

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

---

**FORM 10-Q**

---

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 27, 2004

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-04829

---

**Nabi Biopharmaceuticals**

(Exact name of registrant as specified in its charter)

---

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**59-1212264**  
(I.R.S. Employer  
Identification No.)

**5800 Park of Commerce Boulevard N.W., Boca Raton, FL 33487**  
(Address of principal executive offices, including zip code)

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

---

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding twelve months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

The number of shares outstanding of the registrant's common stock, par value \$0.10 per share, at April 21, 2004 was 57,561,012 shares.

---

[Table of Contents](#)

Nabi Biopharmaceuticals

	<b>INDEX</b>
	<u>Page No.</u>
<b>PART I.</b>	<b><u>FINANCIAL INFORMATION</u></b>
Item 1.	<b><u>Financial Statements</u></b> 3
-	<u>Condensed Consolidated Balance Sheets, as of March 27, 2004 (unaudited) and December 27, 2003</u> 3
-	<u>Condensed Consolidated Statements of Operations (unaudited) for the Three Months Ended March 27, 2004 and March 29, 2003</u> 4
-	<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the Three Months Ended March 27, 2004 and March 29, 2003</u> 5
-	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u> 6
Item 2.	<b><u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></b> 14
Item 3.	<b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b> 22
Item 4.	<b><u>Controls and Procedures</u></b> 23
<b>PART II.</b>	<b><u>OTHER INFORMATION</u></b>
Item 1.	<b><u>Legal Proceedings</u></b> 24
Item 2.	<b><u>Changes in Securities and Use of Proceeds and Issuer Purchases of Equity Securities</u></b> 24
Item 3.	<b><u>Defaults Upon Senior Securities</u></b> 24
Item 4.	<b><u>Submission of Matters to a Vote of Security Holders</u></b> 24
Item 5.	<b><u>Other Information</u></b> 24
Item 6.	<b><u>Exhibits and Reports on Form 8-K</u></b> 24
	<b><u>Signatures</u></b> 25
	<b><u>Certifications</u></b>

[Table of Contents](#)

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

## Nabi Biopharmaceuticals

## CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except for share and per share amounts)	(UNAUDITED) March 27, 2004	December 27, 2003
<b>Assets</b>		
<b>Current assets:</b>		
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 current assets	8,854	10,284
<b>Total current assets</b>	<b>183,699</b>	<b>186,585</b>
<b>Property, plant and equipment, net</b>	<b>100,874</b>	<b>101,831</b>
<b>Other assets:</b>		
Intangible assets, net	94,292	94,991
Other, net	3,740	3,894
<b>Total assets</b>	<b>\$ 382,605</b>	<b>\$ 387,301</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Trade accounts payable	\$ 14,298	\$ 10,874
Accrued expenses	21,803	23,956
Current portion of notes payable, PhosLo acquisition, net	8,233	4,226
<b>Total current liabilities</b>	<b>44,334</b>	<b>39,056</b>
<b>Notes payable, PhosLo acquisition, less current portion, net</b>	<b>15,372</b>	<b>23,167</b>
<b>Other liabilities</b>	<b>5,536</b>	<b>5,762</b>
<b>Total liabilities</b>	<b>65,242</b>	<b>67,985</b>
<b>Stockholders' equity:</b>		
Convertible preferred stock, par value \$.10 per share: 5,000,000 authorized; no shares outstanding	—	—
Common stock, par value \$.10 per share: 75,000,000 authorized; 58,169,911 and 57,772,302 shares outstanding, respectively	5,817	5,773
Capital in excess of par value	300,743	297,909
Treasury stock, 800,315 shares at cost	(5,240)	(5,240)
Retained earnings	16,035	20,874
Other accumulated comprehensive income	8	—
<b>Total stockholders' equity</b>	<b>317,363</b>	<b>319,316</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 382,605</b>	<b>\$ 387,301</b>

See accompanying notes to consolidated financial statements.

## Nabi Biopharmaceuticals

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	(UNAUDITED)	
	For the Three Months Ended	
(In thousands, except per share amounts)	March 27, 2004	March 29, 2003
<b>Sales</b>	\$ 46,349	\$ 51,511
<b>Costs and expenses:</b>		
Costs of products sold	20,200	30,954
Royalty expense	3,575	3,915
<b>Gross margin</b>	22,574	16,642
Selling, general and administrative expense	12,356	10,139
Research and development expense	11,429	5,794
Amortization of intangible assets	2,153	88
Other operating expense, principally freight	63	102
<b>Operating (loss) income</b>	(3,427)	519
Interest income	336	206
Interest expense	(1,490)	(1)
Other (expense) income, net	(1)	9
<b>(Loss) income before provision for income taxes</b>	(4,582)	733
Provision for income taxes	(257)	(184)
<b>Net (loss) income</b>	\$ (4,839)	\$ 549
<b>Basic (loss) earnings per share</b>	\$ (0.08)	\$ 0.01
<b>Diluted (loss) earnings per share</b>	\$ (0.08)	\$ 0.01
<b>Basic weighted average shares outstanding</b>	57,960	38,962
<b>Diluted weighted average shares outstanding</b>	57,960	39,719

See accompanying notes to consolidated financial statements.

## Nabi Biopharmaceuticals

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)	For the Three Months Ended	
	March 27, 2004	March 29, 2003
<b>Cash flow from operating activities:</b>		
Net (loss) income	\$ (4,839)	\$ 549
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:		
Depreciation and amortization	4,739	2,626
Provision for doubtful accounts	144	11
Provision for slow moving or obsolete inventory	310	51
Write-off of loan origination fees	539	—
Gain on sale of assets	(119)	—
Write-off of obsolete fixed assets	145	—
Changes in assets and liabilities:		
Decrease in trade accounts receivable	15	6,875
Decrease (increase) in inventories	1,966	(3,789)
Decrease (increase) in prepaid expenses and other current assets	1,042	(964)
Increase in other assets	(38)	—
Increase (decrease) in accounts payable and accrued liabilities	1,022	(7,644)
Total adjustments	9,765	(2,834)
<b>Net cash provided by (used in) operating activities</b>	<b>4,926</b>	<b>(2,285)</b>
<b>Cash flow from investing activities:</b>		
Proceeds from sales of assets	179	—
Capital expenditures	(1,424)	(562)
Expenditures for Manufacturing Rights	(1,453)	(2,217)
<b>Net cash used in investing activities</b>	<b>(2,698)</b>	<b>(2,779)</b>
<b>Cash flow from financing activities:</b>		
Payment of notes payable, PhosLo acquisition	(4,083)	—
Proceeds from exercise of employee stock options	2,878	266
<b>Net cash (used in) provided by financing activities</b>	<b>(1,205)</b>	<b>266</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>1,023</b>	<b>(4,798)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>115,756</b>	<b>51,737</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 116,779</b>	<b>\$ 46,939</b>

See accompanying notes to consolidated financial statements.

