**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, DC 20549**

---

# FORM 8-K

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

Date of report (Date of earliest event reported): October 22, 2003

# Nabi Biopharmaceuticals

(Exact name of registrant as specified in its charter)

| **Delaware** | **000-04829** | **59-1212264** |
|---|---|---|
| State or other jurisdiction of incorporation | Commission File Number | IRS Employer Identification No. |

**5800 Park of Commerce Boulevard N.W., Boca Raton, FL 33487**
(Address of principal executive offices) (Zip code)

**(561) 989-5800**
(Registrant's telephone number, including area code)

**Item 12. Results of Operations and Financial Condition**

On October 22, 2003, Nabi Biopharmaceuticals ("The Company") issued a press release announcing its financial results for the three and nine months ended September 27, 2003. A copy of the press release is furnished as Exhibit 99 to this report.

The press release includes disclosure of earnings before interest, taxes, depreciation and amortization ("EBITDA"), a non-GAAP financial measure. Pursuant to Regulation G, the Company has provided a presentation of net income, the most directly comparable GAAP financial measure, and a reconciliation of the differences between EBITDA and net income. The Company's management believes that presentation of EBITDA provides useful information to investors regarding the Company's financial condition and results of operations because it is a measure of sustainable operating cash flow used by many investors to assess the Company's profitability from current operations. In particular, EBITDA is important in addressing the Company's financial ability to support its research and development efforts. However, this measure should be considered in addition to, not as a substitute for, or superior to, net income, or other measures of financial performance prepared in accordance with generally accepted accounting principles.

**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 hereunto duly authorized.

**Nabi Biopharmaceuticals**

Date: October 22, 2003

By: /s/ Mark L. Smith

**Mark L. Smith**
Senior Vice President, Finance, Chief Financial Officer, Chief Accounting Officer and Treasurer

**EXHIBIT 99**

[NABI BIOPHARMACEUTICALS LOGO]

Contact:
Mark Soufleris
VP, Investor and Public Relations
(561) 989-5800

## FOR IMMEDIATE RELEASE

**NABI BIOPHARMACEUTICALS REPORTS FINANCIAL RESULTS FOR THE THIRD QUARTER OF 2003**
**— Record Biopharmaceutical Revenues Driven by PhosLo® and WinPho® Sales**

**Boca Raton, Florida October 22, 2003** – Nabi Biopharmaceuticals (Nasdaq: NABI) today announced its financial results for the third quarter ended September 27, 2003. For the third quarter of 2003, the company reported net income of $2.2 million, or $0.05 per share on total sales of $42.4 million. Significantly, Nabi Biopharmaceuticals generated earnings before interest, taxes, depreciation and amortization of $7.6 million in the third quarter to support investment in future research and development activities. For the nine months ended September 27, 2003, the company reported a net loss of $0.3 million, or $0.01 per share on total sales of $128.6 million.

“Nabi Biopharmaceuticals accomplished significant advances on several fronts during the third quarter, both in commercial operations and in product development activities. These accomplishments have redefined us as a company,” stated Mr. Thomas H. McLain, chief executive officer and president, Nabi Biopharmaceuticals. “We realized record sales in our biopharmaceutical business. We are particularly pleased with the successful launch of PhosLo and its positive reception in the marketplace. In line with our goal to rapidly advance StaphVAX toward launch, we signed a manufacturing agreement with Cambrex BioScience, and plan to submit our first license application for the product in Europe by the end of 2004, two years ahead of schedule. In the U.S., we initiated a confirmatory phase III trial for StaphVAX and made significant progress with our other pipeline products. We anticipate continued growth in our biopharmaceutical products business, which will strengthen our cash position and fund our product pipeline.”

