# 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 20, 2005

# **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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

### **Nabi Biopharmaceuticals**

# Item 2.02. Results of Operations and Financial Condition

On April 20, 2005, Nabi Biopharmaceuticals issued a press release announcing its financial results for the three months ended March 26, 2005. A copy of the press release is furnished as Exhibit 99 to this report.

The information in this Item 2.02 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.

### Item 9.01. Financial Statements and Exhibits

Exhibit number	Description	
99	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 20, 2005

## **Nabi Biopharmaceuticals**

By: /s/ Mark L. Smith

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

## **Index of Exhibits**

Exhibit number Description
99 Press release



Mark Soufleris Vice President, Investor & Public Relations (561) 989-5800

### Nabi Biopharmaceuticals Reports First Quarter 2005 Results

Completes Issuance of \$100 Million Convertible Senior Notes

**Boca Raton, Florida, April 20, 2005** – Nabi Biopharmaceuticals (Nasdaq: NABI) today announced its financial results for the first quarter ended March 26, 2005. As announced on April 5<sup>th</sup>, biopharmaceutical sales were \$17.5 million. Also consistent with previous guidance, the company increased its investment in research and development to support the development of StaphVAX® (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine) and its investment to support the initial European commercialization of StaphVAX, PhosLo<sup>R</sup> (Calcium Acetate) and Nabi-HB<sup>R</sup> Intravenous [Hepatitis B Immune Globulin (Human) Intravenous]. These factors contributed to a decrease in cash and short-term investments, from \$103 million at year-end to \$71 million at the end of the first quarter. On April 19<sup>th</sup> the company completed the issuance of \$100 million in convertible debt, significantly improving its cash position. The proceeds will enable the company to invest in other products in its Gram-positive infections program and position the company to continue to pursue business development opportunities aligned with its strategy.

The company's investment in research and development activities continued to focus on driving StaphVAX, the lead product in its Gram-positive infections portfolio, toward commercialization. The company's European license application was accepted for review in January 2005. During the first quarter of 2005, the company continued to advance its confirmatory phase III clinical trial for StaphVAX in the U.S. Based on the progress achieved to date, the company confirmed that it expects to announce results from this trial around the end of the third quarter. The company has also completed enrollment in a StaphVAX immunogenicity study in patients undergoing cardiothoracic surgery. Patient enrollment is ongoing in a second immunogenicity study in patients undergoing orthopedic surgery. Results from these studies are expected in the second half of this year. During this first quarter the company also initiated manufacturing of StaphVAX in its new vaccine facility in Florida. Based on this progress, the company also confirmed that it remains on track to file its Biologics License Application (BLA) for StaphVAX in the U.S. by the end of this year.

During the first quarter, the company also reported important results from a phase I/II clinical trial of Altastaph [Staphylococcus aureus Immune Globulin Intravenous (Human)]. The study evaluated the dosing of Altastaph with standard of care therapy, including antibiotics, in patients with persistent *S. aureus* infections. The study results showed a trend toward reduction in the median time from drug administration to hospital release of five days (nine days versus 14 days) for patients treated with Altastaph. These results indicated that Altastaph could provide a significant benefit in the treatment of infections. This is an important development in applying the company's proven technologies and its knowledge of Staph infections and immune responses in developing innovative products that can address the threat of these infections in at-risk patients.

The company's cash assets, including marketable securities, were \$70.9 million on March 26, 2005 compared to \$103.1 million at year-end. This decrease was expected based on lower sales in the quarter, the increased investment in research and development, the payment of liabilities for sales deductions, royalties and compensation accrued in 2004, the costs to initiate new vaccine manufacturing and payments of \$9.5 million under a note for the acquisition of PhosLo. Yesterday the company completed a private offering of \$100 million principal amount of its 2.875% Convertible Senior Notes due 2025. Nabi Biopharmaceuticals has granted the initial purchasers an option to purchase up to an additional \$20 million principal amount of notes to cover over allotments.

"The progress we have made in advancing our StaphVAX program toward commercialization, as well as the opportunities to broaden our Gram-positive infections program to address treatment and prevention of infections in broader at risk patient populations, were important achievements during the first quarter," stated Thomas H. McLain, chairman, chief executive officer, and president, Nabi Biopharmaceuticals. "We have also significantly strengthened our cash position by completing the convertible debt offering yesterday. These funds will enable us to advance Altastaph and new vaccines in 2005. Our strengthened financial position will also allow us to continue to pursue strategic business development opportunities."