NOTE 1 OVERVIEW

We apply our knowledge of the human immune system to develop and commercialize products that address serious, unmet medical needs. Our 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> and Autoplex<sup>®</sup> T), we have four products in clinical trials. We expect to file a Marketing Authorization Approval, or MAA, for StaphVAX<sup>®</sup> in the European Union, or EU, in 2004 based on existing clinical data. For U.S. licensure, we have advanced StaphVAX to confirmatory Phase III clinical trial development and anticipate completing enrollment in this trial in the third quarter of 2004. We anticipate filing a Biologics License Application, or BLA, for StaphVAX by the end of 2005. StaphVAX is designed to prevent the most dangerous and prevalent strains of Staph aureus bacterial infections, which are a major cause of hospital and community-acquired infections, and Staph aureus bacteria are becoming increasingly resistant to antibiotics. Our other products in development are Altastaph<sup>™</sup>, an antibody based product for prevention of Staph aureus infections, Civacir<sup>™</sup>, an antibody based product for preventing hepatitis C re-infection in liver transplant patients and NicVAX<sup>™</sup>, a nicotine vaccine. Altastaph and NicVAX are currently in Phase II clinical trials. Civacir has completed a Phase I/II clinical trial. We have a state-of-the-art fractionation facility for the manufacture of Nabi-HB and our investigational antibody products, Altastaph and Civacir, and for contract manufacturing. We also collect specialty and non-specific antibodies for use in our products and supply pharmaceutical and diagnostic customers our excess production for the subsequent manufacture of their products.

We are headquartered in Boca Raton, Florida and maintain research and development facilities in Rockville, Maryland and have wholly owned foreign subsidiaries located in Ireland for the purpose of facilitating the regulatory approval, sales and marketing of our products in Europe.

The condensed consolidated financial statements include the accounts of Nabi Biopharmaceuticals and its subsidiaries. All significant intercompany accounts and transactions were eliminated during consolidation. These statements should be read in conjunction with the Consolidated Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 27, 2003.

In the opinion of management, the unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our consolidated financial position as of March 27, 2004 and December 27, 2003, the consolidated results of our operations for the three months ended March 27, 2004 and March 29, 2003 and our cash flows for the three months then ended. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year.

NOTE 2 ACCOUNTING POLICIES

*Accounting estimates:* The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting period. Actual results could differ from those estimates.

*Basis of presentation:* Certain items in the 2003 consolidated financial statements have been reclassified to conform to the current year's presentation.

*New accounting pronouncements:* In January 2003, the Financial Accounting Standards Board, or FASB, issued Interpretation No. 46, *Consolidation of Variable Interest Entities, an interpretation of ARB No. 51*, or FIN 46. FIN 46 addresses the consolidation of entities whose equity holders have either (a) not provided sufficient equity at risk to allow the entity to finance its own activities or (b) do not possess certain characteristics of a controlling financial interest. FIN 46 requires the consolidation of these entities, known as variable interest entities, or VIE's, by the primary beneficiary entity. The primary beneficiary is the entity,

## [Table of Contents](#)

if any, that is subject to a majority of the risk of loss from the VIE's activities, entitled to receive a majority of the VIE's residual returns, or both. FIN 46 applies immediately to variable interests in VIEs created or obtained after January 31, 2003. As amended by FASB Staff Position, or FSP No. FIN 46-6, FIN 46 is effective for variable interests in a VIE created before February 1, 2003 at the end of the first interim or annual period ending after December 15, 2003 (the end of fiscal 2003, December 27, 2003, for us). We have no interests in VIEs and accordingly, the adoption of FIN 46 had no impact on our financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 establishes standards for how companies classify and measure certain financial instruments with characteristics of both liabilities and equity. It requires companies to classify a financial instrument that is within its scope as a liability, or an asset, in some circumstances. SFAS No. 150 is effective beginning with the second quarter of fiscal 2004. We do not currently have financial instruments with characteristics of both liabilities and equity, and therefore, the adoption of SFAS No. 150 is not expected to have an impact on our financial condition, results of operations or cash flows.

*Comprehensive Income (Loss)*: The Company follows SFAS No. 130, *Reporting Comprehensive Income*, which computes comprehensive income as the total of net income and all other changes in shareholders' equity. For the quarter ended March 27, 2004, comprehensive loss included net loss and the effect of foreign currency translation adjustments. For the quarter ended March 29, 2003, there were no comprehensive income items other than net income.

*Stock-Based Compensation*: On December 31, 2002, the FASB issued Statement of Financial Accounting Standards, or SFAS No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure*. This Statement amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation. It also amends the disclosure provisions of that Statement to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation. Finally, this Statement amends Accounting Principles Board, or APB Opinion No. 28, *Interim Financial Reporting*, to require disclosure about those effects in interim financial information. We continue to account for stock-based compensation based on the provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*.

The following table summarizes our results as if we had recorded stock-based compensation expense for the three months ended March 27, 2004 and March 29, 2003, based on the provisions of SFAS No. 123, as amended by SFAS No. 148:

(In thousands, except per share amounts)	For the Three Months Ended	
	March 27, 2004	March 29, 2003
<b>Net (loss) income:</b>		
As reported	\$ (4,839)	\$ 549
Add: Stock-based employee compensation expense included in reported net (loss) income, net of tax	97	—
Deduct: Total stock-based employee compensation expense determined under fair value based method, net of tax	(1,808)	(823)
Pro forma	<u>\$ (6,550)</u>	<u>\$ (274)</u>
<b>Basic (loss) earnings per share:</b>		
As reported	\$ (0.08)	\$ 0.01
Add: Stock-based employee compensation expense included in reported net (loss) income, net of tax	—	—
Deduct: Total stock-based employee compensation expense determined under fair value based method, net of tax	(0.03)	(0.02)
Pro forma	<u>\$ (0.11)</u>	<u>\$ (0.01)</u>
<b>Diluted (loss) earnings per share:</b>		
As reported	\$ (0.08)	\$ 0.01
Add: Stock-based employee compensation expense included in reported net (loss) income, net of tax	—	—
Deduct: Total stock-based employee compensation expense determined under fair value based method, net of tax	(0.03)	(0.02)
Pro forma	<u>\$ (0.11)</u>	<u>\$ (0.01)</u>

[Table of Contents](#)

NOTE 3 INVENTORIES

The components of inventories, stated at the lower of cost or market with cost determined on the first-in first-out (FIFO) method, are as follows:

(In thousands)	March 27, 2004	December 27, 2003
Finished goods	\$ 13,835	\$ 12,746
Work in process	6,539	9,955
Raw materials	788	782
<b>Total</b>	<b>\$ 21,162</b>	<b>\$ 23,483</b>

NOTE 4 (LOSS) EARNINGS PER SHARE

Basic (loss) earnings per share is computed by dividing our net (loss) income by the weighted average number of shares outstanding during the period. When the effects are not anti-dilutive, diluted earnings per share is computed by dividing our net income by the weighted average number of shares outstanding and the impact of all dilutive potential common shares, primarily stock options. The dilutive impact of stock options is determined by applying the “treasury stock” method. The following table reconciles net (loss) income and shares for the basic and diluted (loss) earnings per share computations:

(In thousands, except per share amounts)	For the Three Months Ended					
	March 27, 2004			March 29, 2003		
	Net Loss	Shares	Net loss per share	Net Income	Shares	Net income per share
Basic (loss) earnings per share	\$(4,839)	57,960	\$ (0.08)	\$ 549	38,962	\$ 0.01
Effect of dilutive securities:						
Stock options and other dilutive securities	—	—	—	—	757	—
Diluted (loss) earnings per share	\$(4,839)	57,960	\$ (0.08)	\$ 549	39,719	\$ 0.01

A total of 2,502,491 common stock equivalents have been excluded from the calculation of net loss per share in the period ended March 27, 2004 because their inclusion would be anti-dilutive.



