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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**PRE-EFFECTIVE AMENDMENT NO. 1  
TO  
FORM S-3  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

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**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 Number)

5800 Park of Commerce Boulevard N.W.  
Boca Raton, FL 33487  
(561) 989-5800

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Thomas H. McLain**  
Chief Executive Officer and President  
Nabi Biopharmaceuticals

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**Subject to Completion, dated December 8, 2003**

**PROSPECTUS**

**8,500,000 Shares**



**Common Stock**

We are offering 8,500,000 shares of our common stock, par value \$0.10 per share.

Our common stock is traded on The Nasdaq National Market under the symbol "NABI." On December 8, 2003, the last reported sale price of our common stock was \$11.18 per share.

*Investing in our common stock involves risks. "[Risk Factors](#)" begin on page 7.*

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$	\$
Underwriting discount and commission	\$	\$
Proceeds to Nabi Biopharmaceuticals (before expenses)	\$	\$

We have granted the underwriters a 30-day option to purchase up to an additional 1,275,000 shares of our common stock, on the same terms as set forth above, to cover over-allotments.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

Lehman Brothers, on behalf of the underwriters, expects to deliver the shares on or about December , 2003.

**LEHMAN BROTHERS**

**WACHOVIA SECURITIES**

**U.S. BANCORP PIPER JAFFRAY**

**HARRIS NESBITT GERARD**

December , 2003

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**ABOUT THIS PROSPECTUS**

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. No dealer, salesperson or other person is authorized to give you any information or to represent anything not contained in this prospectus, and, if given or made, you must not rely on any such information or representation as being authorized by us.

The SEC allows us to incorporate into this prospectus certain information contained in other documents that we file with the SEC, which means we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. The reports and other documents that we file after the date of this prospectus will modify, supplement and supercede the information in this prospectus.

References in this prospectus to “we,” “our,” “us” and “the company” refer to Nabi Biopharmaceuticals. Nabi Biopharmaceuticals™, Nabi®, PhosLo®, Nabi-HB®, Nabi-HB Intravenous™, StaphVAX®, Altastaph™, Civacir™ and NicVAX™ are our trademarks, and we have rights to some other trademarks included in this prospectus. This prospectus also includes trademarks of other parties.

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus. You should read the following summary together with the more detailed information regarding our company, our common stock and the financial statements and notes to those statements incorporated in this prospectus by reference from our other filings with the SEC. You should read the entire prospectus carefully, especially the risks of investing in our common stock, which we discuss under "Risk Factors", before making an investment decision.*

### Nabi Biopharmaceuticals

We apply our knowledge of the human immune system to commercialize and develop products that address serious, unmet medical needs. We have a broad portfolio of marketed biopharmaceutical products with growing revenues that generate cash flow to support the development of our clinical product candidates and our research programs. Our clinical product pipeline is composed of novel vaccines and antibody based biopharmaceutical products that are designed to prevent and treat infections, such as *Staphylococcus aureus*, or *S. aureus*, hepatitis B and hepatitis C, and nicotine addiction. We have exclusive rights to commercialize all of our clinical development candidates.

Through our own specialty sales force we market five biopharmaceutical products: PhosLo, Nabi-HB, WinRho SDF, Aloprim and Autoplex T. Sales of our biopharmaceutical products for the nine months ended September 28, 2002 and September 27, 2003 were \$61.8 million and \$75.4 million, respectively. Our principal biopharmaceutical products are PhosLo, Nabi-HB and WinRho SDF.

- PhosLo is a prescription phosphate binder indicated for the control of hyperphosphatemia, or elevated blood phosphorus levels, in end-stage renal, or kidney, disease patients. We currently market PhosLo in the U.S. and plan to seek PhosLo registration and commercialization in other markets, initially in the European Union, or EU. We acquired worldwide rights to PhosLo in August 2003.
- Nabi-HB is a human polyclonal antibody based product for the prevention of hepatitis B infections following accidental exposure to hepatitis B virus, or HBV. We believe that the majority of our Nabi-HB sales are for intravenous use to prevent reinfection with hepatitis B disease in HBV-positive liver transplant patients. Currently, Nabi-HB is not approved for this use. Although we do not market Nabi-HB for this use today, we have filed a Biologics License Application, or BLA, for the use of an intravenous formulation of Nabi-HB to prevent reinfection with hepatitis B disease in HBV-positive liver transplant patients. We anticipate a response from the Food and Drug Administration, or FDA, during the first half of 2004. We also plan to seek Nabi-HB Intravenous registration and commercialization in certain European countries. Nabi-HB Intravenous has received Orphan Drug Designation from the FDA.
- WinRho SDF is a human polyclonal antibody based product for the treatment of immune thrombocytopenia purpura, or ITP. ITP is an autoimmune disease that manifests itself in abnormally low platelet levels resulting in excessive bleeding.

We have four product candidates in clinical development: StaphVAX, Altastaph, Civacir and NicVAX. Our lead clinical candidate is StaphVAX.

### StaphVAX

We are developing StaphVAX for patients who are at high risk of *S. aureus* infection and who are able to respond to a vaccine by producing their own antibodies. In the U.S. alone there are estimated to be 12 million of these patients. We believe that the potential global market for products to prevent *S. aureus* and other Gram-positive infections is approximately \$1-\$2 billion.

We have initiated a confirmatory Phase III clinical trial of StaphVAX to support a BLA filing in the U.S. Enrollment in this trial is underway. We expect to complete enrollment by mid-2004 and to file a BLA for

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StaphVAX by the end of 2005. We recently increased the size of this trial from 3,000 to approximately 3,600 subjects to increase the trial's statistical power so that we can demonstrate statistical significance with a clinical reduction of 50% or more in types 5 and 8 *S. aureus* infections.

After a series of discussions with various EU regulatory agencies, we have decided to file a Marketing Authorization Application, or MAA, with the EU by the end of 2004 for regulatory approval to market StaphVAX for the prevention of *S. aureus* bacteremia for up to 40 weeks in end-stage renal disease patients on hemodialysis. This filing will be based on efficacy data obtained from our previously completed Phase III clinical trial for StaphVAX completed in 2000. If the MAA is approved, we would be granted simultaneous regulatory approval to market StaphVAX for this indication throughout the EU. We also plan to file a supplement to the MAA dossier with the EU in the fourth quarter of 2005 incorporating data from the confirmatory Phase III clinical trial currently underway in the U.S. We will use these data to apply for an expansion of the initial proposed indication to an indication for the prevention of *S. aureus* bacteremia and secondary infections caused by bacteremia in at-risk adults. Related to the submission of our MAA, we have started the process of transferring the StaphVAX manufacturing process to Cambrex Bio Science Baltimore, Inc., or Cambrex Bio Science, our contract manufacturer for the manufacture of StaphVAX.

### **Other Clinical Programs**

#### *Altastaph*

We are conducting a Phase II clinical trial of Altastaph for short-term protection against *S. aureus* types 5 and 8 in very low birth-weight newborns. We also are conducting a Phase I/II clinical trial of Altastaph in adults with persistent *S. aureus* infections. Altastaph is an investigational human polyclonal antibody product that contains high levels of specific antibodies to *S. aureus* types 5 and 8. These antibodies are collected from healthy donors who have been vaccinated with StaphVAX at our antibody collection centers. In contrast to StaphVAX, which is intended to provide long-term protection against *S. aureus* infection, we are initially developing Altastaph to provide short-term protection to patients at immediate risk of infection or who have compromised immune systems and cannot respond effectively to a vaccine. We anticipate reporting results from the clinical trials that are underway by the end of 2004.

#### *Civacir*

We are developing Civacir to prevent hepatitis C disease in liver transplant patients who are positive for hepatitis C virus, or HCV. The National Institutes of Health, or NIH, is funding and conducting a Phase I/II clinical trial of Civacir in HCV-positive liver transplant patients. We anticipate receiving the data from the trial in early 2004. Civacir has received Orphan Drug Designation from the FDA.

#### *NicVAX*

We are conducting a Phase I/II clinical trial and a Phase II clinical trial of NicVAX. NicVAX is an investigational vaccine to prevent and treat nicotine addiction that uses a conjugate vaccine technology similar to StaphVAX and other anti-bacterial vaccines in our pipeline. NicVAX is designed to cause the immune system to produce antibodies that bind to nicotine and prevent it from entering the brain. The stimulus in the brain that is caused by nicotine is therefore no longer present. We expect to report the results from both clinical trials by the second half of 2004.

### **Our Strategy**

The key elements of our business strategy are as follows

- *continue to increase sales of our higher-margin biopharmaceutical products and the percentage these products represent of our total revenues,*
- *expedite initial commercialization of StaphVAX by seeking EU approval for use in end-stage renal disease patients on hemodialysis,*
- *obtain regulatory approval of a broad indication for StaphVAX for use in at-risk adults in the U.S. and the EU,*
- *use cash flow from marketed products to contribute to the continued development of our clinical pipeline and*
- *leverage our marketing expertise from our currently marketed products to advance commercial acceptance of PhosLo and products that emerge from our proprietary clinical pipeline.*

### **Recent Developments**

In October 2003, the National Kidney Foundation issued the Kidney Disease Outcomes Quality Initiative, or K/DOQI, guidelines. In November 2003, the study: Treatment of Hyperphosphatemia in Hemodialysis Patients: The Calcium Acetate Renagel Evaluation (CARE Study) was presented. The results of this randomized, double-blind, controlled clinical trial show that PhosLo is the phosphate binder that best meets the K/DOQI guidelines. This trial shows that patients treated with PhosLo are able to control blood phosphorus levels more effectively than patients treated with Renagel, a competitive product marketed by Genzyme Corporation. The trial also shows that patients treated with PhosLo achieve phosphorus and calcium-phosphorus product levels targeted by the K/DOQI guidelines more often and for longer periods of time than patients treated with Renagel.

### **Additional Information**

We were incorporated in Delaware in 1969. Our principal executive offices are located at 5800 Park of Commerce Boulevard N.W., Boca Raton, FL 33487. Our telephone number is (561) 989-5800, and our website address is <http://www.nabi.com>. The information on our website or any other website is not incorporated by reference into this prospectus and does not constitute a part of this prospectus.

## The Offering

*Unless otherwise indicated, all of the information in this prospectus assumes no exercise of the underwriters' over-allotment option to purchase up to an additional 1,275,000 shares of our common stock.*

Common stock offered by us 8,500,000 shares

Common stock to be outstanding after the offering 55,604,597 shares

Use of proceeds From the net proceeds of the offering, we intend to use approximately \$20 million to develop or acquire an internal capacity to manufacture commercial quantities of StaphVAX and approximately \$9.5 million to repay a term loan under our credit agreement. The remaining funds will be used for clinical programs, sales and marketing and working capital purposes. We also may use some or all of the remaining funds for product acquisitions or licensing.

Nasdaq National Market Symbol NABI

The number of shares of common stock to be outstanding after this offering is based on 47,104,597 shares outstanding as of December 5, 2003 and excludes

- 7,286,611 shares of common stock underlying options and warrants outstanding as of December 5, 2003 at a weighted average exercise price of \$6.68 per share and
- 270,807 shares available for issuance or future grant under our 2000 Equity Incentive Plan, 1,758,272 shares available for issuance or future grant under our 1998 Non-Qualified Employee Stock Option Plan, 17,713 shares available for issuance or future grant under our Stock Plan for Non-Employee Directors and 563,590 shares available for issuance under our 2000 Employee Stock Purchase Plan.

**Summary Financial Data**

The following data, insofar as they relate to each of the years 2000-2002, have been derived from annual financial statements, including the consolidated balance sheets at December 29, 2001 and December 28, 2002 and the related consolidated statements of operations for the three years ended December 30, 2000, December 29, 2001 and December 28, 2002 and the notes thereto, incorporated herein by reference. The data for the nine months ended September 28, 2002 and September 27, 2003 have been derived from unaudited financial statements also incorporated herein by reference and which, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the results for the unaudited interim periods.

**Consolidated Statement of Operations Data**

	Year Ended			Nine Months Ended	
	December 30, 2000	December 29, 2001	December 28, 2002	September 28, 2002	September 27, 2003(1)
	(Amounts in Thousands, Except Per Share Data)				
Sales	\$ 228,783	\$ 234,829	\$ 195,966	\$ 137,871	\$ 128,595
Costs and expenses:					
Cost of products sold	160,766	152,613	119,170	81,649	62,781
Royalty expense	11,175	12,093	12,883	10,105	13,722
Gross margin	56,842	70,123	63,913	46,117	52,092
Selling, general and administrative expense	37,168	40,501	38,380	28,155	32,189
Research and development expense	14,266	15,330	21,096	14,939	18,183
Other operating expense, principally amortization and freight	1,827	1,500	767	551	1,953(2)
Gain on disposition of assets	—	(104,219)	—	—	—
Other non-recurring items	(3,875)	—	—	—	—
Operating income (loss)	7,456	117,011	3,670	2,472	(233)
Interest income	33	1,204	1,287	1,085	502
Interest expense	(3,581)	(2,128)	(2,130)	(2,039)	(570)
Other income (expense), net	551	(28)	(157)	(169)	30
Income (loss) before (provision) benefit for income taxes	4,459	116,059	2,670	1,349	(271)
(Provision) benefit for income taxes	(100)	(11,377)	(615)	(364)	14
Net income (loss)	\$ 4,359	\$ 104,682	\$ 2,055	\$ 985	\$ (257)
Basic earnings (loss) per share	\$ 0.12	\$ 2.76	\$ 0.05	\$ 0.03	\$ (0.01)
Diluted earnings (loss) per share	\$ 0.12	\$ 2.36	\$ 0.05	\$ 0.02	\$ (0.01)
Basic weighted average shares outstanding	36,604	37,980	38,670	38,625	41,152
Diluted weighted average shares outstanding	37,739	44,872	39,641	39,611	41,152



**Consolidated Balance Sheet Data**

	At		
	December 29, 2001	December 28, 2002	September 27, 2003
	(Amounts in Thousands)		
Cash and cash equivalents	\$ 131,192	\$ 51,737	\$ 26,248
Working capital	154,425	74,495	55,461
Total assets	314,624	232,816	307,027
Notes payable, including current maturities	78,500	—	37,061
Total stockholders' equity	187,206	189,029	231,067

- (1) On October 9, 2003, we announced that we had signed a manufacturing agreement for a term of up to 10 years with Cambrex Bio Science. Cambrex Bio Science, a contract manufacturer, has a facility licensed by EU, U.S. and Canadian regulators with immediately available capacity to manufacture StaphVAX to support the launch of StaphVAX in the EU and the U.S. In conjunction with establishing our new manufacturing relationship with Cambrex Bio Science, we ended our manufacturing agreement with Dow Biopharmaceuticals Contract Manufacturing Services, or Dow, on October 9, 2003. As a result of this action, we will write off costs we have capitalized in prior periods relating to the right to manufacture StaphVAX at Dow's facility in future periods. We will record a charge of approximately \$13 million for the write-off relating to the Dow manufacturing right during the fourth quarter of 2003, the period in which we determined that we would not manufacture commercial StaphVAX vaccine at Dow's facility.
- (2) Includes \$1.4 million of expense for the period relating to the amortization of intangible assets acquired in connection with the August 4, 2003 acquisition of PhosLo.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should consider carefully the following risk factors, in addition to the other information in this prospectus, before making an investment decision. Each of these risk factors could adversely affect our business, operating results and financial condition, and the value of an investment in our common stock.*

### **Risks Related to Our Company**

***Our initial Phase III clinical trial for StaphVAX did not achieve statistical significance for the specified end point and neither may our confirmatory Phase III clinical trial.***

In late 2000, we completed our initial Phase III placebo-controlled clinical trial for StaphVAX in hemodialysis patients with end-stage renal disease. The specified end point for this trial was a statistically significant reduction in *S. aureus* infections in end-stage renal disease patients after 12 months. The trial did not achieve this end point. In September 2003, we began enrollment for a Phase III clinical trial for StaphVAX with a primary efficacy end point at eight months post-vaccination. The results from this trial may not establish statistical significance for the eight-month end point. Our inability to achieve statistically significant results in our confirmatory Phase III clinical trial would adversely affect our future business, financial condition and results of operations.

***Our plan to commercialize StaphVAX initially in the EU may not be successful.***

We plan to file our first license application for StaphVAX in the EU by the end of 2004 using the centralized approval process. There can be no assurance that we will file a StaphVAX license application in the EU by the end of 2004 or that we will receive approval to begin commercial sales of the product in the EU by the end of 2005 or at all. Any delays in EU licensure or commercialization could adversely affect our market valuation and our financial position. We have no experience in obtaining licensure of vaccines in the EU or other markets. We have no direct experience marketing and selling biopharmaceutical products in the EU, and we also have no sales or marketing organization to sell and distribute StaphVAX in the EU.

***We may not realize the value of our acquisition of PhosLo.***

On August 4, 2003, we acquired the worldwide rights to PhosLo through the purchase of various intangible assets for \$60.3 million in cash, 1.5 million shares of our common stock and an obligation to pay \$30.0 million in cash over the period ending March 1, 2007. These intangible assets represent approximately one-third of the total assets reflected on our balance sheet at September 27, 2003. PhosLo is marketed to physicians caring for patients suffering kidney failure who have developed elevated phosphorus levels in their blood. This is a market in which we have no previous experience. PhosLo currently competes with two other products, a prescription medication and a non-prescription medication, and we are aware of a third competitive prescription product that may come to market. All of these products are or will be produced, marketed and sold by companies that have substantially greater financial and marketing resources than we have. If we do not achieve the necessary level of success in marketing PhosLo to recover the value of the intangible assets we acquired, we will be required to write down or write off some or all of the PhosLo intangible assets. If this occurs, our balance sheet and results of operations will be adversely affected.

***Our rights to three existing biopharmaceutical products may expire.***

Our rights to WinRho SDF expire in 2005. There can be no assurance that our rights to this product can be extended on terms that will be satisfactory to us.

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We acquired our rights to Autoplex T from Baxter International Inc., or Baxter, under a consent decree of the Federal Trade Commission. Pursuant to this decree, Baxter is obligated to supply Autoplex T to us until May 2004, unless the consent decree is earlier terminated or we receive approval from the FDA to manufacture the product ourselves. We will not obtain approval from the FDA to manufacture Autoplex T by May 2004. We are unlikely to sell Autoplex T after May 2004.

Our rights to Aloprim expire in June 2004. We have an option to purchase the rights to distribute Aloprim in the territories now covered by the Aloprim agreement and to extend the obligation to supply this product to us for five years, subject to the negotiation of a mutually satisfactory supply agreement. Our inability to reach agreement on the terms of this supply agreement would interrupt our supply of Aloprim.

### ***We depend upon third parties to manufacture our products.***

We do not manufacture four of our five marketed products and depend upon third parties to manufacture these products for us. A failure by these manufacturers to timely meet our needs for these products could have a material adverse effect on our future business, financial condition and results of operations. This has occurred in the past. Our biopharmaceutical product sales were constrained in 2000 because of the inability of the contract manufacturer for WinRho SDF to supply product for a period of time. Since 2000, our ability to market Autoplex T and Aloprim has been adversely affected by our inability to obtain necessary quantities of these products.

Our research and development product pipeline principally involves conjugate vaccines. We currently rely on a third party to manufacture StaphVAX. We announced on October 9, 2003 that we have entered into an agreement for up to ten years with Cambrex Bio Science to manufacture StaphVAX. In so doing, we let expire agreements we had for several years with a different party to provide the services we will receive from Cambrex Bio Science. The agreement with Cambrex Bio Science contemplates that it will provide us with product for our clinical needs and for the initial commercial launch of StaphVAX but not for all of our forecasted needs if StaphVAX is a commercial success. Although we intend to develop or acquire an internal capacity to produce commercial quantities of StaphVAX, we will be dependent on Cambrex Bio Science and other third parties for the manufacture of StaphVAX and other products in our research and development pipeline. The failure of our contract manufacturers to supply us with sufficient amounts of product to meet our needs, or to renew their contracts with us on commercially reasonable terms, would have a material adverse effect on our future business, financial condition and results of operations.

### ***We may not utilize the full capacity of our manufacturing facility and have limited manufacturing capability and experience with our clinical product candidates, Altastaph and Civacir.***

We began commercial manufacture of Nabi-HB at our Boca Raton biopharmaceutical manufacturing facility in the fourth quarter of 2001 and intend to use this facility for the manufacture of our clinical product candidates, Altastaph and Civacir, and for the manufacture of products of other parties. For the foreseeable future, we will not utilize the full manufacturing capacity of the facility and there can be no assurance that we can operate the facility efficiently. There can be no assurance that we will have either our own products to manufacture or those of others to offset the cost of the facility's operation. Further, we have limited experience manufacturing our clinical product candidates. Our failure to manufacture our clinical product candidates successfully would have a material adverse effect on our future business, financial condition and results of operations.

### ***A disaster at our sole manufacturing facility would interrupt our manufacturing capability for the products produced there.***

Manufacturing products at a single site presents risks because a disaster, such as a fire or hurricane, may interrupt manufacturing capability. In such an event, we will have to resort to alternative sources of manufacturing that could increase our costs as well as result in significant delays while required regulatory approvals are obtained. Any such delays or increased costs could have a material adverse effect on our future business, financial condition and results of operations.

***Our sales of Nabi-HB are directly related to patient treatment protocols and the number of liver transplants performed in HBV- positive patients.***

Our sales of Nabi-HB are primarily for the care of HBV-positive liver transplant patients at the time of and for a period following liver transplant. The number of liver transplants that occurs depends on the number of livers available for transplant. The number of livers used for HBV-positive liver transplant candidates as well as the dosing of Nabi-HB may vary from time to time based on the following factors

- changes in overall organ availability,
- allocations of available organs to eligible potential recipients and
- changes in the treatment protocols applied to HBV-positive patients.

Each of these factors is outside our control. Sales of Nabi-HB will be adversely affected if patient treatment protocols change or the number of hepatitis B liver transplants decreases. Sales of Nabi-HB Intravenous, if it is licensed, will be similarly affected. This could have an adverse effect on our future results of operations and financial condition.