The positive financial results in the third quarter were driven by record biopharmaceutical product sales totaling $30.7 million, an increase of $9.0 million or more than 40% from the 2002 period. Biopharmaceutical product sales benefited from initial sales of PhosLo® (calcium acetate), which was acquired on August 4, 2003, as well as continued growth in sales of WinRho SDF® [Rho (D) Immune Globulin Intravenous (Human)] and higher sales of Nabi-HB® [Hepatitis B Immune Globulin (Human)] in the third quarter.

*(more)*

**Recent Developments**

- In October, the company announced the acceleration of its commercialization plans for StaphVAX. *(Staphlyococcus aureus Polyraccharide Conjugate Vaccine)* Based on the outcome from meetings in Europe with several key regulatory authorities, the company plans to file its first license application for StaphVAX in Europe by the end of 2004. In conjunction with this development, the company announced that it had signed a manufacturing agreement for StaphVAX with a term of up to ten years with Cambrex Bio Science Baltimore, Inc., a subsidiary of Cambrex Corporation, which includes support for the company's regulatory filing in Europe. At the same time, the company announced that it had ended its relationship with Dow Biopharmaceutical Contract Manufacturing Services ("Dow") and will write off costs it has capitalized in prior periods related to the right to manufacture StaphVAX at Dow's facility. The company will record a non-cash charge of approximately $13 million in the fourth quarter of 2003 related to this write off.

- In September 2003, Nabi Biopharmaceuticals initiated the confirmatory phase III trial for StaphVAX in the US ahead of schedule. The trial, which is planned to be conducted with three leading dialysis providers, will be comprised of approximately 3,000 end-stage renal (kidney) disease ("ESRD") patients on hemodialysis in approximately 200 sites across the US. The primary endpoint of the trial will be the incidence of blood stream infections (bacteremia) caused by types 5 and 8 Staph aureus through eight months post-vaccination, the point of peak efficacy in the first phase III study. Because these patients are at chronic risk for Staph aureus infections, the trial will also include a booster vaccination at eight months. Secondary endpoints for this trial will include the incidence of Staph aureus bacteremia at 6, 10, 12 and 14 months, as well as the cost of infections that occur during the study.

- In September 2003, the company completed a clinical trial to evaluate the immunogenicity of a lot of StaphVAX manufactured in a contract manufacturer's facility. Material from this lot is being used in the confirmatory phase III trial. This open label, single dose trial in 40 healthy volunteers, demonstrated that this lot of vaccine was safe and generated antibody levels at least as high as those generated from vaccine manufactured at the company's research and development pilot plant. The trial result was an important proof of concept that the company can successfully transfer and scale-up production of StaphVAX in a commercial manufacturing facility.

- In September 2003, results of two pharmacoeconomic studies illustrating the substantial costs and illness suffered by ESRD patients who develop Staph aureus bacteremia were presented at the 43rd annual Interscience Conference on Antimicrobial Agents and Chemotherapy ("ICAAC"). These studies concluded that charges for treating serious Staph aureus bacteremia total approximately $32,000 per patient and the mortality associated with these infections ranges from 10% to more than 45%. The company sponsored these studies which were conducted by the Duke University Medical Center.

- In August 2003, Nabi Biopharmaceuticals submitted supplemental data and information to the FDA on its Nabi-HB Intravenous BLA filed for an indication to prevent hepatitis B disease in liver transplant recipients who are positive for hepatitis B virus.

- In August 2003, the company initiated its phase II clinical trial of NicVAX™ (Nicotine Conjugate Vaccine), its proprietary vaccine in development to prevent and treat nicotine addiction, being conducted in the US. This randomized, double-blinded, placebo-controlled study will evaluate nicotine specific antibody levels, trends in smoking habits during the trial, safety and tolerability. The trial was fully enrolled by the end of the third quarter. Results from this trial are anticipated in the second half of 2004.

