

**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 15, 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))

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**Nabi Biopharmaceuticals****Item 2.02. Results of Operations and Financial Condition**

On February 15, 2005, Nabi Biopharmaceuticals issued a press release announcing its financial results for the three and twelve months ended December 25, 2004. 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**

<u>Exhibit number</u>	<u>Description</u>
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.

**Nabi Biopharmaceuticals**

Date: February 15, 2005

By: /s/ Mark L. Smith

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

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**Index of Exhibits****Exhibit  
number**

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**Description**

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Press release



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

**FOR IMMEDIATE RELEASE**

***NABI BIOPHARMACEUTICALS REPORTS YEAR-END AND  
 FOURTH QUARTER 2004 RESULTS***

**Record Biopharmaceutical Revenues Drive Doubling of R&D Investment in StaphVAX and Product Pipeline**

**Boca Raton, Florida, February 15, 2005** – Nabi Biopharmaceuticals (Nasdaq: NABI) announced today that biopharmaceutical sales for 2004 were at a record level of \$131.8 million compared to \$109.5 million for 2003, an increase of 20%. This drove the full-year gross margin earned on sales in 2004 to a record 48% of sales or \$85.8 million, compared to \$76.8 million or 44% of sales for 2003. The higher margin on biopharmaceutical sales funded an unprecedented level of clinical and research achievement, including filing for licensure of three products in Europe: StaphVAX® (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine), PhosLo® (calcium acetate) and Nabi-HB® Intravenous [Hepatitis B Immune Globulin (Human) Intravenous] under the trade name HEBIG™; fully enrolling the confirmatory Phase III clinical trial of StaphVAX in the United States; and establishing external and internal commercial scale vaccine manufacturing capacity. The company doubled its strategic investment in research and development activities to \$61.0 million for 2004 compared to \$29.0 million for 2003.

“Our significant activities in 2004 were directed toward the commercialization of StaphVAX, which will be a significant transforming event for our company. These efforts culminated in the submission of the Marketing Authorization Application or MAA for StaphVAX in Europe in December. In addition, the experience and relationships we are building in marketing PhosLo in the United States will be invaluable as we build our commercial presence in Europe to support the launch of StaphVAX, focused on an initial indication for its use in dialysis patients,” stated Thomas H. McLain, chairman, chief executive officer, and president, Nabi Biopharmaceuticals.

Mr. McLain continued, “The strength of our operating strategy of using cash flow from operating activities, especially the cash flow generated by our biopharmaceutical business, allowed us to self-fund the increased strategic investment in our product development pipeline in 2004. In addition to the StaphVAX MAA, we submitted license applications for HEBIG and PhosLo in Europe, under the Mutual Recognition Procedure. We also reported encouraging clinical results for Altastaph™ [*Staphylococcus aureus* Immune Globulin Intravenous (Human)], an antibody-based Gram-positive infection product for the treatment of adults with persistent *S. aureus* infections, and for NicVAX™ (Nicotine Conjugate Vaccine), our vaccine being developed to treat nicotine addiction. We were also able to accelerate the development of two next generation vaccines to prevent the third common strain of *S. aureus* infections, type 336, and to prevent *S. epidermidis* infections. We expect both products to begin clinical testing in 2005. These vaccines are also key to manufacturing a next generation Altastaph product being developed to prevent *S. aureus* and *S. epidermidis* infections in very low birth-weight infants. Finally, in addition to developing full commercial scale manufacturing for StaphVAX at our contract manufacturer, we also completed the construction of our own state-of-the-art vaccine plant in our manufacturing facility in Boca Raton, Florida. Our plant has now initiated production with a goal of manufacturing three consistency lots of StaphVAX in 2005.

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Clearly, this level of achievement in 2004 is a reflection of the talented and dedicated team working at Nabi Biopharmaceuticals. We have great momentum moving into 2005 as we pursue major global market opportunities in the areas of Gram-positive infections, kidney disease, hepatitis, and nicotine addiction.”