***We sell our products to a small number of customers; therefore, the loss of any major customer could have a material adverse effect on our results of operations or financial condition.***

We sell a significant portion of our biopharmaceutical products to pharmaceutical wholesalers and distributors. A loss of any major customer or a material reduction in such customer's purchases from us could have a material adverse effect on our results of operations and financial condition. We also maintain a significant receivable balance with each of these customers. If these customers become unable or unwilling to pay amounts owed to us, our financial condition and results of operations could be adversely affected.

Our antibody sales are concentrated among a few large pharmaceutical companies. During the 2000, 2001 and 2002 fiscal years, antibody sales to our top three customers collectively accounted for approximately 60%, 66%, and 74%, respectively, of our antibody sales. The loss of certain remaining major customers or a material reduction in these major customers' purchases of antibodies could have a material adverse effect upon our future business, financial condition and results of operations. If these customers are unable to comply with FDA or European Medicines Evaluation Agency, or EMEA, and other non-U.S. regulations, their manufacturing facilities may be temporarily closed, thereby reducing the need for the antibodies we provide. Plant closures and reductions in customers' production because of regulatory problems have occurred in recent years, and our financial performance has been adversely affected as a result. There can be no assurance that customer regulatory problems, which are not within our control, will not reoccur with an adverse impact on us in the future.

***Heightened concerns over antibody products and screening measures could adversely affect our antibody production.***

Our antibody collection centers and our customers for antibody products are subject to extensive regulation by the FDA and non-U.S. regulatory authorities. Concern over the safety of antibody products has resulted in the adoption of more rigorous screening procedures by regulatory authorities and manufacturers of antibody products. In prior years, these changes have resulted in significantly increased costs to us in providing non-specific and specialty antibodies to our customers. New procedures, which include a more extensive investigation into a donor's background, as well as more sensitive tests, also have disqualified numerous potential donors and discouraged other donors who may be reluctant to undergo the screening procedures. These more stringent measures could adversely affect our antibody production with a corresponding, adverse effect on our future business, financial condition and results of operations. In addition, our efforts to increase production to meet customer demand may result in higher costs to attract and retain donors.

***New treatments may reduce the demand for our antibodies and antibody based biopharmaceutical products.***

Most of the antibodies we collect, process and sell to our customers are used in the manufacture of biopharmaceutical products to treat certain diseases. Several companies are marketing and developing products to treat some of these diseases based on technology that would reduce or eliminate the need for human antibodies. Such products could adversely affect the demand for antibodies and antibody based biopharmaceutical products. We are unable to predict the impact of future technological advances on our business.

***A reduction in the availability of specialty antibodies could adversely affect our ability to manufacture an adequate amount of Nabi-HB or to fulfill contractual obligations.***

Our ability to manufacture Nabi-HB depends upon the availability of anti-HB specialty antibodies that we primarily obtain from our FDA-approved antibody collection centers. Similarly, we have contractual obligations to supply other specialty antibodies to third parties that we also obtain from our FDA-approved antibody collection centers. Specialty antibodies are more difficult to obtain than non-specific antibodies. Reduced availability of the necessary specialty antibodies would adversely affect our ability to manufacture an adequate amount of Nabi-HB or to fulfill our contractual obligations, with the result that our future business, financial condition and results of operations would suffer.

***We may not generate sufficient cash flow from our biopharmaceutical and antibody products or obtain financing necessary to fund our research and development activity at an appropriate level.***

We have incurred and expect to continue incurring significant expenses associated with our biopharmaceutical research and development activities, including the cost of clinical trials and marketing expenses. These expenses adversely affect our current ability to be profitable. Products under development may not generate sales for several years or at all. We do not have the financial resources to fund concurrently all of our biopharmaceutical product development programs to completion. Our ability to continue to fund all of our ongoing research and development activities depends on our ability to generate sales from our biopharmaceutical and antibody products or to obtain financing. There can be no assurance, therefore, that we will be able to continue to fund our research and development activities at the level required to commercialize all of our biopharmaceutical product development programs. If we are required to reduce the funding for certain of our research and development activities, this could have a material adverse effect on our future prospects.

***We may enter into strategic alliances that may not be successful and may adversely affect our ability to develop our products.***

We intend to pursue strategic alliances with third parties to develop and/or commercialize certain of our biopharmaceutical products. No assurance can be given that we will be successful in these efforts or, if successful, that our collaborative partners will conduct their activities in a timely manner. If we are not successful in our efforts, our ability to continue to develop our products may be affected adversely. Even if we are successful, if any of our collaborative partners violates or terminates their agreements with us or otherwise fails to conduct their collaborative activities in a timely manner, the development or commercialization of our products could be delayed. This might require us to devote significant additional resources to product development and commercialization or terminate certain development programs. In addition, there can be no assurance that disputes will not arise in the future with respect to the ownership of rights to any technology developed with third parties. These and other possible disagreements between our collaborative partners and us could lead to delays in the collaborative research, development or commercialization of certain products, or could require or result in litigation or arbitration, which would be time consuming and expensive and could have a material adverse effect on our future business, financial condition and results of operations.

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***We may not be able to develop and commercialize new biopharmaceutical products successfully or in a timely manner, which could adversely impact our future operations.***

Our future success will depend on our ability to achieve scientific and technological advances and to translate such advances into commercially competitive products on a timely basis. Our biopharmaceutical products under development are at various stages, and substantial further development, pre-clinical testing and clinical trials will be required to determine their technical feasibility and commercial viability. Our proposed development schedules for these products may be affected by a variety of factors, including

- technological difficulties,
- competition,
- failure to obtain necessary regulatory approvals,
- failure to achieve desired results in clinical trials,
- proprietary technology positions of others,
- reliance on third parties for manufacturing,
- failure to market effectively,
- changes in government regulation and
- funding.

Positive results for a product in a clinical trial do not necessarily assure that positive results will be obtained in future clinical trials or that we will obtain government approval to commercialize the product. In addition, any delay in the development, introduction or marketing of our products under development could result either in such products being marketed at a time when their cost and performance characteristics might not be competitive in the marketplace or in a shortening of their commercial lives. There can be no assurance that our biopharmaceutical products under development will prove to be technologically feasible or commercially viable or that we will be able to obtain necessary regulatory approvals and licenses on a timely basis, if at all. Our failure to develop and commercialize successfully our biopharmaceutical products in a timely manner and obtain necessary regulatory approvals could have a material adverse effect on our future operations. In particular, our failure to obtain regulatory approval for StaphVAX on a timely basis could adversely affect our market valuation.

***The market may not be receptive to our products upon their introduction.***

There can be no assurance that any of our products in development will achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including

- the receipt of regulatory approvals,
- any limited indications of regulatory approvals,
- the establishment and demonstration in the medical community of the clinical efficacy and safety of our products and their potential advantages over existing treatment methods,
- the prices of such products and
- the reimbursement policies of government and third-party payers.

The failure of our product pipeline to gain market acceptance could have a material adverse effect on our future business, financial condition and results of operations.

***We are unable to pass through certain cost increases to our antibody product customers with which we have supply contracts.***

A significant amount of our antibodies are sold under contracts that extend for periods up to five years. Certain contracts do not permit us to increase prices during the contract term except to reflect changes in customer specifications and new governmental regulations. If our costs of collecting antibodies under these contracts rise for reasons other than changes in customer specifications and new governmental regulations, we are unable to pass on these cost increases to our antibody product customers except with the customer's consent.

***An increase in the supply of or a decrease in the demand for antibody products could materially and adversely affect our future business, financial condition and results of operations.***

The worldwide supply of antibodies has fluctuated historically. Future changes in government regulation relating to the collection, fractionation and use of antibodies or any negative public perception about the antibody collection process or the safety of products derived from blood or antibodies could further adversely affect the overall supply of or demand for antibodies. Increases in supply or decreases in demand of antibody products could have a material adverse effect on our future business, financial condition and results of operations.

***If we fail to comply with extensive regulations enforced by the FDA, EMEA and other agencies, the sale of our current products and the commercialization of our product candidates would be prevented or delayed.***

Research, pre-clinical development, clinical trials, manufacturing and marketing of our products are subject to extensive regulation by various government authorities. The process of obtaining FDA, EMEA and other required regulatory approvals is lengthy and expensive, and the time required for such approvals is uncertain. The approval process is affected by such factors as

- the severity of the disease,
- the quality of submission,
- the clinical efficacy and safety,
- the strength of the chemistry and manufacturing control of the process,
- the manufacturing facility compliance,
- the availability of alternative treatments and
- the risks and benefits demonstrated in clinical trials.

Regulatory authorities also may require post-marketing surveillance to monitor potential adverse effects of our products or product candidates. Congress or the FDA in specific situations can modify the regulatory process. Many of our clinical trials are at a relatively early stage and, except for Nabi-HB, WinRho SDF, PhosLo, Aloprim, Autoplex T and certain non-specific and specialty antibody products, no approval from the FDA or any other government agency for the manufacturing or marketing of any other products under development has been granted. There can be no assurance that we will be able to obtain the necessary approvals to manufacture or market any of our pipeline products. Failure to obtain additional regulatory approvals of products currently marketed or regulatory approval for products under development could have a material adverse effect on our future business, financial condition and results of operations. Once approved, a product's failure to comply with applicable regulatory requirements could, among other things, result in warning letters, fines, suspension or revocation of regulatory approvals, product recalls or seizures, operating restrictions, injunctions and criminal prosecutions.

Although we do not have material sales of our biopharmaceutical products outside the U.S. today, our goal is to expand our global presence for these products. Distribution of our products outside the U.S. is subject to extensive government regulation. These regulations, including the requirements for approvals or clearance to

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market, the time required for regulatory review and the sanctions imposed for violations, vary from country to country. There can be no assurance that we will obtain regulatory approvals in such countries or that we will not be required to incur significant costs in obtaining or maintaining these regulatory approvals. In addition, the export by us of certain of our products that have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Failure to obtain necessary regulatory approvals, the restriction, suspension or revocation of existing approvals or any other failure to comply with regulatory requirements would have a material adverse effect on our future business, financial condition and results of operations.

Our U.S. manufacturing, antibody collection, labeling, storage and distribution activities also are subject to strict regulation and licensing by the FDA. Our biopharmaceutical manufacturing facility in Boca Raton, Florida is subject to periodic inspection by the FDA, the EMEA and other regulatory authorities and from time to time, we may receive notices of deficiencies from these agencies as a result of such inspections. Our antibody collection centers in the U.S. also are subject to periodic inspection by the FDA, the EMEA and other regulatory authorities and from time to time, we may receive notices of deficiencies from these agencies as a result of such inspections. Our failure, or the failure of our biopharmaceutical manufacturing facility or our antibody collection centers, to continue to meet regulatory standards or to remedy any deficiencies could result in corrective action by the FDA, including closure of our biopharmaceutical manufacturing facility or one or more antibody collection centers and fines or penalties. New regulations may be enacted and existing regulations, their interpretation and enforcement, are subject to change. Therefore, there can be no assurance that we will be able to continue to comply with any regulations or that the costs of such compliance will not have a material adverse effect on our future business, financial condition and results of operations.

***We may be subject to costly and damaging liability claims relating to antibody contamination and other claims.***

Antibodies we collect, antibody based products we manufacture, antibody based products we market and antibody based products our customers manufacture run the risk of being contaminated with viruses. As a result, suits may be filed against our customers and us claiming that the plaintiffs became infected with a virus as a result of using contaminated products. Such suits have been filed in the past related to contaminated antibodies, and in a number of suits we were one of several defendants. No assurance can be given that additional lawsuits relating to infection with viruses will not be brought against us by persons who have become infected with viruses from antibody based products.

Pharmaceutical and biotechnology companies are increasingly subject to litigation, including class action suits, and governmental and administrative investigations and proceedings related to product pricing and marketing practices. We have been named as one of over 40 pharmaceutical and biotechnology defendants in three class action lawsuits. There can be no assurance that lawsuits based on other causes of action will not be filed or that we will be successful in the defense of any or all existing or potential future lawsuits. Defense of suits can be expensive and time consuming, regardless of the outcome, and an adverse result in one or more suits could have a material adverse effect on our future business, financial condition and results of operations.

***We may not be able to maintain sufficient product liability and directors and officers insurance to cover claims against us.***

Product liability and directors and officers insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of our products progresses, or that existing or future claims against us will be covered by our product liability insurance. Moreover, there can be no assurance that the existing coverage of our insurance policy and/or any rights of indemnification and contribution that we may have will offset existing or future claims. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage and not subject to any indemnification or contribution could have a material adverse effect on our future business, financial condition and results of operations. Further, if we were unable to obtain directors and officers liability insurance, it could affect adversely our ability to attract and retain directors and senior officers.



***We may not be able to maintain sufficient property insurance on our facilities in Florida.***

We maintain significant real property assets in Florida. Property insurance for companies with a high concentration of property assets in Florida is generally expensive to the extent it is available at all. There can be no assurance that we will be able to maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the value of our property increases.

***We may not be able to raise necessary additional capital on acceptable terms, if at all.***

We may need to raise additional capital to increase funding of our product research, development and marketing activities or to acquire additional products. We may seek additional funding through public or private equity or debt financing, collaborative arrangements with strategic partners or from other sources. There can be no assurance, however, that additional financing will be available on acceptable terms, if at all. If adequate funds are not available, we may have to defer certain investments in the areas of research, product development, manufacturing, marketing activity or business development, or otherwise modify our business strategy, and our future business and future prospects could be materially and adversely affected.

***We may not maintain compliance with our credit agreement.***

We may not maintain compliance with the covenants required by our credit agreement. This potential non-compliance may limit our ability to access funds under the credit agreement without receipt of a waiver from the lender, which may not be given. In addition, our borrowing base, as defined in the credit agreement, is limited by eligible accounts receivable and inventory balances. If funds are not available to us under our credit agreement due to non-compliance with debt covenants or borrowing base limitations, we may have to defer certain investments in the areas of research, product development, manufacturing, marketing activity or business development, or otherwise modify our business strategy, and our future business and future prospects could be materially and adversely affected.

***Our patents and proprietary rights may not provide sufficient protection, and patents of other companies could prevent us from developing and marketing our products.***

The patent positions of biopharmaceutical firms generally are highly uncertain and involve complex legal and factual questions. There can be no assurance that existing patent applications will result in issued patents, that we will be able to obtain additional licenses to patents of others or that we will be able to develop additional patentable technology of our own. We cannot be certain that we were the first creator of inventions covered by our patents or pending patent applications or that we were the first to file patent applications for such inventions. There can be no assurance that any patents issued to us will provide us with competitive advantages or will not be challenged by others. Furthermore, there can be no assurance that others will not independently develop similar products, or, if patents are issued to us, design around such patents.

A number of pharmaceutical companies, biotechnology companies, universities and research institutions have filed patent applications or received patents relating to products or processes competitive with or similar to ours. Some of these applications or patents may compete with our applications or conflict in certain respects with claims made under our applications. Such a conflict could result in a significant reduction of the coverage of our patents, if issued. In addition, if patents that contain competitive or conflicting claims are issued to others and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all. Our failure to obtain a license to any technology that we may require in order to commercialize our products could have a material adverse effect on our future business, financial condition and results of operations. Litigation, which could result in substantial cost to us, may also be necessary to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights.

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We also rely on secrecy to protect our technology, especially where patent protection is not believed to be appropriate or obtainable. We maintain strict controls and procedures regarding access to and use of our proprietary technology and processes. However, there can be no assurance that these controls or procedures will not be violated, that we would have adequate remedies for any violation, or that our trade secrets will not otherwise become known or be independently discovered by competitors.

***We compete with larger, better financed and more mature pharmaceutical and biotechnology companies, which are capable of developing new products and approaches that could make our products obsolete.***

Competition in the development of biopharmaceutical products is intense, both from pharmaceutical and biotechnology companies, and is expected to increase. Many of our competitors have greater financial resources and larger research and development staffs than we have, as well as substantially greater experience in developing products, obtaining regulatory approvals, and manufacturing and marketing biopharmaceutical products. We compete with our competitors

- to develop products,
- to acquire products and technologies and
- to attract and retain qualified scientific personnel.

There can be no assurance that our competitors may succeed in developing technologies and products that are more effective or affordable than those that we are developing. In addition, one or more of our competitors may achieve product commercialization of or patent protection for competitive products earlier than us, which would preclude or substantially limit sales of our products. Further, several companies are attempting to develop and market products to treat certain diseases based upon technology that would lessen or eliminate the need for human antibodies. The successful development and commercialization by any of our competitors of any such product could have a material adverse effect on our future business, financial condition and results of operations.

***There are potential limitations on third-party reimbursement and other pricing-related matters that could reduce the sales of our products and may delay or impair our ability to generate sufficient revenues.***

Our ability to commercialize our biopharmaceutical products and related treatments depends in part upon the availability of, and our ability to obtain adequate levels of, reimbursement from government health administration authorities, private healthcare insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and there can be no assurance that adequate third-party payer coverage will be available, if at all. Inadequate levels of reimbursement may prohibit us from maintaining price levels sufficient for realization of an adequate return on our investment in developing new biopharmaceutical products and could result in the termination of production of otherwise commercially viable products.

In the U.S., government and other third-party payers are increasingly attempting to contain healthcare costs by limiting both the coverage and level of reimbursement for new products approved for marketing by the FDA and by refusing, in some cases, to provide any coverage for disease indications for which the FDA has not granted marketing approval. Also, the trend towards managed healthcare in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of healthcare services and products, as well as legislative proposals to reform healthcare or reduce government insurance programs, may all result in lower prices for our products. The cost containment measures that healthcare providers are instituting and the impact of any healthcare reform could have an adverse effect on our ability to sell our products and may have a material adverse effect on our future business, financial condition and results of operations.

There can be no assurance that reimbursement in the U.S. or other markets will be available for our products, or, if available, will not be reduced in the future, or that reimbursement amounts will not reduce the demand for, or the price of, our products. The unavailability of government or third-party reimbursement or the

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inadequacy of the reimbursement for medical treatments using our products could have a material adverse effect on our future business, financial condition and results of operations. Moreover, we are unable to forecast what additional legislation or regulation, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our future business.

### **Risks Related to This Offering**

#### ***New investors in our common stock will experience immediate and substantial dilution.***

The offering price to the public is substantially higher than the book value per share of our common stock. Investors purchasing common stock in this offering will, therefore, incur immediate dilution of \$7.42 in net tangible book value per share of common stock, based on an estimated offering price to the public of \$11.00 per share. Investors may incur additional dilution upon the exercise of outstanding stock options and warrants.

#### ***Future sales of our common stock may depress our stock price.***

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market after the closing of this offering, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. There will be 55,604,597 shares of common stock outstanding immediately after this offering, based on the number of shares outstanding on December 5, 2003. All of the shares sold in this offering will be freely transferable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act. Since June 30, 2003, we have sold 7,077,000 shares of our common stock in private placement transactions. We have registered or intend to register for resale under the Securities Act all of these shares.

#### ***Anti-takeover provisions in our charter documents, under Delaware law and under our stockholder rights plan could make an acquisition of us more difficult.***

Provisions of our certificate of incorporation and bylaws will make it more difficult for a third party to acquire us on terms not approved by our board of directors and may have the effect of deterring hostile takeover attempts. For example, our certificate of incorporation currently contains a fair price provision and also authorizes our board of directors to issue substantial amounts of preferred stock and to fix the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders. The rights of the holders of our common stock will be subject to, and may be harmed by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock could reduce the voting power of the holders of our common stock and the likelihood that common stockholders will receive payments upon liquidation.

We also are subject to provisions of Delaware law that could have the effect of delaying, deferring or preventing a change in control of our company. One of these provisions prevents us from engaging in a business combination with any interested stockholder for a period of three years after the date the person becomes an interested stockholder, unless specified conditions are satisfied.

We also have implemented a stockholder rights plan, or poison pill, that would substantially reduce or eliminate the expected economic benefit to an acquiror from acquiring us in a manner or on terms not approved by our board of directors. These and other impediments to a third-party acquisition or change of control could limit the price investors are willing to pay in the future for shares of our common stock.

## FORWARD-LOOKING STATEMENTS

The information contained in this prospectus, including the information incorporated by reference into this prospectus, includes “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act as enacted by the Private Securities Litigation Reform Act of 1995. These forward-looking statements are often identified by words such as “hope,” “may,” “believe,” “anticipate,” “plan,” “expect,” “require,” “intend,” “assume” and similar expressions. We caution readers that forward-looking statements speak only as of the date of this prospectus, reflect our management’s current expectations, estimations and projections and involve certain factors, such as risks and uncertainties, that may cause our actual results, performance or achievements to be far different from those suggested by our forward-looking statements. These factors include, but are not limited to, risks associated with

- our StaphVAX confirmatory Phase III clinical trial,
- commercialization of StaphVAX initially in the EU,
- our PhosLo acquisition,
- expiration of rights to some of our existing products,
- third-party manufacturers,
- manufacturing,
- natural disasters,
- patient treatment protocols,
- number of hepatitis B liver transplants,
- small number of customers,
- antibody products,
- new treatments and technologies,
- a reduction in the availability of anti-HB specialty antibodies,
- funding to support our research and development efforts,
- strategic alliances,
- commercialization and market acceptance of new products,
- customer contracts,
- governmental regulations,
- liability claims,
- property, products liability, and directors and officers insurance,
- our ability to raise sufficient additional capital,
- compliance with our credit agreement,
- intellectual property rights and protection,
- competition and
- reimbursement sources.

Because all of the foregoing factors are difficult to forecast, you should not place undue reliance on any forward-looking statements. These and other risks and uncertainties are discussed above in the section entitled “Risk Factors.” We do not intend to update any of these factors or to publicly announce the results of any revisions to any of our forward-looking statements other than as required under the federal securities laws.

