# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-Q**

X

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

For the quarterly period ended March 29, 2003

OR

o

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.  $\boxtimes$  Yes o No

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

The number of shares outstanding of registrant's common stock, par value \$0.10 per share, at April 24, 2003 was 39,101,017 shares.

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# PART I. FINANCIAL INFORMATION

# **Item 1. Financial Statements**

# Nabi Biopharmaceuticals

# CONSOLIDATED BALANCE SHEETS

(Amounts in Thousands, Except Per Share Data)	(UNAUDITED) March 29, 2003	December 28, 2002
Assets		
Current assets:		
Cash and cash equivalents	\$ 46,939	\$ 51,737
Trade accounts receivable, net	29,440	36,326
Inventories, net	23,126	19,388
Prepaid expenses and other current assets	6,560	5,595 ———
Total current assets	106,065	113,046
Property, plant and equipment, net	101,730	103,706
Other assets:		
Intangible assets, net	15,178	13,050
Other, net	3,014	3,014
Total assets	\$225,987	\$232,816
Liabilities and stockholders' equity		
Current liabilities:		
Trade accounts payable	\$ 15,022	\$ 21,654
Accrued expenses	15,909	16,897
Total current liabilities	30,931	38,551
Other liabilities	5,212	5,236
Total liabilities	36,143	43,787
Stockholders' equity:		<u> </u>
Convertible preferred stock, par value \$.10 per share:	_	
5,000 shares authorized; no shares outstanding	_	_
Common stock, par value \$.10 per share: 75,000 shares authorized;		
39,095 and 38,947 shares issued and outstanding, respectively	3,910	3,895
Capital in excess of par value	160,017	159,568
Treasury stock, 424 and 386 shares at cost	(2,338)	(2,140)
Retained earnings	28,255	27,706
Total stockholders' equity	189,844	189,029
Total liabilities and stockholders' equity	\$225,987	\$232,816

See accompanying notes to consolidated financial statements

# **Nabi Biopharmaceuticals**

# CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in Thousands, Except Per Share Data)		DITED) Months Ended March 30, 2002	
Sales	\$51,511	\$40,969	
Costs and expenses:			
Costs of products sold	30,954	25,288	
Royalty expense	3,915	1,559	
Gross margin	16,642	14,122	
Selling, general and administrative expense	10,139	9,183	
Research and development expense	5,794	4,412	
Other operating expenses, principally amortization and freight	190	198	
Operating income	519	329	
Interest income	206	647	
Interest expense	(1)	(1,867)	
Other income, net	9		
Income (loss) before (provision) benefit for income taxes	733	(881)	
(Provision) benefit for income taxes	(184)	220	
Net income (loss)	\$ 549	\$ (661)	
Basic earnings (loss) per share:	\$ 0.01	\$ (0.02)	
	_		
Diluted earnings (loss) per share:	\$ 0.01	\$ (0.02)	
Basic weighted average shares outstanding	38,962	38,523	
Diluted weighted average shares outstanding	39,719	38,523	

See accompanying notes to consolidated financial statements

# CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)
For the Three Months Ended

	For the Three Months Ended		
(Dollars in Thousands)	March 29, 2003	March 30, 2002	
Cash flow from operating activities:			
Net income (loss)	\$ 549	\$ (661)	
Adjustments to reconcile net income (loss) to net cash used by operating activities:			
Depreciation and amortization	2,626	2,577	
Provision for doubtful accounts	11	4	
Provision for slow moving or obsolete inventory	51	(135)	
Write-off of loan origination fees	_	400	
Other	_	13	
Changes in assets and liabilities:			
Decrease in trade accounts receivable	6,875	9,165	
Increase in inventories	(3,789)	(2,268)	
(Increase) decrease in prepaid expenses and other assets	(964)	1,920	
Increase in other assets	_	(20)	
Decrease in accounts payable and accrued liabilities	(7,644)	(14,125)	
Total adjustments	(2,834)	(2,469)	
Net cash used by operating activities	(2,285)	(3,130)	
Cash flow from investing activities:			
Capital expenditures	(562)	(1,206)	
Expenditures for intangible asset	(2,217)	(326)	
Net cash used by investing activities	(2,779)	(1,532)	
Cash flow from financing activities:			
Purchase of treasury stock	_	(917)	
Proceeds from exercise of employee stock options	266	504	
Net cash provided (used) by financing activities	266	(413)	
Net decrease in cash and cash equivalents	(4,798)	(5,075)	
Cash and cash equivalents at beginning of period	51,737	131,192	
Cash and cash equivalents at end of period	\$46,939	\$126,117	