- On August 4, 2003, the company completed the acquisition of the worldwide rights to PhosLo from Braintree Laboratories, Inc. Nabi Biopharmaceuticals acquired the rights to PhosLo for a payment of $60 million cash and the issuance of 1.5 million shares of common stock at closing and the issuance of an obligation to pay $30 million cash over the period ending March 1, 2007. PhosLo is indicated for the treatment of hyperphosphatemia for patients with kidney failure. To help fund the acquisition of PhosLo, the company completed private placements totaling 5,577,000 shares of its common stock to selected new and current institutional shareholders and received net proceeds of $31.3 million in July.

*(more)*

- In July 2003, Nabi Biopharmaceuticals began phase II clinical testing of Altastaph™ [*Staphlyococcus aureus Immune Globulin Intravenous (Human)*] in very low birth weight neonates (newborn infants weighing between 500 and 1,500 grams). This multi-center, randomized, double-blinded, placebo-controlled study is being conducted at 20 leading neonatology centers throughout the US. It has been designed to measure safety and Staph aureus antibody levels, as well as to help define endpoints for an expected phase III clinical study in the same patient population.

**Review of Operations**

Initial sales of PhosLo totaled $5.0 million in the third quarter. These sales reflect the success of the company's initial product launch activities. Nabi Biopharmaceuticals will re-launch PhosLo in January 2004, utilizing the new K/DOQI guidelines for the use of phosphate binders and the presentation of clinical data at the November 2003 American Society of Nephrologists meeting.

Sales of WinRho SDF were $13.5 million in the third quarter of 2003 compared to $12.2 million in the comparable quarter of 2002, an increase of 11%. This strong sales growth is in line with continuing record patient demand for this product. Sales of WinRho SDF were $37.6 million for the nine months ended September 27, 2003 compared to $26.8 million for the comparable period of 2002.

Sales of Nabi-HB were $8.9 million in the third quarter of 2003 compared to sales of $7.8 million in the third quarter of 2002. The increase in Nabi-HB sales was achieved despite decreased numbers of hepatitis B liver transplants as reported by the United Network for Organ Sharing through July of this year. The impact of decreased hepatitis B liver transplant activity was partially offset by the company's efforts to increase market share and enhance its competitive position. Because maintenance use of Nabi-HB is sometimes reduced one-year after transplant, the company expects sales of Nabi-HB to be at lower levels in future periods until the number of new hepatitis B liver transplants begins to increase.

Sales of the company's other biopharmaceutical products were $3.2 million in the third quarter of 2003 compared to $1.7 million in the third quarter of 2002, an increase of $1.5 million. Supply of Aloprim™ [(Allopurinol sodium) for injection] from the manufacturer resumed in the second quarter of 2003 and patient use for the product continued to recover in the third quarter. The company continued to experience product supply shortfalls from the supplier of Autoplex T [Anti-Inhibitor Coagulant Complex, Heat Treated] during the third quarter. These supply issues are expected to continue. The fourth of four one-year extensions to the company's rights to this product was approved by the Federal Trade Commission in May 2003. The company is uncertain whether its rights of this product will extend beyond May 2004.

Sales of non-specific antibodies for the third quarter of 2003 were $8.0 million compared to $15.4 million for the third quarter of 2002. This decrease was expected due to the completion of a contract with a single customer, for which the purchaser of the majority of the antibody collection business supplied the company with the non-specific antibodies to fulfill its obligation through April 2003. The company did not record any margin under this arrangement. Sales reported under this arrangement were zero and $18.6 million in the third quarter of 2003 and the nine months ended September 27, 2003 compared to $12.1 million and $39.8 million in the third quarter of 2002 and the nine months ended September 28, 2002. In addition, sales of specialty antibodies were below 2002 levels due to lower revenues for rabies, tetanus and Rho D antibodies.

**Additional Outlook for 2003**

Nabi Biopharmaceuticals expects biopharmaceutical product sales of its five marketed products, including PhosLo, to increase approximately 18% for the full year of 2003. Based on revenue trends and current market conditions, the company currently projects an increase of approximately 20% in biopharmaceutical product sales in 2004.

