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

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**FORM 10-K**

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

For the fiscal year ended December 25, 2004

Commission File Number: 000-04829

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**Nabi Biopharmaceuticals**

(Exact name of registrant as specified in its charter)

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

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

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

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

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**Securities registered pursuant to Section 12(g) of the Act:**

**Common Stock, par value \$.10 per share**

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, as of the last business day of the registrant's most recently completed second fiscal quarter was: \$806,362,914

As of March 3, 2005, 58,774,255 shares of the registrant's common stock were outstanding.

Documents Incorporated by Reference

Portions of the definitive Proxy Statement for the Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Registrant's fiscal year ended December 25, 2004, are incorporated by reference into Part III.

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**ITEM 1. BUSINESS**

**OVERVIEW**

We leverage our experience and knowledge in powering the immune system to develop and market products that fight serious medical conditions. We are poised to capture large, commercial opportunities in our four core business areas: Gram-positive bacterial infections; hepatitis; kidney disease (nephrology); and nicotine addiction. We have four products on the market today and a number of products in various stages of clinical and preclinical development. We invest the gross margins we earn from sales of our marketed products toward funding the development of our product pipeline.

This business model has allowed us to largely self-fund the application of our clinical, regulatory, commercial and manufacturing expertise in developing innovative new products. We believe these products will not only save lives and improve clinical outcomes for patients, but at the same time will make an important contribution to reducing the increasing financial burden on the healthcare system.

As an example, our lead product in development, StaphVAX (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine), is positioned to become a new standard of preventative care for patients at risk of contracting life-threatening *S. aureus* bacterial infections. In the U.S. alone, \$5 billion in additive patient-care costs are incurred annually because of bacterial infections. *S. aureus* and other Gram-positive bacteria are the cause of a majority of these infections and have become serious public health challenges that plague millions of patients around the world. Current approaches do not adequately prevent or treat the most prevalent and dangerous strains of *S. aureus* bacteremia that are becoming increasingly resistant to antibiotic treatments. To combat this problem, thought leaders in government and academic arenas favor preventative approaches to combat bacterial infections. This is based on a belief that prevention is better for patients and less costly than treatment.

In December 2004, we submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMEA, under the Centralized Registration Procedure for approval to market StaphVAX within the European Union. The indication sought under this initial license application is for the prevention of *S. aureus* bacteremia in patients with end-stage kidney disease on hemodialysis for up to 40 weeks. These patients are at a particularly high risk for *S. aureus* infections; approximately 6% of these patients will develop a *S. aureus* infection each year. In 2005, following completion of a confirmatory Phase III clinical trial, we intend to file a Biologics License Application for marketing clearance of StaphVAX in the U.S.

StaphVAX is also an important component of our focus in kidney disease (nephrology). Kidney disease is a growing, global public health problem driven by the increasing incidence of diabetes, obesity and hypertension around the world. In the U.S. alone, the annual direct medical costs for end-stage renal disease, or ESRD, are nearly \$23 billion. Our currently marketed product, PhosLo (calcium acetate), is indicated for the treatment of hyperphosphatemia, or elevated serum phosphate levels, among patients suffering from ESRD. We believe that, combined, StaphVAX and PhosLo will position us as a leader in the large and growing global nephrology market.

Furthermore, we plan to broaden the application of StaphVAX beyond kidney disease patients to prevent a number of dangerous and prevalent Gram-positive bacterial infections in other high-risk patient groups. Globally, our Gram-positive bacterial infections program could represent a \$1 - \$2 billion market opportunity.

In addition to our biopharmaceutical business, we also collect specialty and non-specific antibodies for use in our products and sell the excess production to pharmaceutical and diagnostic customers for the subsequent manufacture of their products.

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We are incorporated in Delaware. Our U.S. operations are headquartered in Boca Raton, Florida and our European headquarters are located in Bray, Ireland. We maintain our commercial and manufacturing operations in Boca Raton and our research and development operations in Rockville, Maryland.

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The following table shows our currently marketed and development products:

<u>Products</u>	<u>Indication/Intended Use</u>	<u>Status</u>
<i>Gram-positive Infections</i>		
StaphVAX®	Protection against Types 5 and 8 <i>S. aureus</i> infections	EU application for licensure for prevention of <i>S. aureus</i> infections in ESRD patients on hemodialysis filed under the centralized registration procedure in December 2004; Ongoing confirmatory Phase III clinical trial in U.S.; Fast Track Designation for use in ESRD patients in the U.S.
Altastaph™	Treatment of <i>S. aureus</i> infections in adults in conjunction with standard of care therapy including antibiotics	Phase I/II clinical trial for treating adults with <i>S. aureus</i> infections in combination with standard of care therapy, including antibiotics, completed in 2004; Phase IIB or Phase III clinical trial being planned for 2005
Altastaph™ NxG	Prevention of <i>S. aureus</i> and <i>S. epidermidis</i> infections among patients who are too immunocompromised to respond to StaphVAX, or who do not have the time to respond to StaphVAX	Phase II trial in very low birth-weight newborns completed in 2004; Orphan Drug Status and Fast Track Designation in the U.S. for preventing <i>S. aureus</i> infections in very low birth weight neonate patients; Next generation product being manufactured in 2005; Phase IIB or Phase III clinical trial planned for 2006
StaphVAX™ 336	Protection against <i>S. aureus</i> Type 336 infections	Phase I/II clinical trial planned for 2005
<i>S. epidermidis</i> Vaccine	Protection against <i>S. epidermidis</i> infections	Phase I/II clinical trial planned for 2005
EnteroVAX™ <i>Kidney Disease</i>	Protection against enterococcal infections	Pre-clinical
PhosLo®	Treatment of hyperphosphatemia in end-stage renal failure patients	Marketed in U.S.; Application for licensure in the EU through mutual recognition process filed October 2004; CARE 2 clinical trial initiated in the fourth quarter of 2004
PhosLo® CKD	Treatment of hyperphosphatemia in pre-dialysis chronic kidney disease patients	Phase IIIB clinical trial in Level 4 chronic kidney disease patients planned for 2005
<i>Hepatitis</i>		
Nabi-HB®	Post-exposure prevention of hepatitis B infection	Marketed in U.S.
Nabi-HB® Intravenous (HEBIG in the EU)	Prevention of re-infection with hepatitis B in liver transplant patients	Application for licensure in the EU through mutual recognition process filed June 2004; BLA filed and under review in U.S.; Orphan Drug Designation in the U.S.
Civacir™	Prevention of re-infection with hepatitis C in liver transplant patients	Phase I/II clinical trial completed in 2004; Orphan Drug Designation in the U.S.
<i>Nicotine addiction</i>		
NicVAX™	Treatment of nicotine addiction	Ongoing Phase II clinical trial in Europe; Phase II trial in U.S. completed in 2004; Phase III clinical trial being planned for 2005
<i>Hematology &amp; Oncology</i>		
WinRho SDF®	ITP	Marketed in U.S. under a distribution agreement that ends in March 2005
Aloprim®	Chemotherapy-induced hyperuricemia	Marketed in U.S.

## PRODUCTS

### GRAM-POSITIVE INFECTIONS

Within the approximately 5,400 acute care hospitals in the U.S., *S. aureus* is the leading cause of hospital-acquired bloodstream infections. In addition, the U.S. Centers for Disease Control, or CDC, estimates that 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. In the EU's approximately 7,600 acute care hospitals, SENTRY reports *S. aureus* to be the cause of blood stream infections 19% of the time, which is nearly as frequent as in the U.S. where *S. aureus* is reported to cause 25% of blood stream infections acquired in acute care hospitals. With its capacity to cause serious complications and its increasing resistance to most antibiotics, *S. aureus* has become a critically dangerous pathogen and a global health concern. *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.

*Staphylococcal* infections are difficult to treat because the bacteria that cause them are virulent and often resistant to antibiotics. The rise of antibiotic resistance as reported by the CDC in the 2003 National Nosocomial Infections Surveillance Systems report has markedly curtailed options for treating these infections. Methicillin-resistant *S. aureus*, or MRSA, from all sites of infection has risen from 22% in 1995 to 57% in 2002 in the U.S. The European Antimicrobial Resistance Surveillance System reported significant increases in MRSA infections throughout Europe from 1998 to 2002. The greatest relative increases were found in Belgium, Germany, Ireland, The Netherlands and the United Kingdom, or UK, with MRSA in the UK increasing from 33% in 1999 to 43% in 2003. And, according to the SENTRY Antimicrobial Surveillance Program in the Asia-Pacific region, similar trends have been described in the Asia-Pacific region with a rate of MRSA of 73% in Japan, and similar rates in certain other Asian countries.

*S. aureus* infection rates in patient populations at high-risk for *S. aureus* infection can be as high as up to 40%. These infections result in longer hospital stays, higher death rates, increased illness and significantly higher medical costs. A retrospective study completed at the Duke University Medical Center determined that dialysis-dependent patients hospitalized with MRSA had a mean in-patient stay of 14.2 days. These patients also incurred mean costs of treatment of \$32,655 and had a 35% mortality rate at 12 weeks.

In 2004, investigators from Duke Clinical Research Institute, Duke University Medical Center, Durham, North Carolina and Health Economics Consulting, Annapolis, Maryland completed a study evaluating heart disease patients with implanted cardiovascular devices such as prosthetic valves, pacemakers and defibrillators, ventricular assist devices, intra-aortic balloon pumps and non-hemodialysis intravascular stents/grafts who developed *S. aureus* bacteremia that was sponsored by us. In this study, 44% of the patients evaluated experienced serious complications as a result of their infection and 35% died within 12 weeks. The study also demonstrated that *S. aureus* bacteremia was associated with substantial medical costs with individual patients incurring a mean cost of \$82,300 for a hospital-acquired infection.

#### *StaphVAX*

StaphVAX, our lead product in clinical development, seeks to address this global healthcare issue. StaphVAX represents a new approach in the available clinical tools against *S. aureus* infections. It is focused on prevention rather than treatment. 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.

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StaphVAX is an investigational polysaccharide conjugate vaccine based on patented vaccine technology licensed on an exclusive basis from the Public Health Service/NIH. StaphVAX represents a novel approach to the prevention of *S. aureus* infections. StaphVAX contains surface polysaccharides found in the outer coating of Types 5 and 8 *S. aureus*. The polysaccharide molecules are linked, or conjugated, to a non-toxic, carrier protein derived from the bacteria *Pseudomonas aeruginosa* (*Pseudomonas* exoprotein A) that causes a strong response by the immune system to the conjugated complex. Once given the vaccine, the patient's immune system produces proteins, called antibodies, to the polysaccharides, 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 and eliminate it before significant damage can be inflicted. Since these antibodies bind to several sites on the bacteria's surface polysaccharides, we believe that it will be much more difficult for the bacteria to develop resistance to the antibodies, contrary to what has been observed with most antibiotics in the treatment of *S. aureus* bacteria.

The initial formulation of StaphVAX is intended to stimulate a patient's immune system to produce antibodies to *S. aureus* Types 5 and 8, which are responsible for approximately 85% of *S. aureus* infections.

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

- elderly patients 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 at least seven days in advance,
- patients undergoing various types of prosthetic and vascular graft surgery who are at longer-term risk of *S. aureus* infections due to their implants,
- chronic osteomyelitis patients, spinal cord injury and spinal fusion patients,
- hematology/oncology patients undergoing chemotherapy and
- patients who have previously been treated for *S. aureus* infections.

In December 2004, we filed a MAA in the EU using the Centralized Registration Procedure. This MAA submission is based on efficacy data obtained from our first Phase III clinical trial. Based on the results of this trial, we are seeking an initial indication that StaphVAX prevents *S. aureus* bacteremia for up to 40 weeks in ESRD patients on hemodialysis. The MAA submission included manufacturing conformance data generated at Cambrex Bio Science Baltimore, Inc., or Cambrex Bio Science, our contract manufacturer for StaphVAX. If the MAA is approved, we will be granted simultaneous regulatory approval to market StaphVAX for this indication throughout the 25 member states within the EU. Following receipt of regulatory approval, we would then seek reimbursement approval in specific EU country markets. We also plan to file a supplement to the MAA dossier in the EU upon approval of the initial application incorporating safety and immune

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response data from immunogenicity clinical trials that are being conducted in the U.S. and the EU in patients undergoing orthopedic and cardiothoracic surgery as well as data from a confirmatory Phase III clinical trial in dialysis patients currently underway in the U.S. The purpose of this supplemental filing is to expand the indication to the prevention of *S. aureus* bacteremia and secondary infections caused by bacteremia in at-risk adults.

In general, reimbursement by government payer systems requires demonstration of the cost-effectiveness of new products and treatments. We will initially seek reimbursement for StaphVAX in the EU. We are currently conducting country specific pharmacoeconomic studies for StaphVAX to comply with requirements for pharmacoeconomic data in reimbursement dossiers. Based on our understanding of the costs of treating *S. aureus* infections in hospital settings, we believe that these studies will demonstrate the cost-effectiveness of vaccination of at-risk patients with StaphVAX.

In August 2004, we completed enrollment in our confirmatory Phase III clinical trial for StaphVAX in the U.S. with a prospectively defined primary efficacy end point at eight months post-vaccination. This double-blinded, placebo-controlled, randomized trial is being conducted in ESRD patients undergoing hemodialysis, the same patient population in which we conducted our initial Phase III clinical trial of StaphVAX. A total of 3,976 patients were enrolled in the trial, exceeding our target enrollment of 3,600 patients and a total of 3,447 patients have been randomized for injection with either StaphVAX or placebo, also exceeding our target of 3,240 patients. As enrolled, the study is powered to demonstrate a 50% reduction in infection with 90% power. At the eight-month primary end point of this trial, we will administer a booster dose of the vaccine and subjects will be monitored for antibody levels and infection rates for at least an additional four months as secondary end points. Consequently, patients enrolled in the trial will be followed for at least 12 months in total. The study will remain blinded during the entire period of the trial. If we achieve positive results from this efficacy trial, we plan to file a BLA for StaphVAX with the U.S. Food and Drug Administration, or FDA by the end of 2005. Our BLA filing will incorporate the efficacy data from both the current Phase III trial of StaphVAX and the initial Phase III clinical trial as well as safety and immune response data from immunogenicity trials being conducted in the U.S. and in the EU in patients undergoing orthopedic and cardiothoracic surgery.

Our initial Phase III double-blinded, placebo-controlled and randomized clinical trial for StaphVAX was conducted in hemodialysis patients with ESRD. We targeted these patients because of their high infection rate and they were at long-term risk of infection. 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. All patients were evaluated at intervals for up to a year for vaccine safety and *S. aureus* infection rates. Some patients were followed for up to 36 months. The results of the trial demonstrated that a single injection of StaphVAX was safe and showed a 57% reduction in the incidence of *S. aureus* bacteremia through 10 months post-vaccination. The highest effect was seen after 8 months, where a 63% reduction in *S. aureus* event rate was observed. After the 8-month time point, the cumulative reduction in infections started to wane as antibody levels on average began to fall below what are believed to be protective levels. The reduction in bacteremia one-year after vaccination, the prospectively defined efficacy end-point of the trial, was 26% and was not statistically significant. No significant side effects attributable to the vaccine were noted. The results in ESRD patients are especially significant because these patients are severely immune-compromised and 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 with higher levels of antibody to StaphVAX than ESRD patients. The significance of the results of this trial was confirmed by publication in the New England Journal of Medicine in February 2002.

