months ended | | Nine months ended | |
|---|---|---|---|---|
| | July 6, 2003 | June 30, 2002 | July 6, 2003 | June 30, 2002 |

| | Three months ended | | Nine months ended | |
|---|---|---|---|---|
| | (unaudited) | (unaudited) | (unaudited) | (unaudited) |
| Cash and cash equivalents, beginning of period | $ 33,648 | $ | $ 70,905 | $ |
| Cash flows from operating activities: | | | | |
| Net earnings | 31,252 | 27,723 | 57,508 | 46,926 |
| Adjustments for: | | | | |
| Depreciation and amortization | 5,871 | 4,604 | 17,028 | 12,696 |
| Future income taxes | 1,586 | 1,812 | 4,445 | 1,586 |
| Other | 515 | 2,138 | 1,330 | 1,986 |
| | 39,224 | 36,277 | 80,311 | 63,194 |
| Net changes in non-cash working capital balances: | | | | |
| Accounts receivable | (7,711) | 8,115 | (27,523) | 19,265 |
| Inventories | 16,968 | 41,363 | (12,906) | 40,269 |
| Prepaid expenses and deposits | 522 | 16 | (2,444) | (1,080) |
| Accounts payable and accrued liabilities | 1,261 | 602 | 13,764 | (18,042) |
| Income taxes payable | 4,589 | 1,106 | 2,431 | 2,742 |
| | 54,853 | 87,479 | 53,633 | 106,348 |
| Cash flows from financing activities: | | | | |
| Decrease in revolving bank loan | | (42,562) | | (35,083) |
| Repayment of capital leases and other long term debt | (1,575) | (864) | (4,842) | (3,617) |
| Increase in unsecured debt | | 2,515 | 151 | 2,515 |
| Proceeds from the issuance of shares | 1,490 | 1,243 | 5,037 | 3,082 |
| | (85) | (39,668) | 346 | (33,103) |
| Cash flows from investing activities: | | | | |
| Purchase of fixed assets, net of disposals | (13,562) | (22,960) | (46,117) | (47,770) |
| Decrease (increase) in other assets | 105 | 542 | 345 | (82) |
| | (13,457) | (22,418) | (45,772) | (47,852) |
| Effect of exchange rate changes on cash and cash equivalents | (6,452) | (813) | (10,605) | (813) |
| Cash and cash equivalents, end of period | $ 68,507 | $ 24,580 | $ 68,507 | $ 24,580 |

See accompanying notes to interim consolidated financial statements.

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS**

**(For the period ended July 6, 2003)**
**(Tabular amounts in thousands, except per share data)**

**1. Basis of presentation:**

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with Canadian generally accepted accounting principles for interim financial information. Accordingly, they do not include all of the information and notes required by Canadian generally accepted accounting principles for complete financial statements, and should be read in conjunction with the Company's annual consolidated financial statements.

The Company applied the same accounting policies in the preparation of the interim consolidated financial statements, as described in note 1 of its audited financial statements in the Company's annual report for the year ended September 29, 2002.

Certain prior year amounts have been reclassified to conform to the current fiscal year presentation. These reclassifications had no impact on previously reported results of operations, financial position, cash flow or shareholders' equity.

The Company's revenues and income are subject to seasonal variations. Consequently, the results of operations for the third quarter ended July 6, 2003 are not necessarily indicative of the results to be expected for the full year.

All amounts in the attached notes are unaudited unless specifically identified.

**2. Significant accounting policies:**

a)

Stock-based compensation:

Effective September 30, 2002, the Company adopted prospectively the new recommendations of the Canadian Institute of Chartered Accountants ("CICA"), Handbook Section 3870, with respect to the accounting for stock-based compensation and other stock-based payments. The new recommendations require that all stock-based payments to non-employees, and employee awards that are direct awards of stock, call for settlement in cash or other assets, or are stock appreciation rights that call for settlement by the issuance of equity instruments, granted on or after adoption of the standard be accounted for using the fair value method. The Company presently does not have any such awards which must be accounted for using the fair value method. For all other stock-based employee compensation awards, the new standards permit the Company to continue to follow its existing policy of using the settlement date method of accounting. Under this method, no compensation expense is recognized when stock options are issued to employees.

The Company has employee share purchase plans and a stock option plan. No compensation expense is recognized under the stock-based compensation plans. The stock options are granted at an exercise price equal to the market value of the common shares at the date of grant. Any consideration paid by employees on exercise of the stock options or purchase of stock is credited to share capital.

The following outlines the impact and assumptions used if the compensation cost for the Company's employee share purchase and stock option plans was determined under the fair value based method of



accounting for awards granted in fiscal 2003. The pro forma disclosure omits the effect of awards granted before September 30, 2002.

| | July 6, 2003 | |
|---|---|---|
| | Three months ended | Nine months ended |
| Net earnings, as reported | $ 31,252 | $ 57,508 |
| Pro forma net earnings | $ 31,153 | $ 57,278 |
| Pro forma earnings per share: | | |
| Basic | $ 1.06 | $ 1.96 |
| Diluted | $ 1.05 | $ 1.93 |
| Assumptions used in the Black Scholes option pricing model: | | |
| Expected option life (years) | 3 | 3 |
| Risk-free interest rate | 3.55% | 3.72% |
| Expected stock price volatility | 33.80% | 36.09% |
| Dividend yield | 0 | 0 |
| Number of options granted | 20,000 | 121,206 |
| Weighted average fair value of options granted | $ 11.13 | $ 10.65 |

b)

Guarantees:

In accordance with CICA Accounting Guideline 14, Disclosure of Guarantees, significant guarantees that have been provided to third parties are the following:

*Standby letters of credit and surety bonds*

The Company, including certain of its subsidiaries, have granted irrevocable standby letters of credit and surety bonds, issued by highly rated financial institutions, to third parties to indemnify them in the event the Company does not perform its contractual obligations. As at July 6, 2003, the maximum potential liability under these guarantees was $12.5 million of which $11.0 million was surety bonds and $1.5 million was for standby letters of credit.

As at July 6, 2003, the Company has not recorded a liability with respect to these guarantees, as the Company does not expect to make any payments in excess of what is recorded on the Company's financial statements for the aforementioned items. The standby letters of credit mature at various dates between 2003 and 2004 and the surety bonds are automatically renewed on an annual basis.



**3. Share capital:**

| | July 6, 2003 | | September 29, 2002 | | June 30, 2002 | |
|---|---|---|---|---|---|---|
| | Shares | $ | Shares | $ | Shares | $ |
| | | | (audited) | | | |
| Authorized without limit as to number and without par value: | | | | | | |
| First preferred shares, issuable in series, non-voting | | | | | | |
| Second preferred shares, issuable in series, non-voting | | | | | | |
| Class A subordinated voting shares, participating, one vote per share | | | | | | |
| Class B multiple voting shares, participating, eight votes per share | | | | | | |
| Issued and outstanding: | | | | | | |
| Class A subordinate voting shares: | | | | | | |
| Total outstanding, beginning of period | 22,827 | $ 99,842 | 22,096 | $ 95,278 | 22,095 | $ 95,279 |
| Shares issued under employee share purchase plan | 4 | 125 | 8 | 182 | 7 | 143 |
| Shares issued pursuant to exercise of stock options | 499 | 4,912 | 723 | 4,382 | 525 | 2,939 |
| Total outstanding, end of period | 23,330 | 104,879 | 22,827 | 99,842 | 22,627 | 98,361 |
| Class B multiple voting shares | 6,094 | 5,083 | 6,094 | 5,083 | 6,094 | 5,083 |
| | 29,424 | $ 109,962 | 28,921 | $ 104,925 | 28,721 | $ 103,444 |

On December 5, 2002, the Board of Directors approved a stock repurchase program authorizing the Company to purchase up to a maximum of 200,000 of the Company's Class A subordinate voting shares in the open market commencing December 20, 2002 and ending December 19, 2003. As at July 6, 2003 no shares have been repurchased under this plan.

**4. Earnings per share:**

The following table sets forth the computation of basic and diluted earnings per share:

| | Three months ended | | Nine months ended | |
|---|---|---|---|---|
| | July 6, 2003 | June 30, 2002 | July 6, 2003 | June 30, 2002 |
| Basic weighted average number of common shares outstanding | 29,373 | 28,570 | 29,165 | 28,386 |
| Basic earnings per share | | | | |
| Canadian $ | $ 1.06 | $ 0.97 | $ 1.97 | $ 1.65 |
| U.S. $(a) | 0.74 | 0.62 | 1.33 | 1.05 |
| Basic weighted average number of common shares outstanding | 29,373 | 28,570 | 29,165 | 28,386 |
| Plus impact of stock options | 395 | 940 | 535 | 916 |
| Diluted weighted average number of common shares outstanding | 29,768 | 29,510 | 29,700 | 29,302 |
| Diluted earnings per share | | | | |
| Canadian $ | $ 1.05 | $ 0.94 | $ 1.94 | $ 1.60 |
| U.S. $(a) | 0.73 | 0.60 | 1.31 | 1.02 |

(a) The U.S. dollar earnings per share are based on the Canadian GAAP results converted at the average exchange rate for the respective periods.



**5. Financial instruments:**

The following table summarizes the Company's commitments to buy and sell foreign currencies as at July 6, 2003 and June 30, 2002:

| | Notional amount | Exchange rate | Maturity | Notional Canadian equivalent |
|---|---|---|---|---|
| 2003: | | | | |
| Buy contracts: | | | | |
| Foreign exchange contracts | Euro 606 | 1.5756 | July-August 2003 | $ 955 |
| Sell contracts: | | | | |
| Foreign exchange contracts | US$29,590 | 1.4619 | July-August 2003 | $ 43,258 |
| | Euro 4,889 | 1.4339 | July-November 2003 | $ 7,010 |
| 2002: | | | | |
| Buy contracts: | | | | |
| Foreign exchange contracts | US$19,000 | 1.5116 | July 2002 | $ 28,720 |
| | Euro 2,550 | 1.4832 | July 2002 | $ 3,782 |

**6. Segmented information:**

The Company manufactures and sells activewear apparel, specifically T-Shirts, fleece products and placket collar sport shirts. The products are sold as undecorated "blanks", primarily to wholesale distributors, and are ultimately decorated with logos by screenprinters and embroiders.

| Three months ended | | Nine months ended |
|---|---|---|
| July 6, 2003 | June 30, 2002 | July 6, 2003 |

| | Three months ended | | Nine months ended |
|---|---|---|---|
| Individual customers accounting for greater than 10% of total sales are as follows: | | | |
| Company A | 12.9% | 12.0% | 13.9%&nbMARGIN-LEFT: 0pt; TEXT-INDENT: 0pt; MARGIN-RIGHT: 0pt" align="justify">Our business could be harm |

We have only nine employees and we depend upon these employees to manage the day-to-day activities of our busin other qualified employees in a timely manner would likely have a negative impact on our operations. Dr. Christophe Financial Officer, was hired in November 2004, although he was a member of our Board of Directors for two years p Chief Medical Officer, was hired in March 2009; and James Clavijo, our Controller, Treasurer and Corporate Sec Board. In June 2007, Cyrille F. Buhrman was appointed to the Board of Directors. In March 2009, Gregg Lapoint effectively manage and operate our business. Several members of our board of directors are associated with other co these board members to present product opportunities to us of which they become aware outside of their capacity as m

Instability and volatility in the financial markets could have a negative impact on our business, financial condition, res

During recent months, there has been substantial volatility and a decline in financial markets due at least in part to t capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversel and business, including our financial condition, results of operations, and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to incur indebtedness to financ major financial institutions may have an adverse effect on our ability to fund our business strategy through borrowing to be reasonable, if at all.

Risks Related to our Common Stock

Our stock price is highly volatile.

The market price of our common stock, like that of many other research and development public pharmaceutical and variety of factors, including:

- announcements by us or others of results of pre
- announcements of technological innovations, more important bio-threats or new commercial therapeu
- our quarterly operating results
- developments or disputes concerning pate
- acquisitions
- litigation and governmen
- adverse legisla
- changes in government
- economic and other extern
- general market con

In addition, potential dilutive effects of future sales of shares of common stock by the Company, and subsequent sa price of our shares.

| Three months ended | Nine months ended |
|---|---|

Our stock price has fluctuated between January 1, 2005 through April 20, 2009 with the per share price of our comm
common stock traded at $0.10. The fluctuation in the price of our common stock has sometimes been unrelated or dis

| Three months ended | Nine months ended |
|---|---|

Our stock trades on the Over-the-Counter Bulletin Board.

On April 18, 2006, our stock was delisted from the American Stock Exchange ("AMEX") and began trading on the O the AMEX because we did not maintain stockholder equity above $6,000,000, as required under the maintenance req Regulatory Authority in which securities are traded via an electronic quotation system that serves more than 3,000 co of securities to facilitate the buy and sell orders of investors, rather than providing the order matchmaking service Companies traded on the OTCBB must be current in their reports filed with the Securities and Exchange Commission

If our common stock is not listed on a national exchange or market, the trading market for our common stock may applicable to equity securities with a price of less than $5.00 per share, other than securities registered on certain na information with respect to transactions in such securities is provided by the exchange or system. The penny stock ru deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stock customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson the customer's account. In addition, the penny stock rules require that, before a transaction in a penny stock that is no penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the trans stockholders could find it more difficult to sell their shares.

Shareholders may suffer substantial dilution.

We have a number of agreements or obligations that may result in dilution to investors. These include:

- warrants to purchase a total of approximately 43,500,000 shares of our common stock at
- options to purchase approximately 16,370,039 shares of our common stock at a

During 2009, outstanding warrants to purchase approximately 10,580,000 shares of our common stock will expire.

To the extent that warrants or options are exercised, our stockholders will experience dilution and our stock price may

Shareholders are also subject to the risk of substantial dilution to their interests as a result of our issuance of shares un but not the obligation, under certain conditions, to sell shares of common stock to Fusion Capital up to an aggregate be determined based upon the market price of our shares without any fixed discount at the time of each sale.

We already have sold 3,816,317 shares of common stock to Fusion Capital (together with a warrant to purchase 1,388 issued Fusion Capital 1,369,875 shares of common stock as a commitment fee. In addition to the shares already sol shares that are available to be sold to Fusion Capital. We may ultimately sell all, some or none of the 18.96 million the 18.96 million shares would have represented approximately 10.1% of the total outstanding common stock.