See accompanying notes to consolidated financial statements

#### **Nabi Biopharmaceuticals**

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### NOTE 1 OVERVIEW

Nabi Biopharmaceuticals discovers, develops, manufactures and markets products that power the immune system to help people with serious, unmet medical needs. We have a broad product portfolio and significant research capabilities focused on developing and commercializing novel vaccines and antibody-based biopharmaceutical products that prevent and treat infectious, autoimmune and addictive diseases, such as hepatitis B, hepatitis C and *Staphylococcus aureus* infections, immune thrombocytopenia purpura ("ITP") and nicotine addiction. We have four marketed products, Nabi-HB® [Hepatitis B Immune Globulin (Human)] for the prevention of hepatitis B infections, WinRho SDF® [Rho (D) Immune Globulin Intravenous (Human)] for the treatment of acute, chronic and HIV-related ITP, Autoplex® T [Anti-Inhibitor Coagulant Complex, Heat Treated] and Aloprim<sup>TM</sup> [(Allopurinol sodium) for injection]. We have a significant clinical trials program including clinical trials of our lead investigational products, StaphVAX® (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine), Altastaph<sup>TM</sup> [*Staphylococcus aureus* Immune Globulin (Human)], Civacir<sup>TM</sup> [Hepatitis C Immune Globulin (Human)], and NicVAX<sup>TM</sup> (Nicotine Conjugate Vaccine). We have a state-of-the-art fractionation facility for the manufacture of Nabi-HB and our investigational antibody products and for contract manufacturing. We also collect specialty and non-specific antibodies for use in our products as well as to supply pharmaceutical and diagnostic customers for the subsequent manufacture of their products.

The 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 28, 2002.

In the opinion of management, the unaudited consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which, in the opinion of management, are necessary to present fairly our consolidated financial position as of March 29, 2003, the consolidated results of our operations for the three months ended March 29, 2003 and March 30, 2002 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 fiscal year.

## NOTE 2 ACCOUNTING POLICIES

Accounting estimates: The preparation of financial statements in conformity with generally accepted accounting principles 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 March 30, 2002 consolidated financial statements have been reclassified to conform to the current year's presentation.

Stock-Based Compensation: On December 31, 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("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 APB Opinion No. 28, Interim Financial Reporting, to require disclosure about those effects in interim financial information. We intend to continue to account for stock-based

compensation based on the provisions of APB Opinion No. 25.

The following table summarizes our results as if we had recorded stock-based compensation expense for the three months ended March 29, 2003 and March 30, 2002, based on the provisions of SFAS 123, as amended by SFAS 148:

	For the Three Months Ended		
(Dollars in Thousands, except per share amounts)	March 29, 2003	March 30, 2002	
Net income (loss):			
As reported	\$ 549	\$ (661)	
Compensation expense, net of tax	(823)	(807)	
Pro forma	\$ (274)	\$(1,468)	
Basic earnings (loss) per share:			
As reported	\$ 0.01	\$ (0.02)	
Compensation expense, net of tax	(0.02)	(0.02)	
Pro forma	\$(0.01)	\$ (0.04)	
Diluted earnings (loss) per share:			
As reported	\$ 0.01	\$ (0.02)	
Compensation expense, net of tax	(0.02)	(0.02)	
Pro forma	\$(0.01)	\$ (0.04)	

## 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:

(Dollars in Thousands)	March 29, 2003	December 28, 2002
Finished goods	\$13,920	\$12,142
Work in process	8,289	6,235
Raw materials	917	1,011
Total	\$23,126	\$19,388

