# **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): April 21, 2004

# Nabi Biopharmaceuticals (Exact name of registrant as specified in its charter)

Delaware State or other jurisdiction of incorporation

000-04829 **Commission File Number** 

59-1212264 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 April 21, 2004, Nabi Biopharmaceuticals ("the Company") issued a press release announcing its financial results for the three months ended March 27, 2004. 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.

#### Index of Exhibits

Exhibit number

99

Exhibit description

Press Release

## 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.

Date: April 21, 2004

# Nabi Biopharmaceuticals

By: /s/ Mark L. Smith

# Mark L. Smith

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



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

#### NABI BIOPHARMACEUTICALS REPORTS FINANCIAL RESULTS FOR THE FIRST QUARTER OF 2004

#### Strong Biopharmaceutical Sales Fully Support Significant Increase in Development Programs

**Boca Raton, Florida April 21, 2004** – Nabi Biopharmaceuticals (Nasdaq: NABI) today announced its financial results for the first quarter ended March 27, 2004. Strong first quarter sales of biopharmaceutical products drove a 36% increase in gross margin from 2003 to \$22.6 million. This increased gross margin fully funded a 97% increase in research and development spending which totaled \$11.4 million. Despite this increase in spending for research, clinical studies and internal costs to develop manufacturing capacity for StaphVAX<sup>®</sup> (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine), cash flow from operations totaled a positive \$4.9 million for the first quarter. From an earnings standpoint, this increased investment in key research and development programs resulted in the company reporting a net loss of \$4.8 million, or \$0.08 per share for the period.

"We entered 2004 in a strong financial position to execute our business strategy. During the first quarter, we achieved significant advances in all aspects of our operations, particularly the gains in biopharmaceutical product revenues and our progress toward the commercialization of StaphVAX," stated Mr. Thomas H. McLain, chief executive officer and president of Nabi Biopharmaceuticals. "In line with our strategy, the higher margins earned on biopharmaceutical product sales, particularly PhosLo, generated increased cash flow to fund key research and development programs. We are pleased with the progress we achieved in expanding the enrollment in our confirmatory phase III trial of StaphVAX. To date we have initiated more than 200 clinical sites for this study. We have also advanced the commercial scale manufacture of StaphVAX in Cambrex Bio Science's manufacturing facility. These successes put us on track to achieve our key 2004 and 2005 milestones."

To advance its strategic business plan in 2004, Nabi Biopharmaceuticals has set performance milestones in six key areas:

- For StaphVAX, completing enrollment in the confirmatory phase III clinical trial, manufacturing consistency lots, initiating immunogenicity studies in surgical patient populations, initiating the development of internal vaccine manufacturing capability, completing additional pharmacoeconomic studies in the US and Europe and filing a Marketing Application Authorization, or MAA, in Europe;
- For PhosLo, initiating a study among Chronic Kidney Disease or CKD patients, initiating the PRECISE study and filing a MAA for European approval;
- For Nabi-HB<sup>®</sup> [Hepatitis B Immune Globulin (Human)], obtaining approval for the Biologics License Application or BLA from the US Food and Drug Administration for use of the product in hepatitis B positive liver transplant recipients and filing a MAA for European approval.
- For Altastaph<sup>™</sup> [*Staphylococcus aureus* Immune Globulin (Human)], completing and announcing results from the phase II study in very low birth weight infants;
- For NicVAX<sup>™</sup> (Nicotine Conjugate Vaccine), completing and announcing results from the phase II study in smokers; and
- For Civacir<sup>™</sup> [Hepatitis C Immune Globulin (Human)] announcing results from a phase I/II study in liver transplant patients in the first quarter and defining next clinical development steps with input from the FDA.

#### **Recent Developments**

- The full results of the Calcium Acetate Renagel Evaluation (CARE) study were published in the May 2004 (Volume 65, Issue 5) issue of *Kidney International (KI)*, the official publication of the International Society of Nephrology and one of the most cited peer reviewed journals in nephrology. The CARE study, the first, and so far, only randomized, double-blinded, controlled, head-to-head comparison between PhosLo and Renagel<sup>®</sup> (sevelamer hydrochloride), supports the use of PhosLo as the first line therapy for control of blood phosphorus levels for end-stage renal disease patients.
- In February 2004, Altastaph, which is initially being developed for immediate protection against Staph aureus infections in low birth weight infants, received Orphan Drug Designation and later received Fast Track Designation by the US Food and Drug Administration (FDA) for this indication.