To evaluate the immune response to a booster dose, for patients at long-term risk for infection, we conducted a booster trial in 2001, giving a second dose of StaphVAX to 77 hemodialysis patients who had previously received an initial dose of the vaccine in the first Phase III clinical trial. On average the booster was dosed 36 months after the initial vaccination. The trial demonstrated that a booster dose of the vaccine



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given to previously vaccinated hemodialysis patients significantly increased the concentration of the vaccine-specific antibodies against *S. aureus*. Hence, 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 in this trial were above what were demonstrated to be protective in the Phase III clinical trial, although the levels were not as high as those following the first dose of vaccine. However, the decline of antibody levels over time was slower after the booster vaccination than following the initial vaccination.

The FDA has awarded StaphVAX Fast Track Designation for the prevention of *S. aureus* bacteremia in ESRD patients.

### *Altastaph. [Staphylococcus aureus Immune Globulin Intravenous (Human)]*

Altastaph is an investigational human polyclonal antibody product that contains high levels of *S. aureus* Types 5 and 8 specific antibodies. These antibodies are collected from the plasma of healthy donors who have been vaccinated with StaphVAX at our FDA approved antibody collection centers. Altastaph is also being developed to treat patients with active *S. aureus* infections in conjunction with standard of care therapy including antibiotic treatment. Altastaph can also provide a prevention option for patients who cannot respond to vaccines due to their compromised immune system or who do not have the 10 to 14 days time-period necessary to respond to the vaccine, prior to being at-risk of infection.

The mechanism of action for Altastaph is the same as for StaphVAX. The *S. aureus* Types 5 and 8 specific antibodies included in Altastaph bind to the polysaccharide capsule of the bacteria at several sites upon exposure to in the bloodstream, and help the body's immune system to eliminate it in the bloodstream.

High-risk patient populations that could benefit from Altastaph include patients with persistent *S. aureus* infections, very low birth-weight newborns, emergency surgery patients, trauma patients and patients in intensive care and burn units.

Patients with active *S. aureus* infections could also benefit from a combination therapy of Altastaph plus StaphVAX at the conclusion of their treatment to reduce the otherwise high risk for re-infection. Re-infection with *S. aureus* following initial treatment and release from hospital has been reported in up to 30% of patients within 18 months after discharge.

In January 2005, we announced results from our U.S. Phase I/II clinical trial using Altastaph to treat adult in-hospital patients with persistent *S. aureus* bloodstream infections, or bacteremia. The study was a double-blinded, placebo-controlled, randomized trial in 40 patients designed to evaluate the safety of Altastaph and to measure *S. aureus* specific antibody levels. Patients were randomly allocated to receive two intravenous doses of Altastaph or saline placebo in combination with standard-of-care treatment, which included treatment with antibiotics. The results of the study demonstrated that Altastaph was well tolerated and no drug-related, serious adverse events were reported. Patients were able to maintain antibody titers at or above levels previously demonstrated to be protective against *S. aureus* infections in patients with ESRD. In this study there was an observed 36% reduction in median time from administration of the study drug to hospital discharge in the Altastaph-treated patients as compared to the placebo-treated patients, representing nine days in the Altastaph group versus 14 days in the placebo group. Because this overall result in a small safety/immunogenicity trial approached statistical significance, we believe this reduction in the length of hospital stay for the Altastaph-treated group indicates that the *S. aureus* antibodies in Altastaph could be associated with a measurable medical benefit in the treatment of persistent *S. aureus* infections.

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In November 2004, we announced the results of our Phase II clinical trial for the prevention of *S. aureus* infections in very low birth-weight newborns, defined as newborns with birth weights between 500 and 1500 grams. This randomized, double-blinded, placebo-controlled Phase II clinical trial was conducted in approximately 200 newborns at 20 neonatology centers throughout the U.S. Newborns were randomly selected to receive Altastaph at one of two dose levels or placebo and followed for up to 42 days for safety and incidence of infections. The results from this study showed that Altastaph was safe and was able to elevate Types 5 and 8 *S. aureus* specific antibodies to what are believed to be protective levels, the primary endpoints of the trial. However, the rate of serious *S. aureus* infections reported in each arm of this trial was 3%, too low to allow us to make any inferences about the efficacy of Altastaph as administered in this study. In order to maximize the clinical and commercial potential for Altastaph in preventing bacterial infections in very low birth-weight neonates, we plan to advance development of a next generation Altastaph product, or Altastaph NxG which could prevent a majority (up to two-thirds) of bacterial infections observed in neonates, specifically *S. aureus* Types 5 and 8 plus Type 336 and *S. epidermidis*. *S. epidermidis* is one of the most prevalent and dangerous bacteria to infect very low birth-weight neonates.

Altastaph for prevention of *S. aureus* in very low birth-weight neonates has been designated an Orphan Drug by the FDA, entitling us to marketing exclusivity for this indication for a period of seven years post licensure, and has received Fast Track Designation from the FDA for this indication.

### *Next Generation Products and Other Anti-Bacterial Vaccines in Development.*

We have identified and patented an antigen called Type 336, found on a serotype of *S. aureus*. Based on all isolates we have tested to date, Type 336 accounts for 15% to 20% of all clinically significant *S. aureus* infections. We have 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. In 1998, we were issued a U.S. patent for the Type 336 antigen. Included in the patent were claims relating to vaccines made from Type 336 antigen as well as the corresponding monoclonal and polyclonal antibodies reactive to the antigen. Patents for Type 336 antigen and its use are being pursued worldwide. Next generation StaphVAX and Altastaph products are expected to contain *S. aureus* Type 336 antigen in addition to *S. aureus* Types 5 and 8 antigens. We expect the next-generation StaphVAX and Altastaph products to provide protection against virtually all clinically significant *S. aureus* infections today.

*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 18 patents containing claims covering both a *S. epidermidis* vaccine as well as the corresponding 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. We have prepared a clinical lot of *S. epidermis* conjugate vaccine and plan to initiate a Phase I/II clinical trial using this material during 2005.

## KIDNEY DISEASE

### *PhosLo (calcium acetate)*

PhosLo is a prescription calcium acetate phosphate binder indicated for the control of elevated blood, or serum, phosphorus levels, or hyperphosphatemia in ESRD patients. The Kidney Disease Outcome Quality Initiative, or K/DOQI, guidelines issued by the National Kidney Foundation, or NKF, specifies that controlling elevated phosphorus levels in dialysis patients 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 including calcification of the arterial walls, heart valves and joints, bone pain and bone deformity and may result in death.

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We acquired the worldwide rights to PhosLo in August 2003 as our initial step to establish our commercial presence in the nephrology market and with the physicians who treat ESRD patients. This will be an important early market for our lead product in clinical development, StaphVAX. We currently market PhosLo in the U.S. In October 2004, we filed a MAA in the EU under the Mutual Recognition Procedure, or MRP, for PhosLo. The MRP provides that following approval of a product in one country, other countries within the EU may approve a product on the basis of the initial approval. The filing used the Common Technical Document, or CTD, format, which is widely accepted on a global basis. Under this format, the filing can be readily submitted in other countries around the world, facilitating our ability to expand the marketing of PhosLo in key ESRD markets beyond the U.S. and the EU.

When given with food, the calcium acetate in PhosLo combines with dietary phosphorus to form insoluble calcium-phosphate complexes that are eliminated from the body, thereby reducing phosphorus absorption and lowering serum phosphorus levels.

PhosLo is distinct from calcium carbonate containing phosphate binder products, typically prescription products in the EU or over-the-counter products such as TUMS in the U.S., due to its higher phosphate binding activity. Hence, PhosLo achieves control of serum phosphorus levels as well as calcium-phosphorus product in accordance with the K/DOQI guidelines to a greater extent than calcium carbonate products. Many ESRD patients in the U.S. use over-the-counter calcium carbonate based products to treat elevated phosphorus levels for reasons of cost despite its inferior activity.

According to the U.S. Renal Disease Service, orUSRDS, at December 2001, 406,000 patients in the U.S. met the criteria for ESRD. The USRDS also projects that the population of ESRD patients will grow to over 2.2 million patients by 2030. This growth in the number of ESRD patients is largely attributable to increases in the incidence of 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 market research, we believe ESRD patients undergoing chronic dialysis are likely to experience elevated phosphorus levels at some point during each year of their treatment and therefore will require phosphate binder therapy to control their blood phosphorus levels for a period of time.

Kidney disease is the ninth leading cause of death in the U.S. It has been estimated in the Morbidity and Mortality Weekly Report that approximately 19 million people in the U.S. suffer from chronic kidney failure. According to the American Journal of Kidney Disease, of these patients, an estimated 5.9 million individuals suffer from level 1 kidney failure, the lowest level of kidney failure, 5.3 million individuals were estimated to be at level 2 kidney failure, 7.6 million individuals were estimated at level 3 kidney failure, 400,000 individuals were estimated at level 4 kidney failure and 300,000 individuals had level 5 kidney failure. Level 5 kidney failure typically requires dialysis treatment.

According to national renal associations, in Germany, France, Italy, Spain and the UK alone, there are currently approximately 176,000 patients undergoing chronic renal dialysis. This figure increases to nearly 230,000 patients when Europe is looked at in total. This patient population is expected to grow due to increased incidence of diabetes, hypertension and the overall aging of the EU population. Consistent with treatment practices in the U.S., European nephrologists utilize phosphate binders on a regular basis. Currently, the phosphate binder market in the five largest European markets exceeds 200 million Euros and is primarily served by Renagel (sevelamer hydrochloride) as well as a number of calcium acetate and calcium carbonate products.

In the U.S., dialysis providers are primarily reimbursed by the Federal government through the ESRD Program. The Federal government reimburses approved providers for 80% of allowed

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dialysis costs. The remainder is paid by other sources, including Medicaid, private insurers and through state renal programs. Reimbursement for dialysis services is made via the Composite Rate, which includes all dialysis services and supplies, including certain drugs, but excluding oral products such as PhosLo and other phosphate binders. Effective January 1, 2006, The Medicare Prescription Drug Improvement and Modernization Act, or MMA, will include an outpatient prescription drug benefit, under a new Part D that will incorporate PhosLo and other prescription phosphate binders.

For those patients who meet defined qualification for financial assistance, PhosLo is available at no charge under our Patient Assistance Program.

In the EU, the Reference Pricing System, or RPS, is typically applied to pharmaceutical products that derive from the same therapeutic class as an alternative pharmaceutical product for which the patent has expired. Using the RPS, prices may be set at the average of prices in effect for the same class of pharmaceutical products currently available or prices may be set within a range below the price of the most expensive product in the group and above the least expensive product in the group. Patients have to pay the difference if the price charged exceeds the reference price. The RPS is expected to be applied to PhosLo following regulatory approval in the EU as certain EU countries currently reimburse for calcium acetate products that would compete with PhosLo.

In the May 2004 issue of *Kidney International*, the study: Treatment of Hyperphosphatemia in Hemodialysis Patients: The Calcium Acetate Renegel Evaluation, or CARE, was published as a full original paper. This is the only double-blinded, randomized controlled comparison study of PhosLo and Renegel. The results of the study showed that patients treated with PhosLo were able to control serum phosphorus levels more effectively than patients treated with Renegel throughout the 8-week study period. Specifically, patients in the CARE study treated with PhosLo achieved K/DOQI guideline targets for phosphorus and calcium-phosphorus product levels more often and for longer periods of time than patients treated with Renegel. In addition, the CARE study identified there were significant differences in the cost of treatment between PhosLo and Renegel. The mean daily cost of treatment with PhosLo, based on the level of treatment provided to patients in the study at the end of the study period was \$2.14 compared to \$11.70 for Renegel. Based on average wholesaler prices in January 2004, and assuming continuous use, on an annualized basis, this would translate into \$753 in projected treatment costs for PhosLo compared to \$4,319 for Renegel, a potential cost-savings of \$3,566 per year for patients treated with PhosLo.

Cardiac illness is a leading cause of death among ESRD patients. Training and education recommendations issued by the American Society of Nephrology in their NEPHSAP publication during the first quarter of 2004 focused on a number of factors instrumental to the ESRD patient's cardiac health, including the control of serum phosphorus, calcium phosphorus product and lipid levels in the blood. We believe any difference in cardiac calcification between patients treated with PhosLo versus patients treated with Renegel is due to the lipid lowering benefit associated with Renegel. During 2004 we initiated the CARE 2 study that will compare the efficacy, safety and arterial calcification in patients treated with PhosLo plus Lipitor (atorvastatin calcium), and Renegel plus Lipitor. Lipitor will be added to patients in each treatment regimen as appropriate to secure Low Density Lipoprotein, or LDL, levels in accordance with the guidelines recently issued by the National Cholesterol Education Program. These guidelines recommend that LDL levels in very high-risk patients such as ESRD patients should be at or below 70mg/dL of blood. The goal of the CARE 2 study is to demonstrate that when patients with ESRD treated with either PhosLo or Renegel achieve the same level of lipid control, there will be no significant difference in the development of coronary artery calcification thereby refuting the hypothesis that calcium intake as part of the PhosLo treatment is associated with cardiovascular calcification. The study is further designed to demonstrate that the combination of PhosLo and Lipitor will achieve superior control of serum phosphorus levels and calcium phosphorus product. It is expected that the total annual cost of PhosLo plus Lipitor in combination will be significantly less than the cost of Renegel alone. Preliminary data evaluating serum phosphorus levels, serum calcium levels, calcium phosphorus product and lipid levels are expected to be available in the second half of 2005. Final data evaluating arterial calcification using electron beam computer tomography, or EBCT, is expected in the second half of 2006.

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In line with recommendations included in the K/DOQI guidelines that pre-dialysis chronic kidney disease, or CKD, patients may benefit from phosphate binder therapy, we expect to initiate a study using PhosLo in CKD patients in the first half of 2005 entitled Effect of PhosLo in Chronic Kidney Disease, or EPICK. PhosLo is well positioned for the CKD patient, as it is likely to control serum phosphorus and a secondary endpoint of parathyroid hormone levels without causing very low calcium levels, or hypocalcemia, or high levels of acidity in the blood, or metabolic acidosis. The EPICK trial will seek to demonstrate that PhosLo can safely and effectively control parathyroid hormone levels, serum phosphorus levels and calcium phosphorus product in CKD patients. This possible extension of the labeled use for PhosLo is significant because of estimates that there are approximately 400,000 CKD patients suffering level IV kidney failure in the U.S. alone.

### HEPATITIS

#### *Nabi-HB [Hepatitis B Immune Globulin (Human)]*

Nabi-HB is a human polyclonal antibody product indicated to prevent hepatitis B following accidental exposure to hepatitis B virus, or HBV. However, we believe the majority of our Nabi-HB sales are for use to prevent re-infection with hepatitis B disease in HBV-positive liver transplant patients. In November 2002, we filed a BLA with the FDA for Nabi-HB Intravenous, to prevent re-infection with hepatitis B disease in HBV-positive liver transplant patients. In June 2004 we filed a MAA in Europe for regulatory approval for Nabi-HB Intravenous under the MRP.