## NOTE 4 EARNINGS PER SHARE

Basic earnings per share is computed by dividing our net 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 income (loss) and shares for the basic and diluted earnings (loss) per share computations:

## For the Three Months Ended

(Amounts in Thousands, Except Per Share Amounts)	March 29, 2003			March 30, 2002		
	Net Income	Shares	Per Share Amount	Net Loss	Shares	Per Share Amount
Basic earnings (loss) per share	\$549	38,962	\$0.01	\$(661)	38,523	\$(0.02)
Effect of dilutive securities:						
Stock options and other dilutive securities	_	757	_	_	_	_
Diluted earnings (loss) per share	\$549	39,719	\$0.01	\$(661)	38,523	\$(0.02)

## NOTE 5 OPERATING SEGMENT INFORMATION

The following table presents information related to our two operating business segments:

For the	Three	Months	Ended

(Dollars in Thousands)	March 29, 2003	March 30, 2002			
Sales:					
Biopharmaceutical products	\$22,660	\$15,309			
Antibody products	28,851	25,660			
Total	\$51,511	\$40,969			
Gross Margin:					
Biopharmaceutical products	\$15,467	\$11,062			
Antibody products	1,175	3,060			
Total	\$16,642	\$14,122			
Operating income (loss):					
Biopharmaceutical products	\$ 2,736	\$ 100			
Antibody products	(2,217)	229			
Total	\$ 519	\$ 329			

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

For the Three Months Ende	
March 29, 2003	March 30, 2002
\$ 519	\$ 329
206	647
(1)	(1,867)
9	10
\$ 733	\$ (881)
	March 29, 2003  \$ 519 206 (1) 9

## NOTE 6 TREASURY STOCK

In transactions dated February 24, 2003 and March 28, 2002, an officer of the Company exercised stock options for 67,627 shares and 60,000 shares, respectively, of our stock. The purchases were paid for by delivery of 38,358 shares of common stock and 40,107 shares of common stock, each valued at \$0.2 million, for the respective 2003 and 2002 transactions. In each of the transactions, the shares delivered had been acquired more than six months earlier by the officer. These shares have been accounted for as treasury stock.

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 quarter of 2002, we acquired 171,483 shares of Nabi Biopharmaceuticals stock for \$0.9 million under this program. To date we have acquired 345,883 shares of Nabi Biopharmaceuticals stock for a total of \$1.9 million under this buy back program. Repurchased shares have been accounted for as treasury stock.

## NOTE 7 INTANGIBLE ASSETS

The components of our intangible assets are as follows:

(Dollars in Thousands)	March 29, 2003	December 28, 2002
Manufacturing Right	\$13,127	\$10,911
Other intangible assets	4,603	4,603
Less accumulated amortization	(2,552)	(2,464)
Total	\$15,178	\$13,050

The Manufacturing Right represents the cost to acquire the right to use manufacturing capacity at the facility of the contract manufacturer for StaphVAX, Dow Biopharmaceuticals Contract Manufacturing Services ("Dow"), in future periods. Amortization of the Manufacturing Right is expected to commence when commercial manufacture of StaphVAX commences at Dow.

## NOTE 8 NOTES PAYABLE

On April 8, 2002, we redeemed our 6.5% Convertible Subordinated Notes ("Notes") aggregating \$78.5 million. The Notes were redeemed for cash at 100% of the principal balance plus accrued interest through April 8, 2002. The Notes had an original maturity date of February 1, 2003. In conjunction with the notification made to the holders of the Notes on March 15, 2002, we recorded \$0.4 million as interest expense for the write-off of loan origination fees at that time.

## NOTE 9 SUPPLEMENTAL CASH FLOW INFORMATION

		(UNAUDITED) For the Three Months Ended		
(Dollars in Thousands)	March 29, 2003	March 30, 2002		
Interest paid	\$ 1	\$2,587		
Income taxes (refunded) paid	\$(184)	\$ 137		
Supplemental non-cash financing activities:				
Stock options exercised for common stock	\$ 198	\$ 243		

## 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 29, 2003 and March 30, 2002. The discussion and analysis should be read in conjunction with the Consolidated Financial Statements and Notes thereto.

