

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 OR 15(d) of
The Securities Exchange Act of 1934**

October 19, 2004

Date of Report (Date of earliest event reported)

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
(Address of principal executive offices)

33487
(Zip Code)

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

(Former name or former address, if changed since last report)

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 October 19, 2004, Nabi Biopharmaceuticals issued a press release announcing its financial results for the three and nine months ended September 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.

Date: October 19, 2004

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

<u>Exhibit number</u>	<u>Description</u>
99	Press release



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

**NABI BIOPHARMACEUTICALS REPORTS STRONG CASH FLOW FROM OPERATIONS
FOR THE THIRD QUARTER OF 2004**

- - Supports Advancement of Research and Development Pipeline - -

Boca Raton, Florida October 19, 2004 – Nabi Biopharmaceuticals (Nasdaq: NABI) today announced that strong sales performance for PhosLo® (calcium acetate) and Nabi-HB® [Hepatitis B Immune Globulin (Human)] drove an increase in net cash provided by operating activities in the third quarter of 2004. The gross margin earned on product sales exceeded 50% for the second quarter in a row, underscoring the pace of the company’s transformation to become a fully integrated biopharmaceutical company. Despite increasing its investment in research and clinical trial support for StaphVAX® (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine) by \$12.3 million from 2003 levels, operating cash flow totaled a positive \$5.2 million in the 2004 third quarter. Led by increases in year-to-date biopharmaceutical sales, including the strength of sales of PhosLo and Nabi-HB, gross margin for the first nine months of 2004 exceeded 50%. Year-to-date net cash provided by operating activities totaled a positive \$10.4 million, as the increased cash return on product sales more than funded a \$27.9 million or 153% increase in total research and development spending. Consistent with expectations, this increased investment in research and clinical programs has resulted in a net loss for the third quarter and year-to-date periods.

Also, as announced previously, the company began its investment in constructing a state-of-the-art vaccine plant in its manufacturing facility in Boca Raton, Florida. Capital expenditures for this project totaled \$8.4 million during the third quarter. When completed at the end of this year, the total investment is projected to total between \$18 and \$20 million.

“We continue to successfully execute on our strategy of advancing key research and clinical programs by generating cash flow from product sales,” stated Thomas H. McLain, chairman, chief executive officer and president of Nabi Biopharmaceuticals. “Our significant increase in research and development spending drove important progress in our clinical programs during the third quarter. We completed enrollment in the StaphVAX Phase III clinical trial, completed the manufacture of three consistency lots of StaphVAX at our manufacturing partner’s site and are on target to file the Marketing Authorization Application for StaphVAX in the EU during the fourth quarter. In addition, we recently announced very encouraging clinical trial results for NicVAX, our vaccine being developed to treat and prevent nicotine addiction. We are also excited by the rapid progress in the construction of our vaccine manufacturing facility in Boca Raton, Florida. We have also announced important additions that strengthen our intellectual property portfolio, namely the issuance of patents in the US related to antigens for another Gram-positive bacteria that causes serious infections in the hospital, Enterococcus, and for NicVAX in Europe. The entire Nabi team is working together to drive our progress toward achieving all of our strategic goals for 2004.”

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Recent Developments

- StaphVAX received Fast Track Designation from the US Food and Drug Administration (FDA) for the prevention of *S. aureus* bloodstream infections in end-stage renal (kidney) disease (ESRD) patients.
- The company fully enrolled its Phase III efficacy trial designed to confirm that StaphVAX can prevent *S. aureus* infections. The trial is being conducted in ESRD patients who are at a particularly high-risk for infection due to the invasive nature of their dialysis treatment.
- The company completed the successful manufacture of three consistency lots of StaphVAX at its manufacturing partner's location ahead of schedule. The data from manufacturing the vaccine at commercial scale is required for the StaphVAX Marketing Authorization Application (MAA) that will be submitted to the European Union (EU) by the end of 2004.
- The company initiated construction of a state-of-the-art bulk vaccine manufacturing facility within available space in its licensed biopharmaceutical manufacturing facility in Boca Raton, Florida. It is expected to be completed by year-end.
- The company was granted US Patent No. 6,756,361 covering the composition of multiple *Enterococcus* capsular polysaccharide antigens that have been shown to raise specific antibodies against multi-drug resistant enterococcal species. These antigens cover more than 85% of all enterococcal infection isolates from hospitals across the US.
- Nabi Biopharmaceuticals is initiating the CARE 2 study that will compare efficacy, including lipid control and arterial calcification in patients treated with PhosLo plus Lipitor® (atorvastatin calcium) and Renagel® (sevelamer hydrochloride) plus Lipitor.
- The company announced positive Phase II clinical results for NicVAX. The results indicated a 33% quit rate in smokers who received NicVAX at the highest dose level versus 9% in the placebo group. The results represented a vaccine-only effect, as patients were only given NicVAX without any supplemental treatments, behavioral support or counseling.
- The European Patent Office issued patent number EP 1,135,166 to the company. This patent, together with the company's other patents significantly expand its global intellectual property position for NicVAX.