## **USE OF PROCEEDS**

Our net proceeds from the sale of the 8,500,000 shares of common stock being offered by this prospectus will be approximately \$87.5 million, or approximately \$100.7 million if the underwriters exercise their over-allotment option in full, based on an assumed public offering price of \$11.00 per share and after deducting the underwriting discount and the estimated offering expenses.

From the net proceeds of the offering, we intend to use approximately \$20 million to develop or acquire an internal capacity to manufacture commercial quantities of StaphVAX and approximately \$9.5 million to repay a term loan under our credit agreement. The term loan bears interest at LIBOR plus 4.5%, an effective interest rate of 5.6% at September 27, 2003, and matures on June 20, 2006. The remaining funds will be used for clinical programs, sales and marketing and working capital purposes. We also may use some or all of the remaining funds for product acquisitions or licensing, although currently we do not have any agreements or other commitments for any such transactions. The precise amounts and timing of the application of the proceeds will depend upon our funding requirements and the availability of other funds. Pending any such uses, we will invest the proceeds in short-term, interest-bearing, investment-grade securities.

The foregoing represents our current intentions based upon our present plans and business condition. The occurrence of unforeseen events or changed business conditions could result in the application of the net proceeds from this offering in a manner other than as described in this prospectus.

## **DIVIDEND POLICY**

We have never declared or paid cash dividends on our common stock and we anticipate that, for the foreseeable future, we will continue to retain any earnings for use in the operation of our business. Our existing credit agreement does not permit payment of cash dividends.

**PRICE RANGE OF OUR COMMON STOCK**

Our common stock is traded on The Nasdaq National Market under the symbol "NABI." The following table shows, for the periods indicated, the high and low sale prices of our common stock reported on Nasdaq.

	<u>High</u>	<u>Low</u>
<b>Fiscal Year 2003</b>		
Current quarter to December 8, 2003	\$12.19	\$8.00
Quarter ended September 27, 2003	9.60	5.25
Quarter ended June 28, 2003	8.00	5.60
Quarter ended March 29, 2003	6.59	5.00
<b>Fiscal Year 2002</b>		
Quarter ended December 28, 2002	\$ 7.61	\$4.85
Quarter ended September 28, 2002	6.00	3.32
Quarter ended June 29, 2002	7.26	4.71
Quarter ended March 30, 2002	11.50	4.67
<b>Fiscal Year 2001</b>		
Quarter ended December 29, 2001	\$11.08	\$5.45
Quarter ended September 29, 2001	7.74	4.85
Quarter ended June 30, 2001	8.50	5.13
Quarter ended March 31, 2001	6.38	3.88

As of December 5, 2003, there were approximately 1,118 holders of record of our common stock. This may not be an accurate indication of the total number of beneficial owners of our common stock as of that date, since many shares are held by nominees in street name for beneficial owners.

## CAPITALIZATION

The following table shows our unaudited capitalization as of September 27, 2003 on an actual basis and as adjusted to give effect to the sale of 8,500,000 shares of our common stock in this offering based on an assumed public offering price of \$11.00 per share, after deducting the underwriting discount and the estimated offering expenses, and the repayment of \$9.5 million under our credit agreement.

	At September 27, 2003	
	Actual	As Adjusted
	(Amounts in Thousands) (Unaudited)	
Cash and cash equivalents	\$ 26,248	\$ 104,238
Current portion of long-term debt	\$ 6,014	\$ 4,514
Long-term debt, less current portion	31,047	23,047
Stockholders' equity:		
Preferred stock, par value \$0.10 per share; 5,000,000 shares authorized, including 1,538,462 shares authorized as Series A Convertible Preferred Stock; none issued	—	—
Common stock, par value \$0.10 per share; 75,000,000 shares authorized; 47,239,150 shares issued and outstanding as of September 27, 2003 and 55,739,150 shares issued and outstanding as adjusted	4,724	5,574
Capital in excess of par value	204,134	290,774
Treasury stock, 800,315 shares at cost	(5,240)	(5,240)
Retained earnings	27,449	27,449
Total stockholders' equity	231,067	318,557
Total capitalization	\$268,128	\$ 346,118

The number of shares of common stock outstanding after the offering is based on the number of shares outstanding as of September 27, 2003 and excludes

- 7,951,558 shares of common stock underlying options and warrants outstanding as of September 27, 2003 at a weighted average exercise price of \$6.52 per share and
- 270,807 shares available for issuance or future grant under our 2000 Equity Incentive Plan, 1,724,825 shares available for issuance or future grant under our 1998 Non-Qualified Employee Stock Option Plan, 17,713 shares available for issuance or future grant under our Stock Plan for Non-Employee Directors and 622,677 shares available for issuance under our 2000 Employee Stock Purchase Plan.

## DILUTION

The net tangible book value of our common stock on September 27, 2003 was \$121.7 million, or \$2.58 per share of common stock. Net tangible book value per share is calculated by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets of \$109.0 million, and dividing this amount by the number of shares of our common stock outstanding as of September 27, 2003. Based on the sale by us of 8,500,000 shares of common stock in this offering at the assumed public offering price of \$11.00 per share and after deducting the underwriting discount and the estimated offering expenses, our net tangible book value as of September 27, 2003 would have been \$199.2 million, or \$3.58 per share of common stock. This represents an immediate increase in the net tangible book value of \$1.00 per share to our existing stockholders and an immediate decrease in the net tangible book value of \$7.42 per share to new investors. Dilution in the net tangible book value per share represents the difference between the offering price per share and the net tangible book value per share of our common stock immediately after the offering. The following table illustrates this per share dilution:

Offering price per share		\$11.00
Net tangible book value per share as of September 27, 2003	\$ 2.58	
Increase per share attributable to new investors	1.00	
		<hr/>
Net tangible book value per share after the offering		3.58
		<hr/>
Dilution per share to new investors		\$ 7.42
		<hr/>

The number of shares of common stock outstanding after the offering is based on the number of shares outstanding as of September 27, 2003 and excludes

- 7,951,558 shares of common stock underlying options and warrants outstanding as of September 27, 2003 at a weighted average exercise price of \$6.52 per share and
- 270,807 shares available for issuance or future grant under our 2000 Equity Incentive Plan, 1,724,825 shares available for issuance or future grant under our 1998 Non-Qualified Employee Stock Option Plan, 17,713 shares available for issuance or future grant under our Stock Plan for Non-Employee Directors and 622,677 shares available for issuance under our 2000 Employee Stock Purchase Plan.



**BUSINESS**

**Overview**

We apply our knowledge of the human immune system to commercialize and develop products that address serious, unmet medical needs. We have a broad portfolio of marketed biopharmaceutical products with growing revenues that generate cash flow to support the development of our clinical product candidates and our research programs. Our clinical product pipeline is composed of novel vaccines and antibody based biopharmaceutical products that are designed to prevent and treat infectious and addictive diseases, such as *S. aureus* infections, hepatitis B and hepatitis C, and nicotine addiction. We have exclusive rights to commercialize all of our clinical development candidates.

Through our own specialty sales force we market five biopharmaceutical products: PhosLo for the control of hyperphosphatemia in end-stage renal disease patients, Nabi-HB for the prevention of hepatitis B infections, WinRho SDF for the treatment of acute, chronic and HIV-related ITP, Aloprim for the treatment of chemotherapy-induced hyperuricemia, or high uric acid levels, and Autoplex T for the treatment of hemophilia A patients who have developed inhibitors to factor VIII. We have filed a BLA for the use of an intravenous formulation of Nabi-HB to prevent reinfection with hepatitis B disease in HBV-positive liver transplant patients. Sales of our biopharmaceutical products for the nine months ended September 28, 2002 and September 27, 2003 were \$61.8 million and \$75.4 million, respectively.

We have four product candidates in clinical development: StaphVAX, Altastaph, Civacir and NicVAX. Our lead clinical candidate is StaphVAX, a vaccine designed to prevent *S. aureus* infections. We have initiated a confirmatory Phase III clinical trial of StaphVAX to support a BLA filing in the U.S. by the end of 2005. In addition, we plan to file an MAA in the EU by the end of 2004 for regulatory approval to market StaphVAX for the prevention of *S. aureus* bacteremia for up to 40 weeks in end-stage renal disease patients on hemodialysis. This filing will be based on efficacy data at 40 weeks obtained from our previously completed Phase III clinical trial for StaphVAX. We believe that the potential global market for products to prevent *S. aureus* and other Gram-positive infections is approximately \$1-\$2 billion.

**Our Marketed and Development Products**

Products	Indication/Intended Use	Status
PhosLo	Hyperphosphatemia	Marketed
Nabi-HB	Post-exposure prevention of hepatitis B infection	Marketed
Nabi-HB Intravenous	Prevention of reinfection with hepatitis B in liver transplant patients	BLA filed in U.S.; Orphan Drug Designation
WinRho SDF	ITP	Marketed
Aloprim	Chemotherapy-induced hyperuricemia	Marketed
Autoplex T	Hemophilia A	Marketed
<i>Clinical Development</i>		
StaphVAX	Long-term protection against <i>S. aureus</i> infections	Phase III confirmatory trial in U.S.; Application for licensure in EU planned for late 2004
Altastaph	Immediate protection against <i>S. aureus</i> infections	Phase II trial in very low birth-weight newborns; Phase I/II trial in adults with persistent <i>S. aureus</i> infections
Civacir	Prevention of reinfection with hepatitis C in liver transplant patients	Phase I/II trial; Orphan Drug Designation
NicVAX	Nicotine addiction	Phase II trial in U.S.; Phase I/II trial in Europe

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In addition to our biopharmaceutical product portfolio, we collect specialty and non-specific antibodies that are used in our manufacture of Nabi-HB and our antibody based clinical products in development. In September 2001, we sold the operating assets of a majority of our antibody collection centers and our testing laboratory for \$156.3 million in cash. We retained nine centers to supply our antibody requirements for the manufacture and development of our antibody based products. We also supply specialty and non-specific antibodies to pharmaceutical and diagnostic companies.

### **Our Strategy**

The key elements of our business strategy are as follows

- *Continue to increase sales of our higher-margin biopharmaceutical products and the percentage these products represent of our total revenues.* We have successfully transitioned to a biopharmaceutical products company. We have grown our biopharmaceutical revenues each year since 2000. For the nine months ended September 28, 2002 and September 27, 2003 biopharmaceutical products represented 44.8% and 58.6% of our total sales, respectively. In the third quarter of 2003, biopharmaceutical products represented 72.4% of our total sales. We believe that the increasing percentage of our total revenues generated by sales of biopharmaceutical revenues reflects our increasing emphasis on our biopharmaceutical products business.
- *Expedite initial commercialization of StaphVAX by seeking EU approval for use in end-stage renal disease patients on hemodialysis.* After a series of discussions with various EU regulatory agencies, we have decided to file an MAA with the EU by the end of 2004 for regulatory approval to market StaphVAX for the prevention of *S. aureus* bacteremia for up to 40 weeks in end-stage renal disease patients on hemodialysis. This filing will be based on efficacy data obtained from our previously completed Phase III clinical trial that demonstrated a reduction in *S. aureus* bacteremia in those patients for up to 40 weeks. By using these data to support licensure, we will file two years earlier than we originally planned.
- *Obtain regulatory approval of a broad indication for StaphVAX for use in at-risk adults in the U.S. and the EU.* We commenced our confirmatory Phase III clinical trial for StaphVAX in September 2003. We recently increased the size of this trial from 3,000 to approximately 3,600 subjects to increase the trial's statistical power so that we can demonstrate statistical significance with a clinical reduction of 50% or more in types 5 and 8 *S. aureus* infections. The primary efficacy end point of this trial is to reduce the incidence of *S. aureus* bacteremia and secondary infections caused by bacteremia for up to eight months after vaccination. Our plan to file with the FDA for approval of a broad indication for StaphVAX by the end of 2005 remains unchanged. We also plan to file a supplement to the MAA dossier with the EU in the fourth quarter of 2005 incorporating data from the confirmatory Phase III clinical trial to apply for an expansion of the initial proposed indication.
- *Use cash flow from marketed products to contribute to the continued development of our clinical pipeline.* We expect to continue to generate meaningful revenues from our currently marketed biopharmaceutical products. We use the cash flow generated from sales of these products to contribute to the continued development of our product candidates in clinical development. By using cash flow from our marketed products to finance our clinical development programs, we intend to continue to reduce our need for external sources of financing.
- *Leverage our marketing expertise from our currently marketed products to advance commercial acceptance of PhosLo and products that emerge from our proprietary clinical pipeline.* We have an experienced specialty sales force that has successfully grown sales of our biopharmaceutical products. In August 2003, we acquired worldwide rights to PhosLo, which is sold in the nephrology market. We intend to use our sales force to grow sales of PhosLo and enhance our presence in this market. We believe that the experience we gain with nephrologists, the physicians who prescribe PhosLo, will enable us to build rapidly initial sales of StaphVAX.

## Currently Marketed Products

*PhosLo [Calcium Acetate]*. PhosLo is a prescription phosphate binder indicated for the control of hyperphosphatemia in end-stage renal disease patients. When given with food, PhosLo combines with dietary phosphorus to form insoluble calcium-phosphate complexes that are eliminated from the body, thereby reducing phosphorus absorption and lowering blood phosphorus levels. Controlling elevated phosphorus levels in dialysis patients with chronic kidney disease is critical because these patients are unable to eliminate excess phosphorus on their own. Elevated levels of phosphorus are associated with significant increases in illness and may result in death. In addition, elevated levels of phosphorus and calcium-phosphorus product have been associated with coronary calcification. We acquired worldwide rights to PhosLo in August 2003. We currently market PhosLo in the U.S. and plan to seek PhosLo registration and commercialization initially in the EU. Based upon customer demand, we anticipate reporting net sales of PhosLo of approximately \$10.0 million to \$11.0 million for the period August 5, 2003 through December 27, 2003.

According to the U.S. Renal Disease Service, or USRDS, as of December 2000, 382,000 patients in the U.S. met the criteria of chronic end-stage renal disease. The USRDS also projects that the population of end-stage renal disease patients will grow to over 650,000 patients in the U.S. by 2010. This growth in the number of chronic renal dialysis patients is largely attributable to increases in patients with diseases such as diabetes and hypertension, the primary causes of kidney failure, the overall aging of the U.S. population and increased life expectancy for dialysis patients. Based on our interviews with nephrologists, we believe that most dialysis patients are likely to experience elevated phosphorus levels during any 12-month period and therefore will require phosphate binder therapy to control their blood phosphorus levels for a period of time.

We believe that PhosLo has distinct competitive advantages over its principal competitors, Renagel and calcium carbonate products such as TUMS. In October 2003, the National Kidney Foundation issued the K/DOQI guidelines. The K/DOQI guidelines establish the primary goal of phosphate binder therapy to maintain the phosphorus levels in the blood below 5.5mg/dL and the calcium-phosphorus product below 55 mg/dL. We believe that PhosLo is the phosphate binder that best meets the K/DOQI guidelines.

In November 2003, the study: Treatment of Hyperphosphatemia in Hemodialysis Patients: The Calcium Acetate Renagel Evaluation (CARE Study) was presented. The results of this randomized, double-blind, controlled clinical trial, which compared the efficacy of calcium acetate (PhosLo) and sevelamer (Renagel (sevelamer hydrochloride)), show that patients treated with PhosLo were able to control blood phosphorus more effectively than patients treated with Renagel, the only other prescription drug currently indicated for the treatment of hyperphosphatemia in the U.S. In addition, patients treated with PhosLo achieved target phosphorus and calcium-phosphorus product levels more often and for longer periods of time than patients treated with Renagel. In addition to marked differences in efficacy, the mean daily cost of treatment with PhosLo in this study was \$2.14 compared to \$11.70 for Renagel. On an annualized basis, assuming continuous use, this would translate into \$781 in projected treatment costs for PhosLo compared to \$4,270 for Renagel, a potential cost-savings of \$3,489 per year for patients treated with PhosLo.

PhosLo is distinct from calcium carbonate products, typically over-the-counter products such as TUMS in the U.S. or prescription calcium carbonate products in the EU. Although many chronic end-stage renal disease patients in the U.S. use over-the-counter calcium carbonate products to treat elevated phosphorus levels for reasons of cost, calcium carbonate products do not meet the K/DOQI guidelines due to the comparatively lower phosphate binding activity of calcium carbonate. As a result of this reduced activity, calcium carbonate products would be expected to result in calcium loads that fail to meet K/DOQI guidelines for non-dietary calcium absorption.

*Nabi-HB [Hepatitis B Immune Globulin (Human)]*. Nabi-HB is a human polyclonal antibody product indicated to prevent hepatitis B following accidental exposure to HBV. We believe the majority of our Nabi-HB sales are for intravenous use to prevent reinfection with hepatitis B disease in HBV-positive liver transplant patients. Currently, Nabi-HB is not indicated for this use. We have submitted a briefing document to European

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regulators, and we plan to seek regulatory approval for Nabi-HB in certain European countries using the mutual recognition process. We plan to submit our first license application for Nabi-HB in Europe in the first half of 2004. Sales of Nabi-HB for the nine months ended September 28, 2002 and September 27, 2003 were \$25.5 million and \$26.3 million, respectively.

In November 2002, we submitted a BLA to the FDA for an intravenous formulation of Nabi-HB to prevent hepatitis B disease in HBV-positive liver transplant patients. Nabi-HB Intravenous has received Orphan Drug Designation from the FDA, entitling us to marketing exclusivity for this indication for a period of seven years. In January 2003, we received notification that the FDA had accepted our BLA for Nabi-HB Intravenous for priority review. We received a complete response letter from the FDA in May 2003 requesting supplemental data and information but no additional clinical trials. We responded to the complete response letter in August 2003. In addition, we are gathering longer-range follow-up data from previously completed clinical trials, which we will provide to the FDA. We anticipate a response from the FDA during the first half of 2004.

HBV is a major health concern globally. The Hepatitis B Foundation currently estimates that one out of 20 people in the U.S. has been infected with HBV. The U.S. Centers for Disease Control, or CDC, currently estimates that in the U.S. alone there are an estimated 1.25 million chronic hepatitis B carriers, 78,000 new hepatitis B infections per year, and 5,000 individuals who die annually from hepatitis B or its complications. Chronic HBV infection is a frequent cause of end-stage liver disease and is present in approximately 10%-15% of liver transplant patients. Moreover, during surgery and in the period immediately following transplant surgery patients do not have any other treatment options to prevent reinfection of the transplanted liver. Reinfection of the transplanted liver is almost inevitable after surgery in HBV-positive patients.

*WinRho SDF [Rho(D) Immune Globulin Intravenous (Human)]*. WinRho SDF is a human polyclonal antibody based product approved and marketed for the treatment of ITP, an autoimmune disease that manifests itself in abnormally low platelet levels, thrombocytopenia, resulting in excessive bleeding. We began exclusive marketing of WinRho SDF in the U.S. in 1995 under a license and distribution agreement with Cangene Corporation, or Cangene. We pay a royalty to Cangene equal to approximately half of the net profits from sales of WinRho SDF. Sales of WinRho SDF for the nine months ended September 28, 2002 and September 27, 2003 were \$26.8 million and \$37.6 million, respectively.

ITP is recognized by the appearance of purple patches on the body caused by bleeding into the skin and mucus membranes. In ITP, the body's immune system produces antibodies that attach to platelets causing them to be removed from circulation, primarily by the spleen. Because platelets are required for blood clotting, as platelet counts decrease, the incidence of bleeding episodes increases. In certain cases, such as severe trauma or spontaneous intracranial hemorrhage, the bleeding can be life threatening. The Platelet Disorder Support Association currently estimates that approximately 30,000 people develop ITP in the U.S. each year. In children, the disease is usually acute at onset and is often resolved with treatment in six months. In adults, the onset is gradual and rarely resolves itself without treatment. ITP can occur as either a primary disease or secondary to another underlying disease such as HIV or lupus. Chronic thrombocytopenia is currently estimated to occur in about 10% of HIV-infected patients and in about one third of patients with AIDS.

### **Other Products**

*Aloprim [(Allopurinol sodium) for injection]*. Aloprim is indicated for the treatment of chemotherapy-induced hyperuricemia in patients with leukemia, lymphoma or solid organ tumors. Complications associated with chemotherapy-induced hyperuricemia in these patients include renal failure. Aloprim is targeted to those patients who develop chemotherapy-induced hyperuricemia and are not treatable by oral therapies. Based on 2002 data from the American Cancer Society, there are approximately 90,000 patients annually suffering from leukemia and lymphoma in the U.S. that could potentially be at risk for developing chemotherapy-induced hyperuricemia. We acquired certain rights to distribute Aloprim from DSM Pharmaceuticals, or DSM, in June 1999 and currently have the exclusive right to distribute Aloprim in the U.S. We pay a royalty to DSM equal to a percentage of the net profits from sales of Aloprim. The royalty rate varies based on the level of annual sales.

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*Autoplex T [Anti-Inhibitor Coagulant Complex, Heat Treated]*. Autoplex T is a blood clotting agent used to treat hemophilia A patients who have developed inhibitors to factor VIII. Hemophilia A is a blood clotting disorder characterized by a lack of functional coagulation factor VIII. Physicians typically treat hemophilia A by replacing the deficient factor with either recombinant clotting factor VIII or human factor VIII. In most cases, replacement therapy is effective in stopping bleeding episodes. However, the treatment of hemophilia A is complicated when an inhibitor or antibody is produced in response to outside sources of factor VIII. These antibodies neutralize infused factor VIII, rendering the patient at risk for excessive bleeding episodes. We acquired exclusive rights to distribute Autoplex T in the U.S., Canada and Mexico from Baxter in May 1997; however, these rights expire in May 2004.

### **Clinical Development Products**

We have a significant pipeline of biopharmaceutical products under development. Our research and development pipeline products consist of vaccines for long-term protection and antibody based biopharmaceutical products for immediate short-term protection from blood infections caused by Gram-positive bacteria such as *S. aureus*, *S. epidermidis* and *Enterococci*, antibody based biopharmaceutical products for the treatment and/or prevention of various diseases, including hepatitis B and hepatitis C, and a vaccine for treating and preventing nicotine addiction.