The company’s cash and cash equivalents at December 25, 2004 were \$103.1 million compared to \$115.8 million at December 27, 2003 after spending over \$25 million in vaccine manufacturing capacity and capability, including a \$17.8 million investment in the Boca Raton, Florida vaccine manufacturing plant.

## **2004 Milestones and Recent Developments**

### **StaphVAX**

- Filed Marketing Authorization Application (MAA) with the European Medicines Evaluation Agency (EMA) to market StaphVAX within the European Union (EU).
- Completed the transfer of the manufacturing process for StaphVAX to Cambrex Bioscience and successfully produced three consistency lots of the vaccine at its facility.
- Completed the construction of a new state-of-the-art vaccine plant within the existing facility in Florida.
- U.S. Food and Drug Administration (FDA) granted StaphVAX Fast Track Designation in the prevention of *S. aureus* bloodstream infections in end-stage renal disease (ESRD) patients.
- Completed patient enrollment for the company’s Phase III trial in the United States designed to confirm that StaphVAX prevents *S. aureus* infections in ESRD patients through 8 months.
- Initiated immunogenicity studies for StaphVAX in other at-risk patient populations of cardiovascular and orthopedic surgery patients. The data will be used to support broader labeling for StaphVAX in the United States and Europe.
- Study results presented at the 2004 Interscience Conference on Antimicrobial Agents and Chemotherapy and the American Heart Association showed that *S. aureus* bloodstream infections in surgical patients with cardiovascular and orthopedic implant devices significantly increased the incidence of medical complications, treatment costs and death.

### **Altastaph**

- Announced encouraging results from a U.S. Phase I/II clinical trial using Altastaph to treat adult patients hospitalized with persistent *S. aureus* bloodstream infections.
- Reported results from a Phase II trial demonstrating that Altastaph was safe and able to generate levels of *S. aureus* specific antibodies believed necessary for protection in neonates. The company also announced its plans to rapidly advance a next generation Altastaph product that will target all three strains of *S. aureus* (types 5, 8 and 336), as well as *S. epidermidis* infections, before continuing clinical studies in these patients. In fact, *S. epidermidis* is more prevalent than *S. aureus* bacteria in neonates and is a cause of significant illness and death among these patients.

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### NicVAX

- Reported positive Phase II clinical results for NicVAX, which is being developed as an aid to smoking cessation.

### Additional Product Filings

- Filed a MAA using the Common Technical Document (CTD) format in Europe to obtain registration for the use of PhosLo in controlling elevated phosphorus levels (hyperphosphatemia) in patients with ESRD.
- Filed a MAA seeking approval to market HEBIG™ in Europe.
- Filed additional data with the FDA to support our Biologics License Application (BLA) for Nabi-HB Intravenous in the United States to support an indication for liver transplantation.

### Intellectual Property

- Awarded a European patent for NicVAX, which in combination with three U.S. issued patents, significantly bolsters the company's global intellectual property position for this product.
- Awarded a U.S. Patent for Enterococcus Antigens and Vaccines that further strengthens the company's intellectual property position around its Gram-positive product portfolio.

### Leadership

- Thomas H. McLain was elected chairman of the company's board of directors, in addition to his roles as chief executive officer and president.
- H. LeRoux Jooste joined the company as senior vice president, global sales and marketing. Mr. Jooste is responsible for advancing the company's commercial presence in Europe, the United States and in other important markets around the world. In 2005, he will direct efforts toward the launches of StaphVAX, PhosLo, and HEBIG in Europe; build marketing, reimbursement and selling initiatives for the company's currently marketed products (focused initially on PhosLo); and lead the planning for the launch of StaphVAX in the United States.
- Richard G. Clark joined the company as senior vice president, administration and chief administration officer. Mr. Clark will lead the company's efforts to continue building a world-class organization equipped to address the important global opportunities for the company's products.
- Pamela Joy Barton, Ph.D., also joined the company as vice president, business development. Dr. Barton's focus will be in three strategic areas: products, technologies and alliances.