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- In February 2004, the company announced preliminary results from its phase I/II clinical trial of Civacir being developed to prevent hepatitis C virus (HCV) re-infection of transplanted livers in patients with chronic hepatitis C. The study demonstrated that Civacir was well tolerated in both high and low dose treatment arms of the trial. Although the clinical trial was not statistically powered to identify significant differences in effect, there was a dose-related trend towards normalizing serum alanine aminotransferase (ALT) levels. ALT levels are an important measure of liver health. In addition, a trend toward a reduction of hepatitis C viral levels was observed at the higher dose.
- In February 2004, results were presented from Nabi Biopharmaceuticals' phase I/II trial of NicVAX, its investigational vaccine being developed to
  prevent and treat nicotine addiction, conducted in healthy smoking and non-smoking volunteers in the Netherlands. The results of the study, conducted
  in conjunction with the University of Maastricht, demonstrated that NicVAX was both well tolerated and able to generate high levels of nicotine
  specific antibodies.
- In March 2004, the company signed an agreement with Novation, LLC to supply Nabi-HB through the Novaplus<sup>®</sup> Private Label Program. Novaplus, the private label of VHA, University Hospital Consortium and Healthcare Purchasing Partners International, provides the members of Novation's alliances with commonly used pharmaceutical products. This contract will enable the company to increase patient access to Nabi-HB during the maintenance phase of the treatment of liver transplant patients.
- In February 2004, Nabi Biopharmaceuticals signed an international distribution agreement for Nabi-HB with Kamada, Ltd.. Under terms of the
  agreement, Kamada will coordinate the regulatory approval process for registration of Nabi-HB in several countries, including Israel, Argentina,
  Brazil, Mexico and India. When approved, Kamada will distribute Nabi-HB in these markets.

#### **Review of Operations**

Total sales for the first quarter of 2004 were \$46.3 million, including \$33.9 million of biopharmaceuticals revenue.

Sales of PhosLo totaled \$11.3 million in the first quarter. Increased capacity for the manufacture of PhosLo gelcaps came online in the first quarter, allowing the company to satisfy customer demand. As a result, wholesaler customers significantly increased their gelcap inventories by the end of the quarter. Based on strong prescription trends, the benefit of a January price increase of 13% and the exhaustion of wholesaler inventories of Braintree Laboratories labeled product in the first quarter, the company continues to expect full year sales for PhosLo will total between \$32 and \$35 million.

Sales of Nabi-HB were \$11.2 million in the first quarter of 2004 compared to sales of \$10.3 million in 2003. Sales benefited significantly from an initial buy-in of product from a new contract under which Novation will supply finished Nabi-HB through its Novaplus<sup>®</sup> Private Label Program. As previously reported by the company, sales of Nabi-HB are closely correlated with the number of hepatitis B liver transplants in the US. Internally generated data indicates that the number of hepatitis B liver transplants continued to increase in the first quarter and were above the numbers reported in both the first and fourth quarters of 2003. While this trend is encouraging, the company will not adjust full year expectations for Nabi-HB sales until a sustained increased in hepatitis B liver transplants is substantiated by data from the United Network of Organ Sharing or UNOS. That data will be reported later in the year.

Sales of WinRho SDF<sup>®</sup> [Rh<sub>o</sub> (D) Immune Globulin Intravenous (Human)] were \$9.3 million in the first quarter of 2004 compared to \$11.3 million in the comparable quarter of 2003. Patient demand for WinRho SDF continued to increase in the first quarter of 2004. As a result, the company believes that inventory levels at wholesaler customers decreased during the period. Based on continued strong patient demand for WinRho SDF, as well as the impact of a 10% price increase in January, the company continues to expect full year sales of this product to increase from 2003 levels.

Sales of the company's other biopharmaceutical products were \$2.1 million in the first quarter of 2004 compared to \$1.1 million in the first quarter of 2003, an increase of \$1.0 million. Sales of both Aloprim<sup>®</sup> [(Allopurinol sodium)

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for injection] and Autoplex  $T^{\text{B}}$  [Anti-Inhibitor Coagulant Complex, Heat Treated] increased in comparison to sales of these products during the first quarter of 2003. As previously reported, the supplier of Autoplex T has advised the company that supply of Autoplex T will cease in May 2004 and future sales will be limited to sales from existing inventory on hand.

Research and development expenses in the quarter increased almost twofold compared to the first quarter of 2003 due primarily to the costs associated with the confirmatory phase III clinical trial of StaphVAX initiated in September 2003. Research and development expenses also included costs related to the transfer of commercial scale manufacturing of StaphVAX to the contract manufacturer's facility.

Selling, general and administrative expenses increased \$2.1 million due to increased marketing costs related to PhosLo and costs related to initial commercialization activities in Europe. The investment in Europe is in line with the company's expectation of filing MAA's for StaphVAX, PhosLo and Nabi-HB in Europe during 2004.