#### ***Gram-positive Infections Program***

According to current CDC estimates, more than two million patients in the U.S. each year contract an infection as a result of exposure to a pathogen while receiving care in a hospital. Within the approximately 5,400 acute care hospitals in the U.S., *S. aureus* is the leading cause of hospital-acquired bloodstream infections. With its capacity to cause serious complications and its increasing resistance to most antibiotics, *S. aureus* has become a critically dangerous pathogen. *S. aureus* can spread from the blood to the bones or the inner lining of the heart and its valves, or cause abscesses in internal organs such as the lungs, kidneys and brain. Patients who are most at risk for these infections include surgical patients, trauma or burn victims, newborns whose immune systems are not yet developed and people with chronic illnesses such as chronic skin diseases, diabetes, cancer and lung diseases or kidney diseases. People whose immune systems are suppressed due to disease, drugs or radiation therapy also are more susceptible to these bacterial infections.

Staphylococcal infections are difficult to treat because the bacteria that cause them are highly virulent and in many cases resistant to currently available antibiotics. This rise of antibiotic resistance has markedly curtailed options for treating *S. aureus* infections.

*StaphVAX (Staphylococcus aureus Polysaccharide Conjugate Vaccine)*. We are developing StaphVAX for patients who are at high risk of *S. aureus* infection and who are able to respond to a vaccine by producing their own antibodies. In the U.S. alone there are estimated to be 12 million of these patients. StaphVAX is intended to stimulate a patient's immune system to produce antibodies to *S. aureus* that provide active, long-term protection from the bacteria. StaphVAX targets *S. aureus* types 5 and 8, which are responsible for approximately 85% of *S. aureus* infections.

StaphVAX is an investigational polysaccharide conjugate vaccine based on patented vaccine technology licensed from the Public Health Service/NIH on terms that provide exclusivity for seven years following FDA approval. StaphVAX represents a novel approach to the prevention of *S. aureus* infections. StaphVAX contains surface polysaccharides found in the outer coating of *S. aureus* types 5 and 8. The polysaccharide molecules are linked, or conjugated, in the vaccine with a non-toxic, carrier protein derived from the bacteria *Pseudomonas aeruginosa*. Once given the vaccine, the patient's immune system produces proteins, called antibodies, which bind to *S. aureus* on subsequent exposure to the bacteria. These antibodies help the immune system to identify the *S. aureus* bacteria while it is in the blood, or bacteremia, and eliminate it. Since these antibodies bind to several sites on the bacteria's surface polysaccharides, we believe that the bacteria will be unable to develop resistance to the antibodies as it has to antibiotics.

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Potential at-risk patient populations who may benefit from the use of StaphVAX include

- patients such as the elderly and those suffering chronic diseases including end-stage renal disease, congestive heart failure, chronic obstructive pulmonary disease and diabetics who are expected to have long stays in medical or extended care facilities,
- patients undergoing planned surgery who can be vaccinated in advance, for whom *S. aureus* infections can have serious consequences,
- prosthetic surgery and vascular graft patients who are at long-term risk of *S. aureus* infections due to their implants,
- chronic osteomyelitis patients, spinal cord injury and spinal fusion patients and
- hematology/oncology patients undergoing chemotherapy.

*S. aureus* infection rates in these high-risk populations range from 1-10%, and result in longer hospital stays, higher death rates, increased illness and significantly higher medical costs.

In September 2003, we began enrollment in a confirmatory Phase III clinical trial for StaphVAX with a prospectively defined primary efficacy end point at eight months post-vaccination. This trial will be double-blind, placebo-controlled and randomized. Enrollment for this trial is expected to be completed by mid-2004. We recently increased the size of the trial from 3,000 to approximately 3,600 subjects to increase the trial's statistical power so that we can demonstrate statistical significance with a clinical reduction of 50% or more in types 5 and 8 *S. aureus* infections. We estimate that we will incur outside clinical trial costs of approximately \$36.0 million over the period from initiation of the trial through conclusion of the trial in the second half of 2005. In this confirmatory Phase III clinical trial, we also will administer a booster dose eight months following the initial vaccination and subjects will be monitored for an additional four to six months as secondary end points. Consequently, patients will be followed for at least 12 months in total. We plan to file a BLA by the end of 2005.

In September 2003, we also announced the completion of a clinical study in 40 healthy volunteers to compare the immune system response (immunogenicity) to vaccine manufactured at a contract manufacturer's site with the response achieved in previous trials using the vaccine manufactured in our research and development pilot plant. The study showed immunogenicity and safety at least equivalent to the immunogenicity seen in clinical studies with vaccine manufactured at our pilot plant. The study demonstrated that we can transfer the manufacturing process for StaphVAX was reproducible and scalable. We have started the process of transferring the StaphVAX manufacturing process to Cambrex Bio Science, our contract manufacturer for the manufacture of StaphVAX.

After a series of discussions with various EU regulatory agencies, we have decided to file an MAA with the EU by the end of 2004 based on the efficacy data obtained from our previously completed Phase III clinical trial, using the centralized registration procedure. Based on the results of these discussions, we intend to file for regulatory approval to market StaphVAX for the prevention of *S. aureus* bacteremia for up to 40 weeks in end-stage renal disease patients on hemodialysis. If the MAA is approved, we would be granted simultaneous regulatory approval to market StaphVAX for this indication throughout the EU. We also plan to file a supplement to the MAA dossier with the EU in the fourth quarter of 2005 incorporating data from the confirmatory Phase III clinical trial currently underway in the U.S. These data, together with safety and immune response data from immunogenicity clinical trials in other at-risk patient populations such as patients undergoing orthopedic or cardiothoracic surgery, will be used to apply for an expansion of the initial proposed indication to an indication for the prevention of *S. aureus* bacteremia and secondary infections caused by bacteremia in at-risk adults.

We completed our initial Phase III double-blind, placebo-controlled and randomized clinical trial for StaphVAX in hemodialysis patients with end-stage renal disease in late 2000. We targeted this patient population because of its relatively high infection rate and because it is at long-term risk of infection and could maximally benefit from the protection that a vaccine may afford. A total of 1,804 patients were included in the clinical trial. Half the enrolled patients were vaccinated with StaphVAX and half received a placebo. The

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clinical trial population was evaluated at intervals for up to a year to evaluate vaccine safety and *S. aureus* infection rates. The results of the trial showed that a single injection of StaphVAX was safe and showed a statistically significant reduction in the incidence of *S. aureus* bacteremia by almost 60% through 10 months post-vaccination. The reduction in bacteremia one year after vaccination was 26%. The decrease in effect from 10 to 12 months was associated with declining levels of antibodies. No significant side effects attributable to the vaccine were noted. The results in end-stage renal disease patients are especially relevant because these patients are severely immune-compromised and therefore, generally respond poorly to vaccines. Based upon previous clinical trials in healthy volunteers, immune-competent patients who are at risk for *S. aureus* infections are expected to respond more favorably with higher levels of antibody to StaphVAX than end-stage renal disease patients. The significance of the results of this trial was confirmed by publication in the *New England Journal of Medicine* in February 2002.

To build on the results of our previous Phase III clinical trial completed in 2000, we conducted a booster trial in 2001, giving a second dose of StaphVAX to 77 hemodialysis patients who received an initial dose of the vaccine. The booster trial was designed to evaluate whether patients at long-term risk could respond to a booster dose of the vaccine. The trial demonstrated that a booster dose of the vaccine given to previously vaccinated hemodialysis patients increased the concentration of the vaccine-specific antibodies against *S. aureus*. The trial results suggest that periodic booster doses of StaphVAX can be administered to increase and sustain antibody levels for patients at chronic risk of *S. aureus* infection. The average antibody concentrations reached after the booster vaccination were above what our scientists believe to be a protective level, although not as high as those following the first dose of vaccine. In addition, antibody levels decreased more gradually over time after the booster vaccination than following the initial dose.

*Altastaph [Staphylococcus aureus Immune Globulin (Human)]*. Altastaph is an investigational human polyclonal antibody product that contains high levels of specific antibodies to *S. aureus* types 5 and 8. These antibodies are collected from the plasma of healthy donors who have been vaccinated with StaphVAX at our antibody collection centers. In contrast to StaphVAX, which is intended to provide long-term protection against *S. aureus* infection, we are initially developing Altastaph to provide short-term protection to patients at immediate risk of infection, or who have compromised immune systems and cannot respond effectively to a vaccine. High-risk populations that could benefit from a product such as Altastaph include very low birth-weight newborns, trauma patients and patients in intensive care and burn units. This type of protection or treatment may be cost-effective because antibodies in a single dose of Altastaph persist in the bloodstream for a number of weeks and can be available to provide protection for the entire risk period. We are also exploring the use of Altastaph as a therapeutic agent for use in patients with persistent *S. aureus* infections.

In July 2003, we initiated a randomized, double-blind, placebo-controlled Phase II clinical trial for short-term protection against *S. aureus* types 5 and 8 in very low birth-weight newborns, with birth weights between 500 and 1500 grams, in 20 neonatology centers throughout the U.S. Newborns will be randomly selected to receive Altastaph or placebo and followed up to 42 days for safety and incidence of infections. We have also initiated a placebo-controlled, double-blind Phase I/II clinical trial of Altastaph in adults with persistent *S. aureus* infections. We also will monitor clearance and recurrence of infections. We anticipate reporting data from these clinical trials by the end of 2004.

In 1999, we successfully completed a multi-dose Phase I/II clinical trial of Altastaph in very low birth-weight newborns that demonstrated its safety and the presence of measurable antibodies to *S. aureus* at a variety of dosage levels. The trial indicated that titers of the specific anti-staph antibodies are dose-related. Even the lowest dose of 500 mg/kg of Altastaph resulted in antibody titers that pre-clinical models and clinical trials with StaphVAX indicate may be protective against infection.

*Next Generation Products and Other Anti-Bacterial Vaccines in Development*. We have identified and patented an antigen, type 336, found on a serotype of *S. aureus*, that accounts for more than 90% of types 5 and 8 *S. aureus* clinical infections, or about 10-12% of all clinically significant *S. aureus* infections. We

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have identified, purified and characterized the type 336 antigen and have prepared a prototype conjugate vaccine that is capable of protecting animals from challenge with clinical isolates of the serotype. During 1998, we were issued a U.S. patent on the type 336 antigen. Included in the patent were claims relating to vaccines made from type 336 antigen and monoclonal and polyclonal antibodies reactive to the antigen. Patents for type 336 antigen and its use are being pursued worldwide. The second generation of StaphVAX is expected to contain type 336 antigen in addition to *S. aureus* types 5 and 8 antigens. A second generation of Altastaph is expected to contain type 336 antibodies in addition to *S. aureus* types 5 and 8 antibodies. We expect these second-generation vaccines to provide coverage for greater than 95% of all clinically significant *S. aureus* infections.

*S. epidermidis* and *Enterococcus faecalis* are the two other clinically significant Gram-positive bacteria that cause hospital-acquired infections. We intend to extend product coverage to these two Gram-positive bacteria in subsequent generations of StaphVAX and Altastaph. We have been issued two patents containing claims covering both a *S. epidermidis* vaccine and human monoclonal and polyclonal antibodies and have filed patent applications on selected enterococcal antigens. Prototypical *S. epidermidis* and enterococcal vaccines produced by us have been shown to induce antibodies that are protective in animal models and facilitate elimination of bacteria by the same type of immune system response as StaphVAX.

### **Other Programs**

*Civacir [Hepatitis C Immune Globulin (Human)]*. Civacir is an investigational human polyclonal antibody product that contains antibodies to HCV. Pre-clinical studies indicate that Civacir contains antibodies that are neutralizing to HCV. We are developing Civacir to prevent hepatitis C disease in HCV-positive liver transplant patients.

HCV has significant social impact because it causes chronic infections in a large percentage of those infected and often results in severe illness and death in later stages of the disease. Chronic HCV infection is a frequent cause of end-stage liver disease in North America and Europe and is present in approximately one third of patients undergoing liver transplants. Moreover, during surgery and in the period immediately following, these patients have no treatment options to prevent reinfection of the transplanted liver. Reinfection of the transplanted liver is almost inevitable within weeks to months after surgery and can occur within days of transplantation. HCV infection also contributes to frequent hospitalizations and failure of the transplanted liver when it occurs in transplant patients. The CDC currently estimates that there are approximately 2.7 million individuals in the U.S. chronically infected with HCV, and the WHO estimates 170 million individuals worldwide are infected with HCV.

The NIH is funding and conducting a Phase I/II clinical trial of Civacir in HCV-positive liver transplant patients at six study sites in the U.S. This trial is a three-armed, randomized, controlled clinical study evaluating two dose levels of Civacir. In this trial the NIH is evaluating the safety of dosing patients with Civacir during and after transplant surgery. The NIH is also evaluating the level of HCV-specific antibodies in trial subjects following dosing, as well as liver enzyme levels, a measure of liver damage, and HCV levels in the transplanted livers. The results of this trial will help us determine the safety of Civacir in this patient population and define the efficacy markers that may be important in subsequent Phase II and III clinical trials. We anticipate receiving the data from the trial in early 2004. The data will then be used to define our continued development strategy with Civacir. Civacir has received Orphan Drug Designation from the FDA.

*NicVAX (Nicotine Conjugate Vaccine)*. NicVAX is an investigational vaccine to prevent and treat nicotine addiction that uses a conjugate vaccine technology similar to StaphVAX and other anti-bacterial vaccines in our pipeline. NicVAX is designed to cause the immune system to produce antibodies that bind to nicotine and prevent it from entering the brain. The stimulus in the brain that is caused by nicotine is therefore no longer present. Preclinical studies showed that vaccination with NicVAX can prevent nicotine from reaching the brain and block the effects of nicotine, including effects that can lead to addiction or can reinforce and maintain addiction.



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In August 2003, we announced the initiation of a Phase II dose response, double-blind, placebo-controlled, randomized clinical trial in 63 smokers who have expressed a desire to quit smoking. The trial, which is designed to observe safety, specific nicotine antibody levels and the rate of smoking cessation in trial participants in response to vaccination with NicVAX, is being conducted at three sites in the U.S. This trial is funded in part by a grant from the National Institute on Drug Abuse, or NIDA. In addition, in February 2003, we initiated a placebo controlled, double-blind Phase I/II clinical trial of NicVAX in smokers, ex-smokers and non-smokers in collaboration with researchers at the University of Maastricht in The Netherlands. The primary intent of this trial is to evaluate the development of specific nicotine antibody levels and safety of the vaccine in study participants. Both studies are fully enrolled. We expect to report the full results from The Netherlands trial by the first quarter of 2004 and from the U.S. trial by the second half of 2004.

In 2002, we completed a placebo-controlled, double-blind Phase I clinical trial of a single dose of NicVAX in healthy, non-smoker volunteers with the assistance of funding from NIDA. The intent of the trial was to evaluate the safety and immunogenicity of the vaccine. Analysis of blood samples from the participants showed that a single dose of vaccine resulted in a rapid immune response and generated nicotine-specific antibodies. Local reactions to vaccination were generally mild to moderate, temporary and required no therapeutic intervention. Antibody levels were detected within 7-14 days of vaccination and were either maintained or continued to increase through at least 60 days post-vaccination.

### **Supply and Manufacturing**

We manufacture Nabi-HB in our biopharmaceutical manufacturing facility in Boca Raton, Florida. Additionally, we manufacture clinical lots of our investigational products, Altastaph and Civacir, in this facility. We are considering modifying an unused portion of our Boca Raton facility to manufacture commercial quantities of StaphVAX.

All of our marketed products other than Nabi-HB are manufactured for us by third parties. PhosLo is manufactured for us by Braintree Laboratories, Inc. under an agreement that can be extended until 2018. PhosLo is also manufactured for us by another third-party manufacturer. WinRho SDF is manufactured for us by Cangene under an agreement that terminates in 2005. Aloprim is manufactured for us by DSM under an agreement that terminates in 2004, although we intend to exercise an option to extend that agreement. Baxter supplies Autoplex T to us under a contract that ends in May 2004.

In October 2003 we signed a ten-year agreement with Cambrex Bio Science for the contract manufacturing and commercial supply of StaphVAX.

### **Competition**

PhosLo competes with Renagel, a product marketed by Genzyme Corporation, and calcium carbonate products such as TUMS.

There is one antibody based therapy for prevention of hepatitis B post exposure currently on the market that competes with Nabi-HB. We believe that Nabi-HB has achieved a significant share of the U.S. market for the product.

WinRho SDF is the first and only Rh<sub>0</sub>D antibody based biopharmaceutical product approved for the treatment of ITP. We believe that WinRho SDF has a significant and growing share of the U.S. market for ITP treatment. Competing therapies include steroids, intravenous immune globulin and splenectomy (a surgical procedure to remove the spleen). Rituxan also is being used to treat refractory ITP patients.

Aloprim is the first intravenous allopurinol therapy available for the treatment of chemotherapy-induced hyperuricemia. Aloprim provides a therapeutic option for patients that cannot tolerate oral allopurinol therapy. In 2002, a new competitive agent using a different mechanism of action was introduced into this market.

Autoplex T competes in the anti-inhibitor segment of the hemophilia A market. There are two significant biopharmaceutical products currently on the market that compete with Autoplex T.

## Intellectual Property

Our success depends in part on our ability to maintain our rights to our existing marketed biopharmaceutical products and our ability to obtain patent protection for product candidates in clinical development. Currently, we have 31 granted patents and 62 patent applications pending.

### Marketed products

We have two patents granted in the U.S., one patent granted in Canada, and one patent application pending in the U.S. relating to PhosLo. The granted patents contain claims directed to methods of using calcium acetate in an orally ingested form to inhibit gastrointestinal absorption of phosphorus. The claims of the granted patent are directed to methods for the use of PhosLo for our approved application with end-stage renal disease patients. Patent coverage for these claims expires in April 2007. We also have a U.S. patent granted and a U.S. patent application pending with claims to a second-generation, phosphorus-binding composition that comprises calcium acetate in #0 or #2 size capsule form. The capsules are characterized by an enhanced ease of patient use and, as a result, improved treatment management. This granted U.S. patent expires in April 2021 and any patent granted on the pending U.S. patent application would expire in October 2022.

### Products in clinical development

We have 25 patents issued and 38 patent applications pending relating to our Gram-positive infectious disease program. We have several U.S. and non-U.S. patents granted or pending for various *Staphylococcus* and *Enterococcus* antigens. With respect to *Staphylococcus*, the patents and pending patent applications relate both to polysaccharide antigens—our “336” *S. aureus* antigen and “Type I” *S. epidermidis* antigen—and to a glycopeptide antigen common to *S. epidermidis*, *S. haemolyticus*, and *S. hominis*. Our pending patent applications relate to *Enterococcus* and describe polysaccharide antigens from *E. faecalis* and *E. faecium*, respectively. Currently, we are pursuing claims to one of the *E. faecalis* antigens.

With regard to *S. epidermidis*, our two issued U.S. issued patents and many non-U.S. patents contain claims to vaccines and hyperimmune globulins against *S. epidermidis* surface antigen. Most of these patents expire in 2016. Our four granted U.S. patents and two non-U.S. patents in our *S. aureus* program contain claims directed to vaccines, antibody based therapies, methods of preparing antigen and diagnostic assays and kits against surface antigens of *S. aureus*. These patents all expire in September 2016. Additional patent applications still pending include claims directed to the antigens, as well as to compositions, or conjugates, of the antigens, vaccines containing the antigens, antibodies to the antigens, and immunotherapy and diagnostic methods using the antigens and/or the antibodies to the antigens. In addition, we have filed a U.S. patent application covering methods directed to the use of StaphVAX, among other compositions. These two applications, which address a method of protecting a human being with a compromised immune system from *Staphylococcal* or *Enterococcal* bacterial infection, include claims that prescribe our use of proprietary antigens. The applications also encompass a method for the use of types 5 and 8 *S. aureus* antigens.

In addition, we have one U.S. patent and one U.S. and three non-U.S. patent applications pending that contain claims directed to a pharmaceutical composition containing a  $\beta$ glucan and intravenous hyperimmune globulin, which can be specific for a given pathogenic microorganism. This combination produces an unexpected antimicrobial effect that is greater than that obtained when either the  $\beta$ glucan or the intravenous hyperimmune globulin is used separately.

Our patent portfolio for technology related to the NicVAX product concerns both compositions and therapeutic methodology for treating or preventing nicotine addiction. In particular, we have three issued patents and 21 applications pending in the U.S. and abroad. Our patent claims are directed to compositions, or conjugates, that comprise nicotine linked to a carrier protein and to the methods for the use of these conjugates to treat or prevent nicotine addiction. We also have claims to a pharmaceutical composition that contains anti-conjugate antibodies, as well as to methods for using those antibodies against nicotine addiction.

***Trade Secrets and Trademarks***

We rely on unpatented proprietary technologies in the development and commercialization of our products. We also depend upon the unpatentable skills, knowledge and experience of our scientific and technical personnel, as well as those of our advisors, consultants and other contractors. To help protect our proprietary know-how, we often use trade secret protection and confidentiality agreements to protect our interests. We require employees, consultants and advisors to enter into agreements that prohibit the disclosure of confidential information and where applicable require disclosure and assignment to us of the ideas, developments, discoveries and inventions that arise from their activities for us.

We own or license trademarks associated with each of our products, including several national and foreign trademark registrations, or common law rights, for each of our marketed and development products.