[Table of Contents](#)

## NOTE 5 OPERATING SEGMENT INFORMATION

The following table presents information related to our two reportable segments:

(In thousands)	For the Three Months Ended	
	March 27, 2004	March 29, 2003
<b>Sales:</b>		
Biopharmaceutical products	\$ 33,936	\$ 22,660
Antibody products	12,413	28,851
<b>Total</b>	<b>\$ 46,349</b>	<b>\$ 51,511</b>
<b>Gross Margin:</b>		
Biopharmaceutical products	\$ 21,560	\$ 15,467
Antibody products	1,014	1,175
<b>Total</b>	<b>\$ 22,574</b>	<b>\$ 16,642</b>
<b>Operating (loss) income:</b>		
Biopharmaceutical products	\$ (2,394)	\$ 2,736
Antibody products	(1,033)	(2,217)
<b>Total</b>	<b>\$ (3,427)</b>	<b>\$ 519</b>

Selling and marketing expense and research and development expense are allocated almost fully to the biopharmaceutical products segment based on the allocation of effort within those functions. General and administrative expenses are allocated to each segment based primarily on relative sales levels.

The following table reconciles reportable segment operating (loss) income to (loss) income before provision for income taxes:

(In thousands)	For the Three Months Ended	
	March 27, 2004	March 29, 2003
Reportable segment operating (loss) income	\$ (3,427)	\$ 519
Unallocated interest income	336	206
Unallocated interest expense	(1,490)	(1)
Unallocated other (expenses) income, net	(1)	9
(Loss) income before provision for income taxes	<b>\$ (4,582)</b>	<b>\$ 733</b>

## NOTE 6 STOCK OPTIONS

During the first quarter of 2004, we granted 270,807 options to purchase shares of our common stock to our officers in connection with an annual officer stock option grant under our 2000 Equity Incentive Plan. In addition, we granted 62,000 options to purchase shares of our common stock

## [Table of Contents](#)

to our non-officer employees in conjunction with their commencing employment or in connection with attaining years of service levels under our 1998 Non-Qualified Employee Stock Option Plan. Subsequent to the end of the fiscal quarter, on March 29, 2004, we granted 1,276,319 options to purchase shares of our common stock to our non-officer employees in connection with an annual employee stock option grant under our 1998 Non-Qualified Employee Stock Option Plan.

### NOTE 7 TREASURY STOCK

In February 2003, an officer of the company exercised stock options for 67,627 shares of our common stock. The purchase was paid for by delivery of 38,358 shares of common stock valued at \$0.2 million. The shares delivered had been acquired more than six months earlier by the officer. These shares have been accounted for as treasury stock. There were no such transactions in the first quarter of 2004.

On September 19, 2001, our Board of Directors approved the buy back of up to \$5.0 million of our common stock in the open market or in privately negotiated transactions. Repurchases will allow us to have treasury stock available to support our stock option and stock purchase programs. During the first three months of 2004 and 2003 we did not purchase any shares of our common stock. We have acquired 345,883 shares of our common stock for a total of \$1.9 million since the inception of this buy back program. Repurchased shares have been accounted for as treasury stock.

### NOTE 8 INTANGIBLE ASSETS

The components of our intangible assets are as follows:

<u>(In thousands)</u>	<u>March 27, 2004</u>	<u>December 27, 2003</u>
<b>PhosLo related:</b>		
Trademark/tradename	\$ 1,423	\$ 1,423
Tablet patent	11,381	11,381
Gelcap patent	80,680	80,680
Customer relationships	2,337	2,337
Covenant not to compete	508	508
Manufacturing Right - Cambrex	1,777	323
Other intangible assets	3,639	3,639
	<hr/>	<hr/>
Total intangible assets	101,745	100,291
Less accumulated amortization	(7,453)	(5,300)
	<hr/>	<hr/>
<b>Total</b>	<b>\$ 94,292</b>	<b>\$ 94,991</b>

On August 4, 2003, we acquired the worldwide rights to PhosLo. See Note 10. Under the terms of the acquisition, we purchased patent rights, trade secrets, the PhosLo trademarks, regulatory approvals and licenses, certain customer and regulatory data and finished product inventory. All assets purchased, except for inventory, have been recorded at their estimated fair value, adjusted by a pro rata portion of the excess of purchase price, and are included in intangible assets.

## [Table of Contents](#)

The estimated remaining useful lives of the PhosLo related intangible assets are as follows:

	<u>Estimated Remaining Useful Life</u>
<b>PhosLo Intangibles:</b>	
Trademark/tradename	17.0 years
Tablet patent	3.0 years
Gelcap patent	17.0 years
Customer relationships	4.3 years
Covenant not to compete	14.3 years

In October 2003, we entered into a contract manufacturing agreement with Cambrex Bio Science Baltimore, Inc. to acquire the right to commercial manufacturing capacity for StaphVAX. Vaccine manufactured at Cambrex Bio Science will be used to support our MAA for StaphVAX in the EU that we expect to file in 2004. During the quarter ended March 27, 2004, we recorded \$1.4 million of costs for the acquisition of the right to manufacture StaphVAX at Cambrex Bio Science's facility in future periods.

### NOTE 9 RELATED PARTY TRANSACTIONS

In October 2001, we engaged Stonebridge Associates, LLC, or Stonebridge, an investment bank, the president of which is a member of our Board of Directors, to provide financial advisory services in connection with our review and implementation of a corporate expansion strategy. The agreement, as amended in October 2002, provided for a monthly retainer of \$30 thousand plus hourly charges. If the engagement resulted in transactions by us involving aggregate consideration paid in excess of a specified level, Stonebridge would receive additional fees based upon the consideration paid. Stonebridge acted as our financial adviser in connection with our acquisition of the worldwide rights to PhosLo in August 2003 and received a fee of approximately \$0.3 million for its services upon consummation of this transaction. See Note 10. We believe that the terms of the engagement of Stonebridge were no less favorable to us than would have been obtained from an unrelated party. Upon successful completion of the PhosLo transaction, we concluded our agreement with Stonebridge, although we continue to be obligated to pay Stonebridge a fee under certain circumstances. We did not incur any fees to Stonebridge in the first quarter of 2004.