Interest expense includes a \$1.1 million charge related to the early termination of the company's credit agreement at the end of March.

#### **Additional Outlook for 2004**

As previously projected, the company will invest a significant portion of the increased cash margin generated from sales of biopharmaceutical products this year in research and clinical studies, vaccine manufacturing and pre-marketing support for StaphVAX, PhosLo and Nabi-HB in Europe. After accounting for increased non-cash expenses such as depreciation and amortization, the company continues to expect to report positive cash flows from operations in 2004. From an earnings standpoint, the company continues to project these important strategic investments will result in a reported net loss for the year.

During the first quarter, the company continued to increase its activities to support the transfer of StaphVAX manufacturing to Cambrex Bio Science. As progress accelerates, Nabi Biopharmaceuticals now expects to directly complete a more significant proportion of the work in achieving this goal. As a result, while the total investment in manufacturing at the Cambrex Bio Science facility will not increase, certain expenses, which were previously forecasted as an investment in a manufacturing right asset, are now expected to be reported as research and development expense. After accounting for these items, the company now projects research and development expense of approximately 75% from 2003 levels. Projections for the investment in the intangible manufacturing right asset have decreased by approximately \$4 to \$5 million.

Management's discussion of first quarter 2004 results can be accessed through an audio link at Nabi Biopharmaceuticals website at <u>www.nabi.com</u>. The audio webcast will begin today at 4:30 p.m. Eastern Time and a replay of the audio webcast will remain available through April 28, 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 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<sup>®</sup>, Nabi-HB<sup>®</sup>, WinRho SDF<sup>®</sup>, Aloprim<sup>™</sup>, Autoplex<sup>®</sup> T), the company has several products in various stages of preclinical and clinical testing. Nabi Biopharmaceuticals has advanced StaphVAX<sup>®</sup> 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<sup>™</sup>, an antibody for prevention of Staph aureus infections, and NicVAX<sup>™</sup>, a nicotine vaccine, both in Phase II clinical testing, and Civacir<sup>™</sup>, 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 two 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 Annual Report on Form 10-K for the fiscal year ended December 27, 2003 filed with the Securities and Exchange Commission.

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# Nabi Biopharmaceuticals CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three	For the Three Months Ended	
	March 27, 2004	March 29, 2003	
Sales	\$ 46,349	\$ 51,511	
Costs and expenses:			
Costs of products sold	20,200	30,954	
Royalty expense	3,575	3,915	
Gross Margin	22,574	16,642	
Selling, general and administrative expense	12,356	10,139	
Research and development expense	11,429	5,794	
Intangible asset amortization	2,153	88	
Other operating expense, principally freight	63	102	
Operating (loss) income	(3,427)	519	
Other (expense) income, net	(1,155)	214	
(Loss) income before provision for income taxes	(4,582)	733	
Provision for income taxes	(257)	(184)	
Net (loss) income	\$ (4,839)	\$ 549	
Basic (loss) earnings per share	\$ (0.08)	\$ 0.01	
Diluted (loss) earnings per share	\$ (0.08)	\$ 0.01	
Basic weighted average shares outstanding	57,960	38,962	
Diluted weighted average shares outstanding	57,960	39,719	
Dhatea weightea average shares outstanding			
SUPPLEMENTAL INFORMATION:			
Sales by Operating Segment			
Biopharmaceutical Products	\$ 33,936	\$ 22,660	
Antibody Products:	( )70	( 002	
Specialty antibodies Non-specific antibodies	6,270 6,143	6,083 22,768	
	12,413	28,851	
Total	\$ 46,349	\$ 51,511	

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# Nabi Biopharmaceuticals CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, amounts in thousands)

	March 27, 2004	December 27, 2003
Cash and cash equivalents	\$ 116,779	\$ 115,756
Trade accounts receivable, net	36,904	37,062
Inventories, net	21,162	23,483
Prepaid expenses and other assets	8,854	10,284
Property, plant and equipment, net	100,874	101,831
Intangible assets, net	94,292	94,991
Other assets, net	3,740	3,894
Total assets	\$ 382,605	\$ 387,301
Trade accounts payable and accrued expenses	\$ 36,101	\$ 34,830
Notes payable	23,605	27,393
Other liabilities	5,536	5,762
Stockholders' equity	317,363	319,316
Total liabilities and stockholders' equity	\$ 382,605	\$ 387,301

Capital expenditures were \$1,424 and \$562 for the three months ended March 27, 2004 and March 29, 2003, respectively.

Depreciation and amortization expenses were \$4,739 and \$2,626 for the three months ended March 27, 2004 and March 29, 2003, respectively.

The 2003 condensed balance sheet has been derived from the audited balance sheet for the year ended December 27, 2003.

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