Review of Operations

Total sales for the third quarter of 2004 were \$43.8 million, including \$32.8 million of biopharmaceuticals revenue.

Sales of PhosLo totaled \$9.2 million in the third quarter compared to sales of \$5.0 million for the third quarter of 2003 following the acquisition of the product on August 4, 2003. The company's review of third party generated patient prescription data for PhosLo indicates that total prescriptions of PhosLo now exceed those for the competing therapy. Based on this strengthening patient demand, wholesaler customers have sought to maintain their months inventory on hand at approximately six months. In addition, sales of PhosLo have benefited from pricing strategies in the

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current year that have resulted in lower rebate deductions from gross selling price thereby increasing net average selling price for the product. The continued high level of customer demand for PhosLo, combined with an announced price increase to take effect in the fourth quarter of 2004, have resulted in Nabi Biopharmaceuticals reporting unfilled orders of approximately \$4 million at the end of the third quarter. Based on patient demand levels, the company is maintaining its revenue guidance for PhosLo at between \$35 and \$37 million for the full year 2004.

Sales of Nabi-HB were \$13.7 million in the third quarter of 2004 compared to sales of \$8.9 million in 2003. As previously discussed 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 recent hepatitis B liver transplants levels have sustained the increases reported in the second quarter of 2004 leading to further increased demand for Nabi-HB from customers. Sales of Nabi-HB also benefited from a price increase that went into effect in early 2004.

Sales of WinRho SDF[®] [Rho (D) Immune Globulin (Human)] were \$7.8 million in the third quarter of 2004 compared to \$13.5 million in the comparable quarter of 2003. Year-to-date patient demand for WinRho SDF in 2004 is consistent with 2003 levels as measured by internal company reports. Customer buying trends for this product have resulted in quarter-to-quarter fluctuations in sales levels. Factors that have contributed to these trends have included implementation of a new pricing strategy by the company in the first quarter of 2004 and changes in provider contracts amongst the wholesaler customers who are significant suppliers of this product. Sales of WinRho SDF for the first nine months of 2004 totaled \$34.4 million compared to \$37.6 million for the 2003 period. Based primarily on sustained patient demand and the impact a new pricing strategy implemented in 2004, the company continues to expect full year sales of this product to increase from 2003 levels. In conjunction with the announcement of second quarter earnings, the company announced that its right to distribute WinRho SDF will end in March 2005.

Sales of the company's other biopharmaceutical products were \$2.1 million in the third quarter of 2004 compared to \$3.2 million in the second quarter of 2003. While sales of Aloprim[®] [(Allopurinol sodium) for injection] were lower in the third quarter of 2004 compared to 2003, gross margin from this product increased in the period due to reduced royalty expense as a result of the company's acquisition of this product on June 29, 2004. As previously reported, supply of Autoplex[®] T [Anti-Inhibitor Coagulant Complex, Heat Treated] to Nabi Biopharmaceuticals ceased in May 2004 limiting sales in the third quarter.

Research and development expenses in the third quarter increased significantly compared to the third quarter of 2003 due primarily to the costs associated with the confirmatory phase III clinical trial of StaphVAX that was initiated in late September 2003 and fully enrolled in August 2004. Research and development expenses also included costs related to manufacturing consistency lots of StaphVAX at Cambrex Bio Science to support the license application in the EU as well as work to establish a vaccine manufacturing facility in Nabi Biopharmaceuticals' Boca Raton, Florida location.

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Selling, general and administrative expenses in the 2004 third quarter increased \$2.7 million due to marketing costs for PhosLo, initial commercialization activities in Europe and costs to meet Sarbanes-Oxley requirements. Because PhosLo was acquired in August 2003, there were limited marketing and sales costs related to PhosLo in the first nine months of 2003. The investment in Europe is in line with the company's expectation of filing MAA's for StaphVAX and PhosLo later this year. The company filed a MAA for Nabi-HB in June.

