
**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): February 18, 2004

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 February 18, 2004, Nabi Biopharmaceuticals ("The Company") issued a press release announcing its financial results for the three and twelve months ended December 27, 2003. A copy of the press release is furnished as Exhibit 99 to this report.

The information in this report and the exhibit attached hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liability of that section, and it shall not be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

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: February 18, 2004

By: /s/ Mark Smith

Mark L. Smith

Senior Vice President, Finance,
Chief Financial Officer, Chief Accounting Officer and Treasurer

Exhibit Index

Exhibit Number

Description

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Press Release dated February 18, 2004



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

NABI BIOPHARMACEUTICALS REPORTS YEAR-END AND FOURTH QUARTER 2003 RESULTS
Record Biopharmaceutical Revenues Support Increased Investment in Research and Clinical Programs

Boca Raton, Florida, February 18, 2004—Nabi Biopharmaceuticals (Nasdaq: NABI) today announced its financial results for the year and fourth quarter ended December 27, 2003. Total 2003 revenues of \$177 million included record biopharmaceutical sales of \$109 million based on the strong performance of PhosLo[®] (calcium acetate), acquired in August 2003. Due to the increasing significance of biopharmaceutical revenues, gross margin earned on product sales was 44% of sales for 2003 versus 33% of sales in 2002. These continued gains in operating performance allowed Nabi Biopharmaceuticals to increase its investment in research and clinical trial programs by almost \$8 million or almost 40% from 2002 and by almost \$14 million or more than 90% from 2001. This significant increase in research and development spending in 2003 was accomplished while still generating positive cash flow from operations of \$7.5 million. Based on the strength of its operating performance and the successful completion of an underwritten offering of its common stock in December, Nabi Biopharmaceuticals ended the year with cash on hand of \$115.8 million to support future strategic development of its business. These efforts are expected to include developing vaccine manufacturing capability, increasing clinical trial activities and preparing for the launch of StaphVAX[®] (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine).

Earnings results for 2003 included a previously announced non-cash write-off of a manufacturing right asset of \$12.6 million in the fourth quarter and a \$3.3 million charge reported in the second quarter related to the retirement of its former chief executive officer, which contributed to a reported net loss of \$6.8 million or \$0.16 per share for the year and \$6.6 million or \$0.14 per share in the fourth quarter. These earnings results were ahead of the company's expectations because of a tax benefit recorded in the fourth quarter that is supported by the company's strategy for licensing StaphVAX and PhosLo in Europe and its successful equity offering in December. This business strategy is expected to allow the company to utilize research and development tax credits and net operating loss carryforwards which had been reserved and could have expired unused. This resulted in an effective tax benefit rate of 49% for the full year 2003 and 50% for the fourth quarter of 2003.

"We achieved many major milestones in 2003. These milestones have redefined us as a company and have solidly positioned us to continue to execute our business strategy," stated Thomas H. McLain, chief executive officer and president. "During 2003, we initiated our confirmatory Phase III clinical trial of StaphVAX in the U.S., identified the opportunity to file for licensure of StaphVAX in Europe by the end of 2004, and advanced the manufacturing process for StaphVAX through a new contract manufacturing relationship. Our acquisition of PhosLo in 2003 is driving growth in our biopharmaceutical sales and generating important incremental cash earnings to support our accelerating clinical and regulatory activities. These 2003 achievements culminated in the completion of a successful underwritten public offering of our common stock that generated approximately \$92 million in net proceeds in December, providing us with additional financial resources to expand the commercialization of our products globally and prepare for the launch of StaphVAX in Europe and the U.S. Our ultimate objective is to build value for our investors and we are pleased that our market capitalization tripled during the year, increasing from \$239 million at the end of 2002 to \$723 million at December 2003."