## MANAGEMENT

The following table presents information about our executive officers and directors.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Thomas H. McLain	45	Chief Executive Officer, President and Director
Raafat E.F. Fahim, Ph.D.	50	Senior Vice President, Technical and Production Operations
Robert B. Naso, Ph.D.	58	Senior Vice President, Research and Development
Henrik S. Rasmussen, M.D., Ph.D.	45	Senior Vice President, Clinical, Medical and Regulatory Affairs
Gary A. Siskowski	58	Senior Vice President, Sales and Marketing
Mark L. Smith	42	Senior Vice President, Finance, Chief Financial Officer, Chief Accounting Officer and Treasurer
David J. Gury	64	Chairman of the Board and Director
David L. Castaldi	63	Director
Geoffrey F. Cox, Ph.D.	60	Director
George W. Ebright	65	Director
Richard A. Harvey, Jr.	54	Director
Linda Jenckes	56	Director
Stephen G. Sudovar	57	Director

*Mr. McLain* has served as Chief Executive Officer and President since June 2003 and has been a director since April 2001. From November 2002 to June 2003 Mr. McLain served as President and Chief Operating Officer. From April 2001 to November 2002, he served as Executive Vice President and Chief Operating Officer. From 1998 to April 2001, Mr. McLain served as Senior Vice President, Corporate Services and Chief Financial Officer. From 1988 to 1998, Mr. McLain was employed by Bausch & Lomb, Inc., a global eye care company, where, as Staff Vice President, Business Process Reengineering, he led a cross-functional team to restructure the global finance and purchasing organizations. During his tenure with Bausch & Lomb, Mr. McLain held various positions of increasing responsibility, including Staff Vice President, Accounting and Reporting, and Assistant Corporate Controller. Before joining Bausch & Lomb, Mr. McLain practiced with the accounting firm of Ernst & Young LLP.

*Dr. Fahim* has served as Senior Vice President, Technical and Production Operations since May 2003. He joined us in March 2003 as Vice President of Vaccine Manufacturing Operations. His career includes 14 years, from 1987 to 2001, with Aventis Pasteur, a global vaccine company, where he was instrumental in developing several vaccines from early research to marketed products. During his tenure with Aventis Pasteur he held the positions of Vice President, Industrial Operations; Vice President, Development, Quality Operations and Manufacturing; Director of Product Development; and head of bacterial vaccines research/research scientist. For the year prior to joining Nabi Biopharmaceuticals, Dr. Fahim was an independent consultant, working with Aventis Pasteur and other companies worldwide, on projects that included manufacturing, process improvement, quality operations and regulatory issues. From 2001 until 2002, he served as President and Chief Operating Officer of Lorus Therapeutics, Inc., a biopharmaceutical company.

*Dr. Naso* has served as Senior Vice President, Research and Development, since August 1998. From 1995 to August 1998, Dr. Naso served as Senior Vice President, Research and Development and General Manager, Rockville Operations. From 1992 to 1995, Dr. Naso served as Vice President of Research and Development (through 1995) and Vice President of Research (through 1994) of Univax Biologics, Inc., which merged with us in 1995. From 1983 to 1992, Dr. Naso was employed at Johnson & Johnson where he held various positions of increasing responsibility in research and development. From 1973 to 1983, Dr. Naso was on the faculty at the University of Texas M.D. Anderson Cancer Center.

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*Dr. Rasmussen* has served as Senior Vice President, Clinical, Medical and Regulatory Affairs since May 2003. He joined us in February 2003 as Vice President of Clinical and Regulatory Affairs. From April 1999 to February 2003, he was Vice President/Senior Vice President of Clinical Research & Regulatory Affairs with GenVec, Inc., a biotech company focusing on gene therapy. From November 1994 to March 1999, Dr. Rasmussen was Vice President of Clinical Research/Senior Vice President of Clinical Research/Regulatory Affairs with British Biotech in Annapolis, Maryland. From 1985 to 1989, he worked at a major university hospital in Copenhagen, focusing on internal medicine (cardiology, gastroenterology, infectious diseases). Dr. Rasmussen spent six years with Pfizer Central Research in Sandwich, England, where he held various management positions within the worldwide clinical development group.

*Mr. Siskowski* has served as Senior Vice President, Sales and Marketing since October 2001. From June 2000 to October 2001, Mr. Siskowski served as Vice President of New Business Development. In 1994, Mr. Siskowski co-founded Advanced Biologics LLC, a clinical research organization specializing in anti-infectives, and from 1994 to 2000, he served as Vice President of Business Development of Advanced Biologics. From 1988 to 1994, Mr. Siskowski was employed at Ortho-McNeil Pharmaceutical, Inc. to develop and launch products with the anti-infectives franchise. From 1969 to 1988, Mr. Siskowski was employed at Roche Laboratories where he held various positions of increasing responsibility, most recently as its Product Director for the anti-infectives franchise.

*Mr. Smith* has served as Senior Vice President, Finance, Chief Financial Officer and Chief Accounting Officer since April 2001. From August 1999 to April 2001, Mr. Smith served as Vice President of Finance and Chief Accounting Officer and as Senior Director of Finance and Chief Accounting Officer. From 1998 to 1999, Mr. Smith served as Vice President of Finance and Administration and Chief Financial Officer of Neuromedical Systems, Inc., where he played a leadership role in that company's strategic restructuring and sale in connection with a pre-packaged Chapter 11 proceeding under federal bankruptcy laws. From 1996 to 1998, Mr. Smith served in various financial executive capacities at Genzyme Corporation. From 1991 to 1996, Mr. Smith was employed by Genetrix, Inc., most recently as its Chief Financial Officer. Before joining Genetrix Inc., Mr. Smith practiced with the accounting firm of PricewaterhouseCoopers LLP in both Australia and the U.S.

*Mr. Gury* has served as non-executive Chairman of the Board since June 2003. From November 2002 to June 2003, Mr. Gury served as Chairman of the Board and Chief Executive Officer. From April 1992 to November 2002, Mr. Gury served as Chairman of the Board, President, and Chief Executive Officer. From May 1984 to April 1992, Mr. Gury served as President and Chief Operating Officer. Mr. Gury has been a director since 1984. Mr. Gury began his career at Abbott Laboratories and served in a variety of staff operations and executive capacities at Abbott Laboratories and a spin-off company, Alpha Therapeutic Products, until he joined the Company in 1984.

*Mr. Castaldi* has been a director since July 1994. He is currently an independent consultant. He was Chancellor and Chief Financial Officer of the Roman Catholic Archdiocese of Boston in 2001. From August 1998 to December 1999, he was Chief Executive Officer of Cadent Medical Corp., a medical device company that he co-founded. Mr. Castaldi was Chairman of the Board of Cadent from October 1996 until Cadent was acquired by Cardiac Science Corp. in July 2000. From August 1996 to August 1998, he was Chairman of the Board and Chief Executive Officer of Biolink Corporation. Mr. Castaldi also serves on the board of directors of Embrex, Inc.

*Dr. Cox* has been a director since December 2000. He has been Chairman and Chief Executive Officer of GTC Biotherapeutics, Inc., a biopharmaceutical company, since July 2001. From November 1997 to July 2001, he was Chairman of the Board and Chief Executive Officer of Aronex Pharmaceuticals, Inc., a biotechnology company. From 1984 to November 1997, he was employed by Genzyme Corporation, serving most recently as its Executive Vice President, Operations. Dr. Cox also serves on the board of directors of GTC Biotherapeutics, Inc.

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*Mr. Ebright* has been a director since November 1995. Until he retired in December 1994, Mr. Ebright was Chairman of the Board of Cytogen Corporation, a biopharmaceutical company, which he joined in February 1989 as President, Chief Executive Officer, and director. For 26 years prior to 1989, he held various management positions at SmithKline Beecham Corporation, a pharmaceutical company, including President and Chief Operating Officer from 1987 to 1989. Mr. Ebright also serves on the boards of directors of West Pharmaceutical Services, Inc. and Arrow International, Inc.

*Mr. Harvey* has been a director since 1992. He has been President of Stonebridge Associates, LLC, an investment banking firm, since January 1996.

*Ms. Jenckes* has been a director since 1997. Ms. Jenckes has been President of Linda Jenckes & Associates, a government relations consulting firm that she founded, since 1995. Ms. Jenckes also serves on the boards of directors of the National Multiple Sclerosis Society and the National Polycystic Kidney Disease Research Foundation.

*Mr. Sudovar* has been a director since January 2002. He has been President and Chief Executive Officer of EluSys Therapeutics, Inc., a biopharmaceutical company, since September 1999. From 1988 to August 1999, he was President of Roche Laboratories, a global healthcare company. Mr. Sudovar also serves on the board of directors of Atherogenics, Inc.

**PRINCIPAL STOCKHOLDERS**

The following table sets forth certain information regarding the ownership of our common stock as of December 5, 2003 (except as otherwise indicated in the notes) on an actual basis and as adjusted to give effect to the issuance of 8,500,000 shares of our common stock in this offering, assuming no exercise of the underwriters' over-allotment option, for the following persons

- each director,
- each of our current executive officers named in our proxy statement for our 2003 annual meeting of stockholders,
- all of our directors and executive officers as a group and
- each person whom we know beneficially owns more than five percent of our outstanding shares of common stock.

For purposes of this table, the term "beneficial owner" means any person who, directly or indirectly, has or shares the power to vote or dispose of shares of common stock or who has the right to acquire shares of common stock within sixty days of December 5, 2003.

Name of Beneficial Owner	Shares Beneficially Owned(1)	Percent of Shares Beneficially Owned	
		Before Offering	After Offering
<b>Directors</b>			
David J. Gury	1,195,915(2)	2.51%	2.13%
David L. Castaldi	67,215(3)	*	*
Geoffrey F. Cox, Ph.D.	39,102(4)	*	*
George W. Ebright	43,578(5)	*	*
Richard A. Harvey, Jr.	45,996(6)	*	*
Linda Jenckes	44,247(7)	*	*
Thomas H. McLain	374,392(8)	*	*
Stephen G. Sudovar	26,497(9)	*	*
<b>Named Executive Officers</b>			
Thomas H. McLain	374,392(8)	*	*
Robert B. Naso, Ph.D.	336,086(10)	*	*
Mark L. Smith	144,404(11)	*	*
All executive officers and directors as a group (13 persons)	2,362,213(12)	4.85%	4.13%
<b>More Than 5% Stockholders</b>			
Deerfield Capital, L.P. et al. 780 Third Avenue, 37th Floor New York, NY 10017	4,200,000(13)	8.92%	7.55%
Heartland Advisors, Inc. 789 North Water Street Milwaukee, WI 53202	3,536,800(14)	7.51%	6.36%
Dimensional Fund Advisors Inc. 1299 Ocean Avenue, 11th Floor Santa Monica, CA 90401	2,427,372(15)	5.15%	4.37%

\* Less than 1%.

(1) Unless otherwise noted, the nature of beneficial ownership consists of sole voting and investment power.

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- (2) Consists of (i) 528,158 shares of common stock owned by Mr. Gury, (ii) 106,400 shares of common stock owned by Mr. Gury's immediate family and 1,500 shares held by Mr. Gury as trustee under trusts for the benefit of his children, as to which Mr. Gury disclaims beneficial ownership, and (iii) 559,856 shares of common stock that may be acquired under stock options that are presently exercisable.
- (3) Consists of (i) 23,515 shares of common stock owned by Mr. Castaldi, (ii) 6,200 shares of common stock owned by Mr. Castaldi's wife and daughter, as to which Mr. Castaldi disclaims beneficial ownership, and (iii) 37,500 shares of common stock that may be acquired under stock options that are presently exercisable.
- (4) Consists of (i) 9,102 shares of common stock owned by Dr. Cox and (ii) 30,000 shares of common stock that may be acquired under stock options that are presently exercisable.
- (5) Consists of (i) 6,078 shares of common stock owned by Mr. Ebright and (ii) 37,500 shares of common stock that may be acquired under stock options that are presently exercisable.
- (6) Consists of (i) 8,496 shares of common stock owned by Mr. Harvey and (ii) 37,500 shares of common stock that may be acquired under stock options that are presently exercisable.
- (7) Consists of (i) 6,747 shares of common stock owned by Ms. Jenckes and (ii) 37,500 shares of common stock that may be acquired under stock options that are presently exercisable.
- (8) Consists of (i) 45,083 shares of common stock jointly owned by Mr. McLain and his wife, (ii) 130 shares of common stock owned by Mr. McLain's children, as to which Mr. McLain disclaims beneficial ownership and (iii) 329,179 shares of common stock that may be acquired under stock options that are presently exercisable.
- (9) Consists of (i) 3,997 shares of common stock owned by Mr. Sudovar and (ii) 22,500 shares of common stock that may be acquired under stock options that are presently exercisable.
- (10) Consists of (i) 11,417 shares of common stock owned by Dr. Naso and (ii) 324,669 shares of common stock that may be acquired under stock options that are presently exercisable.
- (11) Consists of (i) 16,286 shares of common stock owned by Mr. Smith and (ii) 128,118 shares of common stock that may be acquired under stock options that are presently exercisable.
- (12) See notes 2-12. Also includes (i) 4,497 shares of common stock and (ii) 40,284 shares of common stock that may be acquired under stock options that are presently exercisable.
- (13) The information in the table and in this note is derived from a Form 13F-HR/A for the calendar quarter ended September 30, 2003 filed with the SEC on November 12, 2003 by Deerfield Management Corporation.
- (14) The information in the table and this note is derived from a Schedule 13G/A filed with the SEC on February 13, 2003 by Heartland Advisors, Inc., a registered investment advisor, which has sole voting power over 761,400 shares and sole investment power over 3,536,800 shares, and William J. Nasgovitz, the president and principal shareholder of Heartland Advisors, Inc., who has sole voting power over 2,500,000 shares.
- (15) The information in the table and this note is derived from a Schedule 13G/A filed with the SEC on February 10, 2003 by Dimensional Fund Advisors Inc., a registered investment advisor. Dimensional Fund Advisors Inc. disclaims beneficial ownership of these shares.



## UNDERWRITING

Under the underwriting agreement, which is filed as an exhibit to the registration statement relating to this prospectus, each of the underwriters named below, for whom Lehman Brothers Inc. is acting as representative, has severally agreed to purchase from us, on a firm commitment basis, subject only to the conditions contained in the underwriting agreement, the number of shares of common stock shown opposite its name below:

Underwriters	Number of Shares
Lehman Brothers Inc.	
Wachovia Capital Markets, LLC	
U.S. Bancorp Piper Jaffray Inc.	
Harris Nesbitt Corp.	
Total	

The underwriting agreement provides that the underwriters' obligations to purchase common stock depend on the satisfaction of the conditions contained in the underwriting agreement, which include

- if any shares of common stock are purchased by the underwriters, then all of the shares of common stock the underwriters agreed to purchase must be purchased,
- the representations and warranties made by us to the underwriters are true and correct in all material respects,
- there is no material change in the financial markets and
- we deliver customary closing documents to the underwriters.

### Commissions and Expenses

The underwriters have advised us that they propose to offer the common stock directly to the public at the public offering price presented on the cover page of this prospectus, and to selected dealers, that may include the underwriters, at the public offering price less a selling concession not in excess of \$      per share. The underwriters may allow, and the selected dealers may re-allow, a concession not in excess of \$      per share to brokers and dealers. After the offering, the underwriters may change the offering price and other selling terms.

The following table summarizes the underwriting discounts and commissions to be paid to the underwriters by us. The underwriting discount is the difference between the offering price and the amount the underwriters pay to purchase the shares from us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 1,275,000 shares. The underwriting discounts and commissions equal      % of the public offering price.

Per share	Amount We Will Pay	
	No Exercise	Full Exercise
Total		

We estimate that the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$400,000. We have agreed to pay such expenses.

### Over-Allotment Option

We have granted to the underwriters an option to purchase up to an aggregate of 1,275,000 additional shares of common stock, exercisable solely to cover over-allotments at the public offering price less the underwriting discounts and commissions shown on the cover page of this prospectus. The underwriters may exercise this

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option at any time, and from time to time, until 30 days after the date of the underwriting agreement. To the extent the underwriters exercise this option, each underwriter will be committed, so long as the conditions of the underwriting agreement are satisfied, to purchase a number of additional shares of common stock proportionate to that underwriter's initial commitment as indicated in the preceding table, and we will be obligated, under the over-allotment option, to sell the additional shares of common stock to the underwriters.

### **Lock-up Agreements**

We, along with our directors and executive officers, have agreed under lock-up agreements not to, directly or indirectly, offer, sell or otherwise dispose of any shares of common stock or any securities which may be converted into or exchanged for any shares of common stock without the prior written consent of Lehman Brothers Inc., or except as contemplated by the underwriting agreement, for a period of 90 days from the date of this prospectus.

### **Indemnification**

We have agreed to indemnify the underwriters against certain liabilities relating to the offering, including liabilities under the Securities Act and liabilities arising from breaches of the representations and warranties contained in the underwriting agreement, and to contribute to payments that the underwriters may be required to make for these liabilities.

### **Over-Allotment, Stabilization, Short Positions and Penalty Bids**

The underwriters may engage in over-allotment, stabilizing transactions, syndicate covering transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

- Over-allotment involves sales by the underwriters of shares of common stock in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by either exercising their over-allotment option, in whole or in part, or purchasing shares in the open market.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

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Over-allotment, stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The Nasdaq National Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

### **Passive Market Making**

In connection with the offering, the underwriters may engage in passive market making transactions in our common stock on The Nasdaq National Market in accordance with Rule 103 of Regulation M under the Exchange Act during the period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bids at a price not in excess of the highest independent bid of the security. However, if all independent bids are lowered below the passive market maker's bid, that bid must be lowered when specified purchase limits are exceeded.

### **Investment Banking**

From time to time, certain of the underwriters or their affiliates provide investment banking services for us. In particular, Lehman Brothers Inc. acted as placement agent for a private placement of our common stock in July 2003. Lehman Brothers Inc. received a fee that we believe was customary for its services. In the July 2003 placement, an affiliate of Lehman Brothers Inc. purchased from us 500,000 shares of common stock at a price of \$6.00 per share. The Lehman Brothers Inc. affiliate invested on the same terms and conditions as other investors in that offering.

### **Stamp Taxes**

Purchasers of the shares of our common stock offered in this prospectus may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus. Accordingly, we urge you to consult a tax advisor with respect to whether you may be required to pay those taxes or charges, as well as any other tax consequences that may arise under the laws of the country of purchase.

### **Electronic Distribution**

A prospectus in electronic format may be made available on Internet sites or through other online services maintained by one or more of the underwriters participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations.

Other than the prospectus in electronic format, information on any underwriter's web site and any information contained in any other web site maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been endorsed by us and should not be relied on by investors in deciding whether to purchase any shares of our common stock. The underwriters are not responsible for information contained in web sites that they do not maintain.

## Offers and Sales in Canada

Any offers in Canada will be made only under an exemption from the requirements to file a prospectus in the relevant province of Canada where the sale is made.

## LEGAL MATTERS

Nutter, McClennen & Fish, LLP, Boston, Massachusetts will pass upon the validity of the issuance of the shares of common stock offered by this prospectus. Constantine Alexander, a partner of Nutter, McClennen & Fish, LLP, is the corporate secretary of Nabi Biopharmaceuticals. Morrison & Foerster LLP, New York, New York will pass upon certain legal matters for the underwriters.

## EXPERTS

The consolidated financial statements of Nabi Biopharmaceuticals appearing in Nabi Biopharmaceuticals' Annual Report (Form 10-K) for the year ended December 28, 2002, have been audited by Ernst & Young LLP, independent certified public accountants, as set forth in their report thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The statements of revenues and certain costs and expenses of the PhosLo Product Line of Braintree Laboratories, Inc. appearing in Nabi Biopharmaceuticals' Current Report (Form 8-K) filed on August 15, 2003, as amended on October 7, 2003, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference. Such statements of revenues and certain costs and expenses are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet website at <http://www.sec.gov> that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC.

We make available free of charge through our Internet website at <http://www.nabi.com> our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information on our website or any other website is not incorporated by reference into this prospectus and does not constitute a part of this prospectus.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus certain information contained in other documents that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. We incorporate by reference the documents listed below.

- our annual report on Form 10-K for the fiscal year ended December 28, 2002, filed on February 28, 2003 (SEC File No. 000-04829),
- our definitive proxy statement on Schedule 14A for our 2003 annual meeting of stockholders, filed on April 17, 2003 (SEC File No. 000-04829),

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- our quarterly report on Form 10-Q for the quarter ended March 29, 2003, filed on April 28, 2003 (SEC File No. 000-04829),
- our current report on Form 8-K, filed on June 23, 2003 (SEC File No. 000-04829),
- the information contained in item 5 of our current report on Form 8-K, filed on July 14, 2003 (SEC File No. 000-04829),
- our current report on Form 8-K, filed on July 23, 2003 (SEC File No. 000-04829),
- our quarterly report on Form 10-Q for the quarter ended June 28, 2003, filed on July 25, 2003 (SEC File No. 000-04829),
- our current report on Form 8-K, filed on August 15, 2003 (SEC File No. 000-04829),
- our amendment no. 1 to current report on Form 8-K/A, filed on October 7, 2003 (SEC File No. 000-04829),
- our amendment no. 2 to current report on Form 8-K/A, filed on October 7, 2003 (SEC File No. 000-04829),
- our current report on Form 8-K, filed on October 9, 2003 (SEC File No. 000-04829),
- our quarterly report on Form 10-Q for the quarter ended September 27, 2003, filed on October 27, 2003 (SEC File No. 000-04829),
- our amendment no. 1 to quarterly report for the quarter ended September 27, 2003 on Form 10-Q/A, filed on October 29, 2003 (SEC File No. 000-04829) and
- the description of our common stock contained in our registration statement on Form 10, filed on May 4, 1970, as amended by our current report on Form 8-K, filed on August 15, 2003 (SEC File No. 000-04829).

All documents that we file after the date of this prospectus pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering shall be deemed to be incorporated by reference into this prospectus. All documents that we file after the date of the initial registration statement pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, prior to the effectiveness of the registration statement, shall be deemed to be incorporated by reference into this prospectus.