### Review of Operations

Total sales for 2004 were \$179.8 million compared to total sales \$176.6 million for 2003.

Sales of PhosLo were \$37.6 million in 2004, ahead of internal expectations. Sales of PhosLo totaled \$9.3 million in the fourth quarter compared to \$7.8 million in fourth quarter of 2003. The increase in full-year sales reflects higher patient demand for PhosLo, which increased 7% in 2004 compared to 2003, as reported by third party prescription tracking data and higher wholesaler inventories of the product. In addition, PhosLo sales benefited from price increases announced in January and September 2004.

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In planning for 2005, the company made a strategic decision to convert from PhosLo tablets to the compliance enhancing gelcap formulation. Results in the fourth quarter included actions that converted tablet inventories to cash. This resulted in incremental revenue of approximately \$2.5 million and a corresponding increase in wholesaler tablet inventory levels. These tablet inventories are expected to be depleted throughout 2005. PhosLo gelcap inventory levels at wholesaler customers have remained relatively stable after the company brought additional PhosLo gelcap manufacturing capacity on line to meet increased wholesaler demand in the first quarter of 2004.

Full-year revenues of Nabi-HB totaled \$40.2 million, an increase of 7% from 2003. Sales of Nabi-HB were \$5.3 million for the fourth quarter of 2004 compared to \$11.3 million for the fourth quarter of 2003. Sales of Nabi-HB are correlated to the number of hepatitis B liver transplants in the United States. Internally generated data indicates that the number of liver transplants for hepatitis B patients for 2004 have increased by approximately 20% compared to the corresponding period in 2003. Sales of Nabi-HB did not grow in tandem with this increase because of the impact of changes in maintenance treatment protocols for HBV-positive liver transplant patients that have resulted in increased usage of less costly anti-viral drugs and lower dosing of Nabi-HB.

Full-year sales of WinRho SDF<sup>®</sup> [Rho (D) Immune Globulin Intravenous (Human)] totaling \$47.9 million were approximately 4% lower in 2004 compared to the record sales levels of \$50.0 million in 2003. Fourth quarter sales of WinRho SDF totaled \$13.5 million in 2004, nearly a 10% increase over the same period in 2003. Based on internally generated patient use data, the company believes patient demand for WinRho SDF in 2004 has decreased in line with reported sales trends in 2004. As previously communicated, Nabi Biopharmaceuticals' agreement with Cangene Corporation to distribute WinRho SDF in the United States will end in March 2005.

Sales of the company's other biopharmaceutical products, which include Aloprim<sup>®</sup> [(Allopurinol sodium) for injection], Autoplex<sup>®</sup> T [Anti-Inhibitor Coagulant Complex, Heat Treated], intermediate products manufactured in its plant and contract manufacturing, were \$6.2 million in 2004 compared to \$9.0 million for 2003. Sales of Aloprim were lower in 2004 compared to 2003 reflecting new competition in this niche market. Sales of Autoplex were consistent in 2004 and 2003. The company's contract with the manufacturer of Autoplex ended on May 11, 2004.

Selling, general and administrative expense was \$55.3 million for 2004 compared to \$43.9 million for 2003. Increased selling, general and administrative expense for 2004 was primarily related to full-year selling and marketing expense for PhosLo, initial commercialization activities in Europe and costs related to implementation of the requirements of Section 404 of the Sarbanes-Oxley Act. Selling, general and administrative expense for 2003 included a charge of \$3.3 million related to the retirement of the company's former chief executive officer.

Other operating expense was \$9.2 million for 2004 compared to \$4.3 million for 2003. The increase in 2004 is due primarily to full-year amortization of the intangible assets associated with the acquisition of PhosLo.