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquir

On February 14, 2008, we entered into an $8,500,000 common stock purchase agreement with Fusion Capital. The million, depending on certain conditions, of our common stock up to an aggregate of $8.5 million over approximate stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capita stock at $0.22 per share, for an aggregate price of $500,000. To date, we have sold an additional 1,038,589 shares of

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 25,327,778 shares upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stoc the price of our common stock. All 25,327,778 shares registered for sale by Fusion Capital are freely tradable. It is a pertaining to those shares. Depending upon market liquidity at the time, a sale of shares under the registration statem ultimately purchase all, some or none of the approximately 18.96 million shares of common stock not yet issued. A Capital by us under the agreement may result in substantial dilution to the interests of other holders of our common st make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we m sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without

The common stock purchase agreement with Fusion Capital also may be terminated in the event of a default under th if the purchase price is less than $0.10 per share. Thus, we may be unable to sell shares of our common stock to Fus and our ability to continue to develop and commercialize our products. The closing price of our common stock on Ap

| Three months ended | | Nine months ended |
|---|---|---|
| | 8 | |

| Three months ended | Nine months ended |
|---|---|

Our shares of common stock are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if th

Our common stock has from time to time been “thinly-traded,” meaning that the number of persons interested in pur
This situation is attributable to a number of factors, including the fact that we are a small company that is relatively u
that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk
the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may
compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support con
broader or more active public trading market for our common shares will develop or be sustained, or that current tradi

Fusion Capital's purchase and sale into the market of our common stock could cause our common stock price to decl
volume of our common stock. The market price of our common stock could decline given our minimal average tradin
and value of your investment would be subject to continual dilution if Fusion Capital purchases the shares and resells
adverse affect on the market price of our common stock would increase the number of shares issuable to Fusion Capit

| Three months ended | Nine months ended |
|---|---|

BUSINESS

Overview

We were incorporated in Delaware in 1987. We are a late-stage research and development biopharmaceutical compa
gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccin
is to:

(a) initiate and execute the pivotal Phase 3 confirmatory clinical trial for or
(b) identify a development and marketing partner for orBec® for territories outside of North America, as we have
Sigma-Tau will pay us a 35% roylaty on net sales in these territories as well as pay for commercialization expenses, i
(c) conduct a Phase 2 clinical trial of orBec® for t
(d) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indic
Crohn's disease;
(e) make orBec® available worldwide through NPAP
(f) reinitiate development of our other biotherapeutics
(g) continue to secure additional government funding for each of our biodefense programs, I
(h) convert our biodefense vaccine programs from early stage development to advanced development and manufactu
(i) acquire or in-license new clinical-stage compounds for development; and
(j) explore other business development and acquisition strategies under which we may

Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our tel

BioTherapeutics Overview

orBec®

orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation
orBec® is intended to reduce the need for systemic immunosuppressive drugs to treat acute GI GVHD. The active
inflamed tissue. BDP has been marketed in the U.S. and worldwide since the early 1970's as the active pharmaceu
rhinitis and asthma. orBec® is specifically formulated for oral administration as a single product consisting of two tal
intended to release BDP in the distal portions of the GI tract.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, orBec
which provide for seven and 10 years of post-approval market exclusivity, respectively.

| Three months ended | Nine months ended |
|---|---|

Clinical and Regulatory History

Two prior randomized, double-blind, placebo-controlled Phase 2 and 3 clinical trials support orBec's® ability to prov exposure to systemic corticosteroids following allogeneic transplantation. Currently, there are no approved products t Hutchinson Cancer Research Center. The second trial was a 129-patient pivotal Phase 3 multi-center clinical trial o Although orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely median t other key secondary endpoints such as the proportion of patients free of GVHD at Day 50 (p-value 0.05) and Day 80 66% reduction in mortality among patients randomized to orBec® at 200 days post-transplant with only 5 patient 0.0139). At one year post randomization in the pivotal Phase 3 trial, 18 patients (29%) in the orBec® group and 28 p p=0.04).

In the Phase 2 study, the primary endpoint was the clinically relevant determination of whether GI GVHD patients a they were able to consume at least 70% of their estimated caloric requirement. The GVHD treatment response at D 0.02). Additionally, the GVHD treatment response at Day 40 (10 days post cessation of therapy) was 16 of 31 (52%) v

Based on the data from Phase 2 and the Phase 3 studies, on September 21, 2006, we filed a new drug application ("N of acute GI GVHD. On November 3, 2006, we also filed a Marketing Authorization Application ("MAA") for orBec 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® for the treatment of and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls informatio with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announc sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically long as it does not interfere with patient accrual in a confirmatory trial. In May 2008, we voluntarily withdrew the M determining that confirmatory evidence of clinical efficacy will be required for approval. This is consistent with the making a new application at a later stage.

We recently reached agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluat FDA's Special Protocol Assessment ("SPA") procedure. An agreement via the SPA procedure is an agreement wi analyses) is acceptable to support a regulatory submission seeking new drug approval. After the study begins, the orBec®, the upcoming confirmatory Phase 3 protocol will be a highly powered, double-blind, randomized, placebo-c treatment failure rate at Study Day 80. This endpoint was successfully measured as a secondary endpoint (p-valu treatment with orBec® (i.e., 30 days following cessation of treatment).

We have entered into a collaboration agreement with Numoda Corporation ("Numoda"), for the execution of our up advantage of a scope of services including using their industry benchmarking capabilities to develop an operationa Barring any unforeseen modifications to the Phase 3 clinical program, Numoda will guarantee the agreed clinical trial common stock in exchange for a portion of its services in connection with the conduct of the upcoming confirmator payment for its services. Working with Numoda, we also will be able to take full advantage of early reporting of resu trial in the second half of 2009.

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercializati in the U.S., Canada and Mexico (the "Territory"). Sigma-Tau is obligated to make payments upon the attainment of made upon the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment o from Sigma-Tau for orBec® under the agreement could reach up to $10 million. Sigma-Tau will pay us a 35% royalty

In connection with the execution of the collaboration and supply agreement, we entered into a common stock purc Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price is equal to one hundred fi February 11, 2009. On November 26, 2008, prior to entering the collaboration agreement, we sold Sigma-Tau 16,6 exchange for the exclusive right to negotiate a collaboration deal with us until March 1, 2009. As part of these tr pharmaceutical company that creates novel therapies for the unmet needs of patients with rare diseases. They have bo

| Three months ended | Nine months ended |
|---|---|

On March 4, 2007, we entered into an investment banking agreement with RBC Capital Markets ("RBC"). As a res
agreement. Although RBC has indicated that it is willing to settle the matter for approximately $1.6 million, we disp
any lawsuit filed by RBC against us.

On November 25, 2008, we announced that the Therapeutics Goods Administration of Australia designated orBec®
transplantation.

On September 10, 2008, we announced that we entered into a collaboration agreement with BurnsAdler Pharmace
BurnsAdler will act as our distributor of a NPAP for orBec® to patients suffering from acute GI GVHD in all countri
announced that we expanded our collaboration with BurnsAdler, as our distributor of orBec® to patients suffering fro

On August 27, 2008, we announced that we entered into a collaboration agreement with Pacific Healthcare Thailand
as our sponsor to administer an NPAP for orBec® to patients suffering from acute GI GVHD in Thailand as well as
Indonesia, Laos, Myanmar, Philippines and Vietnam.

On July 18, 2008, we announced that we entered into collaboration agreement with Steward Cross Pte Ltd ("Steward
our Sponsor to administer an NPAP for patients suffering from acute GI GVHD in Singapore and Malaysia. We w
distribution costs in Singapore and Malaysia.

On July 15, 2008, we announced that we entered into a definitive collaborative agreement with IDIS Limited ("IDIS
GVHD in the European Union. IDIS is the leading specialist in the management of NPAPs in Europe.

On February 15, 2008, we announced that we entered into a Letter of Intent with BL&H Co. Ltd. ("BL&H"), a specia
regard to the administration of an NPAP for orBec® to patients suffering from acute GI GVHD in South Korea.

On November 28, 2007, we announced that we entered into a Letter of Intent with Orphan Australia Pty Ltd. ("Or
Orphan Australia will act as our sponsor with regard to the administration of an NPAP for orBec® to acute GI GVHD

On September 12, 2007, we announced that our academic partner, the Fred Hutchinson Cancer Research Center (
dipropionate (oral BDP, also the active ingredient in orBec®) for the treatment of GI radiation injury. While we wi
enhance the value of our orBec®/oral BDP program. The purpose of the studies funded by the grant, entitled "Impro
drugs, including oral BDP, given alone or in combination, that are likely to significantly mitigate the damage to the
model. The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of first eff
often the primary cause of death in acute radiation injury. This type of therapy, if successful, would benefit cancer pa
injury to the hematopoietic (blood) system and gastrointestinal tract are the main determinants of survival. The studi
added to supportive care intended to boost proliferation of blood cells. The principal investigator of the study is Georg

On July 12, 2007, we announced that patient enrollment commenced in a randomized, double blind, placebo-cont
myeloablative conditioning regimens. The trial is being conducted by Paul Martin, M.D., at the FHCRC in Seattle, W
benefit from this grant, but if successful, this funded trial could serve to increase the value of our orBec®/oral BDP pr
endpoint of the trial is the proportion of subjects who develop acute GVHD with severity sufficient to require syste
begin dosing at the start of the conditioning regimen and continue through day 75 following HCT. Enrollment in this t

| Three months ended | Nine months ended |
|---|---|

orBec® Survival Results at 200 Days Post Transplantation

| | Phase 3 trial | |
|---|---|---|
| | orBec® | Placebo |
| Number of patients randomized | 62 | 67 |
| Number (%) who died | 5 (8%) | 16 (24%) |
| Hazard ratio (95% confidence interval) | 0.33 (0.12, 0.89) | |
| Death with infection* | 3 (5%) | 9 (13%) |
| Death with relapse* | 3 (5%) | 9 (13%) |

*Some patients died with both infection and relapse of their underlying malignancy.

In this Phase 3 clinical trial, survival at the pre-specified endpoint of 200 days post-transplantation showed a clinicall the 200-day post-transplantation period was 67% lower with orBec® treatment compared to placebo treatment (haza death by transplantation day-200 were relapse of the underlying malignancy and infection. Relapse of the underlying 3/62 patients (4.8%) in the BDP arm. Infection contributed to the deaths of 9/67 patients (13.4%) in the placebo ar patients (4.5%) in the placebo arm and in 1/62 (1.6%) in the BDP arm.

A retrospective analysis of survival at 200 days post-transplantation in the supportive Phase 2 clinical trial showed co had died, compared with six deaths (21%) among patients who had been randomized to placebo, leading to a reduce likely proximate cause of death showed that mortality with infection or with relapse of underlying malignancy transplantation day-200, relapse of hematologic malignancy had contributed to the deaths of 1 of 31 patients (3%) in t 31 patients (6%) in the orBec® arm and 5 of 29 patients (17%) in the placebo arm.

In this Phase 3 trial, orBec® achieved these mortality results despite the fact that there were more “high risk of und 43%, respectively. There was also an imbalance of non-myeloablative patients in the orBec® treatment group, 26, or disadvantage. In addition, a subgroup analysis also revealed that patients dosed with orBec® who had received stem

orBec® Comprehensive Long-Term Mortality Results

Among the data reported in the January 2007 issue of Blood, the peer-reviewed Journal of the American Society randomization in the pivotal Phase 3 clinical trial. Overall, 18 patients (29%) in the orBec® group and 28 patie p=0.04). Results from the Phase 2 trial also demonstrated enhanced long-term survival benefit with orBec® versus died while 9 of 29 patients (31%) in the placebo group had died (45% reduction in mortality, p=0.26). Pooling the sur after orBec® was discontinued and extended well beyond 3 years after the transplantation. As of September 25, 200 patients), with a range of 10.6 months to 11.1 years. The risk of mortality was 37% lower for patients randomized to

Safety and Adverse Events

The frequencies of severe adverse events, adverse events related to study drug, and adverse events resulting in st remained on orBec® until Day 50 in the Phase 3 study had a higher likelihood of having biochemical evidence of abn

| Three months ended | Nine months ended |
|---|---|

Commercialization and Market

We anticipate the market potential for orBec® for the treatment of acute GI GVHD to be approximately 50 percent o U.S.

On December 1, 2008, we received $1.5 million under a non-binding letter of intent with Sigma-Tau, which grante strategic alliance regarding orBec® and potentially other pipeline compounds until March 1, 2009. Sigma-Tau is a Sigma-Tau has both prescription and consumer products in the metabolic, oncology, and renal markets.

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercializat license to commercialize orBec® in the U.S., Canada and Mexico. Sigma-Tau is obligated to make payments upon t million will be made upon the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for payments due from Sigma-Tau for orBec® under the agreement could reach up to $10 million. Sigma-Tau will pay us

Research and Development Analysis for orBec®

Since 2000, we have incurred expenses of approximately $16,000,000 in the development of orBec®. Research a $2,288,615 and $3,060,778 for the years ended December 31, 2007 and 2006, respectively.

About GVHD

GVHD occurs in patients following allogeneic bone marrow transplantation in which tissues of the host, most frequ mild to moderate GI GVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If lef epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50% of the more than 10,000 ann

GI GVHD is one of the most common causes for the failure of bone marrow transplantation. These procedures are residual disease and reducing the likelihood of relapse. orBec® represents a first-of-its-kind oral, locally acting thera frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressi substantially inhibit the highly desirable Graft-versus-Leukemia (“GVL”) effect of bone marrow transplantatio opportunistic infection.

About Allogeneic Bone Marrow/Stem Hematopoietic Cell Transplantation (HCT)

Allogeneic HCT is considered a potentially curative option for many leukemias as well as other forms of blood ca relative or unrelated person, and are transplanted into the patient following either high-dose chemotherapy or inte attributed to the GVL or Graft-versus-Tumor effects of the newly transplanted donor cells to recognize and destroy m

The use of allogeneic HCT has grown substantially over the last decade due to advances in human immunogenetics, cells and the advent of non-myeloablative conditioning regimens, or mini-transplants, that avoid the side effects of 10,000 allogeneic HCT procedures annually in the U.S. and a comparable number in Europe. Estimates as to the cur occur in this patient population. Clinical trials are also underway testing allogeneic HCT for treatment of some metas transplantation has also been used as curative therapy for several genetic disorders, including immunodeficiency allogeneic HCT, however, is GVHD in which the newly transplanted donor cells damage cells in the recipient’s gastro

Future Potential Indications of orBec® and Oral BDP

Based on its pharmacological characteristics, orBec® may have utility in treating other conditions of the gastrointest of oral BDP as a method for preventing and treating the tissue damage that is associated with both GI GVHD follow Phase 2 trial of orBec® in the prevention of acute GVHD in the third quarter of 2007. In addition, we are exploring th Crohn’s Disease, Lymphocytic Colitis, Irritable Bowel Syndrome, Ulcerative Colitis, among other indications.

| Three months ended | Nine months ended |
|---|---|

DOR 201

On December 8, 2008, we announced that the FDA has completed its review and cleared the Investigational New D
radiation enteritis. Consequently, we are able to initiate a Phase 1/2 clinical trial in acute radiation enteritis, expected
"Fast Track" designation from the FDA. Fast Track is a designation that the FDA reserves for a drug intended to treat
need for the condition. Fast track designation is designed to facilitate the development and expedite the review of n
rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additio
implies an abbreviated review time of six months.