### NOTE 10 PRODUCT ACQUISITION

On August 4, 2003, we acquired the worldwide rights to PhosLo from Braintree Laboratories, Inc., or Braintree. PhosLo is currently approved for the control of hyperphosphatemia in patients with end-stage kidney (renal) failure. Under the terms of the agreement, we acquired the worldwide rights to PhosLo for payment of \$60.3 million in cash, issuance of 1.5 million shares of our common stock at the closing date valued at \$8.4 million and the payment of \$30.0 million in cash over the period ending March 1, 2007. In addition, we paid total professional fees and closing costs of \$0.9 million in connection with the acquisition. The discounted value of the future payment obligation on March 27, 2004 was \$23.6 million and has been reported as Notes Payable, PhosLo acquisition, net. The future payment obligation was discounted at 4.5%, our estimated rate of interest under our credit facility on August 4, 2003, the date of the closing of the agreement. Braintree will continue to manufacture the product for us under a long-term manufacturing agreement. Stonebridge, an investment banking firm, the president of which is a member of our Board of Directors, acted as our financial adviser in connection with the PhosLo transaction and received a fee of approximately \$0.3 million for its services upon consummation of this transaction. See Note 9.

## [Table of Contents](#)

The following table reconciles the notes payable related to the acquisition of PhosLo:

<u>In thousands</u>	<u>March 27, 2004</u>	<u>December 27, 2003</u>
Notes payable, PhosLo acquisition, net:		
Notes payable, PhosLo acquisition	\$ 23,605	\$ 27,393
Less: Current maturities	(8,233)	(4,226)
Notes payable, PhosLo acquisition long-term	\$ 15,372	\$ 23,167

### NOTE 11 CONTINGENT LIABILITIES, LEGAL PROCEEDINGS AND CAPITAL COMMITMENTS

In October 2003 we entered into an agreement to have StaphVAX manufactured for us at Cambrex Bio Science for up to ten years. Under the terms of the agreement we have a remaining commitment to pay \$4.7 million, including costs to acquire the right to future commercial manufacturing capacity for StaphVAX and activities related to the transfer of the StaphVAX manufacturing process to Cambrex Bio Science. Through March 27, 2004, we had paid \$4.2 million under this agreement, of which \$1.8 million has been recorded as acquisition of a Manufacturing Right asset. See Note 8.

During 2002, we were named as one of over 40 pharmaceutical and biopharmaceutical defendants in three lawsuits filed in the Superior Court of the State of California; two filed in the County of San Francisco on August 23, 2002 and September 9, 2002 and one filed in the County of Alameda on July 12, 2002. All three cases were removed to United States District Court for the Northern District of California. The cases each involved claims that insurers and consumers of the defendants' products made overpayments for those products based on an alleged manipulation of Average Wholesale Price, a standard which governs amounts that physicians, hospitals and other providers receive as reimbursement for purchases of the defendants' products. The plaintiffs sought damages, equitable relief and disgorgement of profits. All three cases were transferred to the United States District Court for the District of Massachusetts for inclusion in the consolidated multi-district litigation, or MDL. We were not named as a defendant in this proceeding's Master Consolidated Complaint, nor were we included as a defendant in the Amended Master Consolidated Complaint, which was filed by the MDL plaintiffs in June 2003. The plaintiffs in the three California cases in which we were named as a defendant have voluntarily dismissed those actions without prejudice. The dismissal for one case was filed on November 25, 2003, and the dismissals for the other two cases were filed on February 27, 2004. Because the dismissals are without prejudice, the plaintiffs are entitled to refile the lawsuits at a later date within the applicable statute of limitations period.

### NOTE 12 CREDIT FACILITY

On March 26, 2004, we cancelled our credit agreement with Wells Fargo Foothill, Inc., part of Wells Fargo & Company that had an original term through June 2006. As a result of cancelling the credit facility we incurred an early termination penalty of \$0.6 million that has been included in interest expense. By cancelling the credit agreement at this time we will avoid unused credit fees and other credit charges that would have been incurred during the remaining term of the agreement through June 2006. In addition, we reported the write-off of previously capitalized loan origination fees of approximately \$0.5 million recorded at the time of entering into the credit agreement that is also included in interest expense in the accompanying statement of operations.

[Table of Contents](#)

## NOTE 13 INCOME TAXES

In connection with our planned European expansion, we expect to generate taxable income in the U.S. during 2004 related to the planned transfer of certain product rights to international jurisdictions. This transfer will result in a gain for U.S. income tax purposes, however we anticipate the gain will be substantially offset by the utilization of previously incurred net operating loss benefits and research and development tax credits. As a result of these transfers, we have recorded \$0.3 million in income tax expense. Although we recognized an operating loss during the current quarter and anticipate a loss for the remainder of the year, we expect to incur income tax expense for the full year 2004 due to the timing of the reversal of certain deferred tax items.

## NOTE 14 SUPPLEMENTAL CASH FLOW INFORMATION

(In thousands)	For the Three Months Ended	
	March 27, 2004	March 29, 2003
Interest paid	\$ 610	\$ 1
Income taxes paid (refunded)	\$ 37	\$ (184)
<b>Supplemental non-cash financing and investing activities:</b>		
Stock options exercised in exchange for common stock	\$ —	\$ 198

[Table of Contents](#)**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following is a discussion and analysis of the major factors contributing to our financial condition and results of operations for the three months ended March 27, 2004 and March 29, 2003. The discussion and analysis should be read in conjunction with the Condensed Consolidated Financial Statements and Notes thereto.

**RESULTS OF OPERATIONS**

Information concerning our sales by operating segments is set forth in the following tables:

(In thousands, except percentages)	For the Three Months Ended			
	March 27, 2004		March 29, 2003	
<b>Biopharmaceutical products:</b>				
-PhosLo	\$ 11,337	24.5%	\$ —	— %
-Nabi-HB	11,218	24.2	10,264	19.9
-WinRho SDF	9,322	20.1	11,320	22.0
-Other biopharmaceuticals	2,059	4.4	1,076	2.1
<b>Biopharmaceutical subtotal</b>	<b>33,936</b>	<b>73.2</b>	<b>22,660</b>	<b>44.0</b>
<b>Antibody products:</b>				
-Non-specific antibodies	6,143	13.3	22,768	44.2
-Specialty antibodies	6,270	13.5	6,083	11.8
<b>Antibody subtotal</b>	<b>12,413</b>	<b>26.8</b>	<b>28,851</b>	<b>56.0</b>
<b>Total</b>	<b>\$ 46,349</b>	<b>100.0%</b>	<b>\$ 51,511</b>	<b>100.0%</b>

FOR THE THREE MONTHS ENDED MARCH 27, 2004 AND MARCH 29, 2003

*Sales.* Total sales for the first quarter of 2004 were \$46.3 million compared to \$51.5 million for the first quarter of 2003, a decrease of 10%.

Biopharmaceutical sales were \$33.9 million for the first quarter of 2004 compared to \$22.7 million for the first quarter of 2003, an increase of 50%.

*PhosLo® (calcium acetate).* Sales of PhosLo for the first quarter of 2004 were \$11.3 million. Sales of PhosLo, which was acquired in August 2003, benefited from increased capacity for the manufacture of PhosLo Gelcaps that came on line in the first quarter that allowed us to meet customer demand for this formulation of PhosLo. As a result, we believe that wholesaler customers have increased their Gelcap inventories by the end of the first quarter of 2004.