The reports and other documents that we file after the date of this prospectus will modify, supplement and supercede the information in this prospectus. We will provide you with a copy of any or all of the information that has been incorporated by reference in this prospectus but not delivered with this prospectus at no cost to you upon written or oral request to:

Nabi Biopharmaceuticals  
5800 Park of Commerce Boulevard N.W.  
Boca Raton, FL 33487  
(561) 989-5800  
Fax: (561) 989-5801  
Attn: Investor Relations



**8,500,000 Shares**



**Common Stock**

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**PROSPECTUS**  
**December , 2003**

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**LEHMAN BROTHERS**

**WACHOVIA SECURITIES**  
**U.S. BANCORP PIPER JAFFRAY**  
**HARRIS NESBITT GERARD**

**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth an estimate of the fees and expenses in connection with the issuance and distribution of the securities being registered hereby, other than underwriting discounts and commissions, all of which shall be borne by Nabi Biopharmaceuticals (the “Registrant” or the “Company”). All of such fees and expenses, except for the SEC registration fee, are estimated:

SEC registration fee	\$ 10,003
Legal fees and expenses	175,000
Printing fees and expenses	75,000
Accounting fees and expenses	100,000
Miscellaneous fees and expenses	39,997
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Total	\$ 400,000

**Item 15. Indemnification of Officers and Directors**

The Company’s by-laws, as amended and restated, provide for indemnification of officers and directors to the fullest extent permitted by the Delaware General Corporation Law. The provisions of Article VII of the Company’s by-laws constitute a contract of indemnification between the Company and its officers and directors. Article VII, Section 8 of the Company’s by-laws permits the Company to purchase and maintain insurance against any liability asserted against officers or directors and incurred by them in such capacities whether or not the Company would have the power to indemnify them against such liability under the Delaware General Corporation Law. The Company provides officers’ and directors’ liability insurance for its officers and directors.

The Company has entered into indemnification agreements with its directors and certain of its executive officers providing contractual indemnification by the Company to the fullest extent permissible under Delaware law.

**Item 16. Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
1	Form of Underwriting Agreement.
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.4 to the Company’s Current Report on Form 8-K filed on August 21, 1997).
4.2	Rights Agreement dated as of August 1, 1997, as amended, between the Company and Registrar and Transfer Company (incorporated by reference to Exhibit 10.28 to the Company’s Annual Report on Form 10-K for the year ended December 31, 1997).
4.3	Agreement of Substitution and Amendment of Rights Agreement dated July 1, 2002 among the Company, Registrar and Transfer Company, and American Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.4 to the Company’s Annual Report on Form 10-K for the year ended December 28, 2002).
5*	Opinion of Nutter, McClennen & Fish, LLP.
23.1	Consent of Ernst & Young LLP, Fort Lauderdale, Florida.
23.2	Consent of Ernst & Young LLP, Boston, Massachusetts.
23.3*	Consent of Nutter, McClennen & Fish, LLP (included in Exhibit 5).
24*	Power of Attorney (contained on signature page).

\* Previously filed.



**Item 17. Undertakings.**

The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, as amended, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

The undersigned Registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purposes of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers, and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.



[Table of Contents](#)

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Director

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**Richard A. Harvey, Jr.**

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Director

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**Linda Jenckes**

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Director

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**Stephen G. Sudovar**

\* Signed pursuant to a power of attorney filed with the Securities and Exchange Commission as Exhibit 24 to this registration statement on November 26, 2003.

/s/ MARK L. SMITH

December 15, 2003

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**Mark L. Smith**

**INDEX TO EXHIBITS**

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24*	Power of Attorney (contained on signature page).

\* Previously filed.

8,500,000 Shares

NABI BIOPHARMACEUTICALS

Common Stock

UNDERWRITING AGREEMENT

December \_\_, 2003

LEHMAN BROTHERS INC.  
WACHOVIA CAPITAL MARKETS, LLC  
U.S. BANCORP PIPER JAFFRAY INC.  
HARRIS NESBITT CORP.

As Representatives of the  
several underwriters named in Schedule 1 hereto  
c/o LEHMAN BROTHERS INC.  
745 Seventh Avenue  
New York, NY 10019

Ladies and Gentlemen:

Nabi Biopharmaceuticals, a Delaware corporation (the "**Company**"), proposes to sell 8,500,000 shares (the "**Firm Stock**") of the Company's Common Stock, par value \$0.10 per share (the "**Common Stock**"). In addition, the Company proposes to grant to the Underwriters named in Schedule 1 hereto (the "**Underwriters**") an option to purchase up to an additional 1,275,000 shares of the Common Stock on the terms and for the purposes set forth in Section 3 (the "**Option Stock**"). The Firm Stock and the Option Stock, if purchased, are hereinafter collectively called the "**Stock**." This is to confirm the agreement concerning the purchase of the Stock from the Company by the Underwriters.

SECTION 1. *Representations, Warranties and Agreements of the Company.* The Company represents, warrants and agrees that:

(a) A registration statement on Form S-3, and an amendment thereto, with respect to the Stock has (i) been prepared by the Company in conformity with the requirements of the Securities Act of 1933, as amended (the "**Securities Act**"), and the rules and regulations (the "**Rules and Regulations**") of the United States Securities and Exchange Commission (the "**Commission**") thereunder, (ii) been filed with the Commission under the Securities Act and (iii) become effective under the Securities Act. Copies of such registration statement and each of the amendments thereto have been delivered by the Company to you as the representatives (the "**Representatives**") of the Underwriters. As used in this Agreement, "**Effective Time**" means the date and the time as of which such registration statement, or the most recent post-effective amendment thereto, if any, was declared effective by the Commission; "**Effective Date**" means the date of the Effective Time; "**Preliminary Prospectus**" means each prospectus included in such registration statement, or amendments thereof, before it became effective under the Securities Act and any prospectus filed with the Commission by the Company with the consent of the Representatives pursuant to Rule 424(a) of the Rules and Regulations; "**Registration Statement**" means such registration statement, as amended at the Effective Time, including any documents incorporated by reference therein at such time and all information contained in the final prospectus filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations and deemed to be a part of the registration statement as of the Effective Time pursuant to Rule 430A of the Rules and Regulations; and "**Prospectus**" means such final prospectus, as first filed with the Commission pursuant to paragraph (1) or (4) of Rule 424(b) of the Rules and Regulations. Reference made herein to any Preliminary Prospectus or to the Prospectus shall be deemed to refer to and include any documents incorporated by reference therein pursuant to Item 12 of Form S-3 under the Securities Act, as of the date of such Preliminary Prospectus or the Prospectus, as the case may be, and

any reference to any amendment or supplement to any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include any document filed under the United States Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), after the date of such Preliminary Prospectus or the Prospectus, as the case may be, and incorporated by reference in such Preliminary Prospectus or the Prospectus, as the case may be as of the date of such amendment or supplement; and any reference to any amendment to the Registration Statement shall be deemed to include any annual report of the Company filed with the Commission pursuant to Section 13(a) or 15(d) of the Exchange Act after the Effective Time that is incorporated by reference in the Registration Statement. If the Company has filed an abbreviated registration statement to register additional shares of Common Stock pursuant to Rule 462(b) under the Securities Act (the “**Rule 462 Registration Statement**”), then any reference herein to the term “**Registration Statement**” shall be deemed to include such Rule 462 Registration Statement. The Commission has not issued any order preventing or suspending the use of any Preliminary Prospectus.

(b) The Registration Statement conforms, and the Prospectus and any further amendments or supplements to the Registration Statement or the Prospectus will, when they become effective or are filed with the Commission, as the case may be, comply as to form in all respects with the requirements of the Securities Act and the Rules and Regulations and do not and will not, as of the applicable effective date (as to the Registration Statement and any amendment thereto) and as of the applicable filing date (as to the Prospectus and any amendment or supplement thereto) contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; provided that no representation or warranty is made as to information contained in or omitted from the Registration Statement or the Prospectus in reliance upon and in conformity with written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein.

(c) The documents incorporated by reference in the Prospectus, when they became effective or were filed with the Commission, as the case may be, complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as applicable, and the Rules and Regulations, and none of such documents contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading; and any further documents so filed and incorporated by reference in the Prospectus prior to the completion of this offering, when such documents become effective or are filed with Commission, as the case may be, will comply as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as applicable, and the Rules and Regulations and will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading.

(d) The Company and each of its subsidiaries have been duly incorporated and are validly existing as corporations in good standing under the laws of their respective jurisdictions of incorporation, are duly qualified to do business and are in good standing as foreign corporations in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such qualification (except where the failure to be so qualified or in good standing would not reasonably be expected to have, individually or in the aggregate, a material adverse effect on the business, financial condition, properties and results of operations of the Company and its subsidiaries, taken as a whole (a “Material Adverse Effect”)), and have all power and authority necessary to own or hold their respective properties and to conduct the businesses in which they are engaged; and none of the subsidiaries of the Company is a “significant subsidiary”, as such term is defined in Rule 405 of the Rules and Regulations.

(e) The Company has an authorized capitalization as set forth in the Prospectus. All of the issued shares of capital stock of the Company have been duly authorized and validly issued, were issued in compliance with federal and state securities laws, are fully paid and non-assessable and conform to the description thereof contained in the Prospectus. All of the issued shares of capital stock of each subsidiary of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and are owned directly or indirectly by the Company, free and clear of all liens, encumbrances, equities or claims.

(f) The shares of the Stock to be issued and sold by the Company to the Underwriters hereunder have been duly authorized and, when issued and delivered against payment therefor in accordance with this Agreement, will be validly issued, fully paid and non-assessable; and the Stock will conform to the description thereof contained in the Prospectus. Upon payment for and delivery of the Stock to be sold by the Company pursuant to this Agreement, the Underwriters will acquire good and valid title to such Stock, in each case free and clear of all liens, encumbrances, equities, preemptive rights, subscription rights, other rights to purchase, voting or transfer restrictions and other claims arising as a result of the Company's actions.

(g) This Agreement has been duly authorized, executed and delivered by the Company.

(h) The execution, delivery and performance of this Agreement by the Company and the consummation of the transactions contemplated hereby will not conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject (except where such conflict, breach, violation or default would not reasonably be expected to have a Material Adverse Effect), nor will such actions result in any violation of (i) the provisions of the charter or by-laws of the Company or any of its subsidiaries or (ii) any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its subsidiaries or any of their properties or assets (except where such violation would not reasonably be expected to have a Material Adverse Effect); and except for the registration of the Stock under the Securities Act and such consents, approvals, authorizations, registrations or qualifications as may be required under the Exchange Act and applicable state securities laws in connection with the purchase and distribution of the Stock by the Underwriters, no consent, approval, authorization or order of, or filing or registration with, any such court or governmental agency or body is required for the execution, delivery and performance of this Agreement by the Company and the consummation of the transactions contemplated hereby.

(i) There are no contracts, agreements or understandings between the Company and any person granting such person the right (other than rights which have been satisfied or waived) to require the Company, with respect to any securities of the Company owned or to be owned by such person, to include such securities in the securities registered pursuant to the Registration Statement. The holders of outstanding shares of the Company's capital stock are not entitled to preemptive or other rights to subscribe for the Stock. Except as disclosed in the Prospectus or granted pursuant to employee benefit plans, stock option plans or other employee compensation plans, no options, warrants or other rights to purchase, agreements or other obligations to issue, or rights to convert any obligations into or exchange any securities for, shares of capital stock of or ownership interests in the Company are outstanding.

(j) Except as described in the Prospectus, the Company has not sold or issued any shares of Common Stock during the six-month period preceding the date of the Prospectus, including any sales pursuant to Rule 144A under, or Regulations D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, stock options plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

(k) Neither the Company nor any of its subsidiaries has sustained, since the date of the latest audited financial statements included in the Prospectus, any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth or contemplated in the Prospectus; and, except for shares and options issued in the ordinary course of the Company's business pursuant to its employee benefit plans, stock option plans or other employee compensation plans or as otherwise described in the Prospectus, since such date, there has not been any change in the capital stock or long-term debt of the Company or any of its subsidiaries or any material adverse change, or any development involving a prospective material adverse change, in or affecting the consolidated financial position, stockholders' equity, results of operations, business and prospects of the Company and its subsidiaries, taken as a whole, otherwise than as set forth or contemplated in the Prospectus.

(l) The financial statements of the Company and its subsidiaries (including the related notes and supporting schedules) filed as part of the Registration Statement or included in the Prospectus present fairly in all material respects the consolidated financial condition and results of operations of the Company and its subsidiaries, at the dates and for the periods indicated, in conformity with generally accepted accounting principles applied on a consistent basis throughout the periods involved.

(m) [To the Company's knowledge,] Ernst & Young LLP, who have certified certain financial statements of the Company, whose report appears in the Prospectus and who have delivered the letters referred to in Section 7(f) hereof, are independent public accountants as required by the Securities Act and the Rules and Regulations.

(n) The Company and each of its subsidiaries have good and marketable title in fee simple to all real property and good and marketable title to all personal property owned by them, in each case free and clear of all liens, encumbrances and defects, except such as are described in the Prospectus or reflected in an exhibit to a document incorporated by reference thereto or such as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiaries; and all real property and buildings held under lease by the Company and its subsidiaries are held by them under valid, subsisting and enforceable leases, with such exceptions as are not material and do not interfere with the use made and proposed to be made of such property and buildings by the Company and its subsidiaries.

(o) The Company and each of its subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as the Company believes is adequate for the conduct of their respective businesses and the value of their respective properties and as the Company believes is customary for companies engaged in similar businesses in similar industries.

(p) To the Company's knowledge, (a) neither the Company nor any of its subsidiaries is currently infringing or has infringed any valid patent, valid trademark or valid copyright rights of others, except to the extent that such infringement would not reasonably be expected to have a Material Adverse Effect (b) all trade secrets, know how, technical processes and procedures developed and belonging to the Company (or any of its subsidiaries) which are material to the business of the Company (or any of its subsidiaries) as presently conducted and which have not been patented have been kept confidential, and (c) except as set forth in the Prospectus, the Company and each of its subsidiaries own or possess the right to use, free and clear of claims or rights of others, all patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, trade secrets, customer lists, processes, and owned computer software required for their respective businesses as presently conducted or believe that they can acquire the same on reasonable terms. Except as set forth or contemplated in the Prospectus, neither the Company nor any of its subsidiaries has knowledge of or has received any notice of any claim of conflict with any such rights of others, which individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect. To the Company's knowledge, neither the Company nor any of its subsidiaries is using or has used any confidential information, trade secrets, or computer software (not licensed to the Company) of any former employer of any of its past or present employees, except to the extent that such use would not reasonably be expected to have a Material Adverse Effect .

(q) Except as set forth in the Prospectus, to the Company's and each of its subsidiaries' knowledge, they have all material licenses, certificates, permits, consents, orders, approvals and authorizations from U.S. and foreign government authorities, including, without limitation, the United States Food and Drug Administration (the "FDA") and any agency of any foreign government and any other foreign regulatory authority exercising authority comparable to that of the FDA (including any non-governmental entity whose approval or authorization is required under foreign law comparable to that administered by the FDA), for its investigational products, as described in the Prospectus, that are necessary to the ownership of its property or to the conduct of its business in the manner and to the extent now conducted.

(r) There are no legal or governmental proceedings pending to which the Company or any of its subsidiaries is a party or of which any property or assets of the Company or any of its subsidiaries is the subject which, if determined adversely to the Company or any of its subsidiaries, would reasonably be expected to have a Material Adverse Effect, except for the proceedings described in the Prospectus that might, if adversely determined, reasonably be expected to have a Material Adverse Effect;



and to the best of the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or threatened by others.

(s) There are no contracts or other documents which are required to be described in the Prospectus or filed as exhibits to the Registration Statement (which include documents incorporated by reference into the Prospectus or Registration Statement, as the case may be, by the Securities Act or by the Rules and Regulations) which have not been described in the Prospectus or filed as exhibits to the Registration Statement.

(t) No relationship, direct or indirect, exists between or among the Company on the one hand, and the directors, officers and stockholders of the Company on the other hand, which is required to be described in the Prospectus which is not so described.

(u) No labor disturbance by the employees of the Company exists or, to the knowledge of the Company, is imminent, which would reasonably be expected to have a Material Adverse Effect.

(v) The Company is in compliance in all material respects with all presently applicable provisions of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("ERISA"); no "reportable event" (as defined in ERISA) has occurred with respect to any "pension plan" (as defined in ERISA) to which the Company contributes or which the Company maintains that would reasonably be expected to have a Material Adverse Effect; the Company has not incurred and does not expect to incur liability under (i) Title IV of ERISA with respect to the termination of, or withdrawal from, any "pension plan" or (ii) Sections 412 or 4971 of the Internal Revenue Code of 1986, as amended, including the regulations and published interpretations thereunder (the "Code"); and each "pension plan" for which the Company would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified in all material respects and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification, except where the loss of such qualification would not reasonably be expected to have a Material Adverse Effect.

(w) The Company has filed all federal, state and local income and franchise tax returns required to be filed through the date hereof and has paid all taxes due thereon, and no tax deficiency has been determined adversely to the Company or any of its subsidiaries which has had (nor does the Company have any knowledge of any tax deficiency which, if determined adversely to the Company or any of its subsidiaries, would reasonably be expected to have) a Material Adverse Effect.

(x) Since the date as of which information is given in the Prospectus through the date hereof, and except as may otherwise be disclosed in the Prospectus, the Company has not (i) issued or granted any securities, other than shares issued pursuant to employee benefit plans, stock option plans or other employee compensation plans or pursuant to outstanding options, rights or warrants, (ii) incurred any liability or obligation, direct or contingent, other than non-material liabilities and obligations and material liabilities and obligations which were incurred in the ordinary course of business, (iii) entered into any material transaction not in the ordinary course of business or (iv) declared or paid any dividend on its capital stock.

(y) The Company (i) makes and keeps accurate books and records and (ii) maintains internal accounting controls which provide reasonable assurance that (A) transactions are executed in accordance with management's authorization, (B) transactions are recorded as necessary to permit preparation of its financial statements and to maintain accountability for its assets, (C) access to its assets is permitted only in accordance with management's authorization and (D) the reported accountability for its assets is compared with existing assets at reasonable intervals.

(z) Neither the Company nor any of its subsidiaries (i) is in violation of its charter or by-laws, (ii) is in default, and, to the Company's knowledge, no event has occurred which, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any material indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which it is a party or by which it is bound or to which any of its properties or assets is subject, except to the

extent that any such default would not reasonably be expected to have a Material Adverse Effect, or (iii) is in violation of any law, ordinance, governmental rule, regulation or court decree to which it or its property or assets may be subject or has failed to obtain any material license, permit, certificate, franchise or other governmental authorization or permit necessary to the ownership of its property or to the conduct of its business, except to the extent that any such violation or failure would not reasonably be expected to have a Material Adverse Effect.

(aa) Neither the Company nor any of its subsidiaries, nor, to the Company's knowledge, any director, officer, agent, employee or other person associated with or acting on behalf of the Company or any of its subsidiaries, has used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds; violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977; or made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment.

(bb) There has been no storage, disposal, generation, manufacture, refinement, transportation, handling or treatment of toxic wastes, medical wastes, hazardous wastes or hazardous substances by the Company or any of its subsidiaries (or, to the knowledge of the Company, any of their predecessors in interest) at, upon or from any of the property now or previously owned or leased by the Company or its subsidiaries in violation of any applicable law, ordinance, rule, regulation, order, judgment, decree or permit or which would require remedial action under any applicable law, ordinance, rule, regulation, order, judgment, decree or permit, except for any violation or remedial action which would not have, singularly or in the aggregate with all such violations and remedial actions, a Material Adverse Effect; there has been no material spill, discharge, leak, emission, injection, escape, dumping or release of any kind onto such property or into the environment surrounding such property of any toxic wastes, medical wastes, solid wastes, hazardous wastes or hazardous substances due to or caused by the Company or any of its subsidiaries or with respect to which the Company or any of its subsidiaries have knowledge, except for any such spill, discharge, leak, emission, injection, escape, dumping or release which would not have, singularly or in the aggregate with all such spills, discharges, leaks, emissions, injections, escapes, dumpings and releases, a Material Adverse Effect. The terms "**hazardous wastes**", "**toxic wastes**", "**hazardous substances**" and "**medical wastes**" shall have the meanings specified in any applicable local, state, federal and foreign laws or regulations with respect to environmental protection.

(cc) Neither the Company nor any subsidiary is an "investment company" within the meaning of such term in the Investment Company Act of 1940, as amended.

(dd) There are no contracts, agreements or understandings between the Company and any person that would give rise to a valid claim against the Company or any Underwriter for a brokerage commission, finder's fee or other like payment in connection with the purchase of the stock from the Company by the Underwriters.

(ee) The statistical and market-related data included in the Prospectus and the Registration Statement are based on or derived from sources which the Company believes to be reliable and accurate.

(ff) The conditions for use of Form S-3, as set forth in the General Instructions thereto, have been satisfied.

(gg) The Company believes that it has established and maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act), which (i) have been designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; (ii) have been evaluated for effectiveness as of the end of the period covered by the Company's most recent quarterly report filed with the Commission; and (iii) have been designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level.

(hh) The Company's principal executive officer and its principal financial officer have disclosed, based on their most recent evaluation of the Company's internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors: (i) all significant deficiencies or material weaknesses in the design or operation of internal controls which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; or (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

(ii) There has been no change in the Company's internal control over financial reporting that has occurred during the Company's current fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

SECTION 2. *Purchase of the Stock by the Underwriters.* On the basis of the representations and warranties contained in, and subject to the terms and conditions of, this Agreement, the Company agrees to sell 8,500,000 shares of the Firm Stock to the several Underwriters and each of the Underwriters, severally and not jointly, agrees to purchase the number of shares of the Firm Stock set forth opposite that Underwriter's name in Schedule 1 hereto.

In addition, the Company grants to the Underwriters an option to purchase up to 1,275,000 shares of Option Stock. Such option is granted for the purpose of covering over-allotments in the sale of Firm Stock and is exercisable as provided in Section 4 hereof. Shares of Option Stock shall be purchased severally for the account of the Underwriters in proportion to the number of shares of Firm Stock set forth opposite the name of such Underwriters in Schedule 1 hereto. The respective purchase obligations of each Underwriter with respect to the Option Stock shall be adjusted by the Representatives so that no Underwriter shall be obligated to purchase Option Stock other than in 100 share amounts.