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Income tax expense of \$10.5 million for the year resulted from recording a taxable gain in the United States due to an internal restructuring for the licensure of the EU marketing rights for StaphVAX and PhosLo. This restructuring is an important early step in the company's European commercialization plans and should produce long-term tax benefits for the company. The company anticipates that the majority of this gain will be offset by the utilization of previously incurred net operating loss benefits and research and development tax credits reducing the deferred tax assets recorded for these items.

Including the increased investment in research and development and income tax expense, Nabi Biopharmaceuticals reported a net loss for 2004 of \$50.4 million, or \$0.86 per share.

**Outlook for 2005**

In commenting on key drivers beyond the company's efforts to license and launch StaphVAX, Mr. McLain noted, "We will be focused not only on the significant medical need for our products, but also on the contribution they can make in addressing the increasing cost and burden of medical care on society. We expect the need in Europe and the United States to balance the cost of care with outcomes will, out of necessity, continue to intensify over the remainder of this decade. For our industry to succeed, we must focus on offering innovative solutions that not only improve health and save lives, but that are also cost effective. We believe our company is positioned to play an important role in this changing environment. StaphVAX will not only fill a significant and growing unmet medical need, but it will help to define a new economic paradigm in preventing a costly infection in high risk patients. In the same way, we believe PhosLo is an ideal solution to the U.S. commitment to provide an effective prescription drug benefit program for patients on Medicare. PhosLo has clinically proven advantages over the competitive prescription product at a significant cost savings and can be one contributor to society's demand for safe, effective and more affordable healthcare solutions."

Total 2005 sales are expected to be in the range of \$142 to \$148 million, including biopharmaceutical revenues in the range of \$93 to \$96 million. As announced previously, the company's distribution agreement for WinRho SDF will end in the first quarter. WinRho SDF contributed \$48 million in sales in 2004. The company expects to generate a double-digit increase in patient demand for PhosLo in 2005. However, we are holding our guidance for reported revenues at 5 to 10% below 2004 levels to anticipate three factors which may lead to reduced wholesaler inventories. These are exhaustion of PhosLo tablet inventories, Medicare driven limits on future price increases and the stocking of new competitive therapies.

Nabi-HB revenues are expected to be level with 2004 sales. The company continues to monitor the protocol changes that have resulted in reduced Nabi-HB usage in liver transplant patients and are looking forward to receiving feedback from European and U.S. regulators on its Nabi-HB filings for use in liver transplant patients. WinRho SDF revenues will continue through the first quarter of 2005. Antibody sales are expected to be at approximately the same levels as reported in 2004.

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Research and development expenses are expected to increase by approximately 10% in 2005 above 2004 levels. This increase will be driven by StaphVAX related costs for completion of the confirmatory Phase III trial, two sets of bridging and consistency lot clinical trials, completion of immunogenicity studies, and a boosting study in preparation for filing of the U.S. BLA. The company will define next steps to advance its Altastaph clinical program following discussions with United States and European regulators on the recently completed phase I/II study in patients with persistent *S. aureus* infections. The company also expects to continue its clinical programs in support of expanded labeling and usage of PhosLo.

During 2005, the company expects capital expenditures to be approximately \$10 million to \$11 million. Overall, based on available cash resources and the expected cash margin earned on product sales the company believes it has the financial resources to successfully execute its 2005 plans. However, the company does not anticipate generating a positive cash flow from operating activities in 2005 due to its continued investment in research and development and expiration of the WinRho SDF distribution agreement.