*Nabi-HB® [Hepatitis B Immune Globulin (Human)].* Sales of Nabi-HB increased 9% compared to the first quarter of 2003. Sales of Nabi-HB benefited significantly under an initial buy-in of product from a new contract entered into during the first quarter of 2004 with Novation LLC, or Novation. Under the terms of the agreement, we will supply finished Nabi-HB product to Novation for distribution through their Novaplus® Private Label Program.

## [Table of Contents](#)

*WinRho SDF® [Rh<sub>0</sub>(D) Immune Globulin Intravenous (Human)]*. Sales of WinRho SDF decreased 18% as compared to the first quarter of 2003. Based on internally generated estimates, we believe patient demand for WinRho SDF increased in the first quarter of 2004 compared to 2003 levels. As a result, we believe that wholesaler and distributor inventory levels have decreased. Wholesaler customers increased their level of inventory at year end to offset the impact of an announced price increase for WinRho SDF that went into effect in the first quarter of 2004. The impact from lower unit sales to wholesaler and distributor customers was partially offset by the benefit of increased unit pricing in the first quarter.

*Other biopharmaceutical products*. Other biopharmaceutical products primarily include Aloprim™ [(Allopurinol sodium) for injection] and Autoplex® T [Anti-Inhibitor Coagulant Complex, Heat Treated]. Sales of both products increased in comparison to sales of these products during the first quarter of 2003 due to increased product supply from the manufacturers although sales of Autoplex T were limited by product supply shortfalls. The supplier of Autoplex T has advised us that supply of Autoplex T will cease in May 2004 and future sales of this product will be limited to sales from existing inventories.

We expect biopharmaceutical product sales of our five marketed products to increase approximately 23% to 27% for the full year 2004 compared to the full year 2003. Based on new prescription trends we have noted from third party data, the benefit of a January price increase of 13% and the exhaustion of Braintree Laboratories labeled product during the first quarter, we continue to anticipate reporting net sales of PhosLo of approximately \$32 million to \$35 million for the full year of 2004. Based on increasing patient use trends, we believe that sales of WinRho SDF will grow for the full year of 2004, although at a lower rate than in 2003. The most significant use of Nabi-HB is for the treatment of hepatitis B positive liver transplant recipients during and after liver transplant. Internally generated data indicates that liver transplants for hepatitis B patients in the year to date period ended March 2004 have increased from the first quarter and fourth quarters of 2003. While we are encouraged by this data, we have not increased our sales expectations for Nabi-HB, as we assess long-term trends for hepatitis B liver transplants and confirm these trends with United Network of Organ Sharing, or UNOS, data that will be reported later in the year. We continue to expect unit sales of Nabi-HB to be at lower levels in 2004 compared to 2003. However, we plan to offset the decreased unit sales by increased pricing.

Total antibody sales for the first quarter of 2004 were \$12.4 million compared to \$28.9 million for the first quarter of 2003.

*Non-specific antibody sales*. Sales of non-specific antibodies for the first quarter of 2004 were \$6.1 million compared to \$22.8 million for the first quarter of 2003. Non-specific antibody sales decreased due to the impact of completing our obligations in April 2003 under a single contract retained by us following the sale of the majority of our antibody collection business and testing laboratory in September 2001. The purchaser of the majority of the antibody collection business and testing laboratory supplied us with non-specific antibodies to fulfill this obligation at the selling price under this contract. As a result, we did not record any margin under this contract. We reported sales under this arrangement because we retained the risk of credit loss associated with this customer. There were no such non-specific antibody sales in the first quarter of 2004 and \$18.4 million in the first quarter of 2003. Non-specific antibody sales from our antibody collection centers were \$6.1 million in the first quarter of 2004 compared to \$4.4 million in the first quarter of 2003 reflecting increased production levels and unit sales in the first quarter of 2004.

*Specialty antibody sales*. Specialty antibody sales were \$6.3 million in the first quarter of 2004 compared to \$6.1 million in the first quarter of 2003, primarily reflecting increased sales of anti-HBs and Rh<sub>0</sub>D antibodies. We have a contractual commitment to supply substantial quantities of Rh<sub>0</sub>D antibodies to the purchaser of the majority of our antibody collection and laboratory testing business at a low margin through 2004. This commitment limits our ability to sell these antibodies to other customers.

*Gross margin*. Gross margin for the first quarter of 2004 was \$22.6 million compared to \$16.6 million for the first quarter of 2003. The increase in gross margin for the first quarter of 2004 is primarily a result of the increased sales of our higher margin biopharmaceutical products, primarily, sales of PhosLo and Nabi-HB. Gross margin for each of the first quarters of 2004 and 2003 further benefited from non-performance penalty amounts from the manufacturer of Autoplex T of \$1.5 million and \$2.2 million, respectively. In addition, during the first quarter of 2004 gross margin included excess plant capacity expense of \$3.4 million resulting from decreased utilization of our Boca Raton, Florida manufacturing facility in the quarter compared to no excess capacity expense for the first quarter of 2003. The increase in excess capacity was expected as

## [Table of Contents](#)

the manufacturing facility has undergone minor modifications to comply with European Union, or EU, regulations. We expect to file for licensure of Nabi-HB in the EU in the second quarter of 2004. Projected lower sales of Nabi-HB may result in reduced manufacturing activity at our Boca Raton, Florida manufacturing facility and increased excess capacity expense in future periods. However, if increased hepatitis B liver transplant activity drives increased production of Nabi-HB, excess capacity expense will decrease in future periods.

Royalty expense for the first quarter of 2004 was \$3.6 million, or 11% of biopharmaceutical sales compared to \$3.9 million, or 17% of biopharmaceutical sales, for the first quarter of 2003, primarily reflecting decreased sales of WinRho SDF.

*Selling, general and administrative expense.* Selling, general and administrative expenses were \$12.4 million for the first quarter of 2004 compared to \$10.1 million for the first quarter of 2003. Increased selling, general and administrative expenses were primarily related to selling and marketing expense for PhosLo that was acquired in August 2003 and initial commercialization activities in Europe.

*Research and development expense.* Research and development expense was \$11.4 million for the first quarter of 2004 compared to \$5.8 million for the first quarter of 2003. Consistent with the strategic focus of our research and development activities, 81% of research and development expense in the first quarter of 2004 was incurred to support activity under our Gram-positive infections program. The confirmatory Phase III clinical trial of StaphVAX<sup>®</sup> (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine) initiated in September 2003 is currently being enrolled and is expected to be fully enrolled during the third quarter of 2004. Patient enrollment and related clinical trial expense increased substantially during the first quarter of 2004 as enrollment in the trial proceeded. There was no Phase III clinical trial activity in the first quarter of 2003. Also under the StaphVAX clinical program, we incurred expenses related to transferring commercial scale manufacture of StaphVAX to Cambrex Bio Science Baltimore Inc.'s, or Cambrex Bio Science's site to establish commercial scale manufacture of StaphVAX at this facility. During the first quarter of 2004, the Phase II clinical trial of Altastaph<sup>™</sup> [*Staphylococcus aureus* Immune Globulin (Human)] in approximately 200 very low birth weight newborns has continued under an agreement with Duke University. We expect to report results from this trial in the second half of 2004. In addition, the Phase II clinical trial of NicVAX<sup>™</sup> (Nicotine Conjugate Vaccine) in smokers in the U.S. is currently underway and is now fully enrolled and we expect to report results from this trial in the second half of 2004. This clinical trial is substantially funded by our grant from the National Institute of Drug Abuse. Research and development activities in the first quarter of 2004 further included costs to support our Nabi-HB Intravenous Biologics License Application filed with the FDA and preparation of materials for submitting MAA's for PhosLo and Nabi-HB to European authorities in 2004.