DOR201 contains BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue.
ingredient in inhalation products for the treatment of patients with allergic rhinitis and asthma. BDP is also the act
prevention of GI GVHD, respectively. DOR201 is time-release formulation of BDP specifically designed for oral use

About Acute Radiation Enteritis

External radiation therapy is used to treat most types of cancer, including cancer of the bladder, uterine, cervix, rectu
healthy tissue, including the bowel, leading to acute and chronic toxicities. The large and small bowels are very se
Radiation enteritis is a condition in which the lining of the bowel becomes swollen and inflamed during or after radiat
and almost all patients receiving radiation to the abdomen, pelvis, or rectum will show signs of acute enteritis.

Patients with acute enteritis may have nausea, vomiting, abdominal pain and bleeding, among other symptoms. Som
does not function normally, and nutrients such as fat, lactose, bile salts, and vitamin B12 are not well absorbed.

Symptoms will usually resolve within 2-6 weeks after therapy has ceased. Radiation enteritis is often not a self-lim
change in bowel habits. Moreover, acute radiation injury increases the risk of development of chronic radiation ente
chronic radiation enteritis.

There are over 100,000 patients in the U.S. annually who receive abdominal or pelvic external beam radiation treatme

| Three months ended | Nine months ended |
|---|---|

BioDefense Overview

RiVax™

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first and only ricin
of castor plants. It can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes
targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contami
works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting prote
reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ri
antidote for ricin toxin exposure.

We have announced positive Phase 1 clinical trial results for RiVax™ which demonstrated that the vaccine is well
antibodies was confirmed by animal challenge studies in mice which survived exposure to ricin toxin after being injec
of the National Academy of Sciences. A second Phase 1 trial is currently underway, utilizing the adjuvanted formulati

The initial Phase 1 clinical trial was conducted by Dr. Ellen Vitetta at the University of Texas Southwestern Medica
Health ("NIH") has awarded us two grants one for $6.4 million and one for $5.2 million for a total of $11.6 millio
preclinical toxicology testing pursuant to the FDA's "animal rule."

The development of RiVaxTM has progressed significantly. In September 2006, we received a grant of approxi
recombinant vaccine against ricin toxin. This RiVax™ grant will provide approximately $5.2 million over a three yea
to the vaccine with protective efficacy in animals. This is necessary for ultimate licensure by the FDA, when h
characterization of the vaccine containing a well-characterized adjuvant that is needed to enhance the immune respon
over a period of years. A prototype version of RiVax™ has been evaluated in a Phase 1 clinical trial and was shown t
studies.

On April 29, 2008, we announced the initiation of a comprehensive program to evaluate the efficacy of RiVax™, in
provide data that will further aid in the interpretation of immunogenicity data obtained in the human vaccination trials

On January 29, 2008, we announced that we successfully achieved a two-year milestone in the long-term stability pr
the two-year analysis, undertaken as part of the formal stability program, demonstrate that the immunogen compone
two years without loss of its natural configuration or the appearance of any detectable degradation products. A vac
against ricin toxin. As this vaccine would potentially be added to the Strategic National Stockpile and dispensed in t
stockpile storage conditions.

On November 15, 2007, we announced that we entered into a Cooperative Research and Development Agreement wi
immunogenic protein subunit component of RiVax™, our preventive vaccine against ricin toxin. The agreement wil
underlying protein structure that is important in inducing human immune responses to ricin toxin. Ricin toxin is an ea
features that are critical to induce protective immune responses by vaccination with RiVax™ include structural determ
protein structure with induction of protective immunity and long-term stability of the protein. These studies will invo
appear primarily in the blood of animals and humans. Some of these antibodies recognize determinants on the pro
Overall, antibodies in the blood are correlated to protection against exposure when the toxin enters the circulat
inflammation, tissue necrosis and death. RiVax™ induces such antibodies in humans as well as other animal species
lead the studies to be conducted at WRAIR, which will include X-ray crystal analysis to determine the structural par
take part in evaluating the data that is found by WRAIR's studies, which they are funding. If successful, this will enha

In July 2007, we announced that the Office of Orphan Products Development ("OOPD") of the FDA has awarded a
further the development of RiVaxTM. We will not receive any monetary benefits from this grant; however, the succe
forward. The principal investigator for the project is Dr. Vitetta, Director of the Cancer Immunobiology Center at UT
adjuvant for use with the vaccine. Typically, awards made by the OOPD are to support clinical trials for development
UTSW began a second Phase 1 human clinical trial with RiVaxTM in August of 2008.

Research and Development Analysis for RiVax™

The costs that we have incurred to develop RiVax™ since 2002 total approximately $6,900,000. Research and devel
$2,130,516 for the years ended December 31, 2007 and 2006, respectively. Of the amount spent during the years e
grant, respectively.

| Three months ended | | Nine months ended |
|---|---|---|

| Three months ended | Nine months ended |
|---|---|

BT-VACC™

Our botulinum toxin vaccine, called BT-VACC™, originated from the research of Dr. Lance Simpson at Thomas Je formulation to be given as a primary immunization series or as oral or nasal booster to individuals who have been p Botulinum toxin is the most poisonous natural substance known to man. Botulinum toxin causes acute, symmetric, de 12 to 72 hours after exposure. Death results from paralysis of the respiratory muscles. Current treatments include resp occur, which leaves little time post-exposure for effective treatment.

In the context of oral and nasal formulations, we are developing a multivalent vaccine against botulinum neurotoxi antigens against Serotypes A, B and E consisting of the Hc50 fragment of the botulinum toxin. Typically, vaccines gi case of the combination BT-VACCTM, both the A and the B antigens were capable of attaching to cells in the muc preclinical data suggests that a bivalent formulation of serotypes A and B is completely effective at low, mid and high The animals were given a small quantity of the bivalent combination vaccine containing each of the type A and ty equivalent immune responses to A and B types in the serum. Importantly, they were then protected against exposu responses were also comparable to the same vaccines when given by intramuscular injection.

In July 2007, we announced that the first results from testing of a multivalent form of BT-VACCTM were publish 3043). These results are the first to describe the protective immunity elicited by a multivalent vaccine that is active by that induced protection against the corresponding versions of the natural toxins. The results published in Infection serotypes of botulinum toxin that cause almost all instances of human disease, namely serotypes A, B, and E, can b serum of mice and protected against subsequent exposure to high doses of a combination of the natural A, B, and E booster to animals that have been given a primary vaccine injection.

In September 2006, we were awarded a NIAID Phase 1 SBIR grant totaling approximately $500,000 to conduct fu vaccine. This program is currently ongoing and the grant funding has supported further work in characterizing antigen be encountered naturally or in the form of a bioweapon. This work will continue the research conducted by Dr. Lanc toxin can be given by the oral as well as the intranasal route to induce a strong protective immune response in anima that can be used in humans. Currently, the recombinant vaccines under development are given by intramuscula administration option, which would offer the distinct advantage of bypassing the requirement for needles and personn

Research and Development Analysis for BT-VACC™

The costs that we have incurred to develop BT-VACC™ from 2002 total approximately $2,300,000. Research a $360,997 and $130,381 for the years ended December 31, 2007 and 2006, respectively. Of the amount spent during under the SBIR grant, respectively.

Anthrax Vaccine Option

On May 8, 2008, we entered into a one-year exclusive option with the President and Fellows of Harvard College t disease caused by the spore-forming, gram-positive bacterium Bacillus anthracis. The option, which was obtained th U.S. patent that covers engineered variants of protective antigen (“PA”) developed in the Harvard Medical School lab developed for second- and third-generation anthrax vaccines. There has been a major effort on the part of the fede currently in use. This vaccine, known as AVA (for anthrax vaccine adsorbed), consists of a defined, but impure mixtu boosters. Vaccines such as AVA or those based on the purified, recombinant anthrax toxin component PA (“rPA”) spores. Several of the protein variants developed by Dr. Collier have been shown to be more immunogenic than nativ believe that with government funding we will be able to develop the Collier anthrax vaccine into one with an improve do not intend to conduct any new research and development or commit any funds to this program until we receive gra

| Three months ended | Nine months ended |
|---|---|

Additional Programs

LPMTM - Leuprolide

Our Lipid Polymer Micelle ("LPM™") oral drug delivery system is a proprietary platform technology designed to
gastrointestinal tract. We have previously demonstrated in preclinical animal models that the LPM™ technology is
achieved with the peptide hormone drug leuprolide. The LPM™ system utilizes a lipid based delivery system that c
that, through oral administration, can promote intestinal absorption. Reverse micelles are structures that form whe
system in which a stable clear dispersion of the water soluble drug can be evenly dispersed within the lipid phase. LP
through the epithelial layer of the intestines that allow only molecules of a certain dimension to pass through while e
prevent the rapid inactivation of peptides by enzymes in the upper gastrointestinal tract via a non-specific enzyme inh

In preclinical studies, the LPM™ delivery technology significantly enhanced the ability of leuprolide to pass throug
gonadotropin releasing hormone, which is used in the treatment of prostate cancer in men and endometriosis in wom
being less than 5%. Utilizing LPM™ in rats and dogs, the bioavailability of leuprolide averaged 30% compared to 2
Phase 1 study in humans in 2009 to confirm these findings.

An oral version of leuprolide may provide a significant advantage over the currently marketed "depot" formul
men. Injectable forms of leuprolide marketed under trade names such as Lupron® and Eligard® had worldwide
indications, such as endometriosis in women (a common condition in which cells normally found in the uterus becon
and central precocious puberty in children (a condition causing children to enter puberty too soon). Leuprolide is cu
limits its use and utility.

Research and Development Analysis for LPM™ Leuprolide

The costs that we have incurred to develop LPM™-Leuprolide since 2000 total approximately $1,400,000. Research
and $38,254 and $5,679 for the years ended December 31, 2007 and 2006, respectively. These costs are mainly legal

OraprineTM

We anticipate that an orally administered version of the immunosuppressant drug azathioprine may have a signific
provide a niche in the current transplant medicine market for an alternative to solid dosage forms of azathioprine t
believe may be bioequivalent to the oral azathioprine tablet currently marketed in the U.S. as Imuran®. We condu
Washington that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from GVHD. Ora
despite treatment with other immunosuppressive drugs such as prednisone, methotrexate, tacrolimus, and cycl
medicine. Azathioprine is commonly prescribed to organ transplant patients to decrease their natural defense mech
increases the chances of preventing rejection of the transplanted organ in the patient.

On September 25, 2007, we announced a Notice of Allowance of patent claims based on U.S. Patent Application #09
the patent has also been issued by the European Patent Office with the serial number EP 1 212 063 B1. This patent
applied azathioprine. We anticipate filing an ANDA; however this program is suspended pending further funding fro

Research and Development Analysis for OraprineTM

The costs that we have incurred to develop Oraprine™ since 2000 total approximately $400,000. Research and dev
$6,996 for the years ended December 31, 2007 and 2006, respectively. These costs are mainly legal costs in connecti

| Three months ended | Nine months ended |
|---|---|

Summary of Our Products in Development

The following tables summarize the products that we are currently developing:

BioTherapeutic Pr

| Product | Therapeutic Indication |
|---|---|
| orBec® | Treatment of Acute GI GVHD |
| orBec® | Prevention of Acute GI GVHD |
| orBec® | Treatment of Chronic GI GVHD |
| Oral BDP | Radiation Enteritis and Radiation Exposure |
| LPMTM – Leuprolide | Endometriosis and Prostate Cancer |
| OraprineTM | Oral lesions resulting from GVHD |

Biodefense Prod

| Select Agent | Currently Available Count |
|---|---|
| Ricin Toxin | No vaccine or antidote currently |
| Botulinum Toxin | No vaccine or antidote currently |

| Three months ended | Nine months ended |
|---|---|

The Drug Approval Process

General

Before marketing, each of our products must undergo an extensive regulatory approval process conducted by the FI promotion, export and marketing, among other things, of the proposed products are subject to extensive regulation b including advanced human clinical trials, which the FDA is allowed to suspend as it deems necessary to protect the sa

Our products will require regulatory clearance by the FDA and by comparable agencies in other countries, prior to co test, produce and market certain therapeutic products in the U.S., mandatory procedures and safety standards, approva

An IND application is required before human clinical testing in the U.S. of a new drug compound or biological pro efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

Clinical trials are normally done in three Phases, although the phases may overlap. Phase 1 trials are smaller trials product. Phase 2 trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condit trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clari other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modificat is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 4, or

With certain exceptions, once successful clinical testing is completed, the sponsor can submit an NDA for approval require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant a if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. An control and manufacturing procedures conform to good manufacturing practice regulations. In complying with standa area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase 4 po approval for the marketing of a product as a treatment for clinical indications other than those for which the product w monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes will likely

In the U.S., the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Federal Trade Commis manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, med things, fines, recall or seizure of products, refusal to permit products to be imported into the U.S., refusal of the go supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess

For the development of biodefense vaccines such as RiVaxTM and BT-VACCTM, the FDA has instituted policies tha use using the results of animal efficacy trials, rather than efficacy trials in humans. However, the Company will still are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct po pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence ove utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to t of the animal rule may raise issues of confidence in the model systems even if the models have been validated. For m the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and post-marketing studies, and could be restricted in use in only certain populations.

| Three months ended | Nine months ended |
|---|---|

Marketing Strategies

Pursuant to the collaboration and supply agreement with Sigma-Tau, we granted an exclusive license to Sigma-Tau to

We are actively seeking a commercialization partner for orBec® and oral BDP outside of North America as well as fo

We have had and are having strategic discussions with a number of pharmaceutical companies regarding the partnerin government agencies. We believe that both military and civilian health authorities of the U.S. and other countries wi could ensue following a bioterrorism attack.

Competition

Our competitors are pharmaceutical and biotechnology companies, most of whom have considerably greater financia is universities and other research institutions, including the U.S. Army Medical Research Institute of Infectious Diseas

Biodefense Vaccine Competition

We face competition in the area of biodefense vaccines from various public and private companies, universities technologies which may directly compete with the our technologies. Acambis, Inc., Dynavax, Emergent Biosolution Pharmaceuticals, Inc., Avanir Pharmaceuticals, Inc., Dynport Vaccine Company, LLC., Pharmathene, SIGA Pharma Some of these companies have substantially greater human and financial resources than we do, and many of the bioterrorism. For example, Avecia Biotechnology, Inc. has received NIH contracts to develop a next generation injec government to produce and deliver 75 million doses of Anthrax vaccine. This contract was rescinded in January 2007 timelines. Several companies have received development grants from the NIH for biodefense products. For example enhancement technology. Dynport Vaccine Company, LLC, a prime contractor with the DOD, currently has a $20 vaccine. Although we have received significant grant funding to date for product development, we have not yet been c

orBec® Competition

Competition is intense in the gastroenterology and transplant areas. Companies are attempting to develop technolog including Sangstat, Abgenix, and Protein Design Labs, Inc., are developing monoclonal antibodies to treat GVHD. N GVHD. All of these products are in various stages of development. For example, Novartis currently markets Cyclospo competition from Osiris Therapeutics if their product Prochymal for the treatment of GVHD is successful in ongoing GVHD. In addition, there are investigator-sponsored clinical trials exploring the use of approved drugs such as Enb GVHD. We believe that orBec®'s unique release characteristics, intended to deliver topically active therapy to bot therapies for inflammatory diseases of the gastrointestinal tract.