The price of both the Firm Stock and any Option Stock shall be \$[ ] per share.

The Company shall not be obligated to deliver any of the Stock to be delivered on any Delivery Date (as hereinafter defined), except upon payment for all the Stock to be purchased on such Delivery Date as provided herein.

SECTION 3. *Offering of Stock by the Underwriters.* Upon authorization by the Representatives of the release of the Firm Stock, the several Underwriters propose to offer the Firm Stock for sale upon the terms and conditions set forth in the Prospectus.

SECTION 4. *Delivery of and Payment for the Stock.* Delivery of and payment for the Firm Stock shall be made at the offices of Morrison & Foerster LLP, 1290 Avenue of the Americas, New York, New York 10104, at 10:00 A.M., New York City time, on the [third / fourth] full business day following the date of this Agreement or at such other date or place as shall be determined by agreement between the Representatives and the Company. This date and time are sometimes referred to as the "**First Delivery Date.**" On the First Delivery Date, the Company shall deliver or cause to be delivered certificates representing the Firm Stock to the Representatives for the account of each Underwriter against payment to or upon the order of the Company of the purchase price by wire transfer in immediately available funds. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligation of each Underwriter hereunder. Upon delivery, the Firm Stock shall be registered in such names and in such denominations as the Representatives shall request in writing not less than two full business days prior to the First Delivery Date. For the purpose of expediting the checking and packaging of the certificates for the Firm Stock, the Company shall make the certificates representing the Firm Stock available for inspection by the Representatives in New York, New York, not later than 2:00 P.M., New York City time, on the business day prior to the First Delivery Date.

The option granted in Section 2 will expire 30 days after the date of this Agreement and may be exercised in whole or in part from time to time by written notice being given to the Company by the Representatives. Such notice shall set forth the aggregate number of shares of Option Stock as to which the option is being exercised,

the names in which the shares of Option Stock are to be registered, the denominations in which the shares of Option Stock are to be issued and the date and time, as determined by the Representatives, when the shares of Option Stock are to be delivered; provided, however, that this date and time shall not be earlier than the First Delivery Date nor earlier than the third business day after the date on which the option shall have been exercised nor later than the fifth business day after the date on which the option shall have been exercised. The date and time the shares of Option Stock are delivered are sometimes referred to as a “**Second Delivery Date**” and the First Delivery Date and any Second Delivery Date are sometimes each referred to as a “**Delivery Date**.”

Delivery of and payment for the Option Stock shall be made at the place specified in the first sentence of the first paragraph of this Section 4 (or at such other place as shall be determined by agreement between the Representatives and the Company) at 10:00 A.M., New York City time, on such Second Delivery Date. On such Second Delivery Date, the Company shall deliver or cause to be delivered the certificates representing the Option Stock to the Representatives for the account of each Underwriter against payment to or upon the order of the Company of the purchase price by wire transfer in immediately available funds. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligation of each Underwriter hereunder. Upon delivery, the Option Stock shall be registered in such names and in such denominations as the Representatives shall request in the aforesaid written notice. For the purpose of expediting the checking and packaging of the certificates for the Option Stock, the Company shall make the certificates representing the Option Stock available for inspection by the Representatives in New York, New York, not later than 2:00 P.M., New York City time, on the business day prior to such Second Delivery Date.

SECTION 5. *Further Agreements of the Company.* The Company covenants and agrees:

(a) To prepare the Prospectus in a form approved by the Representatives and to file such Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission’s close of business on the second business day following the execution and delivery of this Agreement or, if applicable, such earlier time as may be required by Rule 430A(a)(3) under the Securities Act; to make no further amendment or any supplement to the Registration Statement or to the Prospectus prior to the last Delivery Date except as permitted herein; to advise the Representatives, promptly after it receives notice thereof, of the time when any amendment to the Registration Statement has been filed or becomes effective or any supplement to the Prospectus or any amended Prospectus has been filed and to furnish the Representatives with copies thereof; to file promptly all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of the Prospectus and for so long as the delivery of a prospectus is required in connection with the offering or sale of the Stock; to advise the Representatives, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of any Preliminary Prospectus or the Prospectus, of the suspension of the qualification of the Stock for offering or sale in any jurisdiction, of the initiation or threatening of any proceeding for any such purpose, or of any request by the Commission for the amending or supplementing of the Registration Statement or the Prospectus or for additional information; and, in the event of the issuance of any stop order or of any order preventing or suspending the use of any Preliminary Prospectus or the Prospectus or suspending any such qualification, to use promptly its best efforts to obtain its withdrawal;

(b) To furnish promptly to each of the Representatives and to counsel for the Underwriters a signed copy of the Registration Statement as originally filed with the Commission, and each amendment thereto filed with the Commission, including all consents and exhibits filed therewith;

(c) To deliver promptly to the Representatives such number of the following documents as the Representatives shall reasonably request: (i) conformed copies of the Registration Statement as originally filed with the Commission and each amendment thereto (in each case excluding exhibits other than this Agreement and the computation of per share earnings and excluding documents incorporated by reference into the Registration Statement) and (ii) each Preliminary Prospectus, the Prospectus and any amended or supplemented Prospectus; and, if the delivery of a prospectus is required at any time after the Effective Time in connection with

the offering or sale of the Stock or any other securities relating thereto and if at such time any events shall have occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it shall be necessary to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Representatives and, upon their request, to file such document and to prepare and furnish without charge to each Underwriter and to any dealer in securities as many copies as the Representatives may from time to time reasonably request of an amended or supplemented Prospectus which will correct such statement or omission or effect such compliance;

(d) To file promptly with the Commission any amendment to the Registration Statement or the Prospectus or any supplement to the Prospectus that may, in the judgment of the Company or the Representatives, be required by the Securities Act or requested by the Commission;

(e) Prior to filing with the Commission any amendment to the Registration Statement or supplement to the Prospectus, any document incorporated by reference in the Prospectus or any Prospectus pursuant to Rule 424 of the Rules and Regulations, to furnish a copy thereof to the Representatives and counsel for the Underwriters and obtain the consent of the Representatives to the filing (such consent not to be unreasonably withheld or delayed);

(f) As soon as practicable after the Effective Date, to make generally available to the Company's security holders and to deliver to the Representatives an earnings statement of the Company and its subsidiaries (which need not be audited) complying with Section 11(a) of the Securities Act and the Rules and Regulations (including, at the option of the Company, Rule 158);

(g) For a period of three years following the Effective Date, to furnish to the Representatives copies of all materials furnished by the Company to its shareholders and all public reports and all reports and financial statements furnished by the Company to the principal national securities exchange upon which the Common Stock may be listed pursuant to requirements of or agreements with such exchange or to the Commission pursuant to the Exchange Act or any rule or regulation of the Commission thereunder, except to the extent that such materials, reports and financial statements are available through EDGAR;

(h) Promptly from time to time to take such action as the Representatives may reasonably request to qualify the Stock for offering and sale under the securities laws of such jurisdictions as the Representatives may request and to comply with such laws so as to permit the continuance of sales and dealings therein in such jurisdictions for as long as may be necessary to complete the distribution of the Stock; provided that in connection therewith the Company shall not be required to qualify as a foreign corporation, to file a general consent to service of process in any jurisdiction or to subject itself to taxation in any jurisdiction;

(i) For a period of 90 days from the date of the Prospectus, not to, directly or indirectly, (1) offer for sale, sell, pledge or otherwise dispose of (or enter into any transaction or device which is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of Common Stock or securities convertible into or exchangeable for Common Stock (other than the Stock and shares issued pursuant to employee benefit plans, stock option plans or other employee compensation plans existing on the date hereof or pursuant to currently outstanding options, warrants or rights), or sell or grant options, rights or warrants with respect to any shares of Common Stock or securities convertible into or exchangeable for Common Stock (other than the grant of options pursuant to employee benefit plans, stock option plans or other employee compensation plans existing on the date hereof), (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of such shares of Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise, or (3) file or cause to be filed a registration statement (other than on Form S-8 or other similar form) with respect to any shares of Common Stock or securities convertible, exercisable or exchangeable into Common Stock or any other securities of the Company, in each case without the prior written consent of Lehman Brothers Inc. on behalf of the Underwriters;

and to use its good faith efforts to cause each officer and director of the Company to furnish to the Representatives, prior to the First Delivery Date, a letter or letters, dated as of the First Delivery Date, substantially in the form of Exhibit A hereto, pursuant to which each such person shall agree not to, directly or indirectly, (1) offer for sale, sell, pledge or otherwise dispose of (or enter into any transaction or device which is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of Common Stock or securities convertible into or exchangeable for Common Stock or (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of such shares of Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise, in each case for a period of 90 days from the date of the Prospectus, without the prior written consent of Lehman Brothers Inc.;

(j) To provide notification to The Nasdaq Stock Market of the listing of the Stock in accordance with the rules thereof;

(k) To apply the net proceeds from the sale of the Stock as set forth in the Prospectus; and

(l) To take such steps as shall be necessary to ensure that neither the Company nor any subsidiary shall become an "investment company" within the meaning of such term under the Investment Company Act of 1940, as amended and the rules and regulations of the Commission thereunder.

SECTION 6. *Expenses.* The Company agrees to pay (a) the costs incident to the authorization, issuance, sale and delivery of the Stock and any taxes payable in that connection; (b) the costs incident to the preparation, printing and filing under the Securities Act of the Registration Statement and any amendments and exhibits thereto; (c) the costs of distributing the Registration Statement as originally filed and each amendment thereto and any post-effective amendments thereof (including, in each case, exhibits), any Preliminary Prospectus, the Prospectus and any amendment or supplement to the Prospectus or any document incorporated by reference therein, all as provided in this Agreement; (d) the costs of producing and distributing this Agreement, any supplemental agreement among the Underwriters and any other related documents in connection with the offering, purchase, sale and delivery of the stock; (e) the filing fees incident to securing the review by the National Association of Securities Dealers, Inc. ("NASD") of the terms of sale of the Stock; (f) any applicable listing or other fees; (g) the fees and expenses of qualifying the Stock under the securities laws of the several jurisdictions as provided in Section 5(h) and of preparing a Blue Sky Memorandum (including related fees and expenses of counsel to the Underwriters in an amount not to exceed \$4,000); (h) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Stock, including, without limitation, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the officers of the Company and any such consultants, and (i) all other costs and expenses incident to the performance of the obligations of the Company under this Agreement; provided that, except as provided in this Section 6 and in Section 11 the Underwriters shall pay their own costs and expenses, including the costs and expenses of their counsel, their own travel, lodging and other costs and expenses associated with the "road show," any transfer taxes on the Stock which they may sell and the expenses of advertising any offering of the Stock made by the Underwriters. The Company and the Underwriters will share equally the cost of any aircraft chartered in connection with the "road show."

SECTION 7. *Conditions of Underwriters' Obligations.* The respective obligations of the Underwriters hereunder are subject to the accuracy, when made and on each Delivery Date, of the representations and warranties of the Company contained herein, to the performance by the Company of its obligations hereunder, and to each of the following additional terms and conditions:

(a) The Prospectus shall have been timely filed with the Commission in accordance with Section 5(a) hereof; no stop order suspending the effectiveness of the Registration Statement or any part thereof shall have been issued and no proceeding for that purpose shall have been initiated or threatened by the Commission; and any request of the Commission for inclusion of additional information in the Registration Statement or the Prospectus or otherwise shall have been complied with.

(b) All corporate proceedings and other legal matters incident to the authorization, form and validity of this Agreement, the Stock, the Registration Statement and the Prospectus, and all other legal matters relating to this Agreement and the transactions contemplated hereby shall be reasonably satisfactory in all material respects to counsel for the Underwriters, and the Company shall have furnished to such counsel all documents and information that they may reasonably request to enable them to pass upon such matters.

(c) Nutter, McClennen & Fish, LLP shall have furnished to the Representatives its written opinion, as counsel to the Company, addressed to the Underwriters and dated such Delivery Date, in form and substance reasonably satisfactory to the Representatives, to the effect that:

(i) The Company and each of its subsidiaries have been duly incorporated and are validly existing as corporations in good standing under the laws of their respective jurisdictions of incorporation, are duly qualified to do business and are in good standing as foreign corporations in each listed jurisdiction in which they are so qualified;

(ii) The Company has an authorized capitalization as set forth in the Prospectus. All of the issued shares of capital stock of the Company have been duly authorized and validly issued, are fully paid and non-assessable, and conform to the description thereof contained in the Prospectus. All of the issued shares of capital stock of each subsidiary of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and are owned directly or indirectly by the Company, free and clear of all liens, encumbrances, equities or claims, except for a security interest in all assets of the Company granted to Wells Fargo Foothill, Inc.

(iii) The shares of the Stock being delivered on such Delivery Date to the Underwriters hereunder have been duly authorized and, when issued and delivered against payment therefor will be validly issued, fully paid and non-assessable;

(iv) Except as described in the Prospectus, there are no preemptive or other rights to subscribe for or to purchase, nor any restriction upon the voting or transfer of, any shares of the Stock pursuant to the Company's Certificate of Incorporation or by-laws or any agreement or other instrument known to such counsel;

(v) To such counsel's knowledge and other than as set forth in the Prospectus, there are no legal or governmental proceedings pending or overtly threatened in writing to which the Company or any of its subsidiaries is a party or of which any property or assets of the Company or any of its subsidiaries is the subject which are required to be disclosed in the Registration Statement, other than as disclosed therein;

(vi) To the knowledge of such counsel, based solely on a telephonic confirmation by a member of the Staff of the Commission on December 1, 2003, the Registration Statement was declared effective under the Securities Act as of the date and time specified in such opinion, the Prospectus was filed with the Commission pursuant to the subparagraph of Rule 424(b) of the Rules and Regulations specified in such opinion on the date specified therein and, to the knowledge of such counsel, based solely on a telephonic confirmation by a member of the Staff of the Commission on December 1, 2003, no stop order suspending the effectiveness of the Registration Statement has been issued and, no proceeding for that purpose has been initiated by the Commission;

(vii) The Registration Statement and the Prospectus and any further amendments or supplements thereto made by the Company prior to such Delivery Date (except for the financial statements and notes thereto and related schedules therein, information about internal controls over financial reporting and other financial and statistical data included therein and any descriptions of accounting policies applicable to the financial statements, as to which such counsel need express no belief) comply as to form in all material respects with the requirements of the Securities Act and the Rules and Regulations, the documents incorporated by reference in the Prospectus and any further amendment or supplement to any such incorporated document made by the Company prior to such Delivery Date (other than the financial statements and notes thereto and related schedules, information

about internal control over financial reporting and other financial data included therein, and any descriptions of accounting policies applicable to the financial statements, as to which such counsel need express no opinion), when they became effective or were filed with the Commission, as the case may be, complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as applicable, and the Rules and Regulations;

(viii) To such counsel's knowledge, there are no contracts or other documents which are required to be described in the Prospectus or filed as exhibits to the Registration Statement or incorporated by reference into the Registration Statement by the Securities Act or by the Rules and Regulations which have not been described or filed as exhibits to the Registration Statement or incorporated therein by reference as permitted by the Rules and Regulations;

(ix) This Agreement has been duly authorized, executed and delivered by the Company;

(x) The issue and sale of the shares of Stock being delivered on such Delivery Date by the Company pursuant to this Agreement and the execution, delivery and compliance by the Company with all of the provisions of this Agreement and the consummation of the transactions contemplated hereby will not result in a breach or violation of any of the terms or provisions of, or constitute a default under, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument known to such counsel to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject and which is filed as an Exhibit to the Company's reports filed under the Exchange Act, nor will such actions result in any violation of the provisions of the Certificate of Incorporation or by-laws of the Company or any of its subsidiaries or any statute or any order, rule or regulation known to such counsel of any court or governmental agency or body having jurisdiction over the Company or any of its subsidiaries or any of their properties or assets; and, except for the registration of the Stock under the Securities Act and such consents, approvals, authorizations, registrations or qualifications as may be required under the Exchange Act and applicable state securities laws in connection with the purchase and distribution of the Stock by the Underwriters, no consent, approval, authorization or order of, or filing or registration with, any such court or governmental agency or body is required for the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, except for such consents, approvals, authorizations, orders, filings or registrations as have been obtained or made;

(xi) Except as described in the Prospectus, to such counsel's knowledge, there are no contracts or agreements between the Company and any person granting such person the right (other than rights which have been waived or satisfied) to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company owned or to be owned by such person or to require the Company to include such securities in the securities registered pursuant to the Registration Statement; and

(xii) Neither the Company nor any subsidiary is an "investment company" within the meaning of such term in the Investment Company Act of 1940, as amended.

In rendering such opinion, such counsel may state that their opinion is limited to matters governed by the Federal laws of the United States of America, the laws of the State of Massachusetts and the General Corporation Law of the State of Delaware, and that such Counsel is not admitted in the State of Delaware. Such Counsel shall also have furnished to the Representatives a separate written statement, addressed to the Representatives, to the effect that (x) such counsel has participated in conferences with officers and representatives of the Company, representatives of the independent public accountants for the Company and with representatives of the Underwriters and their counsel at which the contents of the Registration Statement and Prospectus were discussed and (y) based on the foregoing, no facts have come to the attention of such counsel which lead them to believe that (I) the Registration Statement, as of the Effective Date, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading, or that the Prospectus contains any untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the



circumstances under which they were made, not misleading or (II) any document incorporated by reference in the Prospectus or any further amendment or supplement to any such incorporated document made by the Company prior to such Delivery Date when they became effective or were filed with the Commission, as the case may be, contained, in the case of a registration statement which became effective under the Securities Act, any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading, or, in the case of other documents which were filed under the Exchange Act with the Commission, an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The foregoing statement may be qualified by statements to the effect that such counsel does not assume any responsibility for the accuracy, completeness or fairness of the statements contained in the Registration Statement or the Prospectus (including any document incorporated by reference in the Prospectus or any further amendment or supplement to any such incorporated document made by the Company prior to such Delivery Date) and that it is understood that such counsel are making no statement with respect to the financial statements and notes thereto and related schedules, other financial and statistical data, and descriptions of accounting policies applicable to the financial statements included in the Registration Statement or Prospectus.

(d) Foley & Lardner shall have furnished to the Representatives its written opinion, as intellectual property counsel to the Company, addressed to the Underwriters and dated such Delivery Date, in form and substance reasonably satisfactory to the Representatives, to the effect that: to the knowledge of those attorneys at Foley & Lardner who have rendered legal services on matters for the Company, the Company owns, holds, licenses to, or otherwise has rights to use the intellectual property covered in the opinion that is necessary for the conduct of the Company's business as now conducted or as proposed in the Prospectus to be conducted. Except as set forth in the Prospectus, (A) there are no rights of third parties to any such intellectual property; (B) to the knowledge of such attorneys, there is no infringement by third parties of any such intellectual property; (C) there is no pending or, to the knowledge of such attorneys, threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any such intellectual property; (D) there is no pending or, to the knowledge of such attorneys, threatened action, suit, proceeding or claim by others challenging the enforceability, validity or scope of any such intellectual property, (E) there is no pending or, to the knowledge of such attorneys, threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any patent, trademark, copyright, trade secret or other proprietary or similar rights of others, and such attorneys are unaware of any other fact which would form a reasonable basis for any such claim, and (F) to the knowledge of such attorneys, there are no facts or circumstances that, if asserted in litigation, would be likely to render any of the intellectual property rights reflected in the Company's identified patents and filed patent applications invalid or unenforceable.

(e) The Representatives shall have received from Morrison & Foerster LLP, counsel for the Underwriters, such opinion or opinions, dated such Delivery Date, with respect to the issuance and sale of the Stock, the Registration Statement, the Prospectus and other related matters as the Representatives may reasonably require, and the Company shall have furnished to such counsel such documents as they reasonably request for the purpose of enabling them to pass upon such matters.

(f) At the time of execution of this Agreement, the Representatives shall have received from Ernst & Young LLP a letter or letters, in form and substance satisfactory to the Representatives, addressed to the Underwriters and dated the date hereof (i) confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X of the Commission and (ii) stating, as of the date hereof (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Prospectus, as of a date not more than five days prior to the date hereof), the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to underwriters in connection with registered public offerings.

(g) With respect to the letter or letters of Ernst & Young LLP referred to in the preceding paragraph and delivered to the Representatives concurrently with the execution of this Agreement (the "**initial letters**"), the Company shall have furnished to the Representatives a letter (the "**bring-down letter**") of such accountants, addressed to the Underwriters and dated such Delivery Date (i) confirming that they are independent public

accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X of the Commission, (ii) stating, as of the date of the bring-down letter (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Prospectus, as of a date not more than five days prior to the date of the bring-down letter), the conclusions and findings of such firm with respect to the financial information and other matters covered by the initial letters and (iii) confirming in all material respects the conclusions and findings set forth in the initial letters.

(h) The Company shall have furnished to the Representatives a certificate on behalf of the Company, dated such Delivery Date, of its President or a Vice President and its chief financial officer stating that:

(i) The representations, warranties and agreements of the Company in Section 1 are true and correct in all material respects, for all representations and warranties not otherwise qualified as to materiality, as of such Delivery Date; the Company has complied in all material respects with all its agreements contained herein; and the conditions set forth in Sections 7(a) and 7(i) have been fulfilled; and

(ii) They have carefully examined the Registration Statement and the Prospectus and, in their opinion (A) as of the Effective Date, the Registration Statement and Prospectus did not include any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and (B) since the Effective Date no event has occurred which should have been set forth in a supplement or amendment to the Registration Statement or the Prospectus which has not been so set forth.