Nabi-HB reflects the application of our clinical, regulatory, manufacturing and commercial expertise in antibody technology to the treatment of patients exposed to HBV and HBV liver transplant patients. We produce the anti-HBV plasma raw material at our FDA approved antibody collection centers, manufacture Nabi-HB in our state of the art fractionation and purification facility and make medical education materials available to physicians through our medical liaison activities.

Nabi-HB is a purified human polyclonal antibody product collected at our FDA approved antibody collection centers from plasma donors, which have been previously vaccinated with a hepatitis B vaccine. Hepatitis B vaccines contain the hepatitis B surface antigen, which is known to provide protection against HBV. When administered, the anti-hepatitis B antibody contained in Nabi-HB binds to the Hepatitis B virus and triggers its clearance by the body's immune system.

HBV is a major global health concern. In a January 2004 issue of the Morbidity and Mortality Weekly Report, the CDC estimated that in the U.S. alone there are approximately 1.3 million chronic hepatitis B carriers, 73,000 new hepatitis B infections per year, and 5,000 individuals who die annually from hepatitis B or its complications. Rates of HBV infection throughout the EU are reported as similar to those in the U.S. Chronic HBV infection is a frequent cause of end-stage liver disease and according to the United Network for Organs Sharing, or UNOS, over 4% of liver transplants through November 2004 were due to underlying hepatitis B liver disease. Moreover, during surgery and in the period immediately following transplant surgery, patients do not have any licensed treatment options to prevent re-infection of the transplanted liver. Re-infection of the transplanted liver is almost inevitable after surgery in HBV-positive patients without treatment with a hepatitis B immunoglobulin product such as Nabi-HB.

When used peri-operatively in liver transplantation, Nabi-HB is administered in the in-patient hospital setting and included in the Diagnosis Related Group, or DRG, reimbursement amount for the procedure. When Nabi-HB is administered as part of the patient's follow-up care in a physician office setting, the MMA establishes the reimbursement rate to average sales price plus 6% from January 2004. Beginning in January 2006, the MMA will allow physicians to choose to

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purchase and store pharmaceutical products in their offices, or to order the product from a distributor who will be responsible for securing reimbursement from the government or other third party payers.

In the EU, RPS is expected to be applied to Nabi-HB Intravenous as certain EU countries currently reimburse for hepatitis immune globulin products that would compete with Nabi-HB Intravenous.

Nabi-HB Intravenous has received Orphan Drug Designation from the FDA for prevention of re-infection of hepatitis B disease in HBV-positive liver transplant patients, entitling us to marketing exclusivity in the U.S. for this indication for a period of seven years post licensure.

### *Civacir [Hepatitis C Immune Globulin (Human)]*

Civacir is an investigational human polyclonal antibody product that contains antibodies to hepatitis C virus, or HCV. Pre-clinical studies indicate that Civacir contains antibodies that are neutralizing to HCV. We are developing Civacir to prevent re-infection with hepatitis C disease in HCV-positive liver transplant patients, an unmet medical need among these patients. During surgery and in the period immediately following transplant surgery, patients do not have any licensed treatment options to prevent re-infection of the transplanted liver. Re-infection of the transplanted liver is 100% after surgery in HCV-positive patients.

Civacir aligns with our commercial model for Nabi-HB, focused on infectious disease and the organ transplant market. The product applies our clinical, regulatory, manufacturing and commercial expertise in antibody technology to the treatment of HCV liver transplant patients. We intend to manufacture Civacir in our state-of-the-art fractionation and purification facility and market the product through our own sales force.

Civacir is derived from human plasma enriched with HCV antibodies collected from screened donors at our nine FDA licensed antibody collection centers. Using the process of fractionation we purify and concentrate the antibodies that neutralize HCV. The antibodies in Civacir have been shown in animal studies to neutralize HCV. It is believed that the antibodies against HCV in Civacir bind to the virus in the blood stream and help the body's immune system to clear these viruses before they re-infect critical organs, such as a transplanted liver in a HCV-positive patient.

HCV is a major cause of acute hepatitis C and chronic liver disease, including cirrhosis and liver cancer. The World Health Organization, or WHO, estimates that about 170 million people, or 3% of the world's population are chronically infected with HCV and 2 to 4 million people are newly infected each year. The CDC currently estimates there are approximately 2.7 million individuals in the U.S. chronically infected with HCV.

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 resulting in the need for liver transplantation. In the U.S. and EU, approximately 40% of liver transplants are due to HCV infection. Moreover, during surgery and in the period immediately following, these patients have no treatment options to prevent re-infection of the transplanted liver. Re-infection of the transplanted liver is 100% 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.

In 2004, we announced results from a Phase I/II clinical trial of Civacir in HCV-positive liver transplant patients funded by The National Institute of Allergy and Infectious Diseases, or NIAID, which is a part of the NIH. The trial was conducted by the NIAID sponsored Collaborative Anti-Viral Study Group at four study sites in the U.S. This trial was a three-armed, randomized, controlled clinical study evaluating two different dose levels of Civacir in a total of 18 patients undergoing liver transplantation. In this trial, the NIH

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evaluated the safety of dosing patients with Civacir during and after transplant surgery. The NIH also evaluated 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. Although this trial was not designed to show efficacy, the results contributed to supporting the safety of Civacir in this patient population and will assist us in defining the efficacy markers that may be important in subsequent Phase II and III clinical trials. Preliminary results from this trial were released in February 2004. The results showed that Civacir was well tolerated at both dose levels. In addition, a trend towards a reduction in ALT levels, an important indicator of improved liver function, was observed. There also appeared to be a reduction in viral levels in liver tissue in the group receiving high dose Civacir. This data will be used to define our continued development strategy for Civacir.

Civacir has received Orphan Drug Designation from the FDA for use in prevention of re-infection with HCV in HCV-positive liver transplant patients, entitling us to seven years marketing exclusivity post licensure for this indication.

### NICOTINE ADDICTION

#### *NicVAX (Nicotine Conjugate Vaccine)*

NicVAX is an investigational vaccine designed as an aid to smoking cessation, as well as an aid to prevent relapses of a treated smoker.

NicVAX represents an opportunistic application of our conjugate vaccine technology that allows us to address a significant medical need. We believe that broad commercialization of NicVAX will be in conjunction with a marketing partner that has a demonstrated expertise in executing large scale sales and marketing programs because the physician audience will be very broadly and focused outside the hospital setting.

Nicotine is a small molecule that upon inhalation into the body quickly passes into the bloodstream and subsequently reaches the brain by crossing the blood-brain barrier. Once in the brain, the nicotine binds to specific nicotine receptors that result in the release of stimulants, such as dopamine, providing the smoker with a positive sensation, which causes addiction. NicVAX is designed to stimulate the immune system to produce antibodies that bind to nicotine in the bloodstream and prevent it from crossing the blood-brain barrier and entering the brain. The net effect is that the brain does not produce the positive sensation stimulants as a response to nicotine. Pre-clinical animal studies with NicVAX have shown that vaccination could 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.

According to the World Health Organization, or WHO, there are approximately 1.3 billion smokers worldwide, including 65 million in the U.S. Among the 65 million smokers in the U.S., 70% have an expressed desire to quit. However, of smokers who do attempt to quit, up to 90% relapse. In addition, according to CDC estimates, smoking is directly responsible for approximately 440,000 deaths in the U.S. each year, which makes it one of the largest causes of preventable death in the U.S. The financial implications are equally staggering and it is estimated that smoking results in an annual health-related economic cost of approximately \$157 billion. According to the WHO, tobacco use is expected to kill 4 million people worldwide within the next year.

Nicotine addiction is difficult to treat effectively. We believe NicVAX has advantages over existing treatment therapies because NicVAX's effect is irreversible for potentially six to 12 months following vaccination as antibodies to nicotine continue to be produced by the body's immune system. This is important due to the extremely high relapse rate that has been observed when a smoker attempts to quit smoking. Currently, the smoker is being treated for nicotine addiction can stop using the therapy and resume their addiction.

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In September 2004, we announced the results of a Phase II dose response, double-blinded, placebo-controlled, randomized clinical trial in 63 smokers. The objectives of the study, which were met, were to demonstrate that NicVAX was able to safely generate nicotine-specific antibodies in smokers, and to assess its potential use as an aid in smoking cessation among smokers who wanted to quit. The effect of the vaccine in the limited number of smokers included in the trial, and therefore not statistically significant, indicated a 33% quit rate in smokers who received NicVAX at the highest dose level versus 9% in the placebo group. The results represented a vaccine-only effect, as patients were only given NicVAX without any supplemental treatments, behavioral support or counseling. This trial was funded in part by a grant from the National Institute of Drug Abuse, or NIDA. Based on these results, we have initiated a second Phase II clinical trial in the EU dosing NicVAX at doses equal to and higher than those administered in the first Phase II clinical trial and at more frequent intervals. The clinical end points of this trial are also to assess safety, measure nicotine specific antibody titers and measurement of smoking cessation.

In February 2004, we announced the results of a placebo controlled, double-blinded 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 end point of this trial was to evaluate the development of nicotine specific antibody levels and safety of the vaccine in study participants. The results showed that multiple injections of NicVAX were well tolerated and resulted in a rapid and boosted immune response that generated nicotine specific antibodies.

### OTHER - HEMATOLOGY AND ONCOLOGY

#### *WinRho SDF [Rh<sub>0</sub>(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, or thrombocytopenia, that can result in excessive bleeding.

We market WinRho SDF in the U.S. 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 after accounting for the cost of production and marketing and sales expense. Our license and distribution agreement with Cangene ends on March 24, 2005 and we will no longer market WinRho SDF after that date.

WinRho SDF is generally administered as a part of the patients care in a physician office setting. The MMA establishes the reimbursement rate to average sales price plus 6% from January 2004. Beginning in January 2006, the MMA will allow physicians to choose to purchase and store pharmaceutical products in their offices or to order the product from a distributor who will be responsible for securing reimbursement from the government or third party payers.



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### *Aloprim [(Allopurinol sodium) for injection]*

Aloprim is indicated for the treatment of chemotherapy-induced hyperuricemia, or elevated uric acid levels, for patients with leukemia, lymphoma or solid organ tumors that cannot tolerate oral therapy. Complications associated with chemotherapy-induced hyperuricemia in these patients include renal failure.

The Leukemia and Lymphoma Society estimates that approximately 96,000 patients will be diagnosed with leukemia and lymphoma in the U.S. in 2004. These patients could potentially be at-risk for developing chemotherapy-induced hyperuricemia.

Aloprim is generally administered in the in-patient hospital setting. When administered as part of in-patient care in a hospital, Aloprim is included in the DRG reimbursement amount for the related procedure.

In 2004, we exercised our right under our distribution agreement to acquire Aloprim from DSM Pharmaceuticals, Inc., or DSM. In conjunction with acquiring Aloprim, we entered into a manufacturing agreement with DSM for DSM to continue to supply product to us for a term of up to five years.

### CONTRACT MANUFACTURING

We have a state-of-the-art facility for the fractionation and purification of human immunoglobulin. Our facility was designed to accommodate manufacture of Nabi-HB, as well as our antibody-based products in clinical development, Altastaph and Civacir. Based on current utilization forecasts, we have available manufacturing capacity for the manufacture of the antibody-based products of other companies on a contract basis. Although we do not consider contract manufacturing to be a core operating strategy, we utilize contract manufacturing to partially offset the fixed costs for maintaining the facility.

Potential contract manufacturing customers are primarily research and development stage companies that do not possess their own manufacturing capacity or companies that possess mature products that are being manufactured in older facilities that would require significant capital expenditure to upgrade to current compliance requirements.

Our facility has been licensed by the FDA since 2001 and, as such, is among the most recently licensed fractionation and purification facilities in the U.S.

### CURRENTLY MARKETED ANTIBODIES

We operate nine FDA licensed antibody collection centers located in six states within the U.S. that supply specialty antibodies and non-specific antibodies to our customers in the pharmaceutical and diagnostic industries. Our operating strategy for these products is to sell our excess production under contracts that provide a consistent operating cash flow. As we are able to achieve licensure for antibody-based biopharmaceutical products in our research and development pipeline, we anticipate a strategic shift in our antibody segment of converting production of non-specific antibodies into the production of specialty antibodies which we will use to manufacture our own antibody-based biopharmaceutical products.

### *Specialty Antibodies*

Specialty antibody products contain high concentrations of a specific antibody and are used primarily to manufacture antibody-based biopharmaceutical products to treat chronic immune disorders and to prevent and treat viral and bacterial diseases as well as to develop diagnostic products.

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We identify potential specialty antibody donors through screening and testing procedures. We also have developed FDA-licensed programs to vaccinate potential donors to stimulate their production of specific antibodies. We believe that our antibody collection capabilities, operational expertise in donor immunization programs, clinical and medical experience in conducting clinical trials under Investigational New Drug Applications, or IND's, and access to a diverse antibody donor base provides us with the ability to produce specialty antibodies.

Our specialty antibody products include hepatitis B, Rh<sub>0</sub>D, tetanus, cytomegalovirus, or CMV, Varicella Zoster Virus, or VZV, and rabies antibodies as well as other plasma products sold to diagnostic customers. Hepatitis B antibodies are the primary raw material in the manufacture of Nabi-HB.

### *Non-specific Antibodies*

Our nine FDA licensed antibody collection centers also supply non-specific human antibodies from normal healthy donors to our customers.

Although non-specific antibodies lack high levels of antibodies to specific antigens, such antibodies are used by our customers to manufacture standard IVIG, a product used to fight infections, and in the treatment of several conditions, including bone marrow transplantation, B-cell chronic lymphocytic leukemia, hypogammaglobulinemia, Kawasaki syndrome and other chronic immune deficiencies.

### **Sales and Segment Sales**

Sales of our biopharmaceutical products totaled \$131.8 million in 2004 compared to \$109.5 million in 2003 and \$89.5 million in 2002. In 2004, biopharmaceutical products accounted for 73% of our sales and 96% of our gross margin.

Total sales of our antibody products were \$48.0 million in 2004 compared to \$67.1 million in 2003 and \$106.5 million in 2002. These decreases were expected due to the conclusion in April 2003 of a single supply contract that generated no gross margin. We retained this contract after the sale of the majority of our antibody collection business and testing laboratory in September 2001. In 2004, antibody products accounted for 27% of our sales and 4% of our gross margin.

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### Research and Development Programs

The following table provides the estimated amounts spent during the last three fiscal years on our research and development programs:

Dollars in Thousands	For the Years Ended		
	December 25, 2004	December 27, 2003	December 28, 2002
StaphVAX	\$ 47,392	\$ 15,031	\$ 8,515
Altastaph	3,073	1,849	691
Other Gram-positive products	482	390	517
<b>Total Gram-positive</b>	<b>50,947</b>	<b>17,270</b>	<b>9,723</b>
Other clinical programs including Civacir and NicVAX, net of reimbursed amounts	5,803	6,219	5,805
Other, pre-clinical programs	271	446	524
PhosLo, including PhosLo CKD	2,506	533	—
Nabi-HB and Nabi-HB Intravenous and other currently marketed products	1,476	4,572	5,044
<b>Total</b>	<b>\$ 61,003</b>	<b>\$ 29,040</b>	<b>\$ 21,096</b>

Research and development expenses of approximately \$0.3 million, \$1.3 million and \$1.2 million related to the NicVAX program were reimbursed by the National Institute on Drug Abuse, or NIDA, for fiscal years 2004, 2003 and 2002, respectively.