The confirmatory Phase III trial of StaphVAX will be conducted over approximately 24 months that started in September 2003. As a result, we expect full year clinical trial costs to increase above historical levels in 2004 and through the completion of this trial. In addition, we will incur incremental cost associated with the transfer of StaphVAX manufacturing to Cambrex Bio Science during 2004. Also, we expect to conduct clinical trials commencing in 2004, in support of our recently acquired product, PhosLo. Cardiac health problems are a major cause of death in kidney disease patients. Training and education recommendations issued by the American Society of Nephrology in their NEPHSAP publication in the first quarter of 2004 clearly focuses on three factors for the benefits of the patient's cardiac health, the control of serum phosphate, calcium phosphate product and lipid levels in the blood. In line with these recommendations, we are on track to initiate the PRECISE study during the second quarter of 2004. The study will evaluate the use of PhosLo with a lipid lowering agent to optimize cardiac health by successfully managing all three of these factors. Preliminary data evaluating serum levels is expected to be available this year. Data evaluating arterial calcification using electron beam computer tomography, or EBCT, is expected in 2005. In addition, in line with the recommendations in the Kidney Disease Outcomes Quality Initiative, or K/DOQI, guidelines issued by the National Kidney Foundation that chronic kidney disease, or CKD, patients may benefit from phosphate binder therapy, we expect to initiate a study using PhosLo in CKD patients in 2004.

*Amortization of intangible assets.* Amortization expense was \$2.2 million for the first quarter of 2004 compared to \$88 thousand for the first quarter of 2003. The increase in 2004 is due to amortization of the intangible assets recorded as part of the acquisition of PhosLo.

*Interest income.* Interest income for the first quarter of 2004 was \$0.3 million compared to \$0.2 million for the comparable period of 2003. Interest income is earned from investing cash and cash equivalents on hand in money market funds and auction rate securities with maturities of three months or less.

*Interest expense.* Interest expense for the first quarter of 2004 was \$1.5 million and there was \$1 thousand



## [Table of Contents](#)

of interest expense reported for the first quarter of 2003. Effective March 26, 2004 we terminated our credit agreement with Wells Fargo Foothill, Inc. in order to avoid future costs for unused credit limit fees and other service charges. As a result of terminating the credit agreement, we incurred an early termination fee of \$0.6 million and wrote off previously capitalized loan origination costs of \$0.5 million. In addition, interest expense included \$0.3 million for amortization of the discount on the notes payable entered into in connection with the acquisition of PhosLo.

*Other factors.* The provision for income taxes reflected a provision of \$0.3 million for the first quarter of 2004, compared to \$0.2 million for the first quarter of 2003. The 6% effective tax rate in the first quarter of 2004 differs from the statutory rate of 34% due to our planned European expansion. We plan to generate taxable income in the U.S. during 2004 related to the planned transfer of certain product rights to international jurisdictions. This transfer will result in a gain for U.S. income tax purposes, however we anticipate the majority of this gain will be offset by the utilization of previously incurred net operating loss benefits and research and development tax credits. As a result of these transfers, we have recorded \$0.3 million in income tax expense. Although we recognized an operating loss during the current quarter and anticipate a loss for the remainder of the year, we expect to incur income tax expense for the full year 2004 due to the timing of the reversal of certain deferred tax items.

### LIQUIDITY AND CAPITAL RESOURCES

Cash provided by operations for the three months ended March 27, 2004 was \$4.9 million. Our cash and cash equivalents at March 27, 2004 were \$116.8 million compared to \$115.8 million at December 27, 2003.

In conjunction with the acquisition of PhosLo in August 2003, we entered into an obligation to pay the seller \$30.0 million over the period ending March 1, 2007. During the first quarter of 2004 we repaid approximately \$4.1 million of this obligation.

Under terms of a contract manufacturing agreement entered into on October 9, 2003 with Cambrex Bio Science, we have a remaining commitment of \$4.7 million including costs to acquire the rights to future commercial manufacturing capacity for StaphVAX at Cambrex Bio Science's facility and to transfer commercial scale manufacture of StaphVAX to this facility. Through March 27, 2004, we have incurred \$4.2 million in costs, of which \$1.8 million has been capitalized as a Manufacturing Right and included in intangible assets.

Capital expenditures were \$1.4 million for the first three months of 2004. Our capital expenditures are expected to total approximately \$25 million for the full year 2004, including \$18 million to develop vaccine manufacturing capacity within unused space at our manufacturing facility in Florida.

In connection with an agreement related to the retirement of our former Chief Executive Officer announced on June 20, 2003, as of March 27, 2004 we have an obligation of \$2.8 million in cash payments through December 2006. The current portion of this obligation is recorded in accrued expenses and the long-term portion is included in other liabilities at March 27, 2004.

In the first quarter of 2004, we cancelled our credit facility with Wells Fargo Foothill, part of Wells Fargo & Company.

On September 19, 2001, our Board of Directors approved the expenditure of up to \$5.0 million to repurchase shares of our common stock in the open market or in privately negotiated transactions. Repurchases will allow us to have treasury stock available to support our stock option and stock purchase programs. We acquired no shares under this program during the first quarter of 2004. We will evaluate market conditions in the future and make decisions to repurchase additional shares of our common stock on a case-by-case basis in accordance with our Board of Directors' approval. We have acquired 345,883 shares of our common stock for a total of \$1.9 million since the inception of this buy back program.

We believe that cash flow from operations and cash and cash equivalents on hand will be sufficient to meet our anticipated cash requirements for operations for at least the next twelve months.

## [Table of Contents](#)

### CRITICAL ACCOUNTING POLICIES

The consolidated financial statements include the accounts of Nabi Biopharmaceuticals and all wholly owned subsidiaries. The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting period. Actual results could differ from those estimates.