*(more)*

As the result of the charges to expense of approximately $13 million related to the write off of the manufacturing right at Dow in the upcoming fourth quarter and $3.3 million related to the retirement of the former chief executive officer reported in the second quarter, the company expects to report a loss for the full year 2003.

Based on cash generated from operations and cash resources on hand and available through the company's credit facility, the company believes it has the resources to make strategic investments in its research and development pipeline and make the investment required for commercial scale manufacture of StaphVAX in the upcoming year. Under its revolving line of credit agreement, the company had no borrowings and approximately $19 million unused borrowing capacity at September 27, 2003.

Management's discussion of third quarter 2003 results can be accessed through an audio link at Nabi Biopharmaceuticals website at www.nabi.com. The audio webcast will begin today at 4:30 p.m. Eastern Time and a replay of the audio webcast will remain available through October 29, 2003 at 5:00 p.m. Eastern Time. If you have any questions concerning the audio webcast, please contact Nabi Biopharmaceuticals Investor Relations Department at 561-989-5815.

**About Nabi Biopharmaceuticals**

Nabi Biopharmaceuticals discovers, develops, manufactures and markets products that power the immune system to help people with serious, unmet medical needs. The company has a broad product portfolio and significant research capabilities focused on developing and commercializing novel vaccines and antibody-based therapies that prevent and treat infectious, autoimmune and addictive diseases, such as *Staphylococcus aureus* and hepatitis infections, immune thrombocytopenia purpura ("ITP"), and nicotine addiction. Nabi Biopharmaceuticals has several products in clinical trials, as well as five marketed products, including Nabi-HB® [Hepatitis B Immune Globulin (Human)], for the prevention of hepatitis B infections upon acute exposure; WinRho SDF® [Rho (D) Immune Globulin Intravenous (Human)], for the treatment of acute, chronic and HIV-related ITP; and PhosLo® (Calcium Acetate) for the control of hyperphosphatemia in end-stage renal (kidney) failure patients. The company is headquartered in Boca Raton, Florida, with principal R&D offices and laboratories in Rockville, Maryland. Additional information about Nabi Biopharmaceuticals may be obtained on the company's web site at www.nabi.com.

*This press release contains forward-looking statements that reflect the company's current expectations regarding future events. Any such forward-looking statements are not guarantees of future performance and involve significant risks and uncertainties. Actual results may differ significantly from those in the forward-looking statements as a result of any number of factors, including, but not limited to, risks relating to the costs of research and development; the company's dependence upon third parties to manufacture its products; the impact of current industry supply and demand factors on the company and its products; the ability of the company to meet its contractual obligations; the future sales growth prospects for the company's biopharmaceutical products; and the company's ability to obtain regulatory approval for its products in the U.S. or abroad or to successfully develop, manufacture and market its products. These factors are more fully discussed in the company's most recent Form 10-K filed with the Securities and Exchange Commission and any subsequent filings.*

*(more)*

**Nabi Biopharmaceuticals**
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited, amounts in thousands, except per share data)