Competition is also intense in the therapeutic area of inflammatory bowel disease. Several companies, including Cen subsidiary of Johnson & Johnson, markets the drug product RemicadeTM for Crohn's disease. Other drugs used to tre is being marketed by AstraZeneca in Europe and Canada and by Prometheus Pharmaceuticals in the U.S. under the t approved Entocort for Crohn's disease late in 2001. In addition, Salix Pharmaceuticals, Inc. markets an FDA approved oral formulation of beclomethasone dipropionate, the active ingredient of orBec®, called CLIPPERTM for ulcerative ("Eurand") has licenses from Chiesi to the same formulation as CLIPPERTM and is developing it for ulcerative co patients.

Several companies have also established various colonic drug delivery systems to deliver therapeutic drugs to the co Corporation, and Elan Pharmaceuticals, Inc. Other approaches to treat gastrointestinal disorders include antisense and disease.

| Three months ended | Nine months ended |
|---|---|

Patents and Other Proprietary Rights

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods
proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek to obtain
proprietary information and proprietary technology through a combination of contractual arrangements and patents, be

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as th
proprietary knowledge and experience that is not patentable, and for inventions for which patents may be difficult to
end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements,
assignment to us of the ideas, developments, discoveries and inventions important to our business.

We are the exclusive licensee of an issued U.S. patent that covers the use of orBec® for the prevention and treatm
Orphan Drug designations provide for seven years of post approval marketing exclusivity in the U.S. and ten year
applications for this indication that, if granted, may extend our anticipated marketing exclusivity beyond the seven ye

orBec® License Agreement

In November 1998, our wholly-owned subsidiary, Enteron Pharmaceuticals, Inc. ("Enteron"), entered into an exclus
grant sublicenses, for the rights to the intellectual property and know-how relating to orBec®. In addition, Dr. McDon

Enteron also executed an exclusive license to patent applications for "Use of Anti-Inflammatories to Treat Irritable B
we will be obligated to make performance-based milestone payments, as well as royalty payments on any net sales of

Ricin Vaccine Intellectual Property

In January 2003, we executed a worldwide exclusive option to license patent applications with UTSW for the nasal,
with UTSW for the injectable rights to the ricin vaccine for initial license fees of $200,000 of our common stock an
vaccine for additional license fees of $150,000 in cash. Our license obligates us to pay $50,000 in annual license fees

We have sponsored research agreements with UTSW funded by two NIH grants. On December 7, 2006, we announ
U.S. Patent Application #09/698,551 entitled "Ricin A chain mutants lacking enzymatic activity as vaccines to protec

Botulinum Toxin Vaccine Intellectual Property

In 2003, we executed an exclusive license agreement with Thomas Jefferson University for issued U.S. Patent No. 6
nontoxic modified botulinum toxins as vaccines. The intellectual property also includes patent applications coverin
license fee of $160,000, payable in $130,000 of common stock and $30,000 in cash. In 2003, we entered into a one-
University, renewable on an annual basis, under which we have provided $300,000 in annual research support. In ad
toxin vaccine for a period of three years. Under this agreement, Dr. Simpson received options to purchase 100,000 sh
license royalty fee no later than January 1 of each calendar year, which increased to $15,000 in 2006 and every year th

Description of Property

We currently lease approximately 5,250 square feet of office space at 29 Emmons Drive, Suite C-10, Princeton, Ne
dated April 1, 2009, we pay rent of approximately $7,450 per month, or $17.00 per square foot per year, through
approximately $7,650, or $17.50 per square foot per year.

Employees

As of April 20, 2009, we had nine full-time employees, four of whom are Ph.D.s and one whom is also an M.D.

Research and Development Spending

We spent approximately $1,600,000 and $3,100,000 in the years ended December 31, 2008 and 2007, respectively, or

Legal Proceedings

| Three months ended | Nine months ended |
|---|---|

From time-to-time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our ma
allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if t

| Three months ended | Nine months ended |
|---|---|

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANC

The following discussion and analysis provides information that we believe is relevant to an assessment and unders with our audited consolidated financial statements and related notes and our unaudited consolidated interim financial relating to future events or our future financial performance. These statements are only predictions, and actual events factors identified in this prospectus, which could cause actual results to differ materially from those expressed in, or i See "Forward-Looking Statements."

Business Overview and Strategy

We are a research and development biopharmaceutical company focused on developing products to treat life-threaten medical need; as well as developing several biodefense vaccines. We were incorporated in Delaware in 1987. We ma

Our business strategy is to:

(a) initiate and execute the pivotal Phase 3 confirmatory clinical trial for orBec® in the tre
(b) identify a development and marketing partner for orBec® for territories outside of North America, as we have gr the U.S., Canada and Mexico, Sigma-Tau will pay us a 35% royalty on net sales in these territories and they will be activities;
(c) conduct a Phase 2 clinical trial of orBec® for the prevention
(d) evaluate and initiate additional clinical trials to explore the effectiveness of oral beclomethasone dipropionate (o tract such as radiation enteritis, radiation injury and Crohn's disease;
(e) make orBec® available worldwide through named patient access pr
(f) reinitiate development of our other biotherapeutics
(g) continue to secure additional government funding for each of our biodefense programs, F
(h) convert our biodefense vaccine programs from early stage development to advanced development and manufactu
(i) acquire or in-license new clinical-stage compounds for development; and
(j) explore other business development and acquisition strategies under which we may be

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated fina in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect t 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 and licen in SFAS 2, "Accounting for Research and Development Costs". Based on this consideration, we capitalized all outsid

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a group of assets.

We capitalize and amortize intangibles over a period of 11 to 16 years. We capitalize legal costs associated with the international markets.

As a late stage research and development company with drug and vaccine products in an often lengthy clinical r applications are a key currency of intellectual property, especially in the early stage of product development, as the industrial partners. These rights can also be sold or sub-licensed as part of our strategy to partner our products at ea preserve, maintain and perhaps extend the lives of the patents. Therefore, our policy is to capitalize these costs and future use as referred to in SFAS No.142 and in paragraph 11 c. of SFAS No. 2.

We capitalize intangible assets that have alternative future uses as this is common practice in the pharmaceutical dev the University of Texas Southwestern Medical Center for $462,234 was for up-front license costs. We capitalize lic believe that both of these intangible assets purchased have alternative future uses.

Research and Development Costs

| Three months ended | Nine months ended |
|---|---|

Research and Development costs are charged to expense when incurred. Research and development includes costs s
use, supplies and materials, salaries and employee benefits, equipment depreciation and allocation of various corpor
for acquired research and development for which there is no alternative future use as of the date of acquisition.

Revenue Recognition

Our revenues are generated from U.S. government grants and from NPAP sales of orBec®. The government gra
administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses hav
NPAP revenues are recorded when orBec® is shipped.

Stock Based Compensation

From time to time, we issue common stock to vendors, consultants, and employees as compensation for services perfo
Equity Incentive Plan, where the stock may be issued as unrestricted. The restricted stock can only have the restrict
statement, which we must file and have approved by the SEC, if the shares underlying the certificate are sold pursu
exemption from the registration requirements of the Securities Act of 1933, as amended.

Stock based compensation expense recognized during the period is based on the value of the portion of share-based pa

| Three months ended | Nine months ended |
|---|---|

Material Changes in Results of Operations

Year Ended December 31, 2008 Compared to Year Ended December 31, 2007.

For the 12 months ended December 31, 2008, we had a net loss of $3,422,027 as compared to a net loss of $6,164,6
primarily attributed to lower research and development costs and lower costs associated with preparation of FDA a
public and investor relation expenses, a reduction in employee, travel and consultant expenses, lower expenses for s
investors from the April 2006 private placement in the amount of $308,743 in 2007.

The 2008 revenues and associated expenses were from NIH Grants awarded in September 2004 and September 2
development of our ricin and botulinum vaccines.

For the 12 months ended December 31, 2008, we had revenues of $2,310,265 as compared to $1,258,017 in the 12
with our September 2006 NIH grant and achieved certain research and development milestones with our subcontract
incurred expenses related to that revenue in the 12 months ended December 31, 2008 and 2007 of $1,886,431 and $94
payments made to subcontractors and universities in connection with the grants. Costs of goods associated with NP
inventory.

Our gross profit for the 12 months ended December 31, 2008 was $423,834 as compared to $314,632 in the 12 month
the aforementioned reclassification of expenses. In the third quarter of 2008, we also capitalized inventory in the ne
research and development expenses and, in 2008 we recorded a $100,000 allowance as a reserve for our orBec® inver

Research and development spending decreased by $1,547,621, or 50%, to $1,552,323, for the 12 months ended De
incurred expenses for FDA and European regulatory matters, for clinical preparation of orBec® and LPMTM for
European regulatory matters with respect to the FDA ODAC meeting and the EMEA applications for orBec®, which

General and administrative expenses decreased $922,651, or 32%, to $1,941,719 for the 12 months ended Decemb
decrease was primarily due to the dilution expense taken in the first quarter of 2007 for stock issued to investors in
reduction in employee and consultant expenses, travel expenses and expenses for public and investor relations of appr

Stock based compensation expenses for research and development decreased $48,500, or 21%, to $182,168 for th
December 31, 2007. The stock based compensation expense for the 12 months ended December 31, 2008 for BioD
corresponding 12 month period in 2007, respectively.

Stock based compensation expenses for general and administrative decreased $243,285, or 54%, to $203,448 for t
December 31, 2007. This decrease was due to having more initial option grants in 2007 requiring a larger expenditure

Interest income for the 12 months ended December 31, 2008 was $37,073 as compared to $164,847 for the 12 mon
lower cash balances in 2008 as compared to 2007.

Interest expense for the 12 months ended December 31, 2008 was $3,276 as compared to $1,020 for the 12 months e
for insurance premiums due.

We had two active segments for the year ended December 31, 2008 and December 31, 2007: BioDefense and Bio
$132,272 as compared to $109,698 for the 12 months ended December 31, 2007, representing an increase of $22,574
as compared to $2,748,764 for the 12 months ended December 31, 2007, representing a decrease of $1,192,335. This
preparation of FDA and European regulatory matters as well as a reduction in general and administrative expenses,
lower expenses for stock based compensation in the amount of $291,785, and the dilution expense taken for stock is
operations for Corporate for the 12 months ended December 31, 2008 was $1,767,123 as compared to $3,468,621 for

Revenues for BioDefense for the 12 months ended December 31, 2008 were $2,269,647 as compared to $1,258,017
progressed with our September 2006 NIH grant and achieved certain research and development milestones with our s
as compared to zero for the 12 months ended December 31, 2007.

Amortization and depreciation expense for BioDefense for the 12 months ended December 31, 2008 was $85,354 a
Amortization and depreciation expense for BioTherapeutics for the 12 months ended December 31, 2008 was $58
$34,517. Amortization and depreciation expense for Corporate for the 12 months ended December 31, 2008 was $5,0

| Three months ended | | Nine months ended |
|---|---|---|

| Three months ended | Nine months ended |
|---|---|

Financial Condition

Cash and Working Capital

The accompanying consolidated financial statements have been prepared assuming we will continue as a going conce
2007. As of February 28, 2009, we had cash of approximately $7,100,000. The increase was the result of the sale of
million from the sale of our common stock and warrants to accredited investors. As of December 31, 2008, we had
representing a decrease of $706,455. For the 12 months ended December 31, 2008, our cash used in operating activit
31, 2007, reflecting both an increase in grant revenues and reduced costs as we conscientiously slowed our spending
to use equity instruments to provide a portion of the compensation due to our employees, vendors and collaboration pa

Based on the our current rate of cash outflows and cash in the bank, we believe that our current cash will be sufficien
2010. We have approximately $2.0 million in grant funding still available to support our programs in 2009 and b
government funding.

Management's plan is as follows:

We are exploring out-licensing opportunities for orBec® and oral BDP in territories outside North Ame
in the U.S. and in Europe.

We have and will utilize NPAPs wherever possible in countries outside the U.S. to generate revenues fro

We intend to utilize our existing $8.5 million common stock purchase agreement with Fusion Capital
through June 2010) when we deem market conditions to be appropriate.

We expect to receive new government grants intended to support existing and new research and develo
and development funding, these grants would provide additional support for our overhead expenditures
our upcoming confirmatory Phase 3 trial of our lead product orBec®. Therefore these grants would ha
file for government grants which support our biotherapeutic and biodefense programs.

We may obtain additional funds through the issuance of equity or equity-linked securities through privat
additional equity financing opportunities and will continue to execute them when appropriate.

If we obtain additional funds through the issuance of equity or equity-linked securities, shareholders may experience
of our common stock. The terms of any debt financing may contain restrictive covenants which may limit our ability
all. If we are unable to obtain such financing when needed, or to do so on acceptable terms, we may be unable to deve
our operations.

In the event that such growth is less than forecasted in our 2009-2010 operating plan, management has developed co
will be able to maintain adequate liquidity to allow us to continue to operate the business or prevent the possible impa

Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when
financial condition and prospects.

Since December 31, 2008, we have issued a total of 45,914,035 shares of common stock and warrants to purchase 20,

| Three months ended | Nine months ended |
|---|---|

Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuan
approximately $6,000,000. We anticipate grant revenues in the next 12 months to offset research and development
approximately $2,000,000, with $600,000 contributing towards our overhead expenses.

The table below details our costs by program for the 12 months ended December 31:

| | 200 |
|---|---|
| Program - Research & Development Expenses | |
| orBec® | |
| RiVax™ | |
| BT-VACC™ | |
| Oraprine™ | |
| LPMTM-Leuprolide | |
| Research & Development Expense | |
| | |
| Program - Cost of Goods Sold and Reimbursed under Grants | |
| orBec® | |
| RiVax™ | |
| BT-VACC™ | |
| Cost of Goods Sold and Reimbursed under Grant | |
| | |
| TOTAL | |

Debt

We had no debt at December 31, 2008 or at December 31, 2007.

| Three months ended | Nine months ended |
|---|---|

Equity Transactions

On February 11, 2009, in connection with a collaboration and supply agreement, we entered into a common stock pu
Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price was equal to one hundred f
February 11, 2009.

On January 20, 2009, we received $2,384,200 from the completed private placement of common stock and warrants
with five year warrants to purchase up to 20,914,035 shares of our common stock at $0.14 per share. The expiration
and we would receive additional gross proceeds of approximately $2.9 million if exercised.