#### *Intangible Assets*

On August 4, 2003, we acquired the worldwide rights to PhosLo. Under the terms of this agreement, we purchased patent rights, trade secrets, the PhosLo trademarks, regulatory approvals and licenses, certain customer and regulatory data and finished product inventory. All assets purchased, except for inventory, have been recorded at their estimated fair value, adjusted by a pro rata portion of the excess of purchase price, and are included in intangible assets. Management estimates the remaining useful lives of the acquired intangible assets are as follows:

<u>(Dollars in Thousands)</u>	<u>March 27, 2004</u>	<u>Estimated Remaining Useful Life</u>
<b>PhosLo Intangibles</b>		
Trademark/tradename	\$ 1,423	17.0 years
Tablet patent	11,381	3.0 years
Gelcap patent	80,680	17.0 years
Customer relationships	2,337	4.3 years
Covenant not to compete	508	14.3 years
	<hr/>	
PhosLo Related Intangible Assets	96,329	
Less accumulated amortization	(5,502)	
	<hr/>	
<b>Total PhosLo Related Intangible Assets</b>	<b>\$ 90,827</b>	

The trademark/tradename and gelcap patents' useful lives are estimated to be the remaining life of the gelcap patent based on our assessment of the market for phosphate binders to treat hyperphosphatemia in end stage renal failure patients and competitive therapies, forecasted growth in the number of patients and trends in patient care. The tablet patent's useful life is estimated as the remaining life for the tablet patent based on the direct competitive benefits derived from the patent. The covenant not-to-compete is based on Braintree Laboratories Inc.'s contractual agreement not to compete directly in the dialysis market for a period of 15 years after the closing of the transaction. We have established a useful life of 5 years after the closing of the transaction for customer relationships based on our review of the time that would be required by us to establish markets and customer relationships within the nephrology and dialysis market place. In future periods, if we assess that circumstances have resulted in changes to the carrying value of the intangible assets or their estimated useful lives, we will record those changes in the period of that assessment.

#### *Manufacturing Right*

In October 2003, we established a contract manufacturing relationship with Cambrex Bio Science Baltimore, Inc. Under our agreement with Cambrex Bio Science, we are committed to make future payments to acquire the right to commercial manufacturing capacity for StaphVAX vaccine. As these payments are made, we intend to record a Manufacturing Right on our balance sheet which we will amortize over the future period of commercial manufacture of StaphVAX at Cambrex Bio Science's facility. If we determine that the manufacture of StaphVAX will not occur at Cambrex Bio Science's facility, we will write off this Manufacturing Right in the period of that determination. As of March 27, 2004, we have recorded \$1.8 million as a Manufacturing Right included in intangible assets, including \$1.4 million during the first quarter of 2004.

## [Table of Contents](#)

### *Property, Plant and Equipment and Depreciation*

We incurred total costs of \$90.3 million to construct our biopharmaceutical manufacturing facility in Boca Raton, Florida. We received approval from the FDA to manufacture our antibody-based biopharmaceutical product, Nabi-HB, at this facility in October 2001. In constructing the facility we incurred approximately \$26.8 million in direct costs of acquiring the building, building systems, manufacturing equipment and computer systems. We also incurred a total of \$63.5 million of costs related to validation of the facility to operate in an FDA approved environment and capitalized interest. Costs related to validation and capitalized interest have been allocated to the building, building systems, manufacturing equipment and computer systems. Buildings and building systems are depreciated on a straight-line basis over 39 years and 20 years, respectively, the estimated useful lives of these assets. The specialized manufacturing equipment and computer systems are depreciated using the units-of-production method of depreciation subject to a minimum level of depreciation based on straight-line depreciation. The units-of-production method of depreciation is based on management's estimate of production levels. Management believes the units-of-production method is appropriate for these specialized assets. Use of the units-of-production method of depreciation may result in significantly different financial results of operation than straight-line depreciation in periods of lower than average or higher than average production levels. However, this differential is limited in periods of lower than average production, as we record a minimum of 60% of the depreciation that would have otherwise been recorded had we used the straight-line method. In the first quarter of 2004, we recorded additional depreciation of \$0.8 million under this policy. For the comparable period of 2003 we recorded additional depreciation of \$0.3 million.

### *Accounts Receivable and Revenue Recognition*

In the first three months of 2004 and 2003, we had biopharmaceutical product sales of \$33.9 million and \$22.7 million, respectively. At March 27, 2004 and December 27, 2003 we had \$36.9 million and \$37.1 million, respectively, of accounts receivable including \$28.1 million and \$29.6 million, respectively, from biopharmaceutical sales. Our primary customers for biopharmaceutical products are pharmaceutical wholesalers. In accordance with our revenue recognition policy, revenue from biopharmaceutical product sales is recognized when title and risk of loss are transferred to the customer. Reported sales are net of estimated customer prompt pay discounts, contractual allowances in accordance with managed care agreements, government payer rebates, customer returns of PhosLo and other wholesaler fees. At March 27, 2004 and December 27, 2003 we had \$8.1 million and \$7.3 million, respectively, recorded in accrued expenses related to these obligations.

### *Inventory and Reserves for Slow Moving or Obsolete Inventory*

At March 27, 2004 and December 27, 2003, we had inventory on hand of \$21.2 million and \$23.5 million respectively. In the three months ended March 27, 2004, we recorded a provision for an inventory valuation allowance of \$0.3 million. For the comparable period of 2003 we recorded a provision for an inventory valuation allowance of \$0.1 million. We review inventory on hand at each reporting period to assess that inventory is stated at the lower of cost or market and that inventory on hand is saleable. Our assessment of inventory includes review of selling price compared to inventory carrying cost, recent sales trends, our expectations for sales trends in future periods and product shelf life expiration. Based on these assessments, we provide for an inventory valuation allowance in the period in which the requirement is identified.

### *Income Taxes*

We follow Statement of Financial Accounting Standards, or SFAS No. 109, *Accounting for Income Taxes*, which requires, among other things, recognition of future tax benefits and liabilities measured at enacted rates attributable to temporary differences between financial statement and income tax bases of assets and liabilities and to tax net operating loss carryforwards to the extent that realization of these benefits is more likely than not. We periodically evaluate the realizability of our net deferred tax assets. Due to our planned European expansion, we have recognized our tax assets for the future use of net operating loss carryforwards and research and development tax credits that we have determined to be realizable. In future periods, if circumstances change we may have to record valuation allowances against some, or all,

---

[Table of Contents](#)

of our deferred tax assets. We recorded a tax provision for income taxes of \$0.3 million for the quarter ended March 27, 2004 to reflect the impact of generating taxable income in the U.S. related to the planned transfer of certain rights to market products in international markets offset by utilization of research and development tax credits and the reversal of certain other deferred tax items.

## [Table of Contents](#)

### NEW ACCOUNTING PRONOUNCEMENTS

In January 2003, the Financial Accounting Standards Board, or FASB, issued Interpretation No. 46, *Consolidation of Variable Interest Entities, an interpretation of ARB No. 51*, or FIN 46. FIN 46 addresses the consolidation of entities whose equity holders have either (a) not provided sufficient equity at risk to allow the entity to finance its own activities or (b) do not possess certain characteristics of a controlling financial interest. FIN 46 requires the consolidation of these entities, known as variable interest entities, or VIE's, by the primary beneficiary entity. The primary beneficiary is the entity, if any, that is subject to a majority of the risk of loss from the VIE's activities, entitled to receive a majority of the VIE's residual returns, or both. FIN 46 applies immediately to variable interests in VIEs created or obtained after January 31, 2003. As amended by FASB Staff Position No. FIN 46-6, FIN 46 is effective for variable interests in a VIE created before February 1, 2003 at the end of the first interim or annual period ending after December 15, 2003 (the end of fiscal 2003, December 27, 2003, for us). We have no interests in VIEs and accordingly, the adoption of FIN 46 had no impact on our financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 establishes standards for how companies classify and measure certain financial instruments with characteristics of both liabilities and equity. It requires companies to classify a financial instrument that is within its scope as a liability, or an asset, in some circumstances. SFAS No. 150 is effective beginning with the second quarter of fiscal 2004. We do not currently have financial instruments with characteristics of both liabilities and equity, and therefore, the adoption of SFAS No. 150 is not expected to have an impact on our financial condition, results of operations or cash flows.