(i) Neither the Company nor any of its subsidiaries shall have sustained since the date of the latest audited financial statements included in the Prospectus (A) any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth or contemplated in the Prospectus or (B) since such date, there shall not have been any change in the capital stock or long-term debt of the Company or any of its subsidiaries or any change, or any development involving a prospective change, in or affecting the management, financial position, stockholders' equity and results of operations of the Company and its subsidiaries, otherwise than as set forth or contemplated in the Prospectus, the effect of which, in any such case described in clause (A) or (B), is, in the judgment of the Representatives, so material and adverse as to make it impracticable or inadvisable to proceed with the public offering or the delivery of the Stock being delivered on such Delivery Date on the terms and in the manner contemplated in the Prospectus.

(j) Subsequent to the execution and delivery of this Agreement there shall not have occurred any of the following: (i) trading in securities generally on the New York Stock Exchange or the American Stock Exchange or in the over-the-counter market, or trading in any securities of the Company on any exchange or in the over-the-counter market, shall have been suspended or materially limited or the settlement of such trading generally shall have been materially disrupted or minimum prices shall have been established on any such exchange or such market by the Commission, by such exchange or by any other regulatory body or governmental authority having jurisdiction, (ii) a banking moratorium shall have been declared by Federal or state authorities, (iii) the United States shall have become engaged in hostilities, there shall have been an escalation in hostilities involving the United States or there shall have been a declaration of a national emergency or war by the United States or (iv) there shall have occurred such a material adverse change in general economic, political or financial conditions (or the effect of international conditions on the financial markets in the United States shall be such), including, without limitation, as a result of terrorist activities after the date hereof, or any other calamity or crisis as to make it, in the judgment of the Representatives, impracticable or inadvisable to proceed with the public offering or delivery of the Stock being delivered on such Delivery Date on the terms and in the manner contemplated in the Prospectus.

(k) The Company shall have provided notification to The Nasdaq Stock Market of the listing of the Stock in accordance with the rules thereof.

(l) No Underwriter shall have discovered and disclosed to the Company on or prior to such Delivery Date that the Registration Statement or the Prospectus or any amendment or supplement thereto contains an untrue statement of a fact which, in the reasonable opinion of Morrison & Foerster LLP, counsel for the Underwriters, is material or omits to state a fact which, in the reasonable opinion of such counsel, is material and is required to be stated therein or is necessary to make the statements therein not misleading.

All opinions, letters, evidence and certificates mentioned above or elsewhere in this Agreement shall be deemed to be in compliance with the provisions hereof only if they are in form and substance reasonably satisfactory to counsel for the Underwriters.

#### SECTION 8. *Indemnification and Contribution.*

(a) The Company shall indemnify and hold harmless each Underwriter, its directors, officers and employees and each person, if any, who controls any Underwriter within the meaning of the Securities Act, from and against any loss, claim, damage or liability, joint or several, or any action in respect thereof (including, but not limited to, any loss, claim, damage, liability or action relating to purchases and sales of Stock), to which that Underwriter, director, officer, employee or controlling person may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, liability or action arises out of, or is based upon, (i) any untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, the Registration Statement or the Prospectus or in any amendment or supplement thereto or (ii) the omission or alleged omission to state in any Preliminary Prospectus, the Registration Statement or the Prospectus, or in any amendment or supplement thereto, any material fact required to be stated therein or necessary to make the statements therein not misleading, and shall reimburse each Underwriter and each such director, officer, employee or controlling person promptly upon demand for any legal or other expenses reasonably incurred by that Underwriter, director, officer, employee or controlling person in connection with investigating or defending or preparing to defend against any such loss, claim, damage, liability or action as such expenses are incurred; provided, however, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage, liability or action arises out of, or is based upon, any untrue statement or alleged untrue statement or omission or alleged omission made in any Preliminary Prospectus, the Registration Statement or the Prospectus, or in any such amendment or supplement, in reliance upon and in conformity with written information concerning such Underwriter furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein which information consists solely of the information specified in Section 8(e); provided, further, that the Company shall not be liable to any Underwriter or person controlling such Underwriter under the indemnity agreement in this Section 8(a) to the extent that such loss, claim, damage or liability of such Underwriter or person controlling such Underwriter results from the fact that such Underwriter sold Stock to a person, and there was not sent or given to such person, at or prior to the written confirmation of such sale to such person, to the extent required by law, a copy of the Prospectus and the loss, claim, damage or liability of such Underwriter or person controlling such Underwriter results from an untrue statement or omission of a material fact contained in the Preliminary Prospectus previously delivered to such person which was corrected in the Prospectus, unless the failure to deliver such Prospectus is the result of the Company's failure to comply with the delivery requirements set forth in Section 5(c) in a timely manner. The foregoing indemnity agreement is in addition to any liability which the Company may otherwise have to any Underwriter or to any director, officer, employee or controlling person of that Underwriter.

(b) Each Underwriter, severally and not jointly, shall indemnify and hold harmless the Company, its officers and employees, each of its directors, and each person, if any, who controls the Company within the meaning of the Securities Act, from and against any loss, claim, damage or liability, joint or several, or any action in respect thereof, to which the Company or any such director, officer or controlling person may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, liability or action arises out of, or is based upon, (i) any untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, the Registration Statement or the Prospectus or in any amendment or supplement thereto, or (ii) the omission or alleged omission to state in any Preliminary Prospectus, the Registration Statement or the Prospectus, or in any

amendment or supplement thereto, any material fact required to be stated therein or necessary to make the statements therein not misleading, but in each case only to the extent that the untrue statement or alleged untrue statement or omission or alleged omission was made in reliance upon and in conformity with written information concerning such Underwriter furnished to the Company through the Representatives by or on behalf of that Underwriter specifically for inclusion therein, which information is limited to the information set forth in Section 8(e), and shall reimburse the Company and any such director, officer or controlling person for any legal or other expenses reasonably incurred by the Company or any such director, officer or controlling person in connection with investigating or defending or preparing to defend against any such loss, claim, damage, liability or action as such expenses are incurred. The foregoing indemnity agreement is in addition to any liability which any Underwriter may otherwise have to the Company or any such director, officer, employee or controlling person.

(c) Promptly after receipt by an indemnified party under this Section 8 of notice of any claim or the commencement of any action, the indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under this Section 8, notify the indemnifying party in writing of the claim or the commencement of that action; provided, however, that the failure to notify the indemnifying party shall not relieve it from any liability which it may have under this Section 8 except to the extent it has been materially prejudiced by such failure and, provided further, that the failure to notify the indemnifying party shall not relieve it from any liability which it may have to an indemnified party otherwise than under this Section 8. If any such claim or action shall be brought against an indemnified party, and it shall notify the indemnifying party thereof, the indemnifying party shall be entitled to participate therein and, to the extent that it wishes, jointly with any other similarly notified indemnifying party, to assume the defense thereof with counsel reasonably satisfactory to the indemnified party. After notice from the indemnifying party to the indemnified party of its election to assume the defense of such claim or action, the indemnifying party shall not be liable to the indemnified party under this Section 8 for any legal or other expenses subsequently incurred by the indemnified party in connection with the defense thereof other than reasonable costs of investigation; provided, however, that the Representatives shall have the right to employ one counsel, in addition to local counsel, to represent jointly the Representatives and those other Underwriters and their respective officers, employees and controlling persons who may be subject to liability arising out of any claim in respect of which indemnity may be sought by the Underwriters against the Company under this Section 8 if, in the reasonable judgment of the Representatives, either (1) there is an actual or potential conflict between the position of the Company and the Underwriters, (2) there may be defenses available to the Underwriters that are different from, or in addition to, those available to the Company, or (3) the Company has failed to assume the defense of such action and employ counsel reasonably satisfactory to the Underwriters, in any of which events, the [reasonable] fees and expenses of one such separate counsel, in addition to local counsel shall be paid by the Company. No indemnifying party shall (i) without the prior written consent of the indemnified parties (which consent shall not be unreasonably withheld), settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding, or (ii) be liable for any settlement of any such action effected without its written consent (which consent shall not be unreasonably withheld), but if settled with the consent of the indemnifying party or if there be a final judgment of the plaintiff in any such action, the indemnifying party agrees to indemnify and hold harmless any indemnified party from and against any loss or liability by reason of such settlement or judgment.

(d) If the indemnification provided for in this Section 8 shall for any reason be unavailable to or insufficient to hold harmless an indemnified party under Section 8(a) or 8(b) in respect of any loss, claim, damage or liability, or any action in respect thereof, referred to therein, then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid or payable by such indemnified party as a result of such loss, claim, damage or liability, or action in respect thereof, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering of the Stock or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i)

above but also the relative fault of the Company on the one hand and the Underwriters on the other with respect to the statements or omissions which resulted in such loss, claim, damage or liability, or action in respect thereof, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other with respect to such offering shall be deemed to be in the same proportion as the total net proceeds from the offering of the Stock purchased under this Agreement (before deducting expenses) received by the Company, on the one hand, and the total underwriting discounts and commissions received by the Underwriters with respect to the shares of the Stock purchased under this Agreement, on the other hand, bear to the total gross proceeds from the offering of the shares of the Stock under this Agreement, in each case as set forth in the table on the cover page of the Prospectus. The relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section were to be determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, damage or liability, or action in respect thereof, referred to above in this Section shall be deemed to include, for purposes of this Section 8(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 8(d), no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the shares of Stock underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages which such Underwriter has otherwise paid or become liable to pay by reason of any untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute as provided in this Section 8(d) are several in proportion to their respective underwriting obligations and not joint.

(e) The Underwriters severally confirm and the Company acknowledges that the statements with respect to the public offering of the Stock by the Underwriters set forth on the cover page of, the legend concerning over-allotments on the inside front cover page of and the concession and reallocation figures appearing under the caption "Underwriting" in, the Prospectus are correct and constitute the only information concerning such Underwriters furnished in writing to the Company by or on behalf of the Underwriters specifically for inclusion in the Registration Statement and the Prospectus.

#### *SECTION 9. Defaulting Underwriters.*

If, on either Delivery Date, any Underwriter defaults in the performance of its obligations under this Agreement, the remaining non-defaulting Underwriters shall be obligated to purchase the Stock which the defaulting Underwriter agreed but failed to purchase on such Delivery Date in the respective proportions which the number of shares of the Firm Stock set opposite the name of each remaining non-defaulting Underwriter in Schedule 1 hereto bears to the total number of shares of the Firm Stock set opposite the names of all the remaining non-defaulting Underwriters in Schedule 1 hereto; provided, however, that the remaining non-defaulting Underwriters shall not be obligated to purchase any of the Stock on such Delivery Date if the total number of shares of the Stock which the defaulting Underwriter or Underwriters agreed but failed to purchase on such date exceeds 9.09% of the total number of shares of the Stock to be purchased on such Delivery Date, and any remaining non-defaulting Underwriter shall not be obligated to purchase more than 110% of the number of shares of the Stock which it agreed to purchase on such Delivery Date pursuant to the terms of Section 3. If the foregoing maximums are exceeded, the remaining non-defaulting Underwriters, or those other underwriters satisfactory to the Representatives who so agree, shall have the right, but shall not be obligated, to purchase, in such proportion as may be agreed upon among them, all the Stock to be purchased on such Delivery Date. If the remaining Underwriters or other underwriters satisfactory to the Representatives do not elect to purchase the shares which the defaulting Underwriter or Underwriters agreed but failed to purchase on such Delivery Date,

this Agreement (or, with respect to the Second Delivery Date, the obligation of the Underwriters to purchase, and of the Company to sell, the Option Stock) shall terminate without liability on the part of any non-defaulting Underwriter or the Company, except that the Company will continue to be liable for the payment of expenses to the extent set forth in Sections 6 and 11. As used in this Agreement, the term “**Underwriter**” includes, for all purposes of this Agreement unless the context requires otherwise, any party not listed in Schedule 1 hereto who, pursuant to this Section 9, purchases Firm Stock which a defaulting Underwriter agreed but failed to purchase.

Nothing contained herein shall relieve a defaulting Underwriter of any liability it may have to the Company for damages caused by its default. If other Underwriters are obligated or agree to purchase the Stock of a defaulting or withdrawing Underwriter, either the Representatives or the Company may postpone the Delivery Date for up to seven full business days in order to effect any changes that in the opinion of counsel for the Company or counsel for the Underwriters may be necessary in the Registration Statement, the Prospectus or in any other document or arrangement.

SECTION 10. *Termination.* The obligations of the Underwriters hereunder may be terminated by the Representatives by notice given to and received by the Company prior to delivery of and payment for the Firm Stock if, prior to that time, any of the events described in Sections 7(i) or 7(j), shall have occurred or if the Underwriters shall decline to purchase the Stock for any reason permitted under this Agreement.

SECTION 11. *Reimbursement of Underwriters' Expenses.* If the Company shall fail to tender the Stock for delivery to the Underwriters by reason of any failure, refusal or inability on the part of the Company to perform any agreement on its part to be performed, or because any other condition of the Underwriters' obligations hereunder required to be fulfilled by the Company is not fulfilled, the Company will reimburse the Underwriters for all reasonable out-of-pocket expenses (including fees and disbursements of one counsel, in addition to local counsel) incurred by the Underwriters in connection with this Agreement and the proposed purchase of the Stock, and upon demand the Company shall pay the full amount thereof to the Representatives. If this Agreement is terminated pursuant to Section 9 by reason of the default of one or more Underwriters, the Company shall not be obligated to reimburse any defaulting Underwriter on account of those expenses.

SECTION 12. *Notices, Etc.* All statements, requests, notices and agreements hereunder shall be in writing, and:

(a) if to the Underwriters, shall be delivered or sent by mail, telex or facsimile transmission to Lehman Brothers Inc., 745 Seventh Avenue, New York, N.Y. 10019, Attention: Syndicate Registration Department, Fax (212) 526-0943, with a copy, in the case of any notice pursuant to Section 8(c), to the Director of Litigation, Office of the General Counsel, Lehman Brothers Inc., 399 Park Avenue, 15th Floor, New York, NY 10022;

(b) if to the Company, shall be delivered or sent by mail, telex or facsimile transmission to the address of the Company set forth in the Registration Statement, Attention: General Counsel (Fax: 561-989-5889); provided, however, that any notice to an Underwriter pursuant to Section 8(c) shall be delivered or sent by mail, telex or facsimile transmission to such Underwriter at its address set forth in its acceptance telex to the Representatives, which address will be supplied to any other party hereto by the Representatives upon request. Any such statements, requests, notices or agreements shall take effect at the time of receipt thereof. The Company shall be entitled to act and rely upon any request, consent, notice or agreement given or made on behalf of the Underwriters by Lehman Brothers Inc. on behalf of the Representatives.

SECTION 13. *Persons Entitled to Benefit of Agreement.* This Agreement shall inure to the benefit of and be binding upon the Underwriters, the Company, and their respective successors. This Agreement and the terms and provisions hereof are for the sole benefit of only those persons, except that (A) the representations, warranties, indemnities and agreements of the Company contained in this Agreement shall also be deemed to be for the benefit of the directors, officers and the person or persons, if any, who control any Underwriter within the meaning of Section 15 of the Securities Act and (B) the indemnity agreement of the Underwriters contained in Section 8(b) of this Agreement shall be deemed to be for the benefit of directors of the Company, officers of the Company who have signed the Registration Statement and any person controlling the Company within the

meaning of Section 15 of the Securities Act. Nothing in this Agreement is intended or shall be construed to give any person, other than the persons referred to in this Section 13, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision contained herein.

SECTION 14. *Survival.* The respective indemnities, representations, warranties and agreements of the Company and the Underwriters contained in this Agreement or made by or on behalf on them, respectively, pursuant to this Agreement, shall survive the delivery of and payment for the Stock and shall remain in full force and effect, regardless of any investigation made by or on behalf of any of them or any person controlling any of them.

SECTION 15. *Definition of the Terms "Business Day" and "Subsidiary."* For purposes of this Agreement, (a) "**business day**" means each Monday, Tuesday, Wednesday, Thursday or Friday which is not a day on which banking institutions in New York are generally authorized or obligated by law or executive order to close and (b) "**subsidiary**" has the meaning set forth in Rule 405 of the Rules and Regulations.

SECTION 16. *Governing Law.* This Agreement shall be governed by and construed in accordance with the laws of New York.

SECTION 17. *Counterparts.* This Agreement may be executed in one or more counterparts and, if executed in more than one counterpart, the executed counterparts shall each be deemed to be an original but all such counterparts shall together constitute one and the same instrument.

SECTION 18. *Headings.* The headings herein are inserted for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.

If the foregoing correctly sets forth the agreement between the Company and the Underwriters, please indicate your acceptance in the space provided for that purpose below.

Very truly yours,

NABI BIOPHARMACEUTICALS

By \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Accepted:

LEHMAN BROTHERS INC.  
WACHOVIA CAPITAL MARKETS, LLC  
U.S. BANCORP PIPER JAFFRAY INC.  
HARRIS NESBITT CORP.

For themselves and as Representatives  
of the several Underwriters named  
in Schedule 1 hereto

By LEHMAN BROTHERS INC.

By \_\_\_\_\_

Authorized Representative

SCHEDULE 1

Underwriter

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Number of Firm Shares to be Purchased

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Lehman Brothers Inc.

Wachovia Capital Markets, LLC

U.S. Bancorp Piper Jaffray Inc.

Harris Nesbitt Corp.



Exhibit A

LOCK-UP LETTER AGREEMENT

LEHMAN BROTHERS INC.  
WACHOVIA CAPITAL MARKETS, LLC  
U.S. BANCORP PIPER JAFFRAY INC.  
HARRIS NESBITT CORP.

As Representatives of the several  
Underwriters named in Schedule 1  
to the Underwriting Agreement,  
c/o Lehman Brothers Inc.  
745 Seventh Avenue  
New York, New York 10019

Dear Sirs:

The undersigned understands that you and certain other firms propose to enter into an Underwriting Agreement (the "Underwriting Agreement") providing for the purchase by you and such other firms (the "Underwriters") of shares (the "Shares") of Common Stock, par value \$0.10 per share (the "Common Stock"), of Nabi Biopharmaceuticals, a Delaware corporation (the "Company"), and that the Underwriters propose to reoffer the Shares to the public (the "Offering").

In consideration of the execution of the Underwriting Agreement by the Underwriters, and for other good and valuable consideration, the undersigned hereby irrevocably agrees that, without the prior written consent of Lehman Brothers Inc., on behalf of the Underwriters, the undersigned will not, directly or indirectly, (1) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of Common Stock (including, without limitation, shares of Common Stock that may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission and shares of Common Stock that may be issued upon exercise of any option or warrant) or securities convertible into or exchangeable for Common Stock (other than the Shares) owned by the undersigned on the date of execution of this Lock-Up Letter Agreement or on the date of the completion of the Offering, or (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of such shares of Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise, for a period of 90 days after the date of the final Prospectus relating to the Offering.

The foregoing sentence shall not apply to bona fide gifts, sales or other dispositions of shares of any class of the Company's capital stock, in each case that are made exclusively between and among the undersigned or members of the undersigned's family, or affiliates of the undersigned, including its partners (if a partnership) or members (if a limited liability company); provided that it shall be a condition to any such transfer that (i) the transferee/donee agrees to be bound by the terms of the lock-up letter agreement (including, without limitation, the restrictions set forth in the preceding sentence) to the same extent as if the transferee/donee were a party hereto, (ii) no filing by any party (donor, donee, transferor or transferee) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), shall be required or shall be voluntarily made in connection with such transfer or distribution (other than a filing on a Form 5, Schedule 13D or Schedule 13G (or 13D-A or 13G-A) made after the expiration of the 90-day period referred to above), (iii) each party (donor, donee, transferor or transferee) shall not be required by law (including without limitation the disclosure requirements of the Securities Act of 1933, as amended, and the Exchange Act) to make, and shall agree to not voluntarily make, any public announcement of the transfer or disposition, and (iv) the undersigned notifies Lehman Brothers' Equity Capital Markets at least two business days prior to the proposed transfer or disposition.

In furtherance of the foregoing, the Company and its Transfer Agent are hereby authorized to decline to make any transfer of securities if such transfer would constitute a violation or breach of this Lock-Up Letter Agreement.

It is understood that, if the Company notifies you that it does not intend to proceed with the Offering, if the Underwriting Agreement does not become effective, or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Shares, we will be released from our obligations under this Lock-Up Letter Agreement.

The undersigned understands that the Company and the Underwriters will proceed with the Offering in reliance on this Lock-Up Letter Agreement.

Whether or not the Offering actually occurs depends on a number of factors, including market conditions. Any Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Lock-Up Letter Agreement and that, upon request, the undersigned will execute any additional documents necessary in connection with the enforcement hereof. Any obligations of the undersigned shall be binding upon the heirs, personal representatives, successors and assigns of the undersigned.

Very truly yours,

By: \_\_\_\_\_

Name:

Title:

Dated: \_\_\_\_\_

**Consent of Independent Certified Public Accountants**

We consent to the reference to our firm under the caption "Experts" in the Pre-Effective Amendment No. 1 to the Registration Statement (Form S-3 No. 333-110813) and related Prospectus of Nabi Biopharmaceuticals for the registration of 11,730,000 shares of its common stock and to the incorporation by reference therein of our report dated February 4, 2003 with respect to the consolidated financial statements and schedule of Nabi Biopharmaceuticals included in its Annual Report (Form 10-K) for the year ended December 28, 2002, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Fort Lauderdale, Florida  
December 10, 2003

**Consent of Independent Auditors**

We consent to the reference to our firm under the caption "Experts" in the Pre-Effective Amendment No. 1 to the Registration Statement (Form S-3 No. 333-110813) and related Prospectus of Nabi Biopharmaceuticals for the registration of 11,730,000 shares of its common stock and to the incorporation by reference therein of our report dated September 17, 2003 with respect to the statements of revenues and certain costs and expenses of the PhosLo Product Line of Braintree Laboratories, Inc. included in the Current Report (Form 8-K/A) of Nabi Biopharmaceuticals dated August 4, 2003, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Boston, Massachusetts  
December 8, 2003