For the third quarter of 2004, the company reported a net loss of \$10.9 million or \$0.18 per share.

After funding research and development activities of \$46.0 million, principally for StaphVAX, the company generated positive cash flow from operations of \$10.4 million for the first nine-months of 2004. For the nine-month period of 2004, on total sales of \$138.1 million, the company reported a net loss of \$33.3 million or \$0.57 per share. During this period, biopharmaceuticals sales increased 37% to \$103.1 million. Overall gross margin increased 35% to \$70.2 million.

Management's discussion of third quarter 2004 results and an update of the outlook for 2004 can be accessed through an audio link at Nabi Biopharmaceuticals website at <http://audioevent.msnow.com/189142/>. The audio webcast will begin today at 4:30 p.m. Eastern Time and a replay of the audio webcast will remain available through October 26, 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 four marketed products (PhosLo[®], Nabi-HB[®], WinRho SDF[®], Aloprim[™]), 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 Staphylococcus aureus bacterial infections. Saureus 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 and treatment of *S. aureus* infections, currently in Phase II testing, NicVAX[™], a vaccine to treat nicotine addiction, and Civacir[™], 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 EU may not be successful; the possibility that we may not realize the value of our acquisition of PhosLo; 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 Months Ended		For the Nine Months Ended	
	Sept. 25, 2004	Sept. 27, 2003	Sept. 25, 2004	Sept. 27, 2003
Sales	\$ 43,774	\$42,435	\$ 138,115	\$ 128,595
Costs and expenses:				
Costs of products sold	17,495	16,101	55,033	62,781
Royalty expense	3,331	5,423	12,924	13,722
Gross Margin	22,948	20,911	70,158	52,092
Selling, general and administrative expense	12,009	9,351	38,846	32,189
Research and development expense	17,718	6,454	46,049	18,183
Amortization of intangible assets	2,105	1,460	6,424	1,629
Other operating expense, principally freight	175	128	370	324
Operating (loss) income	(9,059)	3,518	(21,531)	(233)
Other income (expense), net	141	(363)	(975)	(38)
(Loss) income before (provision) benefit for income taxes	(8,918)	3,155	(22,506)	(271)
(Provision) benefit for income taxes	(2,003)	(962)	(10,832)	14
Net (loss) income	\$(10,921)	\$ 2,193	\$ (33,338)	\$ (257)
Basic (loss) income per share	\$ (0.18)	\$ 0.05	\$ (0.57)	\$ (0.01)
Diluted (loss) income per share	\$ (0.18)	\$ 0.05	\$ (0.57)	\$ (0.01)
Basic weighted average shares outstanding	59,149	45,355	58,632	41,152
Diluted weighted average shares outstanding	59,149	46,285	58,632	41,152
SUPPLEMENTAL INFORMATION:				
Sales by Operating Segment				
Biopharmaceutical Products	\$ 32,823	\$30,710	\$ 103,055	\$ 75,363
Antibody Products:				
Specialty antibodies	4,621	3,679	17,639	16,158
Non-specific antibodies	6,330	8,046	17,421	37,074
Total antibodies	10,951	11,725	35,060	53,232
Total	\$ 43,774	\$42,435	\$ 138,115	\$ 128,595

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

	September 25, 2004	December 27, 2003
Cash and cash equivalents	\$ 110,780	\$ 115,756
Trade accounts receivable, net	34,706	37,062
Inventories, net	21,495	23,483
Prepaid expenses and other assets	7,481	10,284
Property, plant and equipment, net	110,174	101,831
Intangible assets, net	91,975	94,991
Other assets, net	1,479	3,894
Total assets	\$ 378,090	\$ 387,301
Trade accounts payable and accrued expenses	\$ 47,908	\$ 34,830
Notes payable, PhosLo acquisition	22,911	27,393
Other liabilities	7,422	5,762
Stockholders' equity	299,849	319,316
Total liabilities and stockholders' equity	\$ 378,090	\$ 387,301

Capital expenditures were \$15,194 and \$4,082 for the nine months ended September 25, 2004 and September 27, 2003, respectively.

Depreciation and amortization expenses were \$14,093 and \$9,623 for the nine months ended September 25, 2004 and September 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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