### FORWARD LOOKING STATEMENTS

The part of this Quarterly Report on Form 10-Q captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains certain forward-looking statements, which involve risks and uncertainties. These statements are based on current expectations, estimates and projections about the industries in which we operate, management's beliefs and assumptions made by management. Readers should refer to a discussion under "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 27, 2003 concerning certain factors that could cause our actual results to differ materially from the results anticipated in such forward-looking statements. Said discussion and Risk Factors are hereby incorporated by reference into this Quarterly Report.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We do not engage in trading market risk sensitive instruments or purchasing hedging instruments or “other than trading” instruments that are likely to expose us to significant market risk, whether interest rate, foreign currency exchange, commodity price or equity price risk.

*Foreign Currency Exchange Risk.* We have two wholly-owned Irish subsidiaries. During the three months ended March 27, 2004, we did not record any sales by our foreign subsidiaries. One subsidiary incurred expenses during this period, primarily relating to our initial activities to obtain regulatory approval in the EU for our pipeline products and products that we currently market in the U.S. If the U.S. dollar weakens relative to a foreign currency, any losses generated in the foreign currency will, in effect, increase when converted into U.S. dollars and vice versa. We do not speculate in the foreign exchange market and do not manage exposures that arise in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. We also do not engage in derivative activities.

*Interest Rate Risk.* At March 27, 2004, we had cash equivalents in the amount of \$116.8 million. We also had net notes payable for the acquisition of PhosLo of \$23.6 million. Cash equivalents consist of money market funds and auction rate securities with maturities of three months or less placed with major financial institutions.

Our exposure to interest rate risk relates to our borrowings and to our cash and investments. The notes payable related to the PhosLo acquisition were discounted at our estimated interest rate under our credit facility on August 4, 2003, the date of the closing agreement. We maintain an investment portfolio of money market funds, qualified purchaser funds, and auction rate securities. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in interest rates would have a significant negative impact on the value of our investment portfolio.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest our excess cash in debt instruments of the U.S. Government and its agencies, bank obligations, repurchase agreements and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than one month. The table below presents the principal amount and weighted-average interest rate for our investment and debt portfolio:

<u>(In millions, except for percentages)</u>	<u>Estimated Fair Value at March 27, 2004</u>
<b>Assets:</b>	
Cash equivalents	\$ 116.8
Average interest rate	1.2%
<b>Liabilities:</b>	
Notes payable	\$ 23.6
Average interest rate	4.5%

**Item 4. Controls and Procedures**

Our management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures, as of March 27, 2004. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of March 27, 2004. There has been no change in our internal control over financial reporting that occurred during our fiscal quarter ended March 27, 2004 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

During 2002, we were named as one of over 40 pharmaceutical and biopharmaceutical defendants in three lawsuits filed in the Superior Court of the State of California; two filed in the County of San Francisco on August 23, 2002 and September 9, 2002 and one filed in the County of Alameda on July 12, 2002. All three cases were removed to United States District Court for the Northern District of California. The cases each involved claims that insurers and consumers of the defendants' products made overpayments for those products based on an alleged manipulation of Average Wholesale Price, a standard which governs amounts that physicians, hospitals and other providers receive as reimbursement for purchases of the defendants' products. The plaintiffs sought damages, equitable relief and disgorgement of profits. All three cases were transferred to the United States District Court for the District of Massachusetts for inclusion in the consolidated multi-district litigation, or MDL. We were not named as a defendant in this proceeding's Master Consolidated Complaint, nor were we included as a defendant in the Amended Master Consolidated Complaint, which was filed by the MDL plaintiffs in June 2003. The plaintiffs in the three California cases in which we were named as a defendant have voluntarily dismissed those actions without prejudice. The dismissal for one case was filed on November 25, 2003, and the dismissals for the other two cases were filed on February 27, 2004. Because the dismissals are without prejudice, the plaintiffs are entitled to refile the lawsuits at a later date within the applicable statute of limitations period.

**Item 2. Changes in Securities and Use of Proceeds and Issuer Purchases of Equity Securities**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Submission of Matters to a Vote of Security Holders**

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits and Reports on Form 8-K**

(a) Exhibits:

31.1 Rule 13a-14(a)/15d-14(a) Certification

31.2 Rule 13a-14(a)/15d-14(a) Certification

32.1 Section 1350 Certification

(b) Reports on Form 8-K:

On February 18, 2004, we filed a current report on Form 8-K, reporting under Item 12. "Results of Operations and Financial Condition."



**Nabi Biopharmaceuticals**

**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 thereunto duly authorized.

Date: April 26, 2004

**Nabi Biopharmaceuticals**

By: /s/ Mark L. Smith

---

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

---

[Table of Contents](#)

**Exhibit Index**

<u>Exhibit No.</u>	<u>Description</u>
31.1	Rule 13a-14(a)/15d-14(a) Certification
31.2	Rule 13a-14(a)/15d-14(a) Certification
32.1	Section 1350 Certification

## Rule 13a-14(a)/15d-14(a) CERTIFICATION

I, Thomas H. McLain, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Nabi Biopharmaceuticals;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 26, 2004

By: /s/ Thomas H. McLain

---

Thomas H. McLain  
Chief Executive Officer and President

## Rule 13a-14(a)/15d-14(a) CERTIFICATION

I, Mark L. Smith, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Nabi Biopharmaceuticals;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 26, 2004

By: /s/ Mark L. Smith

---

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

## SECTION 1350 CERTIFICATION

The undersigned officers of Nabi Biopharmaceuticals (the "Company") hereby certify that, as of the date of this statement, the Company's quarterly report on Form 10-Q for the quarter ended March 27, 2004 (the "Report") fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 and that, to the best of their knowledge, the information contained in the Report fairly presents, in all material respects, the financial condition of the Company as of March 27, 2004 and the results of operations of the Company for the three months ended March 27, 2004.

The purpose of this certification is solely to comply with Title 18, Chapter 63, Section 1350 of the United States Code, as amended by Section 906 of the Sarbanes-Oxley Act of 2002. This statement is not "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Act or any other federal or state law or regulation.

Date: April 26, 2004

By: /s/ Thomas H. McLain

Name: Thomas H. McLain  
Title: Chief Executive Officer

Date: April 26, 2004

By: /s/ Mark L. Smith

Name: Mark L. Smith  
Title: Chief Financial Officer