Research and development spending in 2003 increased to \$29 million, in line with previous company guidance. This spending funded important advances in the company's lead clinical program. In September, the company completed an important immunogenicity study of StaphVAX using material manufactured at a contract manufacturer's site, demonstrating that the StaphVAX manufacturing process was both transferable and scalable. With this result, the company immediately initiated the confirmatory Phase III clinical trial in the U.S. using vaccine produced by the contract manufacturer. The company also identified Cambrex BioScience of Baltimore, Inc. in October 2003 as its new contract manufacturer to support filing of a Marketing Authorization Approval (MAA) for StaphVAX in the European Union. Transfer of the manufacturing process to Cambrex BioScience progressed significantly in the fourth quarter and the company initiated the

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manufacture of three consistency lots of vaccine in January 2004. This is in line with its plans to file a MAA in Europe by the end of 2004. In addition, the company initiated a Phase II clinical trial of Altastaph™ [*Staphylococcus aureus* Immune Globulin Intravenous (Human)] in very low birth-weight newborns who are at risk of developing *S. aureus* infections and supported completion of a Phase I/II clinical trial of Civacir™ [Hepatitis C Immune Globulin (Human)] in hepatitis C positive liver transplant patients. The company's NicVAX™ (Nicotine Conjugate Vaccine) program progressed significantly in 2003 through initiation of a Phase II clinical trial in the U.S. and a Phase I/II clinical trial in Europe during the year. These trials are fully enrolled and results from each of the clinical trials are expected to be announced in 2004. Research and development activities also supported the company's Biologics License Application (BLA) submission for Nabi-HB Intravenous, as well as the reporting of the CARE Study and other activities in support of PhosLo and the company's other marketed products.

2003 Milestones

- In December, the company completed an underwritten secondary public offering of 9,775,000 shares generating net proceeds of approximately \$92 million.
- In November, the results of the CARE study were presented at the American Society of Nephrology's annual meeting in San Diego, CA. The company believes that the results of the study demonstrate that PhosLo is the phosphate binder that best meets the K/DOQI treatment guidelines released by the National Kidney Foundation in October 2003.
- In October, the company announced that it planned to file its first license application for StaphVAX in Europe by the end of 2004, 24 months ahead of schedule.
- In conjunction with this development, the company announced that it had signed a manufacturing agreement for StaphVAX for a term of up to ten years with Cambrex BioScience of Baltimore, Inc., a subsidiary of Cambrex Corporation.
- In September, Nabi Biopharmaceuticals initiated the confirmatory Phase III clinical trial for StaphVAX in the U.S. ahead of schedule. Patient enrollment for this trial is actively underway. As of today 62 of 110 primary sites at major dialysis providers have been activated and enrollment has achieved planned levels.
- In September, the company announced results from a clinical trial demonstrating that it could successfully transfer and scale up production of StaphVAX in a commercial manufacturing facility.
- In September, results of two pharmacoeconomic studies illustrating the substantial costs and illness suffered by ESRD patients who develop *Staph aureus* bacteremia were presented at the ICAAC (Interscience Conference on Antimicrobial Agents and Chemotherapy) meeting.
- In August, the company initiated its Phase II clinical trial of NicVAX in the U.S. in 63 smokers who have expressed a desire to quit smoking. Study enrollment has been completed and results will be reported in the second half of 2004.
- On August 4, the company completed the acquisition of worldwide rights to PhosLo. To help fund the acquisition of PhosLo, the company raised \$31.3 million through a private placement of 5,577,000 shares of its common stock in July 2003.
- In July, Nabi Biopharmaceuticals began Phase II clinical testing of Altastaph in very low birth-weight neonates (newborn infants weighing between 500 and 1,500 grams). The company anticipates reporting results from this trial in the second half of 2004. In January 2004, Altastaph was designated an Orphan Drug for this indication by the FDA.
- The board of directors elected Thomas H. McLain as the company's chief executive officer and president effective June 20, 2003. Also effective June 20, 2003, David J. Gury retired as chief executive officer. Mr. Gury will continue to serve the company as non-executive chairman of the board of directors until May 2004.
- In April, Nabi Biopharmaceuticals granted an exclusive worldwide license for use and development of a whole cell version of its vaccine technology for the prevention of *Staphylococcus aureus* infections in cattle to Pfizer.
- In February, the company received a second U.S. patent covering NicVAX for the treatment and prevention of nicotine addiction.
- In January, the company initiated a Phase I/II clinical trial for NicVAX in smokers and non-smokers in The Netherlands. The study was fully enrolled in 2003 and results of this clinical trial will be announced in the first quarter of 2004.
- In January, the FDA accepted for priority review a BLA filed by Nabi Biopharmaceuticals for Nabi-HB Intravenous for a liver transplant indication. Based on supplementary data provided to the FDA, Nabi Biopharmaceuticals expects a response to this BLA in the first half of 2004.