During the 12 months ended December 31, 2008, we issued 758,082 shares of common stock as payment to vendors f
value on the date of issuance, respectively.

During the 12 months ended December 31, 2008, we also issued 993,084 shares of common stock under its existing
shares' fair market value on the date of issuance.

During the 12 months ended December 31, 2008, we issued 168,309 shares of common stock as compensation and se
value on the date of issuance, respectively.

On December 1, 2008, we entered into a non-binding letter of intent with Sigma-Tau, which granted Sigma-Tau an
regarding orBec® and potentially other pipeline compounds until March 1, 2009. Under the terms of the letter of i
representing 16,666,667 shares.

On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital. The Fusion Capital
on certain conditions of our common stock up to an aggregate of $8.5 million over approximately a 25-month period.
fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778
aggregate price of $500,000. We issued 75,000 shares as a pro rata commitment fee in connection with the purcha
purchased may be increased under certain conditions as the price of our common stock increases. We cannot require
our common stock is less than $0.10 per share. Furthermore, for each additional purchase by Fusion, additional comm
relative proportion of such purchases compared to the aggregate amount of $8.5 million.

On February 14, 2008, we sold 881,112 shares of our common stock to accredited investors for an aggregate purc
aggregate of 440,556 shares of our common stock at an exercise price of $0.22 per share.

The total issuance of common stock from private placement for 2008 was 3,658,890 shares; which consisted of the
Capital of 2,777,778 shares for $500,000.

The total issuance of common stock for commitment shares for 2008 was 1,369,125 shares; which were issued to Fu
for the $500,000 invested, and 19,125 shares for the commitment fee on the purchase of $127,500 by Fusion Capital.

During 2007, the Company issued 373,607 shares of common stock as part of severance payments to employees.
issuance.

For the 12 months ended December 31, 2007, 1,737,200 stock options were exercised to purchase shares of common s

For the 12 months ended December 31, 2007, 6,458,287 common stock warrants were exercised to purchase of comm

The total issuance of common stock upon exercise of options and warrants for 2007 was 8,195,487 shares, which cons

On February 9, 2007, we sold 11,680,850 shares of our common stock to institutional investors and certain of our offi

On January 3, 2007, in consideration for entering into an exclusive letter of intent, Sigma-Tau agreed to purchase $1,
shares of common stock, and contributed an additional $2 million in cash. The $2 million contribution was to be co
pursuant to any future orBec® commercialization arrangement reached between the two parties. Because of this tran
$0.246. Additionally, certain shareholders who still held shares of the Company's common stock from that place
Company's common stock. Neither these investors, nor any other investors, hold any further anti-dilution rights
Sigma-Tau by April 30, 2007, which was completed on June 1, 2007.

| Three months ended | Nine months ended |
|---|---|

The total issuance of common stock from private placement for 2007 was 15,745,891 shares; which consisted of the
less the $254,596 payable as placement agent fees, and 4,065,041 shares to Sigma-Tau for $1,000,000. The total net p

| Three months ended | Nine months ended |
|---|---|

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements.

Effects of Inflation and Foreign Currency Fluctuations

We do not believe that inflation or foreign currency fluctuations significantly affected our financial position and resul
31, 2007.

| Three months ended | Nine months ended |
|---|---|

DIRECTORS AND EXECUT

The following table contains information regarding the current members of the Board of Directors and executive offic

| Name | Age | Positio |
|---|---|---|
| James S. Kuo, M.D., M.B.A. | 45 | Chairman of the Board |
| Cyrille F. Buhrman | 36 | Director |
| Gregg A. Lapointe, C.P.A., M.B.A. | 50 | Director |
| Christopher J. Schaber, Ph.D. | 42 | Chief Executive Officer, P Director |
| Evan Myrianthopoulos | 44 | Chief Financial Officer, Se President, and Director |
| Brian L. Hamilton, M.D., Ph.D. | 61 | Chief Medical Officer, and President |
| Robert N. Brey, Ph.D. | 58 | Chief Scientific Officer, a President |
| James Clavijo, C.P.A., M.A. | 43 | Controller, Treasurer, and |

| Three months ended | Nine months ended |
|---|---|

James S. Kuo, M.D., M.B.A., has been a director since 2004 and currently serves as the non-executive Chairman of th
Therapeutics, Inc.), a public biopharmaceutical company, since June 2007 and has been Chief Executive Officer since
Cysteine Pharma, Inc. From 2003 to 2006, he served as founder, Chairman and Chief Executive Officer of BioMicro
co-founder, President and Chief Executive Officer of Discovery Laboratories, Inc., a public specialty pharmaceutical
took the company public. He further has been a founder and a Board Director of Monarch Labs, LLC, a private medic
Ventures, LLC, which managed $378 million in venture funds. He has also been a senior licensing and business devel
development. Dr. Kuo is also a director of Adeona Pharmaceuticals, Inc. (formerly Pipex Pharmaceuticals, Inc.), a pul
Kuo simultaneously received his M.D. degree from The University of Pennsylvania School of Medicine and his M.B.

Cyrille F. Buhrman has been a director since June 2007. Mr. Buhrman is Chairman and President of the Pacific Heal
based in Thailand where he has served for approximately ten years. Mr. Buhrman is also a Director of International P
in Thailand, Vision Care (Thailand) Co., Ltd., and Canyon Pharmaceuticals, Inc., a private biotechnology company
Mr. Buhrman is owner of Markle Holdings Ltd., an investment fund specializing in biotech and pharmaceutical invest

Gregg Lapointe, C.P.A., M.B.A., has been a director since March 10, 2009. Mr. Lapointe also serves on the Board of
the Corporate Council of the National Organization for Rare Diseases (NORD). He has served in varying roles for
Officer from November 2003 to April 2008 and Chief Executive Officer since April 2008. From May, 1996 to Augu
(formerly JWI Inc.). Prior to that Mr. Lapointe spent several years in the Canadian medical products industry in both
background, Mr. Lapointe has significant experience in the areas of global strategic planning and implementation,
Commerce from Concordia University in Montreal, Canada, a graduate diploma in Accountancy from McGill Unive
Accountant in Ontario, Canada.

Christopher J. Schaber, Ph.D., has been our President and Chief Executive Officer and a director since August 200
Prior to joining DOR, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Offi
areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distrib
preparation activities. During his tenure at Discovery Laboratories, Inc., Dr. Schaber played a significant role in rais
Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Complia
Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regula
division of Wyeth-Ayerst Laboratories. Dr. Schaber received his B.A. degree from Western Maryland College, hi
Pharmaceutical Sciences from The Union Graduate School.

Evan Myrianthopoulos has been a director since 2002 and is currently our Chief Financial Officer and Senior Vice
November 2001 to November 2004, he was President and founder of CVL Advisors Group Inc., a financial consu
Myrianthopoulos was a co-founder of Discovery Laboratories, Inc. During his tenure at Discovery Laboratories, Inc
and Vice President of Finance, where he was responsible for raising approximately $55 million in four private p
Pharmaceuticals and Acute Therapeutics, Inc. Prior to co-founding Discovery Laboratories, Inc., Mr. Myrianthop
biotechnology venture capital and investment banking firm. Prior to joining Paramount Capital Investments, LLC, M
department at the National Australia Bank where he was employed as a spot and derivatives currency trader. Mr. Myr

Brian L. Hamilton, M.D., Ph.D., has been Chief Medical Officer and Senior Vice President since March 11, 2009.
bone marrow transplantation to treat children with congenital immune deficiency, with research in the immunobiolo
(Astra, USA and Wyeth) and several biotechnology companies. From December 2001 to June 2004, he was Seni
President for Clinical and Regulatory Affairs at Merrimack Pharmaceutical. He was Chief Medical Officer with E
Director with Biopharm Solutions, Inc. from March 2007 to October 2008. From October 2008 to March 2009, he
development and regulatory affairs with small molecules, biologics, vaccines, and genetically modified oncolytic viru
in the clinical development and registration of both Pulmicort Turbuhaler for the treatment of patients with asthma an
Ph.D. degrees from the University of Washington, with post-graduate training in Pediatrics, Allergy, Immunology, an

Robert N. Brey, Ph.D., has been with the Company since January 1996, and is currently our Chief Scientific Officer
Vice President of Research and Development. He also has held Scientific, Management and Project Management
participated in the successful development a of a vaccine for Haemophilius influenzae meningitis, and a vaccine for p
and Project Manager for development of oral vaccines from 1985 through 1993. From 1993 through 1994, Dr. Brey
adjuvant technology and formulations for improved vaccines. From 1994 through 1996, Dr. Brey established an indep
platforms. Before entering into drug and vaccine delivery, he held senior scientific positions at Genex Corporation
Connecticut, his Ph.D. degree in Microbiology from the University of Virginia and performed postdoctoral studies at

James Clavijo, C.P.A., M.A., has been with the Company since October 2004 and is currently our Controller, Treasu
both domestic and international entities, and participating in over $100 million in equity and debt financing. Prior to
FL), from July 2003 to October 2004. During his time with Cigarette he was instrumental in developing a cost accou

| Three months ended | Nine months ended |
|---|---|

related to a 10 acre, 100,000 square foot facility purchase. Prior to joining Cigarette Racing Team, Mr. Clavijo held p
manufacturing garment company. Prior to Gallery Industries, as Corporate Controller for A Novo Broadband, he mar
Manager for Wackenhut Corporation in the U.S. Governmental Services Division. In addition, he served in the U.S.
Clavijo holds an M.A. degree in Accounting from Florida International University, a B.A. degree in Accounting from
is a licensed Certified Public Accountant in the state of Florida.

| Three months ended | | Nine months ended |
|---|---|---|

EXECUTIVE COMPE

Summary Compen

The following table contains information concerning the compensation paid during our fiscal years ended December most highly compensated executive officers during 2008 (collectively, the "Named Executive Officers").

Summary Compensation Table

| Name | Position | Year | Salary | Bonus | |
|---|---|---|---|---|---|
| Christopher J. Schaber (1) | C.E.O. & President | 2008 | $300,000 | $100,000 | |
| | | 2007 | $300,000 | $100,000 | |
| Evan Myrianthopoulos (2) | C.F.O. & Senior V.P. | 2008 | $200,000 | $ 50,000 | |
| | | 2007 | $200,000 | $ 50,000 | $ |
| Robert N. Brey (3) | C.S.O. & Senior V.P. | 2008 | $190,000 | $ 20,000 | |
| | | 2007 | $190,000 | $ 15,000 | $ |

(1) Dr. Schaber deferred payment of his 2008 annual bonus of $100,000 until February 28, 2009. Option Awards inc Other Compensation for 2008 includes $24,844 for insurance costs. Other Compensation for 2007 includes $19,000 costs.

(2) Mr. Myrianthopoulos deferred payment of his 2008 annual bonus of $50,000 until February 28, 2009. Option Awa 123R. Other Compensation for 2008 includes $23,474 for insurance costs. Other Compensation for 2007 includes $ lodging costs.

(1) Dr. Brey deferred payment of his 2008 annual bonus of $20,000 until January 31, 2009. Option Awards include th Compensation for 2008 includes $18,405 for insurance costs. Other Compensation for 2007 includes $18,325 for insu

Potential Issuance of Shares

On February 28, 2007, our Board of Directors approved the issuance of 2,700,000 shares of our common stock to c series or combination of related transactions, negotiated by our Board of Directors whereby, directly or indirectly, a m a third party (an "Acquisition Event"). Of the shares of common stock to be issued upon an Acquisition Event, 1, President; 750,000 shares will be issued to Evan Myrianthopoulos, a director and our Chief Financial Officer; and 300

Employment and Severance Agreements

During August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, Ph.D. Pursua minimum annual bonus of $100,000. This employment agreement was renewed in December 27, 2007 for a term of t third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defi accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependan

Dr. Schaber's monetary compensation (base salary of $300,000 and bonus of $100,000) remained unchanged from 2 of the Company due to merger or acquisition, all of Dr. Schaber's options shall become fully vested, and be exercisab to their terms). In the event of his death during term of the agreement, all of his unvested options shall immediatel immediate family.

| Three months ended | Nine months ended |
|---|---|

In December 2004, we entered into a three-year employment agreement with Mr. Myrianthopoulos. Pursuant to this
one year of service Mr. Myrianthopoulos would be entitled to a minimum annual bonus of $50,000. This employment
to purchase 500,000 shares of our common stock, with the options vesting over three years. This option grant is subje
pay Mr. Myrianthopoulos six months severance subject to set off, as well as any unpaid bonuses and accrued
Myrianthopoulos also received 150,000 options, vested immediately when he was hired in November 2004, as Preside

Mr. Myrianthopoulos' monetary compensation (base salary of $200,000 and bonus of $50,000) remained unchange
control of the Company due to merger or acquisition, all of Mr. Myrianthopoulos' options shall become fully vested,
sooner pursuant to their terms). In the event of his death during term of contract, all of his unvested options shall
Myrianthopoulos' immediate family.

On March 27, 2009, the Compensation Committee approved the increase in salaries for: Dr. Schaber from $300
$200,000. Dr. Brey does not have an employment agreement.

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Sc
or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a
stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopo
such shares to the executives if such event occurs.

| Three months ended | Nine months ended |
|---|---|

Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity ince
issued Stock Appreciation Rights.

Outstanding Equity Awards a

| Name | Number of Securities Underlying Unexercised Options (#) Exercisable | Unexercisable | N Un |
|---|---|---|---|
| Christopher J. Schaber | | 2,083,343 | 416,657 |
| | | 506,250 | 393,750 |
| | | 700,000 | 2,100,000 |
| Evan Myrianthopoulos | 150,000 | | - |
| | | 50,000 | - |
| | | 50,000 | - |
| | | 150,000 | - |
| | | 500,000 | - |
| | | 375,000 | 25,000 |
| | | 309,375 | 240,625 |
| | | 300,000 | 900,000 |
| Robert N. Brey | | 10,000 | - |
| | | 9,000 | - |
| | | 562,500 | 37,500 |
| | | 125,000 | 75,000 |
| | | 200,000 | 600,000 |

| Three months ended | Nine months ended |
|---|---|

Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fisca

Director Compens

| Name | Fees Earned or Paid in Cash ($) (1) | Option Awards ($) (2) | T |
|---|---|---|---|
| James S. Kuo | $16,000 | $- | |
| Cyrille F. Buhrman | $9,000 | $- | |

(1) Directors who are compensated as full-time employees receive no additional compensation for service on our Boa or committee meeting attended ($1,000 if such meeting was attended telephonically).