#### RESULTS OF OPERATIONS

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

		For the Three Months Ended			
(Dollars in Thousands)	March 2	March 29, 2003		March 30, 2002	
Biopharmaceutical products:					
-Nabi-HB	\$10,264	19.9%	\$ 8,981	21.9%	
-WinRho SDF	11,320	22.0	3,926	9.6	
-Other biopharmaceuticals	1,076	2.1	2,402	5.9	
Biopharmaceutical subtotal	22,660	44.0	15,309	37.4	
Antibody products:					
-Specialty antibodies	6,083	11.8	7,158	17.5	
-Non-specific antibodies	22,768	44.2	18,502	45.1	
Antibody subtotal	28,851	56.0	25,660	62.6	
Total	\$51,511	100.0%	\$40.969	100.0%	

FOR THE THREE MONTHS ENDED MARCH 29, 2003 AND MARCH 30, 2002

Sales. Sales for the first quarter of 2003 were \$51.5 million compared to \$41.0 million for the first quarter of 2002, an increase of \$10.5 million or 26%.

Biopharmaceutical sales increased in 2003 by 48% from the first quarter of 2002. Sales of WinRho SDF® [Rho (D) Immune Globulin Intravenous (Human)] increased almost three-fold in the first quarter of 2003 as compared to the first quarter of 2002, and were supported by higher patient usage of the product during the first quarter of 2003. Also, sales of WinRho SDF in the first quarter of 2002 were impacted by an inventory build-up by our wholesaler and distributor customers in 2001 in response to earlier product supply shortages caused by the manufacturer of the product. Sales of Nabi-HB® [Hepatitis B Immune Globulin (Human)] increased 14% from first quarter 2002 levels, in line with patient usage of the product. There were no product back orders for Nabi-HB at March 29, 2003. Other biopharmaceuticals sales, which decreased by 55% compared to the first quarter of 2002, comprise sales of Autoplex® T [Anti-Inhibitor Coagulant Complex, Heat Treated] and Aloprim™ [(Allopurinol sodium) for injection]. Sales were limited in the first quarter of 2003 by product supply shortfalls from the manufacturers of these products. These product shortfalls may continue, although in April 2003 we received two lots of backordered Aloprim product from the manufacturer.

Total antibody sales in 2003 were \$28.9 million compared to \$25.7 million in the comparable quarter of 2002. Non-specific antibody sales include shipments to a single customer under a supply contract that expires in May 2003 of \$18.3 million, which was retained by us following the sale of the majority of the antibody collection business and testing laboratory in September 2001. The purchaser of the majority of the antibody collection business and testing laboratory continues to supply us with non-specific antibodies to fulfill this obligation at the selling price under this contract. As a result, we do not record any margin under this arrangement. Because we retain the risk of credit loss with this customer, we record revenues on these sales. Such sales totaled \$14.3 million for the first quarter of 2002. The commitment was fulfilled at the end of the quarter and we do not expect to record additional sales under the contract prior to its expiration in May 2003. Non-specific antibody sales from our own antibody collection centers were \$4.5 million in the first quarter of 2003 and \$4.2 million in the first quarter of 2002. Specialty antibody sales decreased by approximately \$1.1 million compared to the first quarter of 2002, primarily reflecting reduced sales of hepatitis B and RhoD antibodies. Hepatitis B antibodies produced at our antibody collection centers were primarily used to support increased manufacture of Nabi-HB during the first quarter of 2003, limiting the amount of these antibodies available for sale. Hepatitis B antibodies are the primary raw material in the manufacture of Nabi-HB. In addition, we have a contractual commitment to supply substantial quantities of RhoD antibodies to the acquirer of the majority of our antibody collection and laboratory testing business at a low margin. This commitment limited our ability to sell these antibodies to other customers at higher margins during the first quarter of 2003 and we may be limited in our ability to sell these antibodies to other customers throug