Review of Operations

Sales of PhosLo totaled \$7.8 million in the fourth quarter, ahead of the company's expectations. These sales reflect the success of the company's initial product launch activities including the successful presentation of the CARE study at the ASN meeting in the fourth quarter. The company believes that the CARE study positions PhosLo as the phosphate binder product that best meets the K/DOQI guidelines issued by the National Kidney Foundation. Sales of PhosLo from its acquisition on August 4, 2003 through December 27, 2003 were \$12.9 million, also above company estimates for initial period sales.

Sales of WinRho SDF[®] [Rho (D) Immune Globulin Intravenous (Human)] were \$12.3 million in the fourth quarter of 2003 compared to \$7.2 million in the comparable quarter of 2002, an increase of 71%. Reported use of WinRho SDF for the treatment of ITP (Immune Thrombocytopenia Purpura) continues at record levels. Higher pricing in 2003 also contributed to the increase in reported sales. Sales of WinRho SDF were \$50 million for the year ended December 27, 2003 compared to \$34 million for 2002.

Sales of Nabi-HB[®] [Hepatitis B Immune Globulin (Human)] were \$11.3 million in the fourth quarter of 2003 compared to sales of \$15.7 million in the fourth quarter of 2002. As the company has discussed previously, the decrease in Nabi-HB sales was expected due to the continued impact of lower numbers of hepatitis B liver transplants as reported by the United Network for Organ Sharing through November of this year. The impact of decreased hepatitis B liver transplant activity was partially offset by the company's successful efforts to increase market share for Nabi-HB for maintenance use in transplant patients, as well as increased pricing. Sales of Nabi-HB were \$37.6 million for the full year 2003 compared to \$41.2 million for 2002.

Sales of the company's other biopharmaceutical products were \$2.6 million in the fourth quarter of 2003 compared to \$4.8 million in the fourth quarter of 2002, a decrease of \$2.2 million. This decrease was primarily due to product supply shortfalls from the manufacturer of Autoplex[®] T [Anti-Inhibitor Coagulant Complex, Heat Treated]. Sales of the company's other biopharmaceutical products were \$9 million in 2003 compared to \$14.3 million in 2002.

Sales of non-specific antibodies for the fourth quarter of 2003 were \$8.6 million compared to \$22 million for the fourth quarter of 2002. This decrease was expected due to the completion of a contract with a single customer in April 2003. The company did not record any margin under this contract. Sales reported under this contract were zero and \$18.6 million in the fourth quarter of 2003 and the year ended December 27, 2003, compared to \$15.9 million and \$55.6 million in the fourth quarter of 2002 and the year ended December 28, 2002. Sales of specialty antibodies were 35% below 2002 levels due to lower revenues for rabies, tetanus and hepatitis B antibodies.

Selling, general and administrative expense increased to \$43.8 million in 2003 from \$38.4 million in 2002 primarily as the result of a charge of \$3.3 million related to the retirement of the former chief executive officer and the launch of PhosLo. Selling, general and administrative expense for the fourth quarter of 2003 increased to \$11.7 million compared to \$10.2 million in the fourth quarter of 2002 primarily as the result of the launch of PhosLo.

Other operating expenses, primarily amortization and freight, increased to \$4.3 million in 2003 from \$0.8 million in 2002 due to amortization expense related to the acquisition of PhosLo. Other operating expenses were \$2.3 million in the fourth quarter of 2003 compared to \$0.2 million in the comparable quarter of 2002.

In October 2003, the company established a new contract manufacturing relationship with Cambrex BioScience and ended its agreement with the previous contract manufacturer for StaphVAX. As a result of this action, the company wrote off costs it had previously capitalized relating to the right to manufacture StaphVAX at the previous manufacturer's facility in future periods and recorded a non-cash charge of \$12.6 million in the fourth quarter of 2003.

Outlook for 2004

As a result of the increased cash margins it expects to earn on biopharmaceutical product sales in 2004 and supported by its strengthened cash position, Nabi Biopharmaceuticals will significantly increase its investment in clinical studies and pre-marketing activities for StaphVAX in Europe and the U.S. in 2004. These important strategic investments are expected to result in a reported loss for the year. At the same time, after accounting for increased non-cash expenses such as depreciation and amortization, the company expects to report positive cash flow from operations in 2004. Cash flow from operations combined with cash proceeds from issuing equity in 2003, will be used to support increased strategic investments in vaccine manufacturing, both at Cambrex BioScience and to develop internal vaccine manufacturing capacity within the company's manufacturing facility in Boca Raton, Florida.