(2) We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of vested options to purchase 300,000 shares of common stock, and subsequent prorated annual grants of fully v During 2008, we did not hold an annual meeting. As a result there were no stock options granted to the Board of Stock as required by FASB No. 123R.

| Three months ended | Nine months ended |
|---|---|

SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT

The table below provides information regarding the beneficial ownership of the common stock as of April 20, 2009 o stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a gr persons named in the table have sole voting and investment power with respect to all shares of common stock held by

| Name of Beneficial Owner | Shares of Common Stock Benefici Owned |
|---|---|
| Sigma-Tau Pharmaceuticals, Inc. (1) | 41,666 |
| Biotex Pharma Investments, LLC (2) | 40,000,000 |
| Cyrille F. Buhrman (3) | 5,125,020 |
| Christopher J. Schaber (4) | 4,108 |
| Evan Myrianthopoulos (5) | 2,368 |
| Robert N. Brey (6) | 1,019,000 |
| James Clavijo (7) | 950 |
| James S. Kuo (8) | 630 |
| Gregg A. Lapointe (9) | 300,000 |
| Brian L. Hamilton (10) | 250,000 |
| All directors and executive officers as a group (8 persons) | 14,751 |

* Indicates less than 1%.

** Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are no ownership is based on 167,070,944 shares of common stock outstanding as of April 9, 2009.

(1) Includes 41,666,667 shares of common stock. The amount does not include 1,546,870 shares of common s Pharmaceuticals, Inc. is c/o Sigma-Tau Pharmaceuticals, Inc., 800 South Frederick Avenue, Suite 300, Gaithersburg,

(2) Includes 20,000,000 shares of common stock and warrants to purchase 20,000,000 shares of common stock wi Investments, LLC, 220 West 42nd Street 6th Floor New York, NY 10036.

(3) Includes 4,900,020 shares of common stock and options to purchase 225,000 shares of common stock within 60 C-10, Princeton, New Jersey 08540.

| Three months ended | Nine months ended |
|---|---|

(4) Includes 392,766 shares of common stock owned by Dr. Schaber and options to purchase 3,715,983 shares of c
Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(5) Includes 224,780 shares of common stock owned by Mr. Myrianthopoulos and his wife, options to purchase 2,05
of April 20, 2009. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, 29 Emmons Drive, Suite C-10, Princ

(6) Includes options to purchase 1,019,000 shares of common stock within 60 days of April 20, 2009. The address of

(7) Includes 88,191 shares of common stock owned by Mr. Clavijo and options to purchase 862,500 shares of co
Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(8) Includes options to purchase 625,000 shares of common stock and warrants to purchase 5,000 shares of commo
Drive, Suite C-10, Princeton, New Jersey 08540.

(9) Includes options to purchase 300,000 shares of common stock within 60 days of April 20, 2009. The address of M

(10) Includes options to purchase 250,000 shares of common stock within 60 days of April 20, 2009. The address of

| Three months ended | Nine months ended |
|---|---|

Equity Compensation Plan Information

In December 2005, our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockho
Equity Incentive Plan to increase the maximum number of shares of our common stock available for issuance under th
shares. The following table provides information, as of December 31, 2008, with respect to options outstanding under

| Plan Category | Number of Securities to be issued upon exercise of outstanding options, warrants and rights | Weighted-Average Exercise Price Outstanding options, warrants and rights | N Is |
|---|---|---|---|
| Equity compensation plans approved by security holders (1) | 16,370,039 | $ 0.27 | |
| Equity compensation plans not approved by security holders | - | | - |
| TOTAL | 16,370,039 | $0.27 | |

(1) Includes our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan. Our 1995
the amended 2005 equity incentive plan, we have issued 1,482,669 shares to individuals as payment for services in the

| Three months ended | Nine months ended |
|---|---|

THE FUSION TRANS

General

On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, a conditions, to purchase shares from us in an aggregate amount of $8.5 million from time to time over a 25 month p purchase 1,388,889 shares of our common stock purchase that are not part of this offering) under the agreement for t Fusion Capital received a commitment fee consisting of 1,275,000 shares of our common stock. We have issued 94,8 $632,500 of our common stock.Also, we will issue to Fusion Capital an additional 1,180,125 shares as a commitment to Fusion Capital as a commitment fee are being included in the offering pursuant to this prospectus. There are no neg

As of April 20, 2009, there were 167,070,944 shares outstanding (119,710,379 shares held by non-affiliates), excl purchased from us and the 1,180,125 shares that we will issue to Fusion Capital as a commitment fee as we receive t are offered hereby were issued and outstanding as of the date hereof, the 18,961,461 shares would represent approxim outstanding, as of the date hereof. The number of shares ultimately offered for sale by Fusion Capital is dependent up

We do not have the right to commence any additional sales of our shares to Fusion Capital until the SEC has decl effective such registration statement, generally we have the right but not the obligation from time to time to se conditions. The registration statement was declared effective on April 4, 2008 and the conditions to commence fundi disclosure contained in the registration statement. We have the right to control the timing and amount of any sales of price of our shares without any fixed discount at the time of each sale. Fusion Capital shall neither have the right n common stock is below $0.10. The agreement may be terminated by us at any time at our discretion without any cost

Purchase of Shares Under the Common Stock Purchase Agreement

Under the common stock purchase agreement, on any trading day selected by us, we may direct Fusion Capital to pur

- the lowest sale price of our common stock on the purchase date; or
- the average of the three lowest closing sale prices of our common stock during the 12 c Fusion Capital.

The purchase price will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock spli may direct Fusion Capital to make multiple purchases from time to time in our sole discretion; no sooner then every th

Minimum Purchase Price

Under the common stock purchase agreement, we have set a minimum purchase price (“floor price”) of $0.10. How stock in the event that the purchase price would be less than the floor price.

| Three months ended | Nine months ended |
|---|---|

Our Right to Increase the Amount to be Purchased

In addition to purchases of up to $80,000 from time to time, we may also from time to time elect on any single bus
provided that our share price is not below $0.15 during the three business days prior to and on the purchase date.
business days prior to and on the purchase date. This amount may also be increased to up to $500,000 if our share pri
also be increased to up to $1.0 million if our share price is not below $1.00 during the three business days prior to and
in our sole discretion; however, at least two business days must have passed since the most recent large purchase wa
will be the lesser of (i) the lowest sale price of our common stock on the purchase date and (ii) the lowest purchase pri

Events of Default

Generally, Fusion Capital may terminate the common stock purchase agreement without any liability or payment to th

- the effectiveness of the registration statement of which this prospectus is a part of lapses fo
stop order) or is unavailable to Fusion Capital for sale of our common stock offered hereb
ten consecutive business days or for more than an aggregate of 30 business days in any 365
- suspension by our principal market of our common stock from trading for a period of three
- the de-listing of our common stock from our principal market provided our common stock
Market, the Nasdaq Capital Market, the New York Stock Exchange or the American Stock
- the transfer agent's failure for five business days to issue to Fusion Capital shares of our
common stock purchase agreement;
- any material breach of the representations or warranties or covenants contained in the co
which has or which could have a material adverse effect on us subject to a cure period of fi
- any participation or threatened participation in insolvency or bankruptcy proceedings by or

Our Termination Rights

We have the unconditional right at any time for any reason to give notice to Fusion Capital terminating the commor
such notice.

No Short-Selling or Hedging by Fusion Capital

Fusion Capital has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling o
agreement.

Effect of Performance of the Common Stock Purchase Agreement on Our Stockholders

All 25,327,778 shares registered in connection with the Fusion Capital transaction are expected to be freely tradable.
a period of up to 12 months from the date of this prospectus. The sale by Fusion Capital of a significant amount of
decline and to be highly volatile. Fusion Capital may ultimately purchase all, some or none of the approximately 18
such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the agreeme
have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 20 million shares
common stock purchase agreement, the 1,388,889 shares underlying the warrant, and the 2,550,000 commitment fo
dependent upon the number of shares purchased by Fusion Capital under the agreement. The following table sets
purchase prices, not including the $632,500 we already received for the sale of 3,816,317 shares:

| Assumed Average Purchase Price | Number of Shares to be Issued if Full Purchase | Percentage of Outstanding Shares After Giving Effect to the Issuance to Fusion Capital (1) |
|---|---|---|
| $0.10(2) | 20,000,000 | 11% |
| $0.25 | 20,000,000 | 11% |

| Three months ended | | Nine months ended |
|---|---|---|
| $0.40 | 20,000,000 | 11% |
| $0.50 | 16,000,000 | 9% |
| $0.60 | 13,333,333 | 7% |

(1) The denominator is based on 167,070,944 shares outstanding as of April 20, 2009, which includes the 5,281,06
The numerator is based on the number of shares issuable under the common stock purchase agreement at the correspo

(2) Closing sale price of our shares on April 20, 2009.

Commitment Shares Issued to Fusion Capital

Unless an event of default occurs, the commitment shares must be held by Fusion Capital until the earlier of (i) 25 m
agreement is terminated.

| Three months ended | Nine months ended |
|---|---|

SELLING STOCKHO

The following table sets forth the number of shares of common stock owned by the selling stockholders as of March some or all of their shares available for sale under this prospectus since March 26, 2008. The following table assume are not making any representation that any shares covered by this prospectus will be offered for sale.

None of the selling stockholders nor any of their affiliates has held a position or office, or had any other material rela with Fusion Capital for the purchase of up to $6 million of our common stock over a 15 month period. Under that period for proceeds of approximately $125,000. That agreement expired pursuant to its terms and we cannot sell any

| Name of Selling Stockholders | Number of Shares of Common Stock Owned Before the Offering (1) | Percent of Common Stock Owned Before the Offering** | Shares Avai Sale Unde Prospectu |
|---|---|---|---|
| Fusion Capital II, LLC (2) | 4,052,778 | 2.4 % | 25 |
| Bernard D. Noble | 377,778 | * | |
| Bear Stearns Corp. Custodian For Lloyd R. Brokaw IRA | 182,000 | * | |
| Little Gem Life Sciences Fund LLC (3) | 120,000 | * | |
| Vasili Myrianthopoulos | 144,611 | * | |
| Steven Mark | 225,000 | * | |
| Robin Mirianthopoulos | 66,667 | * | |
| Joan Orwen | 55,556 | * | |
| IBIS Consulting (4) | 7,500 | * | |
| Numoda Corporation (5) | 347,222 | * | |

* Less than 1%

** Percentage of ownership is based on 167,070,944 shares of common stock outstanding as of April 20, 2009.

(1) As of the date hereof, we have issued 3,816,317 shares of our common stock to Fusion Capital under the comm Capital may acquire up to an additional 18,961,461 shares from purchases under the common stock purchase agree future funding, all of which are included in the offering pursuant to this prospectus.

(2) Steven G. Martin and Joshua B. Scheinfeld, the principals of Fusion Capital, are deemed to be the beneficial own shared voting and disposition power over the shares being offered by Fusion Capital under this prospectus.

(3) Jeffrey Benison is the principal of Little Gem Life Sciences Fund LLC, and is deemed to be the beneficial owne sole voting and sole disposition power over the shares being offered by Little Gem Life Sciences Fund LLC under thi

(4) Dina Lyaskovets is the principal of IBIS Consulting, and is deemed to be the beneficial owner of all of the sha power over the shares being offered by IBIS Consulting under this prospectus.

| Three months ended | Nine months ended |
|---|---|

(5) Mary Schaheen is the principal of Numoda Corporation, and is deemed to be the beneficial owner of all of t
disposition power over the shares being offered by Numoda Corporation under this prospectus.

| Three months ended | Nine months ended |
|---|---|

USE OF PROCE

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the sellin
However, we may receive up to $7,867,500 in proceeds from the sale of our common stock to Fusion Capital unde
potential proceeds from this financing to: (a) initiate and conduct the confirmatory Phase 3 clinical trial in acute GI C
therapeutic indications involving inflammatory conditions of the gastrointestinal tract such as radiation enteritis and C
namely LPMTM-Leuprolide; and (e) potentially acquire or in-license new clinical-stage compounds for development.

Based on our current rate of cash outflows, cash in the bank, and potential proceeds from the Fusion Capital transa
capital expenditures through the third quarter of 2010. If we are not able to sell stock to Fusion Capital under our ex
operations into the third quarter of 2010.

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholders. The common stock may b
through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sal
changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following m

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direc
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through regist
have been registered or qualified for sale in the state or an exemption from the registration or qualification requiremen

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive com
purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particula

One of the selling stockholders, Fusion Capital, is deemed an "underwriter" within the meaning of the Securities Act.

Neither we nor the selling stockholders can presently estimate the amount of compensation that any agent will receive
dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time
forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholders, and any c

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than co
selling stockholders and related persons against specified liabilities, including liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers
against public policy as expressed in the Securities Act and is, therefore, unenforceable.

After the effective date of the registration statement, the selling stockholders, other than Fusion Capital, may engage
securities and may sell or deliver shares in connection with these trades. Fusion Capital and its affiliates have agreed
the common stock purchase agreement.

We have advised the selling stockholders that while they are engaged in a distribution of the shares included in this pr
of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholders, any affiliated pur
purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribu
order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may a

This offering will terminate on the date that all shares offered by this prospectus have been sold by the selling stockho

| Three months ended | Nine months ended |
|---|---|

| Three months ended | Nine months ended |
|---|---|

DESCRIPTION OF SE

Our authorized capital stock consists of 255,000,000 shares of capital stock, of which 250,000,000 shares are comm
200,000 are Series B Convertible Preferred Stock, par value $0.05 per share, and 200,000 shares are Series C Conver
167,070,944 shares of common stock, options to purchase approximately 16,370,039 shares of common stock and wa
the $7,867,500 of common stock that may be issued to Fusion Capital and the 1,180,125 shares of common stock th
financing.

Common Stock

Holders of our common stock are entitled to one vote for each share held in the election of directors and in all
directors. Holders of common stock are entitled to receive dividends as may be declared from time to time by our bo
up of the corporation, holders of common stock are to share in all assets remaining after the payment of liabilities. H
assessments. There are no redemption or sinking fund provisions applicable to the common stock. The rights of
stock. All of the outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our Certificate of Incorporation authorizes the issuance of 4,600,000 shares of preferred stock with designations, r
directors is empowered, without stockholder approval, to designate and issue additional series of preferred stock
securities with no limitations on conversion, which could adversely affect the voting power or other rights of the ho
our common stock. No shares of the Preferred Stock are outstanding.

| Three months ended | Nine months ended |
|---|---|

MARKET FOR COMMON EQUITY AND RELA

Our common stock is quoted on the Over-the-Counter Bulletin Board (“OTCBB”) under the symbol "DORB.” The a
and do not represent the prices of actual transactions.

| Period | High | Price R |
|---|---|---|
| Fiscal Year Ended December 31, 2007: | | |
| First Quarter | $0.71 | |
| Second Quarter | $0.95 | |
| Third Quarter | $0.40 | |
| Fourth Quarter | $0.61 | |
| Fiscal Year Ended December 31, 2008: | | |
| First Quarter | $0.25 | |
| Second Quarter | $0.19 | |
| Third Quarter | $0.15 | |
| Fourth Quarter | $0.12 | |

As of April 20, 2009, the last reported price of our common stock quoted on the OTCBB was $0.10 per share. The O
may not represent actual transactions. We have approximately 1,075 registered holders of record.