### STRATEGIC ALLIANCES

We enter into strategic alliances for the manufacture and commercialization of some of our marketed and pipeline products. Our current key strategic alliances are discussed below.

#### *Cambrex Bio Science Baltimore, Inc.*

In October 2003, we entered into a contract manufacturing agreement with Cambrex Bio Science to produce commercial quantities of StaphVAX.

We entered into our contract manufacturing agreement with Cambrex Bio Science in order to have available commercial scale manufacturing capacity to launch the product in Europe and the U.S. The manufacturing process for StaphVAX has been transferred to Cambrex Bio Science from a previous contract manufacturer, as well as from our research and development pilot plant in Rockville, Maryland. In August 2004, we completed the manufacture of three consistency lots of StaphVAX, thereby completing the transfer of the manufacturing process to Cambrex Bio Science. The manufacturing and other technical data from these lots was included in the MAA we filed for StaphVAX December 2004.

Our manufacturing agreement has an initial seven-year term and requires us to make certain payments to Cambrex Bio Science to secure future access to commercial vaccine manufacturing

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capacity and to enable Cambrex Bio Science to ready its facility for the future commercial scale manufacture of StaphVAX. The agreement can be extended an additional three years. The agreement also sets the terms for future purchases of manufactured bulk vaccine.

### *Public Health Services/National Institutes of Health*

Under a license agreement with the Public Health Services/National Institute of Health, or PHS/NIH, we have the exclusive, worldwide right to use their patented conjugation process to manufacture vaccines against *staphylococcal* infections including StaphVAX.

During the term of the license we are obligated to pay PHS/NIH a royalty based on net sales of products made using this technology. This agreement remains in effect until the expiration of the last-to-expire licensed patent, or April 20, 2010. After this date, no further royalties will be due to PHS/NIH for use of the subject technology. In addition to our license with PHS/NIH we own an extensive global portfolio of issued patents and pending patent applications directed to our novel vaccine products and methods of using such products as described in further detail below under "Patents and Proprietary Rights".

### *Chiron Corporation*

We have an agreement with Chiron Corporation, or Chiron, that grants us an exclusive supply agreement for four vaccines, including hepatitis C. In addition, we have rights to 10 additional Chiron vaccines for use in humans to produce immunotherapeutic products. The agreement may also grant us access to a vaccine adjuvant, MF 59.

This agreement may be important to the development of the next generation of our investigational product, Civacir.

We will be responsible for all development, manufacturing and worldwide distribution of these products. We may terminate the agreement on a product-by-product basis in which event we must transfer to Chiron all of our rights with respect to the product as to which the agreement has been terminated. Similarly, Chiron may terminate its obligations to supply immunizing agents to us on a product-by-product basis, in which event Chiron shall grant to us a license of the technology necessary for us to manufacture the applicable immunizing agent and the financial arrangements in the Chiron Agreement with respect to such agent shall continue.

### *Pfizer*

In April 2003, we licensed the worldwide rights to our whole cell vaccine technology for the prevention and treatment of *S. aureus* infections in cattle to Pfizer. In a letter dated March 2, 2005, Pfizer notified us that they would not pursue further development of this product and were terminating the license agreement with us. Pursuant to the license agreement, we retain our full rights to information and data generated under this agreement and have no further obligations to Pfizer.

## **CUSTOMER RELATIONSHIPS**

We sell our biopharmaceutical products to wholesalers, distributors, hospitals and home healthcare companies and sell our antibody products to pharmaceutical and diagnostic product manufacturers.

We sell biopharmaceutical products to AmerisourceBergen, Cardinal Health, Inc. and McKesson Drug Co. under purchase orders placed by them on terms that are generally between 30 days, net and 60 days. During 2004 and in February 2005, we have entered into inventory distribution services agreements with two of our major wholesaler customers that establish that these customers will provide us defined services for a fee measured as at least a minimum discount from our standard prices. We do not believe that these fees will exceed to any material extent the negotiated discounts that have been provided to these customers for the 2004 fiscal year.

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In connection with the sale of the majority of our antibody collection business and testing laboratory, we entered into an agreement for the purpose of assuring that each party would have the ability to meet supply commitments to customers of the transferred business after completion of the sale. Under this agreement we were obligated to provide to the purchaser Rh<sub>0</sub>D antibodies at our cost plus a handling fee in order that the purchaser might fulfill its obligations under a contract it assumed. This agreement, which ended on December 31, 2004, limited our ability to sell these antibodies to other customers at higher margins during 2004.

Pricing for product deliveries under our antibody contract products is fixed for the contract term, generally one year or less, although the contracts generally provide for price increases/decreases during the contract term to reflect changes in customer specifications or new governmental regulations. In addition, in 2004 we expect to sell antibody products in individually negotiated transactions that will be subject to market conditions at the time of negotiation. Our profit margins for these transactions may be adversely or beneficially affected by market conditions for antibody products at those times.

Sales for the year ended December 25, 2004 to significant customers included sales to three customers of our biopharmaceutical products segment, Cardinal Health, Inc., McKesson Drug Co., AmerisourceBergen and one customer of our antibody products segment, Bayer Corporation, representing 26%, 25%, 23% and 15% of total consolidated 2004 sales, respectively.

### **SUPPLY AND MANUFACTURING**

#### *Biopharmaceutical Products*

We manufacture Nabi-HB in our FDA approved biopharmaceutical manufacturing facility in Boca Raton, Florida. Additionally, we manufacture clinical lots of our investigational products, Altastaph and Civacir, in this facility. We have constructed a state-of-the-art bulk vaccine manufacturing capacity within available space in our Boca Raton manufacturing facility. The vaccine production capacity, once licensed, will be used initially to support the commercial manufacture of StaphVAX following FDA approval. We designed this manufacturing capacity to be flexible and expandable so as to support the manufacture of StaphVAX and NicVAX, as well as our next generation Gram-positive vaccines in our research and development pipeline.

In October 2003, we entered into an agreement with Cambrex Bio Science in order to have commercial scale manufacturing in place to support the launch of StaphVAX in Europe and in the U.S. In August 2004, we completed manufacture of the consistency lots that were required to support the MAA. We also intend to incorporate the Cambrex Bio Science manufacturing facility into our BLA for StaphVAX that we expect to file by the end of 2005.

Third parties manufacture each of our marketed products other than Nabi-HB for us. 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. DSM Pharmaceuticals, Inc. manufactures Aloprim for us under an agreement that extends to June 2009.

#### *Antibody Collection Process*

We currently collect and process antibodies from our nine collection centers located in six states across the U.S. Each center is licensed and regulated by the FDA.

## PATENTS AND PROPRIETARY RIGHTS

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 over 30 granted patents and over 60 patent applications pending.

### *Marketed products*

#### PhosLo

We have two patents granted in the U.S., one patent granted in Canada and one patent application allowed 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 patent claims support the use of PhosLo for our approved application in ESRD patients. Patent coverage for these claims expires in April 2007 in the U.S. and in 2012 in Canada. We also have another U.S. patent granted and a U.S. patent application allowed with claims to a second-generation, phosphorus-binding capsule formulation. The next generation capsules are intended to enhance ease of patient use and, as a result, improve treatment management. This granted U.S. patent expires in April 2021 and any patent granted on the pending U.S. application would expire in October 2022.

### *Products in development*

We have 25 patents issued including six U.S. patents, 15 patents in European countries and four in other countries and 38 patents pending worldwide relating to our Gram-positive infections program. With respect to *Staphylococcus*, the patents and pending patent applications relate both to polysaccharide antigens—our “336” *S. aureus* antigen and “PS-1” *S. epidermidis* antigen—and to a glycopeptide antigen common to *S. epidermidis*, *S. haemolyticus* and *S. hominis*. Additional issued patents relate to *Enterococcus* and describe polysaccharide antigens from *E. faecalis* and *E. faecium*, respectively.

In addition to the PHS/NIH patent with respect to which we license rights that relate to the manufacture of StaphVAX, our granted U.S. patents and ex-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. The patent underlying our PHS/NIH licensed rights expires on April 20, 2010. After this date, no further royalties will be due to the PHS/NIH for use of the technology. 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. With regard to *S. epidermidis*, we have issued U.S. patents and ex-U.S. patents, including European countries. The patents contain claims to vaccines and hyperimmune globulins against *S. epidermidis* surface antigen. Most of these patents expire in 2016.

In addition, we have an issued U.S. patent and ex-U.S. patent applications pending that contain claims directed to a pharmaceutical composition containing a glucan and intravenous hyperimmune globulin, which can be specific for a given pathogen like *S. aureus*. This combination produces an unexpected antimicrobial effect that is greater than that obtained when either the glucan or the intravenous hyperimmune globulin is used separately.

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### *NicVAX*

Our patent portfolio for technology related to the NicVAX product comprehends both compositions and therapeutic methodology for treating or preventing a nicotine addiction. Our patent claims are directed to compositions, or conjugates, that comprise nicotine-like molecule 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 nicotine specific antibodies induced by 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 skills, knowledge and experience of our scientific and technical personnel, as well as those of our advisors, consultants and other contractors that cannot be patented. 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 international trademark registrations or common law rights, for each of our marketed and development products.

## **GOVERNMENT AND INDUSTRY REGULATION**

The collection, processing and sale of our products, as well as our research, pre-clinical development and clinical trials, are subject to regulation for safety and efficacy by numerous governmental authorities including the U.S., UK, Germany, Spain, Italy, Australia and France. In the U.S., the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and other Federal and state statutes and regulations govern the collection, testing, manufacturing, safety, efficacy, labeling, storage, record keeping, transportation, approval, advertising and promotion of our products. We believe we are in compliance with all relevant material laws and regulations.

### *Biopharmaceutical Products*

Vaccines and human polyclonal antibody products are classified as biological products under FDA regulations. The steps required before a biological product may be marketed in the U.S. generally include pre-clinical studies and the filing of an Investigational New Drug application, or IND application, with the FDA, which must be accepted by the FDA before human clinical studies may commence. The initial human clinical evaluation, called a Phase I clinical trial, generally involves administration of a product to a small number of normal, healthy volunteers to test for safety. Phase II clinical trials involve administration of a product to a limited number of patients with a particular disease to determine dosage, immunogenicity and safety. In some cases Phase II clinical trials may provide limited indications of efficacy. Phase III clinical trials examine the efficacy and safety of a product in an expanded patient population. Phase IV clinical trials primarily monitor for adverse effects and are undertaken post-licensure, such as additional large-scale, long-term studies of morbidity and mortality. The FDA reviews the clinical plans and the results of trials and can stop the trials at any time if there are significant safety issues. Biological products, once approved, currently have no provision allowing competitors to market generic versions. Each biological product must undergo the entire development process in order to be approved.

The results of all trials are submitted in the form of a BLA or a New Drug Application, or NDA, for small molecules. The BLA or NDA must be approved by the FDA prior to commencement of commercial sales. For BLA/NDA approval, the FDA requires that the sponsor demonstrate a

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favorable risk-benefit ratio. This often involves treatment of large numbers of patients, typically in double-blinded, placebo controlled or comparative randomized trials, followed for protracted periods of time. The actual size of the trials, and the length of follow-up vary from indication to indication. In addition, the prospective manufacturer's methods must conform to the agency's current Good Manufacturing Process, or cGMP regulations, which must be followed at all times. The prospective manufacturer must submit three conformance lots in support of the application. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production, compliance and quality control to ensure full regulatory compliance. The approval process is affected by several factors, including the severity of the disease, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. The FDA also may require post-marketing surveillance to monitor potential adverse effects of the product. The U.S. Congress, or the FDA in specific situations, can modify the regulatory process.

The overall regulatory process is similar within the EU insofar as the sponsor needs to demonstrate a favorable risk-benefit ratio of the drug product, as well as reproducible manufacturing methods. The European equivalent of the BLA/NDA is called the MAA. There are two different procedures to file a MAA, the Centralized Registration Procedure and the Mutual Recognition Procedure. The Centralized Procedure allows for simultaneous approval throughout the EU. The Mutual Recognition Procedure provides for initial approval in one country that can be used to seek approval in additional countries within the EU. There have been different requirements from country to country with regard to initiating clinical trials, however, that is also in the process of being standardized. A new standardized procedure, the Clinical Trials Application was introduced in the EU during 2004.

### *Medicare Prescription Drug Improvement and Modernization Act and Reimbursement*

Effective January 1, 2006, the MMA will include an outpatient prescription drug benefit, under a new Part D. This benefit will provide reimbursement for PhosLo. The new benefit is designed such that after paying an initial estimated premium fee of approximately \$37 per month the patient would be responsible for the following co-payment structure:

<u>Prescriptions costs</u>	<u>Patient Responsibility</u>	<u>Patient Responsibility</u>
\$0 - \$250	\$ 250	100%
\$251 - \$2,250	\$ 500	25%
\$2,251 - \$5,100	\$ 2,850	100%
\$5,100 - above	5% of all costs	5%

The Medicare Part D program will be administered through a combination of Prescription Drug Plans, or PDP's, or Medicare Advantage Plans. The plan design is for the PDP's to assume 100% of the financial risk for this patient population. The MMA requires that each plan offer a minimum of two products in each therapeutic class. Because of the risk bearing nature of the Part D program, PDP's are likely to seek to manage their risk by selecting products that are both efficacious and low cost. As the lowest cost prescription phosphate binder currently market in the US, we believe that the Part D benefit may provide us an opportunity to grow sales and increase market share of PhosLo following implementation of the MMA in January 1, 2006. Prior to the enactment of Part D, the U.S. Federal government introduced a Medicare Discount Card as an interim step until full implementation of the Part D in 2006. Enrollment in the drug discount card program has been relatively low among Medicare participants. We did not participate in the card program.

### *Antibody Products*

The FDA strictly regulates the collection, storage and testing of antibodies and antibody based products derived from human plasma. In order to operate in the U.S., an antibody



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collection facility must hold a Biologics License issued by the FDA's Center for Biologics Evaluation and Research. Each collection facility must be regularly inspected and approved in order to maintain licensure. In addition, collection centers require FDA product licenses to collect each specialty antibody product. We are also subject to and are required to be in compliance with pertinent regulatory requirements of countries to which we export antibody products.

### *Orphan Drug Act*

In January 2004, the FDA granted our investigational product Altastaph, Orphan Drug Designation for use in neonate patients for protection against *S. aureus* infections. Nabi-HB Intravenous has received Orphan Drug Designation under this Act for prevention of hepatitis B re-infection in liver transplant recipients. We filed a BLA for this product in November 2002. In November 2002, the FDA granted our investigational product, Civacir, Orphan Drug Designation for prevention of hepatitis C infection in HCV-positive liver transplant recipients.

Under the Orphan Drug Act, the FDA may designate a product as having Orphan Drug status to treat a "rare disease or condition", which currently is defined as a disease or condition that affects populations of less than 200,000 individuals in the U.S. at the time of designation, or, if victims of a disease number more than 200,000, for which the sponsor establishes that costs of development will not be recovered from U.S. sales in seven years. When a product is designated an Orphan Drug, the sponsor is entitled to receive certain incentives to undertake the development and marketing of the product. In addition, the sponsor that obtains the first marketing approval for a designated Orphan Drug for a given indication effectively has marketing exclusivity for a period of seven years. There may be multiple designations of Orphan Drug status for a given drug and for different indications. However, only the sponsor of the first BLA approved for a given drug for its use in treating a given rare disease may receive marketing exclusivity.