Gross margin. Gross margin, including royalty expense, for the first quarter of 2003 was \$16.6 million, or 32% of sales, compared to \$14.1 million, or 34% of sales, in the first quarter of 2002. The dollar increase in gross profit for the first quarter of 2003 compared to the first quarter of 2002 primarily reflects the increased proportion of higher margin biopharmaceutical sales compared to total sales reported this quarter. During the first quarter we increased production of Nabi-HB and fully absorbed the costs of operating our Boca Raton, Florida manufacturing facility as we worked to re-build inventories to meet patient demand and to ensure adequate inventory on hand during a scheduled maintenance shut down in the second quarter. We incurred excess plant capacity expense of \$0.5 million in the first quarter of 2002. The scheduled maintenance shutdown at the Boca Raton manufacturing facility will increase excess plant capacity expense in the second quarter. Gross margin in each of the first quarters of 2003 and 2002 benefited from non-performance penalty payments from the manufacturer of Autoplex T of \$2.2 million and \$1.2 million, respectively. Offsetting these gross margin gains were the impact of lower sales of hepatitis B and RhoD antibodies, Autoplex T and Aloprim in the quarter.

Royalty expense for the first quarter of 2003 was \$3.9 million, or 17% of biopharmaceutical sales compared to \$1.6 million, or 10% of biopharmaceutical sales, in the first quarter of 2002, primarily reflecting increased sales of WinRho SDF and the higher royalty expense associated with that product.

Selling, general and administrative expense. Selling, general and administrative expense was \$10.1 million, or 20% of sales, for the first quarter of 2003 compared to \$9.2 million, or 22% of sales, in the first quarter of 2002. Increased selling, general and administrative expense in the first quarter of 2003 reflect use of consultants this quarter and the impact of reduced reimbursement for certain administrative services that are provided by us to the acquirer of the majority of antibody collection and laboratory testing business.

Research and development expense. Research and development expense was \$5.8 million, or 11% of sales, for the first quarter of 2003 compared to \$4.4 million, or 11% of sales, in the first quarter of 2002. Consistent with the strategic focus of our research and development activities, 50% of research and development expense in 2003 has been to support activity under our Gram-positive infections program. Our primary focus in the first quarter of 2003 was to successfully advance the manufacturing process for StaphVAX® (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine), including the formulation of bulk product. This product is intended for use in the upcoming immunogenicity study in mid-2003, and the subsequent confirmatory Phase III clinical trial scheduled for later this year. In the first quarter, we also initiated a second Phase I/II clinical trial for NicVAX<sup>TM</sup> (Nicotine Conjugate Vaccine) in smokers and non-smokers in The Netherlands. This trial, which is outside the scope of funding we receive from the National Institute of Drug Abuse for our NicVAX program, is now fully enrolled. We expect to announce results from this Phase I/II clinical trial before the end of 2003. Also this quarter, we concluded an agreement with Duke University

to conduct a Phase II clinical trial of Altastaph<sup>TM</sup> [*Staphylococcus aureus* Immune Globulin (Human)] in low birth weight newborns that is scheduled to commence mid-year. Research and development activities in the first quarter of 2003 included costs related to ongoing support for our Civacir<sup>TM</sup> [Hepatitis C Immune Globulin (Human)] Phase I/II clinical trial, for which we expect to announce results later this year, and to support our Nabi-HB Intravenous Biologics License Application filed with the U.S. Food and Drug Administration in November 2002.

Interest income. Interest income for the first quarter of 2003 was \$0.2 million compared to \$0.6 million for the first quarter of 2002. 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. In September 2001, we received proceeds of \$135 million, net of repayment of then outstanding bank debt and closing costs, from the sale of the majority of the antibody collection business and testing laboratory, which were invested in these financial instruments. In April 2002, a portion of these funds were utilized to redeem our \$78.5 million 6.5% Convertible Subordinated Notes (the "Notes").

*Interest expense*. There was no outstanding indebtedness during the first quarter of 2003 and essentially no interest expense. Interest expense for the first quarter of 2002 was \$1.9 million, which included interest payable on our Notes, amortization of loan origination fees, and \$0.4 million related to the write-off of unamortized loan origination fees in conjunction with the redemption of the Notes announced on March 15, 2002.