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Nabi Biopharmaceuticals expects sales of its marketed biopharmaceutical products in 2004 to increase approximately 25% compared to 2003. Based on the strength of the market response to its initial launch of PhosLo and a January 2004 price increase, the company has increased its expectations for sales of PhosLo to total between \$32 million and \$35 million for the full year 2004. Based on increased patient use trends, the company expects sales of WinRho SDF to continue to increase in 2004, although at a significantly lower rate than in 2003. Unit sales of Nabi-HB are expected to be at lower levels in 2004 until the number of new hepatitis B liver transplants increases. However, the company expects increased pricing to significantly offset the impact of lower unit sales volume of Nabi-HB in 2004. The company has continued to experience product supply issues from the manufacturer of Autoplex T and in January the manufacturer advised in writing that it will cease to supply Autoplex T on May 11, 2004, the termination date under the current agreement. As a result, the margin earned on Autoplex T in 2004 will be limited to product manufactured and any contract penalties earned in the period through that date.

Total antibody sales will be limited to plasma produced in the company's own plasma collection centers. As a result, total antibody sales are expected to decrease by approximately 20% from 2003.

Overall the gross margin earned on product sales is expected to increase approximately 20% from 2003 levels due to the positive impact of increased sales of higher margin biopharmaceuticals products. The company expects this increase in gross margin despite a planned decrease in manufacturing volumes for Nabi-HB in its Boca Raton plant and lower margins from Autoplex T. Lower unit sales of Nabi-HB will result in reduced manufacturing activity at the company's Boca Raton, Florida manufacturing facility and as a result, increased excess capacity expense. In 2003, excess manufacturing expense was \$2.2 million. During the first quarter of 2004, the company is undertaking renovations to its Boca Raton facility to comply with EU requirements that will impact production levels in this period. In 2004, the company expects that this expense could increase to approximately \$6 million. In 2004, gross margin will also be negatively impacted by the conclusion of the Autoplex T manufacturing agreement in May. Under terms of this agreement, the company had earned margin on product sales and had also received a penalty for product supply shortfalls. In 2003, such penalties totaled \$8.1 million.

Research and development spending is expected to increase more than 65% as the company continues to increase enrollment in its Phase III clinical trial of StaphVAX and completes the effort to transfer the StaphVAX manufacturing process to Cambrex BioScience. The Phase III StaphVAX clinical trial is expected to cost a total of \$36 million in outside clinical trial costs over the approximately two-year period of the trial. Approximately \$17 million of this amount is expected to be incurred in fiscal 2004. In addition, the company expects to initiate a clinical trial using PhosLo with a statin to try to optimize control of the three factors that have been demonstrated clinically to affect cardiac health in ESRD patients, serum phosphate levels, calcium and phosphate product levels and cholesterol levels. After twelve months this study will also evaluate arterial calcification in these patients.

The company also expects to initiate studies on the use of PhosLo in chronic kidney disease patients and to file for a license to sell PhosLo in Europe in the second half of 2004. Nabi Biopharmaceuticals will also incur clinical costs related to the preparation of filings for approval to market StaphVAX and Nabi-HB in Europe during 2004 and will incur costs related to continued Phase II clinical studies of Altastaph and NicVAX.

As part of the commercial opportunity Nabi Biopharmaceuticals identified for its products in Europe, the company expects to incur pre-launch costs of approximately \$9 million in 2004. These costs will be incurred to undertake pharmacoeconomic studies and reimbursement initiatives and to build awareness with key opinion leaders in Europe.

The company's capital expenditures in fixed assets and the manufacturing right at Cambrex BioScience are expected to total \$33 million in 2004, including \$18 million to develop vaccine manufacturing capability at the company's manufacturing facility in Florida.