Dividend Policy

We have never declared nor paid any cash dividends, and currently intend to retain all our cash and any earnings for
Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be depend
factors as the Board of Directors deems relevant.

| Three months ended | Nine months ended |
|---|---|

DISCLOSURE OF COMMISSION POSITION ON I
ACT LIABILIT

Section 102(b)(7) of the Delaware General Corporation Law allows companies to limit the personal liability of its di
IX of the Company's Certificate of Incorporation, as amended, provides for the limitation of personal liability of the d

"A Director of the Corporation shall have no personal liability to the Corporation or its stockholders for monetary da
limit the liability of a Director (i) for any breach of the Director's duty of loyalty to the Corporation or its stockho
violation of law; (iii) for the unlawful payment of dividends or unlawful stock repurchases under Section 174 of the
derived an improper personal benefit. If the General Corporation Law is amended after approval by the stockhold
directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted

Article VIII of the Company's Bylaws, as amended and restated, provide for indemnification of directors and officers

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, off
informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is th

EXPERTS

The audited consolidated financial statements of DOR BioPharma, Inc. and subsidiaries included in the Registrati
independent registered public accounting firm, for the year ended December 31, 2007 and by Amper, Politziner & M
set forth in their reports appearing herein. Such financial statements have been so included in reliance upon the report

LEGAL MATTE

The validity of the shares of our common stock offered by the selling stockholders will be passed upon by the law firm

| Three months ended | Nine months ended |
|---|---|

INDEX TO FINANCIAL S

DOR BIOPHARMA, Inc. AND

CONSOLIDATED FINANCIA

Table of Conte

Page

| Three months ended | Nine months ended |
|---|---|

REPORT OF INDEPENDENT REGISTERED

To the Board of Directors of DOR BioPharma, Inc.,

We have audited the accompanying consolidated balance sheet of DOR BioPharma, Inc. and subsidiaries as of Dece
cash flows for the year ended December 31, 2007. These consolidated financial statements are the responsibility of
statements based on our audits.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (U.S.). T
the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis,
includes assessing the accounting principles used and significant estimates made by management, as well as evaluati
our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the con
its cash flows for the year ended December 31, 2007, in conformity with U.S. generally accepted accounting principl

/s/ Sweeney, Matz & Co., LLC

Fort Lauderdale, Florida
March 8, 2008

| Three months ended | Nine months ended |
|---|---|

REPORT OF INDEPENDENT REGISTERED

To the Board of Directors of DOR BioPharma, Inc.,

We have audited the accompanying consolidated balance sheet of DOR BioPharma, Inc. and subsidiaries as of Dece
cash flows for the year ended December 31, 2008. These consolidated financial statements are the responsibility of
statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (Un
about whether the financial statements are free of material misstatement. The Company is not required to have, nor
consideration of internal control over financial reporting as a basis for designing audit procedures that are appropr
Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also include
assessing the accounting principles used and significant estimates made by management, as well as evaluating the
opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the con
its cash flows for the year ended December 31, 2008, in conformity with U.S. generally accepted accounting principl

/s/ Amper, Politziner & Mattia, LLP

Edison, New Jersey
March 27, 2009

| Three months ended | Nine months ended |
|---|---|

DOR BioPharma
Consolidated Balanc
December 31

| |
|---|
| Assets |
| Current assets: |
| Cash and cash equivalents |
| Grants receivable |
| Inventory, net |
| Prepaid expenses |
| Total current assets |
| |
| Office and laboratory equipment, net |
| Intangible assets, net |
| Total assets |
| |
| Liabilities and shareholders' equity |
| Current liabilities: |
| Accounts payable |
| Accrued compensation |
| Total current liabilities |
| |
| Commitments and contingencies |
| |
| Shareholders' equity: |
| Common stock, $.001 par value. Authorized 250,000,000 |
| shares; 118,610,704 and 94,996,547, respectively issued and outstanding |
| Additional paid-in capital |
| Accumulated deficit |
| Total shareholders' equity |
| |
| Total liabilities and shareholders' equity |

The accompanying notes are an integral par

| Three months ended | Nine months ended |
|---|---|

DOR BioPharma
Consolidated Statements
For the years ended De

| |
|---|
| Revenues |
| Cost of revenues |
| Gross profit |
| |
| Operating expenses: |
| Research and development |
| General and administrative |
| Stock based compensation research and development |
| Stock based compensation general and administrative |
| Total operating expenses |
| |
| Loss from operations |
| |
| Other income (expense): |
| Interest income |
| Interest (expense) |
| Other (expense) |
| Total other income (expense) |
| |
| Net loss |
| |
| BasicnBasic and diluted net loss per share |
| |
| Basic Basic and diluted weighted average common shares outstanding |

The accompanying notes are an integral pa

| Three months ended | Nine months ended |
|---|---|

DOR BioPharma
Consolidated Statements of Changes in Sha
For the years ended December

| | Common Stock | |
|---|---|---|
| | Shares | Par Value |
| Balance, January 1, 2007 | 68,855,794 | $68,855 |
| Issuance of common stock | 15,745,891 | 15,746 |
| Issuance of common stock upon exercise of options and warrants | 8,195,487 | 8,195 |
| Issuance of common stock to vendors | 829,821 | 830 |
| Issuance of common stock to investors by contract as dilution protection | 995,947 | 996 |
| Issuance of common stock as payment to employees | 373,607 | 374 |
| Stock option expense | - | - |
| Net loss | - | - |
| Balance, December 31, 2007 | 94,996,547 | $94,996 |
| Issuance of common stock from private placement | 3,658,890 | 3,659 |
| Issuance of common stock for commitment shares | 1,369,125 | 1,369 |
| Issuance of common stock for execution of letter of intent | 16,666,667 | 16,667 |
| Issuance of common stock for equity line | 993,084 | 993 |
| Issuance of common stock to vendors | 758,082 | 758 |
| Issuance of common stock as payment to employees | 168,309 | 168 |
| Stock option expense | - | - |
| Net loss | - | - |
| Balance, December 31, 2008 | 118,610,704 | $118,610 |

| Three months ended | Nine months ended |
|---|---|

The accompanying notes are an integral par

| Three months ended | Nine months ended |
|---|---|

DOR BioPharma
Consolidated Statements o
For the years ending De

| | |
|---|---|
| Operating activities | |
| Net loss | |
| | |
| Adjustments to reconcile net loss to net cash used by operating activities: | |
| Amortization and depreciation | |
| Inventory reserve | |
| Non-cash stock compensation | |
| | |
| Change in operating assets and liabilities: | |
| Grants receivable | |
| Inventory | |
| Prepaid expenses | |
| Accounts payable | |
| Accrued compensation | |
| Total adjustments | |
| | |
| Net cash used by operating activities | |
| | |
| Investing activities: | |
| Purchases of office and laboratory equipment | |
| Acquisition of intangible assets | |
| Net cash used by investing activities | |
| | |
| Financing activities: | |
| Net proceeds from issuance of common stock | |
| Proceeds from equity line | |
| Proceeds from exercise of warrants | |
| Proceeds from exercise of stock options | |
| Net cash provided by financing activities | |
| | |
| Net increase (decrease) in cash and cash equivalents | |
| Cash and cash equivalents at beginning of period | |
| Cash and cash equivalents at end of period | |
| | |
| Supplemental disclosure of cash flow: | |
| Cash paid for interest | |
| Non-cash transactions: | |
| Issuance of commitment shares | |
| Issuance of shares for anti-dilution | |

The accompanying notes are an integral par

| Three months ended | Nine months ended |
|---|---|



1. Nature of Business

Basus of Presentations

The Company is a late stage biopharmaceutical company incorporated in 1987, focused on the development of biotherapeutic business segment intends to develop orBec®, oral BDP, and other biotherapeutic products namely LPI and anthrax vaccine programs from early stage development to advanced development and manufacturing.

During the 12 months ended December 31, 2008, the Company had two customers, the U.S. Federal Government and Australia, through a Named Patient Access Program ("NPAP") for orBec®. Revenues from the U.S. Federal Governm the U.S. Federal Government, the National Institutes of Health and The U.S. Food and Drug Administration and Orph

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, li protections of proprietary technology, and compliance with FDA regulations.

Liquidity

As of December 31, 2008, the Company had cash of $1,475,466 as compared to $2,220,128 as of December 31, 20 capital of $1,243,638 as of December 31, 2007, representing a decrease of $706,455.

As of February 28, 2009, the Company had cash of approximately $7,100,000. The increase was the result of the sal million from the sale of the Company's common stock to accredited investors. For the 12 months ended December $6,000,000 for the corresponding period ended December 31, 2007, reflecting both an increase in grant revenues and raising funding and regulatory progress. The Company continues to use equity instruments to provide a portion of the in the future.

Based on the Company's current rate of cash outflows and cash in the bank, the Company believes that its current ca the third quarter of 2010. The Company has $2.0 million in grant funding still available to support its programs in 20 submitted for government funding.

Management's plan is as follows:

The Company is exploring out-licensing opportunities for orBec® and oral BDP in territories outside N programs in the United States and in Europe.

The Company has and will utilize NPAPs wherever possible in countries outside the United States to ge

The Company intends to utilize its existing $8 million equity line of credit with Fusion Capital (ap Company through June 2010) when it deems market conditions to be appropriate.

The Company expects to receive new government grants intended to support existing and new research research and development funding, these grants would provide additional support for its overhead ex portions of its upcoming confirmatory Phase 3 trial of its lead product orBec®. Therefore these grants Company routinely files for government grants which support its biotherapeutic and biodefense program

The Company may obtain additional funds through the issuance of equity or equity-linked securities thr is currently evaluating additional equity financings opportunities and will continue to execute them when

It is possible that the Company will seek additional capital in the private and/or public equity markets to continue its strategic partnerships.

In the event that such growth is less than forecasted in our 2009-2010 operating plan, management has developed assurance that the Company will be able to maintain adequate liquidity to allow the Company to continue to operate it

| Three months ended | Nine months ended |
|---|---|

| Three months ended | Nine months ended |
|---|---|

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include DOR BioPharma, Inc., and its wholly and majority owned subsidiaries
a result of consolidation.

Segment Information

Operating segments are defined as components of an enterprise about which separate financial information is availabl
deciding how to allocate resources to an individual segment and in assessing the performance of the segment.

Grants Receivable

Receivables consist of unbilled amounts due from grants from the National Institute of Health of the U.S. Federal G
period end and collected shortly thereafter. The Company considers the grants receivable to be fully collectible; acco
are charged to operations.

Intangible Assets

One of the most significant estimates or judgments that the Company makes is whether to capitalize or expense pater
future uses, as defined in SFAS 2, “Accounting for Research and Development Costs”. Based on this consideration, al

The Company capitalizes and amortizes intangibles over a period of 11 to 16 years. The Company capitalizes payme
for our current products in both the domestic and international markets. The Company believes that patent rights a
property, especially in the early stage of product development, as their purchase and maintenance gives the Company
also be sold or sub-licensed as part of its strategy to partner its products at each stage of development. The legal costs
lives of the patents. Therefore, DOR capitalizes these costs and amortizes them over the remaining useful life of the p

The Company capitalized $237,113 and $356,192 in patent related costs during the year ended December 31, 2008
statements, in the section for investing activities presented in the financial statements. On the balance sheet as of Dec
the amount of $1,418,717 and $1,320,787, respectively.

Impairment of Long-Lived Assets

Office and laboratory equipment and intangible assets are evaluated and reviewed for impairment whenever events
recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future
is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between
involve significant judgment.

The Company did not record an impairment of intangible assets for the 12 months ended December 31, 2008 or 2007.

Inventory

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out (“FIFO”) method
inventory. For the three months ended December 31, 2008 an allowance of $100,000 was provided. This allowance
period is finished goods and consists of orBec® treatments.

Fair Value of Financial Instruments

Accounting principles generally accepted in the U.S. require that fair values be disclosed for the Company’s fina
receivable and current liabilities, are considered to be representative of their respective fair values.

Revenue Recognition

The Company’s revenues are from government grants and NPAP sales of orBec® from Orphan Australia. The re
specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expens
internal expenses that are related to the grant. The revenues from the NPAP sales of orBec® are recognized when the

| Three months ended | Nine months ended |
|---|---|

Research and Development Costs

Research and Development costs are charged to expense when incurred. Research and development includes costs s
use, supplies and materials, salaries and employee benefits, equipment depreciation and allocation of various corporat

| Three months ended | Nine months ended |
|---|---|

Stock Based Compensation

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing mo volatility of 115% and 99% in 2008 and 2007, respectively, and average risk-free interest rates of 1.1% and 4.5% in been historically available. The fair value of each option grant at the 12 months ended December 31, 2008 and Decer amortized ratably over the option's vesting periods. The Company awarded 6,800,000 stock options for the 12 mor December 31, 2007. The weighted average fair value of options granted with an exercise price equal to the fair m respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options tha vest. The option's price is re-measured using the Black-Scholes model at the end of each three month reporting period

As stock options are exercised, common stock share certificates are issued via electronic transfer or physical share equity incentive plan and increase the number of shares the Company has outstanding.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between t valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will Company's current and past performance, the market environment in which the Company operates, the utilization measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences a December 31, 2008 due to the net operating losses incurred by the Company since its inception. Additionally, the Cor

Basic earnings per share

Earnings Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income available to common stockh the potential dilution that could occur if securities or other contracts to issue common stock were exercised or conv entity. Since there is a large number of options and warrants outstanding, fluctuations in the actual market price can ha

A reconciliation of the applicable numerators and denominators of the income statement periods presented is as follow

| | Year Ended December 31, 2008 | | |
|---|---|---|---|
| | Loss | Shares | EPS |
| Basic EPS Dilutives: | ($3.42) | 101.88 | ($0.03) |
| Options and Warrants | - | - | - |
| Diluted EPS | ($3.42) | 101.88 | ($0.03) |

Options and warrants outstanding at December 31, 2008 and 2007 were 16,370,039 and 10,349,839 options, and 20, 2007 computations of diluted earnings because the effect would be anti-dilutive due to losses in the respective years.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. req statements and accompanying notes. Actual results could differ from those estimates.

New Accounting Pronouncements

In February 2007, the FASB issued SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabil liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are rep 2008 the Company adopted SFAS 159 to determine the fair value on its financial assets and financial liabilities. This or cash flows.