### *Fast Track Designation*

StaphVAX has been granted Fast Track review designation for the ESRD patient indication while Altastaph has been granted Fast Track review designation for use in very low birth weight neonate patients.

Fast Track designation refers to a process of interacting with the FDA during drug development. The Fast Track mechanism is described in the Food and Drug Administration Modernization Act of 1997. The benefits of the Fast Track designation include scheduled meetings to seek FDA input into development plans, the option of submitting a BLA in sections rather than all components simultaneously and the option of requesting evaluation of studies using surrogate endpoints. The Fast Track designation is intended for a combination of a product and a claim that addresses an unmet medical need. The Fast Track mechanism is independent of Priority Review and Accelerated Approval.

## **COMPETITION**

### *Biopharmaceutical Products*

PhosLo competes with Renagel, a prescription product marketed by Genzyme Corporation, and over-the-counter calcium carbonate products, such as TUMS in the U.S. PhosLo competes with these products on the basis of its efficacy as a phosphate binder and its compliance with key elements of the K/DOQI guidelines issued by the NKF as demonstrated in the CARE study. As compared to Renagel, PhosLo also competes on the basis of a cost of treatment advantage that was also established in the CARE study. Review of third party prescription data indicates that PhosLo is prescribed at approximately the same rate as Renagel among ESRD patients.

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The FDA approved Shire Pharmaceuticals', or Shire's, product Fosrenol for the control of hyperphosphatemia in September 2004. To date Shire's marketing activities have been limited, but we anticipate that we will begin to compete with Fosrenol in the U.S.

In the EU, PhosLo will compete with Renagel, Fosrenol and other calcium acetate products, as well as calcium carbonate products, which are generally prescription products in the EU.

There is one antibody-based therapy for prevention of hepatitis B post exposure currently on the market that competes with Nabi-HB in the U.S. Based on our internal market studies, we believe that Nabi-HB has achieved a significant share of the U.S. market. We believe the majority of our Nabi-HB sales are for use to prevent re-infection with hepatitis B disease in HBV-positive liver transplant patients. In November 2002, we submitted a BLA to the FDA for Nabi-HB Intravenous seeking the indication that Nabi-HB Intravenous prevents re-infection with hepatitis B disease in HBV-positive liver transplant patients and have received Orphan Drug Designation for this indication. If approved, Nabi-HB Intravenous will have seven years marketing exclusivity on the basis of its Orphan Drug Designation.

In June 2004, we submitted a MAA filing for Nabi-HB Intravenous, known as HEBIG in the EU to European regulators. If approved in the EU, Nabi-HB Intravenous will compete in the market to prevent re-infection with hepatitis B disease in HBV-positive liver transplant patients. Unlike the U.S., competitive intravenous hepatitis B immune globulin products are already marketed in most of the EU.

In addition, Nabi-HB also competes in the U.S. and, if approved, in the EU with anti-viral products that, like Nabi-HB, are not currently indicated for use to prevent re-infection in HBV-positive liver transplant patients.

WinRho SDF is the only Rh<sub>0</sub>D antibody based biopharmaceutical product approved for the treatment of ITP. Competing therapies include, steroids, intravenous immune globulin and splenectomy, a surgical procedure to remove the spleen. We believe that Rituxan is also being used to treat refractory ITP patients. Cangene manufactures WinRho SDF for us under an agreement that ends in March 2005.

Aloprim was 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 the third quarter of 2004, a competitive intravenous allopurinol product formulation was introduced to the U.S. market and is competing based on price.

### *Antibody Products*

We sell antibody raw materials to pharmaceutical companies that process this raw material into finished products. Although these pharmaceutical companies generally own plasmapheresis centers, in the aggregate they purchase a portion of their antibody requirements from independent suppliers. There is competition with independent suppliers as well as fractionators who own their own plasmapheresis centers. We compete for sales by maintaining competitive pricing and by providing customers with high-quality products and superior customer service.

## **EMPLOYEES**

We believe that the relations between our management and our employees are generally good. None of our employees are covered by a collective bargaining agreement.

We had a total of 727 employees at December 25, 2004.

## FINANCIAL INFORMATION ABOUT SEGMENTS AND GEOGRAPHIC AREAS

We have provided financial information about (i) our industry segments, and (ii) our domestic and foreign operations for each of the last three fiscal years in Note 21 to our consolidated financial statements set forth in Part II of this Annual Report on Form 10-K.

## AVAILABLE INFORMATION

Our Internet address is <http://www.nabi.com>. We make available, free of charge, through our Internet website 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 Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.

## RISK FACTORS

This document contains forward-looking statements that reflect our current expectations regarding future events. Any such forward-looking statements are not guarantees of future performance and involve significant risks and uncertainties. Actual results may differ significantly from those in the forward-looking statements as a result of any number of factors, including, but not limited to, risks relating to the possibility that our confirmatory Phase III clinical trial for StaphVAX or our plans to commercialize StaphVAX in the EU and the U.S. may not be successful; our inability to raise additional capital on acceptable terms; the possibility that we may not realize the value of our acquisition of PhosLo; our dependence upon third parties to manufacture our products; our ability to utilize the full capacity of our manufacturing facility; the impact on sales of Nabi-HB from patient treatment protocols and the number of liver transplants performed in HBV-positive patients; reliance on a small number of customers; the future sales growth prospects for our biopharmaceutical products; and our ability to obtain regulatory approval for our products in the U.S. or in markets outside the U.S. or to successfully develop, manufacture and market our products. These factors and others are more fully discussed below.

Each of the following risk factors could adversely affect our business, operating results and financial condition.

*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. We have now completed 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 may not be successful.*

We filed a MAA for StaphVAX in the EU using the Centralized Registration Procedure in December 2004. We plan to file a BLA for StaphVAX in the U.S. by the end of 2005. There can be no assurance that we will file the BLA by the end of 2005, or that we will receive approval to begin commercial sales of StaphVAX in the EU or the U.S., or that such approval will be timely. If we receive regulatory approval in Europe we will then need to seek reimbursement approval in specific EU country markets. There can be no assurance that StaphVAX will receive reimbursement pricing from any or all of the markets where we seek such approval or that

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reimbursement, if approved, will be at sufficient levels in each market. Any delays in or failure to obtain EU licensure or reimbursement approvals, or the failure to obtain reimbursement approvals at sufficient levels, and any delays in commercialization could adversely affect our market valuation, results of operations and our financial position and could impact the overall commercial success of StaphVAX. We have no direct experience in obtaining licensure or reimbursement for vaccines in the EU, U.S., or other markets.

Although we believe that our U.S. sales and marketing model can be readily translated to other markets, we may not be successful in doing so. We have no direct experience marketing and selling biopharmaceutical products in the EU, and currently we have no sales or marketing organization to sell and distribute StaphVAX in the EU.

*A number of our product candidates and marketed products in development are in or will undergo clinical trials and the results from these trials may not be favorable.*

Aside from the current Phase III clinical trial for StaphVAX, a number of our products in development are in, or will undergo clinical trials. These trials may not meet their defined endpoints, and, even if they do achieve their endpoints, we cannot be certain that results from future clinical trials will be positive. Unfavorable clinical trial results at any stage could adversely affect our market valuation and our future business.

For instance, in November 2004, we announced the results of our Phase II clinical trial for prevention of *S. aureus* bloodstream infections in very low birth-weight newborns. The study met its primary endpoints, namely, Altastaph was safe and well tolerated and patients dosed with Altastaph were on average maintained above protective levels of antibodies for the entire 42-day study period. However, the rate of *S. aureus* infections in the overall clinical trial population in this trial was 3%, well below the event rate reported in relevant medical literature. This rate was too low to allow us to make any inferences about the efficacy of Altastaph from this study. Our inability to establish statistically significant efficacy in subsequent confirmatory trials of Altastaph could adversely affect our business, operating results and financial condition. Further, our studies related to Altastaph have been in a limited number of patients. To date, we have not observed any significant adverse events related to Altastaph. However, the product safety profile will continue to be monitored in our clinical trials and if there is a significant adverse event related to the product this could have an adverse effect on our future business, financial condition, and results of operations.

In 2004, we initiated the CARE 2 study to demonstrate that when patients with ESRD treated with either PhosLo or Renagel achieve the same level of lipid control, there will be no significant difference in the development of coronary artery calcification thereby refuting the hypothesis that calcium intake as part of the PhosLo treatment is associated with cardiovascular calcification. The study is further designed to demonstrate that the combination of PhosLo and Lipitor will achieve superior control of serum phosphorus levels and calcium phosphorus product. Our inability to establish at least an equivalent result between the study arms could adversely affect our business, operating results and financial condition.

*Claims and concerns may arise regarding the safety or efficacy of our product candidates and marketed products, which could lead to delayed development, product withdrawals, reduced sales, or product recalls.*

In order to receive regulatory approval for the commercialization of our product candidates, we must conduct extensive clinical trials to demonstrate their safety and efficacy. Our clinical trials may not demonstrate the safety and efficacy of our potential products, and we may encounter unacceptable side effects or other problems in our clinical trials. Should this occur, we may have to delay or discontinue development of our potential products. Once obtained, any regulatory approvals may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product, such as a previously unknown safety issue. In addition,

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postmarketing studies, which may be sponsored by our competitors, may present evidence that another product is safer or more effective than one of our products, which could lead to reduced sales of our product. For example, Genzyme is conducting a study called Dialysis Clinical Outcomes Revisited, or D-COR, examining the difference in morbidity and mortality outcomes based on arterial calcification for patients receiving Renagel and those receiving calcium-based phosphate binders, including PhosLo. First results from this study are expected in mid-2005 per Genzyme's public statements. While we believe the calcium acetate formulation of PhosLo is differentiated from the calcium formulations of other binders being used in the comparative product group in the study, if the study's outcome demonstrates a significant advantage to Renagel it may have a negative impact on sales of PhosLo. Finally, claims and concerns may arise regarding the safety or efficacy of one of our marketed products, which could lead to a product recall. Delayed development, product withdrawals, reduced sales, and product recalls could adversely affect our future business, financial condition, and results of operations.

*Our plans to commercialize Nabi-HB Intravenous and PhosLo in the EU may not be successful.*

Using the Mutual Recognition Process, we filed MAA's for Nabi-HB Intravenous and PhosLo in the EU during 2004. There can be no assurance that we will receive approval to begin commercial sales of these products in this or any other country in the EU, or that such approval will be timely. Following approval in each country, we will then need to seek reimbursement in that country. There can be no assurance we will receive reimbursement approval from any or all of the countries where we seek such approval or that reimbursement, if approved, will be at sufficient levels in each country. Any delays in or failure to obtain licensure or reimbursement approvals, or the failure to obtain reimbursement approvals at sufficient levels, and any delays in commercialization could adversely affect our market valuation, results of operations and our financial position. We have no direct experience in obtaining licensure of these products in the EU or other non-U.S. markets. We have no direct experience marketing and selling biopharmaceutical products in the EU, and currently we have no direct sales or marketing organization to sell and distribute Nabi-HB Intravenous and PhosLo in the EU.

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

We may need to raise additional capital to expand our product research, development and marketing activities or to acquire additional products or technologies. In particular, we may need to raise additional capital to support commercialization of StaphVAX, to fund the development of clinical trials of Altastaph or to acquire new products and technologies. 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, 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 research, product development, manufacturing, commercialization or business development, or otherwise modify our business strategy, and it could adversely affect our market valuation, results of operations and financial position.

*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-fourth of the total assets reflected on our balance sheet at December 25, 2004. 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 had no experience prior to the acquisition of PhosLo. In the U.S., PhosLo currently competes with three other products, two prescription medications and a non-prescription medication. In the EU, PhosLo will compete with multiple prescription products. A number of these products are or will be produced, marketed and sold by companies that have substantially greater financial and marketing resources than we have.

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For example, Genzyme is conducting a study called Dialysis Clinical Outcomes Revisited, or D-COR, examining the difference in morbidity and mortality outcomes based on arterial calcification for patients receiving Renagel and those receiving calcium-based phosphate binders, including PhosLo. If D-COR achieves its defined endpoints, it may negatively impact physicians' willingness to prescribe PhosLo and, hence, negatively impact future sales of PhosLo. In addition, we expect the maker of Fosrenol, another competitive product, to begin promotion of that product. 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 market valuation, balance sheet, results of operations and financial position could be adversely affected.

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

We manufacture only one of our marketed biopharmaceutical products and depend upon third parties to manufacture PhosLo, Aloprim and WinRho SDF for us. At times, contract manufacturers have failed to meet our needs 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 Aloprim has been adversely affected at certain times by our inability to obtain necessary quantities of this product from our contract manufacturer. In addition, our research and development product pipeline significantly involves conjugate vaccines. We currently rely on a third party, Cambrex Bio Science, to manufacture StaphVAX. 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 in Europe and the U.S.

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.

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

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

*We may not be successful in licensing or operating an internal commercial scale vaccine manufacturing facility currently under development.*

We have constructed a vaccine plant in our Boca Raton, Florida manufacturing facility designed to allow us to produce vaccines in our product pipeline. We plan to submit a BLA to the FDA for licensure for the manufacture of StaphVAX in this facility in 2005 or 2006. In addition, we plan to submit a supplemental MAA to EU regulatory authorities for licensure for the manufacture of StaphVAX in this facility with a goal of being a back-up site for the production of StaphVAX for

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commercial sale in the EU following approval. No assurance can be given that we will be able to obtain such licensure on a timely basis or at all, and failure to obtain such licensure on a timely basis, or at all, would have a material adverse effect on our future business, financial condition and results of operations.

The new plant is designed to process several vaccines on a commercial scale. We have not previously owned or operated such a facility and have no direct experience in commercial, large-scale manufacturing of vaccine products. There can be no assurance that, if FDA and EU licensures are received, the facility can be operated efficiently and profitably. Our failure to successfully operate our new manufacturing facility would have a material adverse effect on our future business, financial condition and results of operations.

*We are not currently able to utilize the full capacity of our plasma fractionation facility.*

We began commercial manufacture of Nabi-HB at our Boca Raton biopharmaceutical manufacturing facility in the fourth quarter of 2001 and intend to expand the use this facility for the manufacture of polyclonal antibody products in our clinical product pipeline including, Altastaph and Civacir, and for the manufacture of products of other parties. For the foreseeable future, we may not utilize the full manufacturing capacity of the facility and there can be no assurance that we will ever 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 fully utilize the capacity of the plant or to manufacture products successfully could have a material adverse effect on our future business, financial condition and results of operations.

*A disaster at our sole manufacturing sites 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 BLA license application for Nabi-HB Intravenous may not be approved.*

Our BLA license application for Nabi-HB Intravenous that was filed in November 2002 may not be approved by the FDA. Nabi-HB is a human polyclonal antibody product currently indicated to prevent hepatitis B, or HBV, infection following accidental exposure to the virus. We believe the majority of our Nabi-HB sales are used to prevent re-infection with hepatitis B disease in HBV-positive liver transplant patients. Nabi-HB is not currently labeled for this use. Our inability to obtain licensure from the FDA for Nabi-HB Intravenous could have an 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, over which we have no control.*

Our sales of Nabi-HB are primarily for the care of HBV-positive liver transplant patients at the time of and for a maintenance period following liver transplant. The number of liver transplants that occur 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,

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- allocations of available organs to eligible potential recipients,
- changes in the treatment protocols applied to HBV-positive patients;
- availability of alternative treatments and competitive products, such as anti-viral products; and
- changes in reimbursement regimes including the MMA in the U.S., that may provide a negative incentive for the use of certain of our products in future periods.