Other factors. The provision for income taxes was \$0.2 million for the first quarter of 2003, compared to a benefit of \$0.2 million for the first quarter of 2002. The 25% effective tax rate in the first quarter of 2003 differs from the statutory rate of 34% due to expected tax benefits arising from research and development tax credits and foreign sales credits.

## LIQUIDITY AND CAPITAL RESOURCES

Our cash and cash equivalents at March 29, 2003 were \$46.9 million.

Cash used by operations for the quarter ended March 29, 2003 was \$2.3 million primarily reflecting decreased trade payables and accrued expenses of \$7.6 million, including settlement of our prepaid property insurance premiums and amounts accrued for incentive compensation earned in 2002. In addition, cash used by operations reflected increased inventory of \$3.8 million primarily resulting from higher levels of production of Nabi-HB during the first quarter of 2003 to support gains in patient demand for this product and to ensure adequate inventory on hand during the scheduled plant maintenance shut down in the second quarter of 2003. These uses of cash were partly offset by reductions in trade receivables of approximately \$6.9 million and non-cash depreciation and amortization of \$2.6 million.

We also paid \$2.2 million related to the acquisition of a Manufacturing Right at the facility that will be used to manufacture StaphVAX at commercial scale. The acquired Manufacturing Right is recorded as an Intangible Asset in our financial statements. The original contract to ready the Dow Biopharmaceutical Contract Manufacturing Services ("Dow") facility to manufacture StaphVAX, which was scheduled to expire in October 2002, has been extended through April 2003. We expect to sign an amended contract with Dow to complete readying the facility for its intended use, the commercial manufacture of StaphVAX. This modification will require us to make significant additional payments to Dow expected to be in excess of \$15 million relating to the acquisition of the Manufacturing Right in 2003. We also expect to have a right to cancel the amended Dow agreements for a limited period after the amendments are executed.

Capital expenditures were \$0.6 million for the first quarter of 2003. At March 29, 2003, we had total capital commitments of \$3.0 million related to construction of our laboratory and cold storage facilities on our property in Boca Raton, Florida.

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 have acquired no shares under this program in 2003. To date we have acquired 345,883 shares of Nabi Biopharmaceuticals stock, for a total of \$1.9 million, since the inception of this stock buy back program. Repurchased shares have been accounted for as treasury stock. 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 intend to enter into a new credit facility in 2003. We believe that cash flow from operations and cash and cash equivalents on hand, together with our ability to borrow funds should the need arise, will be sufficient to meet our anticipated cash requirements for operations for at least the next twelve months.

#### CRITICAL ACCOUNTING POLICIES

The preparation of financial statements in conformity with generally accepted accounting principles 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.

### Accounts Receivable and Revenue Recognition

In the first quarter of 2003, we had biopharmaceutical product sales of \$22.7 million. At March 29, 2003 we had \$29.4 million of accounts receivable including \$16.5 million from biopharmaceuticals 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 and other wholesaler fees. At March 29, 2003 we had \$4.0 million recorded in other current liabilities related to these contractual obligations as accrued sales deductions.

## Property, Plant and Equipment and Depreciation

We incurred \$90.3 million to construct our biopharmaceutical manufacturing facility in Boca Raton, Florida and received approval to manufacture our own antibody-based biopharmaceutical product, Nabi-HB, at this facility from the FDA in October 2001. In constructing the facility for its intended use, 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 a 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 production levels. However, this differential is limited in periods of lower than average production, as we recorded additional depreciation of \$0.3 million under this policy.