Management's discussion of full year and fourth 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 February 25, 2004 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 applies its knowledge of the human immune system to commercialize and develop products that address serious, unmet medical needs. The company's focus is in the areas of infectious, autoimmune and addictive diseases. In addition to five marketed products (PhosLo[®], Nabi-HB[®], WinRho SDF[®], Aloprim[™], Autoplex[®] T), the company has several products in various stages of preclinical and clinical testing. Nabi Biopharmaceuticals has advanced StaphVAX[®] to Phase III clinical development. StaphVAX is designed to prevent the most dangerous and prevalent strains of Staph aureus bacterial infections. Staph aureus bacteria are a major cause of hospital-acquired infections and are becoming increasingly resistant to antibiotics. The company's other products in development include Altastaph[™], an antibody for prevention of Staph aureus infections, and NicVAX[™], a nicotine vaccine, both in Phase II clinical testing, and Civacir[™], an antibody for preventing hepatitis C virus re-infection in liver transplant patients. For additional information on Nabi Biopharmaceuticals, please visit our 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 possibility that our confirmatory Phase III clinical trial for StaphVAX or our plans to commercialize StaphVAX in the EU may not be successful; the possibility that we may not realize the value of our acquisition of PhosLo; the possibility that our rights to three existing biopharmaceutical products may expire; the company's dependence upon third parties to manufacture its products; the company's ability to utilize the full capacity of its manufacturing facility; the impact on sales of Nabi-HB from patient treatment protocols and the number of liver transplants performed in HBV-positive patients; reliance on a small number of customers; 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 Report on Form 8-K dated December 10, 2003 filed with the Securities and Exchange Commission.

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CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three Months Ended		For the Twelve Months Ended	
	Dec 27, 2003	Dec 28, 2002	Dec. 27, 2003	Dec 28, 2002
Sales	\$ 47,974	\$ 58,095	\$ 176,570	\$ 195,966
Costs and expenses:				
Costs of products sold	18,572	37,521	81,354	119,170
Royalty expense	4,666	2,778	18,387	12,883
Gross Margin	24,736	17,796	76,829	63,913
Selling, general and administrative expense	11,678	10,225	43,867	38,380
Research and development expense	10,857	6,157	29,040	21,096
Other operating expense, principally amortization and freight	2,299	216	4,252	767
Write-off of Manufacturing Right	12,575	—	12,575	—
Operating income (loss)	(12,673)	1,198	(12,905)	3,670
Other (expense) income, net	(493)	123	(532)	(1,000)
Income (loss) before benefit (provision) for income taxes	(13,166)	1,321	(13,437)	2,670
(Provision) benefit for income taxes	6,591	(251)	6,605	(615)
Net income (loss)	\$ (6,575)	\$ 1,070	\$ (6,832)	\$ 2,055
Basic earnings (loss) per share	\$ (0.14)	\$ 0.03	\$ (0.16)	\$ 0.05
Diluted earnings (loss) per share	\$ (0.14)	\$ 0.03	\$ (0.16)	\$ 0.05
Basic weighted average shares outstanding	48,097	38,805	42,888	38,670
Diluted weighted average shares outstanding	48,097	39,728	42,888	39,641
SUPPLEMENTAL INFORMATION:				
Sales by Operating Segment				
Biopharmaceutical Products	\$ 34,095	\$ 27,648	\$ 109,459	\$ 89,466
Antibody Products:				
Specialty antibodies	5,268	8,402	21,425	32,749
Non-specific antibodies	8,611	22,045	45,686	73,751
	13,879	30,447	67,111	106,500
Total	\$ 47,974	\$ 58,095	\$ 176,570	\$ 195,966

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

	Dec. 28, 2003	Dec. 28, 2002
Cash and cash equivalents	\$ 115,756	\$ 51,737
Trade accounts receivable, net	37,062	36,326
Inventories, net	23,483	19,388
Prepaid expenses and other assets	5,660	5,595
Property, plant and equipment, net	101,831	104,066
Intangible assets, net	94,991	12,690
Other assets, net	8,518	3,014
Total assets	\$ 387,301	\$ 232,816
Trade accounts payable and accrued expenses	\$ 34,830	\$ 38,551
Notes payable, PhosLo acquisition	27,393	—
Other liabilities	5,762	5,236
Stockholders' equity	319,316	189,029
Total liabilities and stockholders' equity	\$ 387,301	\$ 232,816

Capital expenditures were \$8,050 and \$6,021 for the twelve months ended December 27, 2003 and December 28, 2002, respectively.

Depreciation and amortization expenses were \$14,236, excluding the write-off of the Manufacturing Right of \$12,575, and \$10,077 for the twelve months ended December 27, 2003 and December 28, 2002, respectively, including amortization of deferred loan costs of \$0.2 million included in interest expense in 2003 and 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.

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