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.

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

Our ability to manufacture Nabi-HB today and Nabi-HB Intravenous, HEBIG, Altastaph and Civacir, if they are licensed, will depend upon the availability of specialty antibodies that we primarily obtain from our FDA-approved antibody collection centers. We also 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, Nabi-HB Intravenous, HEBIG, Altastaph and Civacir, or to fulfill our contractual obligations, with the result that our future business, financial condition and results of operations would suffer.

*We sell our products to a small number of customers. 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. In 2004, three such customers accounted for 74% of our total consolidated sales. These customers maintain inventories of our products at levels that can range as high as six to eight months of end patient demand as measured by prescriptions written. A loss of any of the customers or a material reduction in such customer's purchases or inventories on hand at their sites 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 in 2004 were primarily to a single customer. The loss of this customer or a material reduction in its purchases of antibodies could have a material adverse effect upon our future business, financial condition and results of operations.



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*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 monoclonal antibody 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.

*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 generate revenues from sales of our biopharmaceutical and antibody products. We will cease to generate revenues from sales of one of these products, WinRho SDF<sup>®</sup>, in March 2005 when our exclusive distribution agreement in the U.S. ends. Sales of WinRho SDF may be negatively impacted in the period ended March 2005 due to this change in relationship. 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 external 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.

*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

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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,
- positive clinical results for competitive therapies in the future,
- 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.

*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 have a remaining term of up to four 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.

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*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, European Medicines Agency, or EMEA, the Paul Erlich Institute in Germany, or PEI, the German Federal Institute for Drugs and Medical Devices, or BfArM, 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, PEI, BfArM and other required regulatory approvals are 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 of the product,
- the strength of the chemistry and manufacturing control of the process,
- the compliance record and controls of the manufacturing facility,
- 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. The U.S. 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 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.

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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 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, PEI 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.

*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 have in the past resulted and will likely result in the future 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.

*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 or are developing, such as Nabi-HB, WinRho SDF, Altastaph and Civacir, 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 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.

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Pharmaceutical and biotechnology companies are increasingly subject to litigation, including class action lawsuits, and governmental and administrative investigations and proceedings related to product pricing and marketing practices. There can be no assurance that lawsuits will not be filed against us or that we will be successful in the defense of these 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 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.

*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

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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.

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 will not 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 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

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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.

Within the EU, a number of countries use price controls to limit the reimbursement for pharmaceutical products. These price control limits are often derived from the chemical entity of the product, the competitive environment for a product and pricing in relation to other products. Further, price increases in these settings in future periods may be significantly restricted or price decreases in future periods may be mandated. Reimbursement for products within the EU is negotiated in each country. There can be no assurance that that we will receive reimbursement approval from any or all of the countries where we seek such approval or that reimbursement, if approved, will be at sufficient levels in each country. Any delays in or failure to obtain licensure or reimbursement approvals, or the failure to obtain reimbursement approvals at sufficient levels, and any delays in commercialization could adversely affect our market valuation, results of operations and our financial position.

There can be no assurance that reimbursement in the U.S., the EU 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 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.

*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 junior preferred stock and the likelihood that holders of our common stock and junior preferred stock 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 acquirer 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 our securities.

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*Currency exchange rate fluctuations could adversely affect our results from operations.*

We conduct business in countries outside of the U.S., which expose us to fluctuations in foreign currency exchange rates. Fluctuations in foreign currency exchange rates may affect our results of operations, which in turn may adversely affect reported earnings and the comparability of period-to-period results of operations.

### **ITEM 2. PROPERTIES**

We own an 87,300 square foot facility that houses our corporate headquarters, our licensed biopharmaceutical manufacturing facility and our vaccine manufacturing facility in Boca Raton, Florida. We also own a 46,000 square foot facility in Boca Raton that houses our laboratory and cold storage facility.

We lease office, laboratory, pilot manufacturing and warehouse space in Rockville, Maryland with terms expiring through December 2008 with various options for lease extensions.

We occupy antibody collection centers ranging in size from approximately 3,200 to 20,800 square feet leased from non-affiliates under leases expiring through 2012. A majority of these leases contain renewal options that permit us to renew the leases for varying periods up to ten years at the then fair rental value. We believe that in the normal course of our business, we will be able to renew or replace our existing leases.

### **ITEM 3. LEGAL PROCEEDINGS**

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

### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matter was submitted to a vote of security holders in the fourth quarter of the year ended December 25, 2004.



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### **ITEM 4(a). EXECUTIVE OFFICERS OF THE REGISTRANT**

The executive officers of Nabi Biopharmaceuticals are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Thomas H. McLain	47	Chairman, Chief Executive Officer and President
Richard G. Clark	61	Senior Vice President, Administration and Chief Administrative Officer
Raafat E.F. Fahim, Ph.D.	51	Senior Vice President, Technical and Production Operations
H. LeRoux Jooste	49	Senior Vice President, Global Sales and Marketing
Henrik S. Rasmussen, M.D., Ph.D.	46	Senior Vice President, Clinical, Medical and Regulatory Affairs
Mark L. Smith	43	Senior Vice President, Finance, Chief Financial Officer, Chief Accounting Officer and Treasurer

*Mr. McLain* has served as Chairman, Chief Executive Officer and President since May 2004 and has been a director since April 2002. From June 2003 through May 2004 Mr. McLain served as Chief Executive Officer and President. From November 2002 to June 2003 Mr. McLain served as President and Chief Operating Officer. From April 2001 to November 2002, Mr. McLain 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. In February of 2004, Mr. McLain was elected to the Board of Directors of Eastman Chemical Company, based in Kingsport, Tennessee.

*Mr. Clark* has served as Senior Vice President, Administration and Chief Administrative Officer since May 2004. Mr. Clark was employed from 1994 to 2004 by Right Management Consultants where he served for ten years in positions of increasing responsibilities, most recently as Chief Operating Officer for the Florida / Caribbean region. In his role as Chief Operating Officer, Mr. Clark specialized in senior executive leadership development, strategic planning, organizational performance and career transition services. Prior to joining Right Management Consultants, Mr. Clark

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was the president of the Clark Development Group, Inc., an organizational consulting firm whose practice focused on strategic planning and business development. Previously Mr. Clark worked for twenty-two years in CEO and President capacities in the field of voluntary association management.

*Dr. Fahim* has served as Senior Vice President, Technical and Production Operations since May 2003 having been employed as Vice President of Vaccine Manufacturing Operations in March 2003. From 2002 to 2003 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 to 2002, he served as President and Chief Operating Officer of Lorus Therapeutics, Inc., a biopharmaceutical company. From 1987 to 2001, Dr. Fahim was employed by Aventis Pasteur where he was instrumental in developing several vaccines from early research to marketed products. During his employment with Aventis Pasteur Dr Fahim 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.

*Mr. Jooste* has served as Senior Vice President of Global Sales and Marketing since December 2004. From July 2002 to December 2004, Mr. Jooste was Vice President of Worldwide Product Planning for Cephalon, Inc. From June 2001 to June 2002, Mr. Jooste served as Chief Operating Officer for Aton Pharma, Inc. Prior to joining Aton Pharma, Mr. Jooste served with Wyeth and Eli Lilly and Company from 1983 to 2001, where he held positions of increasing international sales and marketing responsibility working in the U.S., Europe and the Pacific Rim. Mr. Jooste has acquired extensive knowledge and experience in marketing and sales of oral and injectable antibiotics as well as specialty products in oncology, psychiatry, endocrinology and rheumatology. Throughout his career he has had several assignments in the U.S., Europe and Australia where he was responsible for building and expanding a commercial organization and creating capabilities to support marketing and sales of leading brands.

*Dr. Rasmussen* has served as Senior Vice President, Clinical, Medical and Regulatory Affairs since May 2003 having been employed as Vice President of Clinical and Regulatory Affairs in February 2003. From April 1999 to February 2003, Dr Rasmussen was employed as Vice President/Senior Vice President of Clinical Research & Regulatory Affairs for GenVec, Inc., a biotech company focused on gene therapy. From November 1994 to March 1999, Dr. Rasmussen was employed as Vice President of Clinical Research/Senior Vice President of Clinical Research/Regulatory Affairs with British Biotech. From 1989 to 1995, Dr. Rasmussen held various management positions within the worldwide clinical development group of Pfizer Central Research in the UK. From 1985 to 1989, Dr. Rasmussen worked with a major university hospital in Denmark, focusing on internal medicine, including cardiology, gastroenterology and infectious disease.

*Mr. Smith* has served as Senior Vice President of 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 the U.S. and Australia.

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock is quoted on the Nasdaq National Market under the symbol "NABI." The following table sets forth for each period the high and low sale prices for our common stock (based upon intra-day trading) as reported by the Nasdaq National Market.

	<u>High</u>	<u>Low</u>
<b>2004</b>		
First Quarter ending March 27, 2004	17.100	12.000
Second Quarter ending June 26, 2004	17.900	13.550
Third Quarter ending September 25, 2004	14.440	8.750
Fourth Quarter ending December 25, 2004	15.780	11.600
<b>2003</b>		
First Quarter ending March 29, 2003	6.590	5.000
Second Quarter ending June 28, 2003	8.000	5.600
Third Quarter ending September 27, 2003	9.600	5.250
Fourth Quarter ending December 27, 2003	12.370	8.000

The closing price of our common stock on March 3, 2005 was \$12.36 per share. The number of record holders of our common stock on March 3, 2005 was 1,021.

No cash dividends have been previously paid on our common stock and none are anticipated in 2005.

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The following table provides information about purchases made by us of our common stock for each month included in our fourth quarter:

ISSUER PURCHASES OF EQUITY SECURITIES

<u>Period</u>	<u>Total Number of Shares Purchased</u>	<u>Average Price Paid per share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (1)</u>	<u>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (1)</u>
9/26/04-10/30/04	0	N/A	0	\$ 3.1 million
10/31/04-11/27/04	0	N/A	0	\$ 3.1 million
11/28/04-12/25/04	0	N/A	0	\$ 3.1 million
Total:	0	N/A	0	\$ 3.1 million

- (1) On September 19, 2001, our Board of Directors approved the buyback of up to \$5.0 million of our common stock in the open market or in privately negotiated transactions. We have acquired 345,883 shares of our common stock for a total of \$1.9 million since the inception of the buyback program. Repurchased shares have been accounted for as treasury stock.

**ITEM 6. SELECTED FINANCIAL DATA**

As described under Item 7, amortization expense related to an intangible manufacturing right asset and the write off of the intangible manufacturing right asset have been restated for the years ended December 27, 2003 and December 28, 2002.

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	For the Years Ended				
	December 25, 2004	December 27, 2003 (as restated)	December 28, 2002 (as restated)	December 29, 2001 (a) (as restated)	December 30, 2000
<b>Statements of Operations Data:</b>					
<b>Sales</b>	\$ 179,763	\$ 176,570	\$ 195,966	\$ 234,829	\$ 228,783
<b>Costs of products sold, excluding amortization of intangible assets</b>	76,345	81,354	119,170	152,613	160,766
<b>Royalty expense</b>	17,569	18,387	12,883	12,093	11,175
<b>Gross margin, excluding amortization of intangible assets</b>	85,849	76,829	63,913	70,123	56,842
<b>Selling, general and administrative expense</b>	55,286	43,867	38,380	40,501	37,168
<b>Research and development expense</b>	61,003	29,040	21,096	15,330	14,266
<b>Amortization of intangible assets</b>	8,673	5,393	1,116	1,075	1,121
<b>Other operating expenses, principally freight</b>	521	477	583	715	706
<b>Write-off of manufacturing right</b>	—	9,735	—	—	—
<b>Gain on disposition of assets</b>	—	—	— (a)	(104,219)	—
<b>Other non-recurring items</b>	—	—	—	—	(3,875)
<b>Operating (loss) income</b>	(39,634)	(11,683)	2,738	116,721	7,456
<b>Interest income</b>	1,628	614	1,287	1,204	33
<b>Interest expense</b>	(2,199)	(1,350)	(2,130)	(2,128)	(3,581)
<b>Other income (expenses), net</b>	213	204	(157)	(28)	551
<b>(Loss) income before (provision) benefit for income taxes</b>	(39,992)	(12,215)	1,738	115,769	4,459
<b>(Provision) benefit for income taxes</b>	(10,398)	6,149	(264)	(11,272)	(100)
<b>Net (loss) income</b>	\$ (50,390)	\$ (6,066)	\$ 1,474	\$ 104,497	\$ 4,359
<b>Basic (loss) earnings per share:</b>	\$ (0.86)	\$ (0.14)	\$ 0.04	\$ 2.75	\$ 0.12
<b>Diluted (loss) earnings per share:</b>	\$ (0.86)	\$ (0.14)	\$ 0.04	\$ 2.36	\$ 0.12
<b>Balance Sheet Data:</b>					
<b>Working capital</b>	\$ 98,182	\$ 142,905	\$ 74,495	\$ 154,425	\$ 39,594
<b>Total assets</b>	368,171	387,301	231,595	314,334	224,487
<b>Notes payable and capital lease obligations, including current maturities</b>	23,844	27,393	—	78,500	109,535
<b>Total stockholders' equity</b>	284,321	319,316	188,263	187,021	77,394

- (a) On September 6, 2001, we sold the operating assets of a majority of our antibody collection business and testing laboratory for \$156.3 million in cash generating a net gain on disposition of \$104.2 million. The assets sold were certain real estate, leasehold interests, fixtures, furniture, tools, machinery and equipment, other fixed assets, antibody inventories and related supplies, contracts, agreements, arrangements and/or commitments, licenses and permits, business and financial records, intellectual property and goodwill related to the operation of the 47 antibody collection centers and our testing laboratory included in the transaction.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

**OUR STRATEGY**

Our business strategy is to leverage our knowledge of the immune system and our clinical, regulatory, manufacturing and commercial expertise to improve human health by reducing patient mortality and morbidity and deliver products to the marketplace that reduce the financial burden on the healthcare system.

Our currently marketed products assist us in pursuing this strategy by generating gross margin that helps fund our clinical and research and development programs. Through commercialization of our currently marketed products, we have developed a specialty sales and marketing model focused on a differentiated consultative selling style designed to develop strong physician relationships in hospital and dialysis center settings. We believe this model can be scaled up in the U.S. and is readily translated in ex-U.S. markets as we prepare for the launch of additional products.

We maintain clear commercial synergies between our currently marketed products and products in our research and development pipeline. Through our marketing of PhosLo (calcium acetate), we have developed an understanding of the nephrology market that will be an important initial patient population for StaphVAX (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine). Our specialty sales force will be applied in the commercialization of our products in clinical development, StaphVAX, Altastaph [*Staphylococcus aureus* Immune Globulin (Human)] for adults and very low birth weight neonates and Civacir [Hepatitis C Immune Globulin (Human)].