EITF 07-05, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock," Hedging Activities," as to whether or not a derivative is indexed to an entity's own stock. EITF 07-05 will require ma

| Three months ended | Nine months ended |
|---|---|

for as equity. EITF 07-05 becomes effective for fiscal years, including those interim periods, beginning after Dec applicable to all instruments outstanding at the beginning of the period of adoption. The Company is currently evalua

In December 2007, the FASB issued SFAS No. 141(R), “Business Combinations” (“SFAS 141(R)”). This Statemen the acquiring entity in a business combination to recognize all assets acquired and liabilities assumed in the transac liabilities assumed, and requires the acquirer to disclose the nature and financial effect of the business combination. T

In December 2007, the FASB issued SFAS No. 160, “Non-controlling Interests in Consolidated Financial Stateme Statements, to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for impact on the Company’s consolidated financial position, results of operations or cash flows.

In January 2008, the Company adopted the provisions of SFAS No. 157, “Fair Value Measurements,” for financial as in generally accepted accounting principles, and expands disclosures about fair value measurements. The company v recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), in accordanc FASB Statement No. 157,” until January 2009.

In May 2008, the FASB issued SFAS No. 162, "The Hierarchy of Generally Accepted Accounting Principles". SFAS used in the preparation of financial statements of nongovernmental entities that are presented in conformity with gen 2008. The adoption of this statement did not have a material effect on the Company's financial statements.

| Three months ended | Nine months ended |
|---|---|

3. Office and Laboratory Equipment

Office and laboratory equipment are stated at cost. Depreciation is computed on a straight-line basis over five years. C

| | 2008 |
|---|---|
| Office equipment | |
| Laboratory equipment | |
| Total | |
| Accumulated depreciation | |
| | |

Depreciation expense was $10,001 and $10,781 for the years ended December 31, 2008 and 2007.

4. Intangible Assets

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

| | Weighted Average Amortization period (years) |
|---|---|
| December 31, 2008 | |
| Licenses | 11.7 |
| Patents | 9.0 |
| Total | 9.5 |
| | |
| December 31, 2007 | |
| Licenses | 12.7 |
| Patents | 9.7 |
| Total | 10.4 |

Amortization expense was $139,183 in 2008 compared to $108,784 for 2007.

Based on the balance of licenses and patents at December 31, 2008, the annual amortization expense for each of the su

| Year |
|---|
| 2009 |
| 2010 |
| 2011 |
| 2012 |
| 2013 |

License fees and royalty payments are expensed annually as incurred as the Company does not attribute any future be

5. Inventory

In the third quarter of 2008, the Company purchased and recorded inventory for the first time, because of the dev
time. Inventory consists of finished goods. For the 12 month period ended December 31, 2008 the Company also rec

| Three months ended | Nine months ended |
|---|---|

6. Income Taxes

Deferred tax assets as of December 31:

| | |
|---|---|
| Deferred tax assets: | |
| Net operating loss carry forwards | |
| Orphan drug and research and development credit carry forwards | |
| Other | |
| Total | |
| Valuation allowance | |
| Net deferred tax assets | |

At December 31, 2008, the Company had net operating loss carry forwards of approximately $76,000,000 for Feder
Company had $2,000,000 of various tax credits that start expiring from December 2009 to December 2028
liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 38
50 percentage points. In addition, the NOL carryforwards are subject to examination by the taxing authority and c
Section 382 analysis, it is possible that the utilization of the NOLs may be limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and vari
before 2004. However, since the Company has incurred net operating losses in every tax year since inception, all its
purposes of determining the amount of net operating loss carryforward that can be used to reduce taxable income.

The net change in the valuation allowance for the year ended December 31, 2008 and December 31, 2007 was an inc
net operating losses generated. As a result of the Company's continuing tax losses, the Company has recorded a full v

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and

| | |
|---|---|
| Income tax loss at federal statutory rate | |
| State taxes, net of federal benefit | |
| Valuation allowance | |
| Provision for income taxes (benefit) | |

Effective January 1, 2007, the Company adopted Financial Interpretation ("FIN") No. 48, Accounting for Uncert
recognition threshold and measurement attribute for the financial statement recognition and measurement of a t
consolidated financial statements.

| Three months ended | Nine months ended |
|---|---|

7. Shareholders' Equity

Preferred Stock

The Company has 5 million authorized shares of preferred stock, none are issued or outstanding.

Common Stock

During the 12 months ended December 31, 2008, the Company issued 758,082 shares of common stock as payment t
fair market value on the date of issuance, respectively.

During the 12 months ended December 31, 2008 the Company also issued 993,084 shares of common stock un
approximated the shares' fair market value on the date of issuance.

During the 12 months ended December 31, 2008, the Company issued 168,309 shares of common stock as compensa
fair market value on the date of issuance.

On December 1, 2008, the Company entered into a non-binding letter of intent with Sigma-Tau, which granted Sigm
alliance regarding orBec® and potentially other pipeline compounds until March 1, 2009. Under the terms of the lett
of $0.09 per share, representing 16,666,667 shares.

On February 14, 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II,
purchase between $80,000 and $1.0 million every two business days, of the Company's common stock up to an aggre
quoted market price of the Company's common stock on such date. As part of the agreement, the Company issued Fu
the common stock purchase agreement, Fusion Capital made an initial purchase of 2,777,778 common shares and
aggregate price of $500,000. The Company issued an additional 75,000 shares of common stock as a commitment fee
required to be purchased may be increased under certain conditions as the price of the Company's common stock in
stock on any trading days that the market price of the Company's common stock is less than $0.10 per share. Furtherm
to a total of 1,275,000 shares will be issued based upon the relative proportion of such purchases compared to the agg

On February 14, 2008, the Company sold 881,112 shares of its common stock to an institutional and other accredited
warrants to purchase an aggregate of 440,556 shares of our common stock at an exercise price of $0.22 per share.

The total issuance of common stock from private placement for 2008 was 3,658,890; which consisted of the 881,
2,777,778 for $500,000.

The total issuance of common stock for commitment shares for 2008 was 1,369,125; which were issued to Fusion
invested, and 19,125 for the commitment fee shares on the purchase of $127,500 by Fusion Capital.

During the year ended December 31, 2007, the Company issued 829,821 shares of common stock as payment to ven
market value on the date of issuance.

During 2007 the Company issued 373,607 shares of common stock as part of severance payments to employees.
issuance.

For the 12 months ended December 31, 2007, 1,737,200 stock options were exercised to purchase shares of common s

For the 12 months ended December 31, 2007, 6,458,287 common stock warrants were exercised to purchase of comm

The total issuance of common stock upon exercise of options and warrants for 2007 was 8,195,487; which consisted o

On February 9, 2007, the Company sold 11,680,850 shares of its common stock to institutional investors and certain o

On January 3, 2007, in consideration for entering into an exclusive letter of intent, Sigma-Tau agreed to purchase $1,
shares of common stock, and contributed an additional $2 million in cash. The $2 million contribution was to be co
pursuant to any future orBec® commercialization arrangement reached between the two parties. Because of this tran
$0.246. Additionally, certain shareholders in that placement who still held shares of the Company's common stock
common stock and the Company recorded dilution expense of $308,743. Additionally. The dilutive nature of the
placement had their warrants repriced to $0.246. Neither these investors, nor any others for that matter, hold any fu

| Three months ended | Nine months ended |
|---|---|

return the $2 million to Sigma-Tau by April 30, 2007 and on June 1, 2007, the Company returned the $2 million to Si

The total issuance of common stock from private placement for 2007 was 15,745,891; which consisted of the 11,86
$254,596 payable as placement agent fees, and to 4,065,041 to Sigma-Tau for $1,000,000.

| Three months ended | Nine months ended |
|---|---|

8. Stock Option Plans and Warrants to Purchase Common Stock

Stock Options

The 2005 Equity Incentive Plan is divided into four separate equity programs: 1) the Discretionary Option Grant Pro
stock or granted options to purchase shares of common stock, 2) the Salary Investment Option Grant Program, under
purchase shares of common stock, 3) the Automatic Option Grant Program, under which eligible nonemployee Boar
and 4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, o
addition under the plan the Board may elect to pay certain consultants, directors, and employees in common stock.
20,000,000. The table below only accounts for transactions occurring as part of the amended 2005 Equity Incentive Pl

December 31,

| | |
|---|---|
| Shares available for grant at beginning of year | |
| Increase in shares available | |
| Options granted | |
| Options forfeited or expired | |
| Common stock payment for services | |
| Shares available for grant at end of year | |

The Amended and Restated 1995 Omnibus Plan is divided into four separate equity programs: 1) the Discretionary
granted options to purchase shares of common stock, 2) the Salary Investment Option Grant Program, under whic
purchase shares of common stock, 3) the Automatic Option Grant Program, under which eligible nonemployee Boar
and 4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or a

In 2008 there were no stock option exercises. In 2007, 1,487,200 stock options were exercised under the 1995 pla
exercises.

The total option activity for the 1995 plan and the amended 2005 plan for the years ended December 31, 2008 and 200

| | |
|---|---|
| Balance at January 1, 2007 | |
| Granted | |
| Forfeited | |
| Exercised | |
| Balance at December 31, 2007 | |
| Granted | |
| Forfeited | |
| Balance at December 31, 2008 | |

| Three months ended | Nine months ended |
|---|---|

The weighted-average exercise price, by price range, for outstanding options at December 31, 2008 was:

| Price Range | Weighted Average Remaining Contractual Life in Years |
|---|---|
| $0.06-$0.20 | 9.8 |
| $0.22-$0.49 | 7.3 |
| $0.50-$4.00 | 2.9 |
| Total | 8.2 |

Intrinsic Value -

Stock options are issued at the market price on the date of issuance. Stock options issued to directors are fully vested
period of three years. Stock options vest over each three month period from the date of issuance to the end of the thre
In general when an employee or director terminates employment the options will expire within six months.

The intrinsic value was zero and was calculated as the difference between the Company's common stock closing price
number of stock options. The Company's common stock price at December 31, 2008 was $0.06.

The Company's share-based compensation for the 12 months ended December 31, 2008 and 2007 was $385,616 and
Research and Development personnel and $203,448 was for General and Administrative personnel. For the same pe
for General and Administrative personnel. At December 31, 2008, the total compensation cost for stock options not ye

From time to time, the Company grants warrants to consultants and grants warrants to purchase common stock in con
zero shares, respectively, and resulted in expense charges of $21,000 and zero, respectively.

Warrants to purchase common stock

Warrant activity for the years ended December 31, 2008 and 2007 was as follows:

| | |
|---|---|
| Balance at January 1, 2007 | |
| Granted | |
| Expired | |
| Exercised | |
| Balance at December 31, 2007 | |
| Granted | |
| Expired | |
| Balance at December 31, 2008 | |

During 2009, warrants to purchase approximately 10,500,000 of the Company's common stock will expire.

The weighted-average exercise price, by price range, for outstanding warrants at December 31, 2008 was:

| Price Range | Weighted Average Remaining Contractual Life in Years |
|---|---|
| $0.06-$0.25 | 0.8 |
| $0.26-$0.51 | 1.6 |
| $0.52-$0.88 | 1.2 |
| Total | 1.1 |

| Three months ended | Nine months ended |
|---|---|

9. Concentrations

At December 31, 2008 and 2007, the Company had deposits in financial institutions that exceeded the amount un
$1,000,000 by the SIPC. The excess amounts at December 31, 2008 and December 31, 2007 were approximately, $47

10. Commitments and Contingencies

The Company has commitments of approximately $5.6 million at December 31, 2008 in connection with a collabor
orBec® that will began in November 2008 and is expected to continue through November 2010.

The Company has several licensing agreements with consultants and universities, which upon clinical or commercia
there can be no assurance that clinical or commercialization success will occur.

Certain operating leases for office and warehouse space maintained by the Company resulted in rent expense for the y

The Company has approximate future obligations over the next five years as follows:

| Year | Research and Development | Property and Other Leases |
|---|---|---|
| 2009 | $3,300,000 | $92,000 |
| 2010 | 2,900,000 | 95,000 |
| 2011 | 200,000 | 96,000 |
| 2012 | 200,000 | 105,000 |
| 2013 | 200,000 | 115,000 |
| Total | $6,800,000 | $503,000 |

On February 2007, the Company's Board of Directors authorized the issuance of the following shares to Dr. Schaber
transaction, or series or a combination of related transactions negotiated by the Company's Board of Directors w
transferred from the Company and/or its stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 7
employees and a consultant shall be issued.

Employees with employment contracts have severance agreements that will provide separation benefits from the Com

11. Subsequent Events

On April 1, 2009, the Company moved into office space in Princeton, New Jersey. The Company entered into a sub-l
deposit, the rent for the first 18 months will be $7,437.50 per month, or $17.00 per square foot. This increases to $7,6

On March 12, 2009, the Company entered into a two-year employment agreement with Dr. Hamilton. Pursuant to th
After one year of service Dr. Hamilton would be entitled to a minimum annual bonus of $70,000. The Company agre
three years. All vested options shall be exercisable for a period of one year following termination, subject to exte
acquisition, all of Dr. Hamilton's options shall become fully vested, and be exercisable for a period of three years aft
his death during term of the agreement, all of his unvested options shall immediately vest and remain exercisabl
termination without "Just Cause" as defined by this agreement, the Company would pay Dr. Hamilton six months sev
bonuses and accrued vacation would become payable.

On March 6, 2009, the Company entered into a $400,000 common stock equity investment agreement priced at mark
will be completed in January 2010. The investment follows and enhances the collaboration between the Company
collaboration agreement.

On February 11, 2009, the Company entered into a collaboration and supply agreement with Sigma-Tau for the
commercialize orBec® in the U.S., Canada and Mexico (the Territory). Sigma-Tau is obligated to make payments up
$1 million payment, will be made upon the enrollment of the first patient in the Company's confirmatory Phase 3 clin
2009. Total milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $10 mil
commercialization expense, including launch activities.

In connection with the execution of the collaboration and supply agreement, the Company entered into a common
common stock to Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price is equal to
five trading days prior to February 11, 2009. As part of the transaction, the Company granted Sigma-Tau certain dema

| Three months ended | Nine months ended |
|---|---|

On January 20, 2009, the Company received $2,384,200 from the completed private placement of common stock a
common shares together with five year warrants to purchase up to 20,914,035 shares of the Company’s common sto
expiration date of the warrants can be accelerated if the Company's common stock meets certain price thresholds a
exercised.

| | Three months ended | | Nine months ended |
|---|---|---|---|

12. Business Segments

The Company had two active segments for the year ended December 31, 2008 and December 31, 2007: BioDefense a

| |
|---|
| Net Revenues |
| BioDefense |
| BioTherapeutics |
| Total |
| |
| Loss from Operations |
| BioDefense |
| BioTherapeutics |
| Corporate |
| Total |
| |
| Identifiable Assets |
| BioDefense |
| BioTherapeutics |
| Corporate |
| Total |
| |
| Amortization and Depreciation Expense |
| BioDefense |
| BioTherapeutics |
| Corporate |
| Total |
| |
| Interest Income |
| Corporate |
| Total |
| |
| Stock Option Compensation |
| BioDefense |
| BioTherapeutic |
| Corporate |
| Total |
| |

| Three months ended | Nine months ended |
|---|---|