#### Intangible Assets

In 2000, we entered into contract manufacturing agreements with Dow to establish commercial manufacturing capability for StaphVAX. The manufacturing process for StaphVAX is being transferred to Dow from our pilot manufacturing plant in Rockville, Maryland. We plan to use StaphVAX material from initial clinical lots manufactured at Dow under current Good Manufacturing Practices ("cGMP") for an immunogenicity study and for the subsequent confirmatory Phase III trial, both planned to commence in 2003. We expect Dow to complete scale-up of manufacturing at the facility and to begin the production of consistency lots of StaphVAX in 2004. The contract manufacturing agreements required us to make certain payments to Dow to secure future access to commercial vaccine manufacturing capacity and to enable Dow to ready its facility for the future commercial scale manufacture of StaphVAX, its intended use. These payments have been recorded as a Manufacturing Right and included in Intangible Assets. Amortization of the Manufacturing Right is expected to commence when commercial manufacture of StaphVAX commences at Dow. Management believes that we will manufacture StaphVAX at Dow's facility at commercial scale in future periods. If we determine that manufacture of StaphVAX will not occur at Dow's facility, we will write off the Manufacturing Right in the period of that determination. As of March 29, 2003, the Manufacturing Right was \$13.1 million.

Inventory and Reserves for Slow Moving or Obsolete Inventory

At March 29, 2003, we had inventory on hand of \$23.1 million. In the quarter ended March 29, 2003, we recorded a provision for inventory valuation allowance of \$51 thousand. 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 and 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.

#### 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 28, 2002 concerning certain factors that could cause our actual results to differ materially from the results anticipated in such forward-looking statements. Said discussion is 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.

*Interest Rate Risk*. At March 29, 2003, we had cash and cash equivalents in the amount of \$46.9 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 market risk is confined to our cash and investments. 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 market 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 portfolio:

Dollars in Millions	Fair Value at March 29, 2003
Assets:	
Cash equivalents	\$46.9
Average interest rate	1.6%

#### **Item 4. Controls and Procedures**

Within 90 days of filing this report, an evaluation was performed under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our management, including the Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures are adequately designed to ensure that the information that we are required to disclose in this report has been accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding such required disclosure. There have been no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the evaluation.

#### PART II OTHER INFORMATION

## **Item 1. Legal Proceedings**

We are a party to litigation in the ordinary course of business. We do not believe that such litigation will have a material adverse effect on our future business, financial position or results of operations.

During 2002, we were named as one of over 40 pharmaceutical and biopharmaceutical defendants in three class action 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 federal court in the Northern District of California. The cases each involve claims that insurers and consumers of defendants' products made overpayments for those products based on an alleged manipulation of Average Wholesale Price ("AWP"), a standard which governs amounts that physicians, hospitals and other providers receive as reimbursement for purchases of defendants' products. The plaintiffs seek damages, equitable relief and disgorgement of profits. The three lawsuits are in their preliminary stages; no class has been certified. To date, we have been served in only one of the three suits, but all the cases have now been transferred to the District of Massachusetts and assigned to the Hon. Patti Saris for inclusion in the consolidated multi-district litigation ("MDL"). We anticipate that we will be formally added as a defendant in the Master Consolidated Complaint that governs the AWP MDL and, thereafter, will join the pending motion to dismiss.

## Item 2. Changes in Securities and Use of Proceeds

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 Report on Form 8-K

(a) Exhibits:

99.1 Certification of Chief Executive Officer and Chief Financial Officer under Section 906 of the Sarbanes-

Oxley Act of 2002

(b) Reports on Form 8-K:

None

## 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.

Nabi Biopharmaceuticals

Date: April 28, 2003 By: /s/ Mark Smith

Mark L. Smith

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

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#### **Nabi Biopharmaceuticals**

CERTIFICATIONS

#### I, David J. Gury, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Nabi Biopharmaceuticals;
- 2. Based on my knowledge, this quarterly 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 quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
- 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures 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 quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 28, 2003

By: /s/ David J. Gury

**David J. Gury** Chairman and

Chief Executive Officer

# 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 quarterly 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 quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
- 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures 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 quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 28, 2003

By: /s/ Mark Smith

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

Date:

#### STATEMENT UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned officers of Nabi Biopharmaceuticals (the "Company") hereby certify that, as of the date of this statement, the Company's annual report on Form 10-Q for the quarter ended March 29, 2003 (the "Report") fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the quarter ended March 29, 2003.

The purpose of this statement 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.

April 28, 2003 /s/ David J. Gury

Name: David J. Gury Title: Chief Executive Officer

Date: April 28, 2003 /s/ Mark Smith

Name: Mark L. Smith Title: Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.