**KEY OPERATING ACTIVITIES**

During 2004 we began our transformation to become a global company by initiating the commercialization process for StaphVAX, Nabi-HB Intravenous [Hepatitis B Immune Globulin (Human)] and PhosLo in Europe. We have hired clinical and regulatory employees in the European Union, or EU, to support our European regulatory filings and have initiated marketing and pricing studies for our products currently under EU regulatory consideration.

On December 21, 2004, we filed a Marketing Authorization Application, or MAA, for StaphVAX in the EU via the Centralized Registration Procedure. Our MAA was based on efficacy data from our first Phase III clinical trial of StaphVAX and the successful transfer of the commercial scale manufacturing process for StaphVAX to Cambrex Bio Science Baltimore, Inc., or Cambrex Bio Science, that was completed in August 2004. Also during 2004, we filed MAA's for PhosLo in October and Nabi-HB Intravenous in June using the Mutual Recognition Procedure, or MRP. Each of the filings for StaphVAX, PhosLo and Nabi-HB Intravenous was prepared using the Common Technical Document, or CTD, format, which is widely accepted on a global basis. Under this format, the filings can be readily submitted in other countries around the world, facilitating our ability to expand the marketing of our products into markets beyond the EU and the U.S.

Our U.S. clinical strategy for StaphVAX was significantly advanced through fully enrolling our confirmatory Phase III clinical trial in the third quarter of 2004. We also completed a Phase I/II clinical trial of Altastaph in adults with persistent *S. aureus* infections, announcing the results in January 2005, and announced the results from our Phase II clinical trial of Altastaph in very low birth-weight neonates and our Phase I/II clinical trial for NicVAX in 2004. Based on the results of these clinical trials we are currently designing our clinical programs and undertaking further clinical trials to advance the development of each of these programs toward future commercialization.

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During 2004, we began construction of a vaccine manufacturing plant within available space in our Boca Raton, Florida facility. We anticipate that this plant will initially manufacture StaphVAX. The vaccine plant also can be used to manufacture our other vaccine product candidates.

In July 2004, Cangene Corporation, or Cangene, informed us that it would not renew the WinRho SDF license and distribution agreement with us when the agreement expires in March 2005. We will continue to distribute WinRho SDF exclusively in the U.S. through March 2005.

### KEY FINANCING ACTIVITIES

On December 7, 2004, we filed a shelf registration statement on Form S-3 with the U.S. Securities and Exchange Commission. Upon being declared effective by the SEC, this registration statement will permit us, from time to time, to offer and sell up to \$175 million of equity or debt securities. We plan to use net proceeds from sales of securities under this shelf registration statement to provide additional funds for general corporate purposes, including but not limited to clinical trials, research, development and marketing expenses, and new acquisition and licensing costs.

### Results of Operations

The following discussion and analysis of our financial condition and results of operations for each of the three years ended December 25, 2004, December 27, 2003 and December 28, 2002, should be read in conjunction with the Consolidated Financial Statements and Notes thereto and with the information contained under "Risk Factors" in Item 1. All amounts are expressed in thousands, except for per share and percentage data.

Information concerning our sales by industry segment, for the respective periods, is set forth in the following table.

Segment	For the Years Ended					
	December 25, 2004		December 27, 2003		December 28, 2002	
<b>Biopharmaceutical Products:</b>						
- PhosLo	\$ 37,580	20.9%	\$ 12,875	7.3%	\$ —	— %
- Nabi-HB	40,176	22.3	37,638	21.3	41,185	21.0
- WinRho SDF	47,882	26.7	49,957	28.3	33,995	17.4
- Other Biopharmaceuticals	6,175	3.4	8,989	5.1	14,286	7.3
	<u>131,813</u>	<u>73.3</u>	<u>109,459</u>	<u>62.0</u>	<u>89,466</u>	<u>45.7</u>
<b>Antibody Products:</b>						
-Specialty antibodies	23,270	13.0	21,425	12.1	32,749	16.7
-Non-specific antibodies	24,680	13.7	45,686	25.9	73,751	37.6
	<u>47,950</u>	<u>26.7</u>	<u>67,111</u>	<u>38.0</u>	<u>106,500</u>	<u>54.3</u>
<b>Total</b>	<u>\$179,763</u>	<u>100.0%</u>	<u>\$176,570</u>	<u>100.0%</u>	<u>\$195,966</u>	<u>100.0%</u>

### RESTATEMENT OF PRIOR YEARS FINANCIAL STATEMENTS

During the process of preparing our consolidated financial statements for 2004, we determined that we had received a benefit from our intangible manufacturing right asset related to our right to manufacture Staph VAX at Dow Biopharmaceutical Contract Manufacturer of Dow's, site in prior fiscal years when we had recorded no amortization expense. This determination led to our decision to restate the financial statements for these periods to record additional amortization expense. The following table summarizes the impact of the restatement on our statements of operations:

(In thousands)	December 27, 2003	December 28, 2002	December 29, 2001
Increase in amortization expense	\$ (1,618)	\$ (932)	\$ (290)
Decrease in write-off manufacturing right	2,840		
Decrease net operating loss/(decrease net operating income)	\$ 1,222	\$ (932)	\$ (290)
(Increase)/decrease in (provision) benefit for income taxes	(456)	351	105
Decrease net loss/(decrease net income)	<u>\$ 766</u>	<u>\$ (581)</u>	<u>\$ (185)</u>

Net (loss) income originally reported as \$(6.8) million or \$(0.16) per share for the year ended December 27, 2003, \$2.1 million or \$0.05 per share for the year ended December 28, 2002 and \$104.7 million or \$2.36 per share for the year ended December 29, 2001 have been restated as \$(6.1) million or \$(0.14) per share, \$1.5 million or \$0.04 per share and \$104.5 million or \$2.36 per share, respectively.

In October 2003 we made a decision to establish a new manufacturing relationship with Cambrex Bio Science. to support an opportunity for earlier commercialization of our vaccine against *S. aureus* infections, StaphVAX in Europe. As a result, we terminated our contract manufacturing agreement with Dow Biopharmaceutical Contract Manufacturing Services or Dow, on October 9, 2003 and reported a non-cash write off equal to the recorded value of the manufacturing right asset as of that date. As restated, this write off amount totals \$9.7 million versus \$12.6 million reported previously. The restatement of amortization expense related to this asset will not require restatement of the previously reported balance sheet as of December 27, 2003.

The following table sets forth selected consolidated financial data for the five years ended December 25, 2004 that was derived from our audited consolidated financial statements.

The data should be read in conjunction with, and are qualified by reference to, Nabi Biopharmaceuticals' Consolidated Financial Statements and the Notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All amounts in the following table are expressed in thousands, except for per share data.





**2004 as Compared to 2003 (as restated)**

*Sales.* Total sales for 2004 were \$179.8 million compared to sales of \$176.6 million for 2003.

*Biopharmaceutical sales.* Biopharmaceutical sales for 2004 were a record \$131.8 million compared to \$109.5 million for 2003, an increase of 20%.

*PhosLo.* Sales of PhosLo were \$37.6 million for 2004 compared to \$12.9 million for the period of August 4, 2003 through December 27, 2003. We acquired PhosLo on August 4, 2003 and began selling the product utilizing our sales force and distribution channels in September 2003. In planning for 2005, we took the strategic decision to move aggressively to convert patients from the PhosLo tablet formulation to the PhosLo gelcap formulation. We believe the PhosLo gelcap formulation, which is easier for patients to use, will enhance overall patient compliance with their prescriptions. In line with this decision and orders received from wholesaler customers, we significantly reduced our inventory of PhosLo tablet formulation. We believe wholesaler customers increased their inventory levels in response to increased patient demand, anticipated transition to PhosLo gelcaps and our announced price increases that occurred in January 2004 and September 2004. Sales of PhosLo in 2004 included stocking of our gelcap formulation of PhosLo by our wholesaler customers in the first quarter as we increased manufacturing capacity for PhosLo gelcaps in order to facilitate transition to this formulation. Patient prescriptions for PhosLo have increased in 2004 compared to 2003 based on our review of third party prescription data. Overall reported sales of PhosLo in 2004 further benefited from the price increases that went into effect in January 2004 and September 2004 and from our pricing strategies that have resulted in lower rebate deductions from our gross selling price thereby increasing net average selling price for PhosLo.

We have entered into inventory management agreements with two of our major wholesaler customers and, as a result, expect our customers to reduce their inventory levels in 2005. We are aware that a competitive product to PhosLo, Renagel (sevelamer hydrochloride) marketed by Genzyme Corporation, has initiated a clinical trial examining the difference in morbidity and mortality outcomes based on arterial calcification for patients receiving Renagel and those receiving calcium-based phosphate binders, including PhosLo. If the results of this trial are favorable to Renagel, they may impact sales of PhosLo. The results from this trial may impact sales of PhosLo in 2005. We have initiated the CARE 2 study in 2004 that seeks to demonstrate that when a patient's lipid levels are equally controlled, there is no clinical difference in arterial calcification between patients treated with PhosLo and Renagel. We control lipid levels in CARE 2 through use of Lipitor (atorvastatin calcium) administered to all study participants, as required to maintain lipid levels at established target levels. Interim results from this clinical trial for serum phosphorus, serum calcium calcium phosphorus product and lipid levels are expected to be available in the second half of 2005 with final data on arterial calcification measured by electron beam computer tomography being available in the second half of 2006.

*Nabi-HB.* Sales of Nabi-HB increased 7% in 2004 compared to sales reported in 2003. Sales of Nabi-HB in 2004 benefited from initial sales under our new agreement with Novation LLC, or Novation, entered into during the first quarter of 2004. Under the terms of the agreement, we will supply finished Nabi-HB product to Novation for distribution through their Novaplus<sup>®</sup> Private Label Program. We believe the most significant use of Nabi-HB is for the treatment of hepatitis B positive liver transplant recipients and hence, sales of Nabi-HB are directly related to the number of hepatitis B liver transplants in the U.S. Our internally generated data indicates that the number of liver transplants for hepatitis B patients for 2004 have increased by approximately 20% compared to the number for 2003. Sales of Nabi-HB have benefited from this increase in liver transplants for hepatitis B patients and increased pricing that went into effect at the beginning of 2004 offset by the impact of changes in treatment protocols for HBV-positive liver transplant patients that have resulted in lower doses of antibody

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based therapies such as Nabi-HB. Sales reported for 2003 benefited from product backorders of \$3.5 million at December 28, 2002, that were filled in 2003. At December 25, 2004 we had unfilled product orders for Nabi-HB totaling \$3.8 million.

*WinRho SDF [Rho (D) Immune Globulin Intravenous (Human)].* Sales of WinRho SDF were 4% lower in 2004 compared to sales in 2003. Based on internally generated patient use data, we believe patient demand for WinRho SDF in 2004 has decreased in-line with the decrease in reported sales in 2004 as compared to 2003. Our agreement with Cangene to distribute WinRho SDF will end in March 2005.

*Other biopharmaceutical products.* Other biopharmaceutical products, which include Aloprim [(Allopurinol Sodium) for injection], Autoplex T [Anti-Inhibitor Coagulant Complex, Heat Treated], intermediate products manufactured in our plant and contract manufacturing, generated sales of \$6.2 million in 2004 compared to \$9.0 million in 2003. Sales of Aloprim were lower in 2004 compared to 2003 due to the impact from the introduction of a new competitive product. We expect sales of Aloprim to continue to be affected by competition from this new product. Sales of Autoplex T were consistent in 2004 and 2003. Our contract with the manufacturer of Autoplex T ended on May 11, 2004 and sales subsequent to that date were limited to existing inventory on hand. Sales of intermediate products, which are not a strategic focus for us, were lower in 2004 compared to 2003 in line with manufacturing activity and contract-manufacturing revenue was consistent between 2004 and 2003.

*Antibody products.* Total antibody product sales for 2004 were \$48.0 million compared to \$67.1 million for 2003. Total antibody product sales decreased approximately 29% from 2003 levels due to the completion of a zero margin supply agreement for supply of non-specific antibodies in April 2003.

*Non-specific antibodies.* Total non-specific antibody sales were \$24.7 million in 2004 compared to \$45.7 million in 2003. Non-specific antibody sales from our own antibody collection centers were \$24.7 million in 2004 compared to \$27.1 million in 2003 reflecting decreased production levels and decreased unit sales for 2004. In addition, non-specific antibody sales in 2003 included shipments to a single customer under a supply contract that expired in April 2003 under which we earned no margin. This supply contract was retained by us following the sale of the majority of the antibody collection business and testing laboratory in September 2001. We reported sales under this arrangement because we retained the risk of credit loss with this customer. Such non-specific antibody sales totaled \$18.6 million in 2003. In December 2003, we entered into a long-term supply contract for the sale of non-specific antibodies to Bayer Corporation that is expected to generate a consistent cash flow from the excess non-specific antibody production in our centers.

*Specialty antibodies.* Specialty antibody sales were \$23.3 million for 2004 compared to \$21.4 million for the comparable period of 2003, an increase of approximately 9%. The increase in specialty antibodies primarily reflects increased sales of rabies, CMV and anti-HBs antibodies partially offset by a decrease in sales of tetanus antibodies and diagnostic products. Hepatitis B antibodies produced at our antibody collection centers were primarily retained by us to support the manufacture of Nabi-HB in 2003, limiting the amount of these antibodies available for sale. Hepatitis B antibodies are the primary raw material in the manufacture of Nabi-HB. Throughout 2003 and 2004 we had a contractual commitment to supply substantial quantities of Rh<sub>o</sub>D antibodies to the purchaser of the majority of our antibody collection and laboratory testing business. This commitment limited our ability to sell these antibodies produced at our own centers to other customers at higher margins during 2004. This contract ended on December 31, 2004.

*Gross margin.* Gross margin for 2004 was \$85.8 million, or a record level of 48% of sales, compared to \$76.8 million, or 44% of sales, for 2003. The increase in gross profit for 2004 compared to 2003 reflects the increased proportion of our biopharmaceutical product sales to total sales, led by increased sales of PhosLo. Gross margin for 2004 and 2003 also benefited

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from non-performance penalty amounts from the manufacturer of Autoplex T of \$2.0 million and \$8.1 million, respectively. During 2004, our Boca Raton, Florida manufacturing facility underwent renovations related to compliance with EU regulations, as well as routine maintenance, that limited utilization of the facility and resulted in excess plant capacity expense of \$6.4 million. Excess plant capacity expense was \$2.2 million for 2003. Additionally, in the fourth quarter of 2004 we reserved Nabi-HB inventory valued at \$3.0 million due to certain units of product falling outside strict compliance with our product specifications.

Royalty expense for 2004 was \$17.6 million, or 13% of biopharmaceutical sales, compared to \$18.4 million, or 17% of biopharmaceutical sales, for 2003. The decrease in royalty expense as a percentage of biopharmaceutical sales reflects the increase in total biopharmaceutical sales, primarily sales of PhosLo for which we pay no royalties, during 2004, and lower sales of WinRho SDF and Aloprim. Royalty expense includes a 4% patent usage royalty related to the manufacturing process of Nabi-HB and a royalty related to Aloprim that is set at 15% of net Aloprim sales.

*Selling, general and administrative expense.* Selling, general and administrative expense was \$55.3 million for 2004 compared to \$43.9 million for 2003. Increased selling, general and administrative expenses for 2004 was primarily related to full year selling and marketing expense for PhosLo, initial commercialization activities in the EU, employee incentive expenses and costs related to implementation of the requirements of Section 404 of the Sarbanes-Oxley Act. Selling, general and administrative expense for 2003 included a charge of \$3.3 million related to the retirement of our former Chief Executive Officer.