To advance its strategic business plan in 2005, Nabi Biopharmaceuticals has defined the following milestones in key areas:

- File the U.S. BLA for StaphVAX by the end of 2005
- Obtain EU marketing approval for StaphVAX and complete preparations to launch StaphVAX, PhosLo and Nabi-HB Intravenous in major European markets
- Advance the clinical development of Altastaph for treating patients with persistent S. aureus infections
- Advance next generation vaccines for S. aureus Type 336 and S.epidermidis into Phase I clinical trials
- Manufacture next generation Altastaph to prevent *S. aureus* and *S. epidermidis* infections
- Obtain approval and launch Nabi-HB Intravenous in the US market
- Complete the NicVAX<sup>™</sup> [Nicotine Conjugate Vaccine] Phase II dose optimization study and initiate a pivotal NicVAX trial before year-end with outside funding
- Announce preliminary results from the CARE 2 study evaluating PhosLo plus Lipitor® (atorvastatin calcium) versus Renagel® (sevelamer hydrochloride) plus Lipitor.
- Complete enrollment in EPICK studying the use of PhosLo in pre-dialysis chronic kidney disease (CKD) patients with the goal of expanding the labeled indication for PhosLo.

#### Review of Operations

Sales of PhosLo totaled \$3.8 million in the first quarter. As previously reported, Nabi Biopharmaceuticals made a strategic decision to aggressively convert the market from PhosLo tablet formulation to the more compliance enhancing gelcap formulation in 2005. During the first quarter, overall wholesaler inventories for PhosLo were reduced following the company's decision to significantly reduce its inventory on hand of PhosLo tablets prior to year-end and not replenish wholesaler inventories of this formulation in the first quarter. As tablet inventories are depleted, the company expects these inventories to be replenished with PhosLo gelcaps. Third party generated pull through data supports that end-user demand for PhosLo increased 3.4% from the fourth quarter of 2004. Based on this strong end-user demand and increased sales force activity following the conclusion of the WinRho distribution agreement, the company continues to expect that full year sales for PhosLo will total between \$33 and \$36 million.

Sales of Nabi-HB were \$6.7 million in the first quarter of 2005 as compared to sales of \$11.2 million in 2004. Sales during the quarter primarily reflect lower hepatitis B positive liver transplant activity in the period. Based on review of recent literature addressing the increasing incidence of hepatitis B infection breakthroughs among hepatitis B positive liver transplant patients associated with low dosage treatment protocols, the company expects to see increased patient use of Nabi-HB in the second half of 2005.

Sales of WinRho SDF® [Rh<sub>o</sub>(D) Immune Globulin Intravenous (Human)] totaled \$6.2 million in the first quarter of 2005.

Sales of the company's other biopharmaceutical products were \$0.9 million in the first quarter of 2005 compared to \$2.1 million in the first quarter of 2004. Sales were lower in the quarter primarily due to lower Autoplex T (Anti-Inhibitor Coagulant Complex Heat Treated) sales as compared to the first quarter of 2004 as the company's contract with the manufacturer of Autoplex T ended in May 2004 and lower sales of Aloprim™ [All opurinol sodium for injection] due to the introduction of a competitive product. Increased contract manufacturing revenue offset these lower sales.

Sales of antibody products were \$8.6 million in the quarter reflecting lower production of non-specific plasma as the company increased production of specialty plasmas and retention of anti-HBs plasma for future production of Nabi-HB. This transition is consistent with the company's operating strategy for this segment of its operations whereby it will use specialty plasma for the production of its own antibody-based products and sells excess plasma production to customers.

Research and development expenses totaled \$15.3 million in the quarter and increased by approximately 33% compared to the first quarter of 2004. Research and development expenses were driven primarily by the costs associated with advancing the StaphVAX clinical program in preparation for the filing of the StaphVAX BLA expected by the end of 2005. Research and development expenses also included costs related to the ongoing development of StaphVAX manufacturing capabilities at the company's manufacturing facility as well as the company's contract manufacturer's facility.

Selling, general and administrative expenses increased to \$14.4 million due to increased initial commercialization activities in Europe as well as increased employee benefit costs.

Other operating expenses were \$2.3 million for the quarter, comparable to 2004 same quarter totals. These expenses primarily reflect amortization of the intangible assets associated with the acquisition of PhosLo.

As a result, the company reported a net loss of \$15.8 million, or \$0.27 per share for the period compared to a net loss of \$4.8 million or \$0.08 per share in the comparable quarter of 2004.

#### Additional Outlook for 2005

For 2005, total revenues are expected to be in the range of \$137 to \$142 million with biopharmaceutical revenues totaling approximately \$88 to \$91 million. As previously announced, PhosLo revenues are expected to be reported approximately \$33 to \$36 million and Nabi-HB revenues are expected to be level with 2004 totals. Research and development expenses are expected to increase by approximately 10% driven by costs to complete the confirmatory Phase III trial for StaphVAX, the bridging and consistency lot studies, and the immunogenicity studies in other at-risk populations such as orthopedic and cardiovascular surgery patients. As the company assesses the clinical development program for Altastaph and next generation Gram-positive products following completion of the convertible debt offering this week, investment in research and development could increase. Consistent with previous guidance, selling, general and administration expenses are also expected to increase approximately 10% above 2004 levels as the company continues its initial commercialization activities in Europe.