Management's discussion of full-year and fourth quarter 2004 results can be accessed through an audio link at Nabi Biopharmaceuticals' website: [www.nabi.com](http://www.nabi.com). The audio web cast will begin today at 4:30 p.m. Eastern Time and a replay of the audio web cast will remain available through February 22, 2005 at 5:00 p.m. Eastern Time. If you have any questions concerning the audio web cast, 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 four marketed products (PhosLo<sup>®</sup>, Nabi-HB<sup>®</sup>, WinRho SDF<sup>®</sup>, Aloprim<sup>™</sup>), 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 *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<sup>™</sup>, an antibody for prevention and treatment of *S. aureus* infections, currently in Phase II testing, NicVAX<sup>™</sup>, a vaccine to treat nicotine addiction, 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 Website at: [www.nabi.com](http://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 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 Months Ended		For the Twelve Months Ended	
	Dec. 25, 2004	Dec. 27, 2003	Dec. 25, 2004	Dec. 27, 2003
<b>Sales</b>	\$ 41,648	\$ 47,975	\$ 179,763	\$ 176,570
<b>Costs and expenses:</b>				
Costs of products sold, excluding amortization of intangible assets	21,310	18,572	76,345	81,354
Royalty expense	4,646	4,666	17,569	18,387
<b>Gross Margin, excluding amortization of intangible assets</b>	15,692	24,737	85,849	76,829
Selling, general and administrative expense	16,440	11,678	55,286	43,867
Research and development expense	14,954	10,857	61,003	29,040
Amortization of intangible assets	2,248	2,147	8,673	3,775
Other operating expense, principally freight	153	153	521	477
Write-off of intangible asset	—	12,575		12,575
<b>Operating (loss) income</b>	(18,103)	(12,673)	(39,634)	(12,905)
<b>Other income (expense), net</b>	617	(493)	(358)	(532)
<b>(Loss) income before (provision) benefit for income taxes</b>	(17,486)	(13,166)	(39,992)	(13,437)
<b>Benefit (provision) for income taxes</b>	434	6,591	(10,398)	6,605
<b>Net (loss) income</b>	\$ (17,052)	\$ (6,575)	\$ (50,390)	\$ (6,832)
<b>Basic and diluted (loss) income per share</b>	\$ (0.29)	\$ (0.14)	\$ (0.86)	\$ (0.16)
<b>Basic and diluted weighted average shares outstanding</b>	59,302	48,097	58,800	42,888
<b>SUPPLEMENTAL INFORMATION:</b>				
<b>Sales by Operating Segment</b>				
Biopharmaceutical Products	\$ 28,758	\$ 34,095	\$ 131,813	\$ 109,459
Antibody Products:				
Specialty antibodies	5,631	5,268	23,270	21,425
Non-specific antibodies	7,259	8,611	24,680	45,686
<b>Total antibodies</b>	12,890	13,879	47,950	67,111
<b>Total</b>	\$ 41,648	\$ 47,974	\$ 179,763	\$ 176,570

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

	December 25, 2004	December 27, 2003
Cash and cash equivalents	\$ 103,109	\$ 115,756
Trade accounts receivable, net	32,406	37,062
Inventories, net	20,175	23,483
Prepaid expenses and other assets	6,898	10,284
Property, plant and equipment, net	115,406	101,831
Intangible assets, net	89,728	94,991
Other assets, net	449	3,894
<b>Total assets</b>	<b>\$ 368,171</b>	<b>\$ 387,301</b>
Trade accounts payable and accrued expenses	\$ 54,233	\$ 34,830
Notes payable, PhosLo acquisition	23,844	27,393
Other liabilities	5,773	5,762
Stockholders' equity	284,321	319,316
<b>Total liabilities and stockholders' equity</b>	<b>\$ 368,171</b>	<b>\$ 387,301</b>

Capital expenditures were \$22,633 and \$8,050 for the twelve months ended December 25, 2004 and December 27, 2003, respectively.

Depreciation and amortization expenses were \$18,178 and \$14,236 for the twelve months ended December 25, 2004 and December 27, 2003, respectively.

*The 2003 condensed balance sheet has been derived from the audited balance sheet for the year ended December 27, 2003. Certain items in the 2003 consolidated financial statements have been reclassified to conform to the current year's presentation.*

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