| | For the Three Months Ended | | For the Nine Months Ended | |
|---|---|---|---|---|
| | Sept 27, 2003 | Sept 28, 2002 | Sept 27, 2003 | Sept 28, 2002 |
| **Sales** | $42,435 | $46,100 | $128,595 | $137,871 |
| **Costs and expenses:** | | | | |
| Costs of products sold | 16,101 | 26,352 | 62,781 | 81,649 |
| Royalty expense | 5,423 | 4,249 | 13,722 | 10,105 |
| **Gross Margin** | 20,911 | 15,499 | 52,092 | 46,117 |
| Selling, general and administrative expense | 9,351 | 8,732 | 32,189 | 28,155 |
| Research and development expense | 6,454 | 5,597 | 18,183 | 14,939 |
| Other operating expense, principally amortization and freight | 1,588 | 153 | 1,953 | 551 |
| **Operating income (loss)** | 3,518 | 1,017 | (233) | 2,472 |
| **Other (expense) income, net** | (363) | 110 | (38) | (1,123) |
| **Income (loss) before (provision) benefit for income taxes** | 3,155 | 1,127 | (271) | 1,349 |
| **(Provision) benefit for income taxes** | (962) | (302) | 14 | (364) |
| **Net income (loss)** | $ 2,193 | $ 825 | $ (257) | $ 985 |
| **Basic earnings (loss) per share** | $ 0.05 | $ 0.02 | $ (0.01) | $ 0.03 |
| **Diluted earnings (loss) per share** | $ 0.05 | $ 0.02 | $ (0.01) | $ 0.02 |
| **Basic weighted average shares outstanding** | 45,355 | 38,704 | 41,152 | 38,625 |
| **Diluted weighted average shares outstanding** | 46,285 | 39,299 | 41,152 | 39,611 |
| **SUPPLEMENTAL INFORMATION:** | | | | |
| **Sales by Operating Segment** | | | | |
| Biopharmaceutical Products | $30,710 | $21,682 | $ 75,363 | $ 61,818 |
| Antibody Products: | | | | |
| Specialty antibodies | 3,679 | 9,011 | 16,157 | 24,347 |
| Non-specific antibodies | 8,046 | 15,407 | 37,075 | 51,706 |
| | 11,725 | 24,418 | 53,232 | 76,053 |
| **Total** | $42,435 | $46,100 | $128,595 | $137,871 |

**RECONCILIATION OF EARNINGS BEFORE INTEREST, TAXES, DEPRECIATION AND AMORTIZATION**

| | For the Three Months Ended | | For the Nine Months Ended | |
|---|---|---|---|---|
| | Sept 27, 2003 | Sept 28, 2002 | Sept 27, 2003 | Sept 28, 2002 |
| Net income (loss) | $2,193 | $ 825 | $ (257) | $ 985 |
| Provision (benefit) for income taxes | 962 | 302 | (14) | 364 |
| Other (income) expenses, net | 363 | (110) | 33 | 1,123 |
| Depreciation and amortization | 4,079 | 2,465 | 9,330 | 7,246 |
| **Total** | $7,597 | $3,482 | $9,097 | $9,718 |

*(more)*

**Nabi Biopharmaceuticals**
**CONDENSED BALANCE SHEETS**
(Unaudited, amounts in thousands)

| | Sept 28, 2003 | Dec 28, 2002 |
|---|---|---|
| Cash and cash equivalents | $ 26,248 | $ 51,737 |
| Trade accounts receivable, net | 35,954 | 36,326 |
| Inventories, net | 25,819 | 19,388 |
| Prepaid expenses and other assets | 5,224 | 5,595 |
| Property, plant and equipment, net | 100,444 | 104,066 |
| Intangible assets, net | 109,390 | 12,690 |
| Other assets, net | 3,948 | 3,014 |
| Total assets | $307,027 | $232,816 |
| Trade accounts payable and accrued expenses | $ 31,770 | $ 38,551 |
| Notes payable, PhosLo acquisition | 27,061 | — |
| Notes payable, bank | 10,000 | — |
| Other liabilities | 7,129 | 5,236 |
| Stockholders' equity | 231,067 | 189,029 |
| Total liabilities and stockholders' equity | $307,027 | $232,816 |

Capital expenditures were $4,082 and $4,841 for the nine months ended September 27, 2003 and September 28, 2002, respectively.

Depreciation and amortization expenses were $9,422 and $7,465 for the nine months ended September 27, 2003 and September 28, 2002, respectively, including amortization of deferred loan costs of $0.1 million included in interest expense in 2003 and $0.2 million in 2002.

The 2002 condensed balance sheet has been derived from the audited balance sheet for the year ended December 28, 2002. Certain items in the 2002 consolidated financial statements have been reclassified to conform to the current year's presentation.