Management's discussion of first quarter 2005 results and expectations for the remainder of 2005 can be accessed through an audio link at Nabi Biopharmaceuticals website at <a href="https://www.nabi.com">www.nabi.com</a>. 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 27, 2005 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 leverages its experience and knowledge in powering the immune system to develop and market products that fight serious medical conditions. We are poised to capture large, commercial opportunities in our four core business areas: Gram-positive bacterial infections, hepatitis, kidney disease (nephrology), and nicotine addiction. We have three products on the market today: PhosLo® (Calcium Acetate), Nabi-HB® [Hepatitis B Immune Globulin (Human)], and Aloprim™ [Allopurinol sodium (for injection)] and a number of products in various stages of clinical and preclinical development. Nabi Biopharmaceuticals has advanced StaphVAX® [Staphylococcus aureus Polysaccharide Conjugate Vaccine] to Phase III clinical development. StaphVAX is designed to prevent the most dangerous and prevalent strains of Staphylococcus aureus bacterial infections. S. 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™ [Staphylococcus aureus Immune Globulin Intravenous (Human)], an antibody for prevention and treatment of S. aureus infections, NicVAX™ [Nicotine Conjugate Vaccine], a vaccine to treat nicotine addiction, and Civacir™ [Hepatitis C Immune Globulin (Human)], an antibody for preventing hepatitis C virus re-infection in liver transplant patients. For additional information on Nabi Biopharmaceuticals, please visit our Website 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 European Union and United

States may not be successful; the possibility that we may not realize the value of our acquisition of PhosLo; the company's ability to raise additional capital on acceptable terms; 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 United States 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 25, 2004 filed with the Securities and Exchange Commission.

# Nabi Biopharmaceuticals CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three Months Ended	
	March 25, 2005	March 27, 2004
Sales	\$ 26,076	\$46,349
Costs and expenses:		
Costs of products sold, excluding amortization of intangible assets	14,862	20,200
Royalty expense	2,199	3,575
Gross Margin, excluding amortization of intangible assets	9,015	22,574
Selling, general and administrative expense	14,402	12,356
Research and development expense	15,255	11,429
Amortization of intangible assets	2,288	2,153
Other operating expense, principally freight	34	63
Operating (loss) income	(22,964)	(3,427)
Other income (expense), net	447	(1,155)
(Loss) income before (provision) benefit for income taxes	(22,517)	(4,582)
Benefit (provision) for income taxes	6,695	(257)
Net (loss) income	\$(15,822)	\$ (4,839)
Basic and diluted (loss) income per share	\$ (0.27)	\$ (0.08)
Basic and diluted weighted average shares outstanding	59,530	57,960
SUPPLEMENTAL INFORMATION:		
Sales by Operating Segment		
Biopharmaceutical Products	\$ 17,493	\$33,936
Antibody Products:	2 720	C 250
Specialty antibodies Non-specific antibodies	3,738 4,845	6,270 6,143
Non-specific annibodies	4,045	0,143
Total antibodies	8,583	12,413
Total	\$ 26,076	\$46,349

(more)

# Nabi Biopharmaceuticals CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, amounts in thousands)

	March 26, 2005	December 25, 2004
Cash, cash equivalents and marketable securities	\$ 70,713	\$ 103,109
Trade accounts receivable, net	20,442	32,405
Inventories, net	21,972	20,175
Prepaid expenses and other assets	13,552	6,899
Property, plant and equipment, net	115,573	115,406
Intangible assets, net	87,606	89,728
Other assets, net	496	449
Total assets	\$330,354	\$ 368,171
Trade accounts payable and accrued expenses	\$ 40,270	\$ 54,233
Notes payable, PhosLo acquisition	14,490	23,844
Other liabilities	5,875	5,773
Stockholders' equity	269,719	284,321
Total liabilities and stockholders' equity	\$330,354	\$ 368,171

Capital expenditures were \$2,463 and \$1,424 for the three months ended March 26, 2005 and March 27, 2004, respectively.

Depreciation and amortization expenses were \$4,776 and \$4,739 for the three months ended March 26, 2005 and March 27, 2004, respectively.

The 2004 condensed balance sheet has been derived from the audited balance sheet for the year ended December 25, 2004. Certain items in the 2004 consolidated financial statements have been reclassified to conform to the current year's presentation.