*Research and development expense.* Research and development expense increased more than two-fold to \$61.0 million for 2004 compared to \$29.0 million for 2003. Consistent with the strategic focus of our research and development activities, the majority of research and development expense in 2004 and 2003 was incurred to support our Gram-positive infections program composed of StaphVAX and Altastaph as well as our next generation Gram-positive products. These activities included our confirmatory Phase III clinical trial for StaphVAX that was fully enrolled in August 2004, transferring the StaphVAX manufacturing process to our new contract manufacturer, Cambrex Bio Science, establishing StaphVAX vaccine manufacturing capability within our Boca Raton, Florida facility, preparing the filing of our MAA for StaphVAX in the EU and completing our Phase I/II and Phase II clinical trials of Altastaph in adults with persistent *S. aureus* infections and in very low birth weight newborns. During 2004, we incurred approximately \$17.9 million in outside clinical trial costs for the confirmatory Phase III clinical trial for StaphVAX compared to \$2.0 million in 2003.

Research and development expense during 2004 and 2003 also included costs to support our currently marketed products as well as the other products in our development pipeline. In 2004 these costs included expenses to support our MAA's filed in the EU for PhosLo and Nabi-HB Intravenous as well as ongoing costs to support our Biologics License Application, or BLA, filing for Nabi-HB Intravenous seeking an indication for the prevention of re-infection with hepatitis B in HBV-positive liver transplant patients. In addition, we incurred costs related to our Phase II clinical trial of NicVAX in smokers in the U.S. from which we reported results in September 2004, continuing costs related to our Phase II clinical trial of NicVAX in smokers and ex-smokers in The Netherlands, reporting of our Phase I/II clinical trial of Civacir and manufacture of clinical trial Civacir material. During 2003, we incurred costs to support our BLA filing for Nabi-HB Intravenous, costs related to clinical work for PhosLo and support of our Phase I/II clinical trials for NicVAX and Civacir.

We expect research and development expense to increase by more than 10% in 2005 above 2004 levels reflecting completion of the confirmatory Phase III clinical trial of StaphVAX and other clinical trial programs to support the BLA that is expected to be filed by the end of 2005 and the supplemental MAA that is expected to be filed by the end of 2005 in the EU for StaphVAX, advancing our other Gram-positive programs including Altastaph and next generation Gram-positive

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vaccines and increased clinical work in support of PhosLo including continuation of the CARE 2 study, pursuit of label expansion into the pre-dialysis chronic kidney disease patient population through our EPICK clinical trial and support of our initial commercialization activities in the EU.

*Amortization of intangible assets.* Amortization expense was \$8.7 million for 2004 compared to \$5.4 million for 2003. The increase in 2004 is due primarily to full year amortization related to the intangible assets acquired in conjunction with the acquisition of PhosLo.

*Write-off of Manufacturing Right.* In order to meet the filing timeline for our MAA filing in the EU for StaphVAX, we entered into a contract manufacturing relationship with Cambrex Bio Science and we ended our agreement with the previous manufacturer on October 9, 2003. As a result of this action, we wrote off costs we had capitalized in prior periods relating to the right to manufacture StaphVAX at this manufacturer's facility in future periods and recorded a charge of \$9.7 million in 2003.

*Interest income.* Interest income for 2004 was \$1.6 million compared to \$0.6 million for 2003. Interest income is earned from investing cash and cash equivalents on hand in money market funds and auction rate securities with maturities or reset periods of three months or less. The increase in interest income in 2004 compared to 2003 is due to higher average cash balances in 2004 following completion of an equity offering that raised net proceeds of \$91.5 million in December 2003.

*Interest expense.* Interest expense for 2004 was \$2.2 million compared to \$1.4 million for 2003. Effective March 26, 2004, we terminated our credit agreement with Wells Fargo Foothill, Inc. in order to avoid future costs for unused credit fees and other service charges. As a result of terminating the credit agreement, we incurred an early termination fee of \$0.6 million and wrote off previously capitalized loan origination costs of \$0.5 million. In addition, interest expense included \$1.2 million for amortization of the discount on the notes payable entered into in connection with the acquisition of PhosLo. Interest expense in 2003 included interest expense incurred under our credit facility entered into on June 20, 2003, amortization of loan origination fees and unused limit fees related to the credit agreement and non-cash interest expense imputed to our non interest bearing notes payable entered into in connection with the acquisition of PhosLo on August 4, 2003. Capitalized interest relating to construction of our vaccine manufacturing facility in Boca Raton, Florida was \$0.3 million for 2004 and related to construction of our laboratory and cold storage facility in Boca Raton, Florida was \$0.1 million for 2003.

*Income taxes.* The provision for income taxes was \$10.4 million for 2004, compared to a benefit of \$6.1 million for 2003. As a result of licensing the right to market StaphVAX and PhosLo in the EU to one of our ex-U.S. subsidiaries and in recognition of the value of the product rights developed and acquired by us, we realized a gain for U.S. tax reporting purposes of approximately \$55 million. Although we recognized a consolidated operating loss on a GAAP basis during 2004, we nevertheless incurred income tax expense due to the U.S. taxable gain arising from licenses of these product rights to our non-U.S. subsidiary. We anticipate realizing deferred tax assets related to net operating loss carryforwards incurred in prior periods and the exercise of employee stock options to offset future cash payment of income taxes on the reported U.S. taxable gain in 2004. For 2003, the provision for income taxes reflected a benefit of \$6.1 million due to the recognition of research and development tax credits as a result of our activities toward licensing the right to market StaphVAX and PhosLo in the EU that were completed in 2004. If we determine in future periods that it is not more likely than not that we will utilize our deferred tax assets, we may be required to record a valuation allowance against some of our deferred tax assets.

*Fluctuating fiscal year periods.* Our fiscal year ends on the last Saturday of December. Consequently, we will periodically have a 53-week fiscal year. The fiscal years ended December 25, 2004, December 27, 2003, and December 28, 2002, were 52-week years. The fiscal year ending December 31, 2005, will be a 53-week year. The extra week will be included in the fourth quarter of 2005.

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*Stock option expensing.* We will have an expense in 2005 related to our equity compensation plans as a result of the implementation of Financial Accounting Statement, or FAS, 123(R). *Share-Based Payment* that is effective for our accounting periods beginning after June 15, 2005. Using the Black-Scholes model for valuing stock options under FAS 123(R) would result in expense for options granted in prior years on a pre-tax basis in the amounts of \$9.0 million, \$9.4 million and \$7.3 million for the years ending in 2005, 2006 and 2007, respectively.

### **2003 (as restated) as Compared to 2002 (as restated)**

*Sales.* Total sales for 2003 were \$176.6 million compared to sales of \$196.0 million for 2002.

*Biopharmaceutical sales.* Biopharmaceutical sales for 2003 were \$109.5 million compared to \$89.5 million for 2002, an increase of 22%. Biopharmaceutical sales as a percentage of total sales increased, reflecting the increasing importance of our biopharmaceutical products. Sales for 2003 benefited from the initial sales of PhosLo as well as a significant increase in sales of WinRho SDF.

*PhosLo.* We acquired PhosLo on August 4, 2003 and began selling the product utilizing our sales force and distribution channels in September 2003. Sales of PhosLo totaled \$12.9 million for the period August 4 through December 27, 2003. Sales of PhosLo benefited from new prescriptions for the product in 2003 compared to 2002 as reported by an external prescription monitoring service and demand for the product by wholesaler and distributor customers in anticipation of future patient demand.

*Nabi-HB.* Sales of Nabi-HB decreased 9% in 2003 compared to sales reported in 2002. We believe the most significant use of Nabi-HB is for the treatment of hepatitis B positive liver transplant recipients in the period of and following liver transplant. As reported by the United Network for Organs Sharing, liver transplants for hepatitis B patients for 2003 decreased approximately 30% from 2002 levels. Further, use of antibody-based products such as Nabi-HB was affected by increased use of anti-viral therapies by physicians during the period following transplant. Sales of Nabi-HB in 2003 also benefited from \$3.5 million of back ordered product at December 28, 2002 that was shipped in 2003. In addition, wholesaler and distributor customers increased inventory levels of Nabi-HB in 2003. Sales of Nabi-HB in 2002 benefited from completion of the transition to Nabi-HB product manufactured in our Boca Raton facility in that period, the initial period of manufacture at that facility.

*WinRho SDF.* Sales of WinRho SDF increased 47% in 2003 compared to 2002. Patient utilization of WinRho SDF reflected higher dose protocols utilized by treating physicians as a result of findings reported in the March 2002 issue of the New England Journal of Medicine as well as our success versus competitive products, the growth in the overall number of ITP patients and increased pricing. In addition, sales of WinRho SDF in 2002 were negatively impacted by an inventory build-up by our wholesaler and distributor customers in 2001 in response to product supply shortages from the manufacturer of this product in 2000.

*Other biopharmaceutical products.* Other biopharmaceuticals sales, which primarily comprise sales of Autoplex T and Aloprim, decreased 37% in 2003 compared to 2002. Aloprim sales in 2003 were impacted by product supply shortfalls from the manufacturer of the product in the first quarter of 2003, which resulted in patient treatment being supported by alternate products. Aloprim supply from the manufacturer resumed in April 2003 and benefited sales of this product for the balance of 2003. For the full year 2003, patient utilization of Aloprim was consistent with 2002. Aloprim sales in 2002 benefited from receipt of two back-ordered lots that were substantially sold in that period.

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*Antibody products.* Total antibody product sales for 2003 were \$67.1 million compared to \$106.5 million for 2002. In December 2003, we entered into a long-term supply contract for non-specific antibodies with Bayer Corporation that is expected to generate a consistent cash flow from the excess non-specific antibody production in our centers.

*Non-specific antibodies.* Non-specific antibody sales included shipments to a single customer under a supply contract that expired in April 2003 under which we earned no margin. The supply contract was retained by us following the sale of the majority of the antibody collection business and testing laboratory in September 2001. We reported sales under this arrangement because we retained the risk of credit loss with this customer. Such non-specific antibody sales totaled \$18.6 million in 2003 and \$55.6 million in 2002. Non-specific antibody sales from our own antibody collection centers were \$27.1 million in 2003 compared to \$18.2 million in 2002 reflecting increased production levels and increased unit sales for 2003.

*Specialty antibodies.* Specialty antibody sales were \$21.4 million for 2003 compared to \$32.7 million for the comparable period of 2002, a decrease of approximately \$11.3 million. This decrease primarily reflected decreased sales of rabies, tetanus, hepatitis B and Rh<sub>0</sub>D antibodies. Sales of rabies antibodies have decreased due to the conclusion of a contract to provide this product to a single pharmaceutical customer in 2002. Sales of tetanus antibodies decreased due to reduced demand from the international market. Hepatitis B antibodies produced at our antibody collection centers were primarily retained by us to support the manufacture of Nabi-HB in 2003, limiting the amount of these antibodies available for sale. Hepatitis B antibodies are the primary raw material in the manufacture of Nabi-HB. We had a contractual commitment to supply substantial quantities of Rh<sub>0</sub>D antibodies to the purchaser of the majority of our antibody collection and laboratory testing business at a low margin that ended on December 31, 2004. This commitment limited our ability to sell these antibodies produced at our own centers to other customers at higher margins during 2003.

*Gross margin.* Gross margin for 2003 was \$76.8 million, or 44% of sales, compared to \$63.9 million, or 33% of sales, for 2002. The increase in gross profit for 2003 compared to 2002 primarily reflects the increased proportion of higher margin biopharmaceutical sales compared to total sales, including initial sales of PhosLo. During 2003, we also benefited from increased utilization of our Boca Raton manufacturing facility compared to 2002 resulting in excess plant capacity expense of \$2.2 million compared to an excess plant capacity expense of \$3.5 million for 2002. Gross margin for 2003 and 2002 also benefited from gross non-performance penalty amounts from the manufacturer of Autoplex T of \$8.1 million and \$3.5 million, respectively. Offsetting these gross margin gains were reduced margin from sales of specialty antibodies, increased costs of manufacture for Nabi-HB and the impact of inventory write-offs.

We incur royalty expense by reason of our license and distribution agreements for WinRho SDF and Aloprim that provide for profit sharing from sales of these products. In addition, royalty expense includes a 4% patent usage royalty related to the manufacturing process of Nabi-HB. Royalty expense for 2003 was \$18.4 million, or 17% of biopharmaceutical sales, compared to \$12.9 million, or 14% of biopharmaceutical sales, for 2002. The increase in royalty expense primarily reflected increased sales of WinRho SDF in 2003 over 2002.

*Selling, general and administrative expense.* Selling, general and administrative expense was \$43.9 million for 2003 compared to \$38.4 million for 2002. Increased selling, general and administrative expense for 2003 included a charge of \$3.3 million related to the retirement of our former Chief Executive Officer, increased use of a tax consultant compared to 2002 and costs to launch PhosLo.

*Research and development expense.* Research and development expense was \$29.0 million for 2003 compared to \$21.1 million for 2002. Consistent with the strategic focus of our research and development activities, the majority of research and development expense in 2003 and 2002 was incurred to support activity under our Gram-positive infections program including StaphVAX and

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Altastaph as well as pre-clinical programs. Increased research and development expense in 2003 resulted from a number of activities, including preparation for and initiation of our confirmatory Phase III clinical trial for StaphVAX, transfer of the StaphVAX manufacturing process to our new contract manufacturer, Cambrex Bio Science, development costs related to the preparation of our MAA filing for StaphVAX in the EU, initiation of a Phase II clinical trial of Altastaph in very low birth weight newborns, initiation of a Phase II clinical trial of NicVAX in smokers in the U.S. and a Phase I/II clinical trial of NicVAX in smokers and ex-smokers in The Netherlands, ongoing clinical support for our Phase I/II clinical trial of Civacir and manufacture of clinical trial Civacir material, and research and development costs to support our Nabi-HB Intravenous BLA filed with the FDA seeking an indication for the prevention of re-infection with hepatitis B in HBV-positive liver transplant patients.

*Amortization of intangible assets.* Amortization expense was \$5.4 million for 2003 compared to \$1.1 million for 2002. The increase in 2003 is due primarily to amortization related to the intangible assets acquired in conjunction with the acquisition of PhosLo in August 2003.

*Write-off of Manufacturing Right.* In conjunction with establishing our new contract manufacturing relationship with Cambrex Bio Science, we ended our agreement with the previous manufacturer on October 9, 2003. As a result of this action, we wrote off costs we had capitalized in prior periods relating to the right to manufacture StaphVAX at this manufacturer's facility in future periods and recorded a charge of \$9.7 million in 2003.

*Interest income.* Interest income for 2003 was \$0.6 million compared to \$1.3 million for 2002. Interest income is earned from investing cash and cash equivalents on hand in money market funds and auction rate securities with maturities or reset periods of three months or less. The decrease in interest income in 2003 compared to 2002 is due to lower average cash balances in 2003. Our cash balance at December 27, 2003 included the proceeds from our underwritten public offering of our common stock that closed on December 23, 2003 raising net cash proceeds of approximately \$91.5 million. A total of \$9.5 million of the funds were used to pay off our term loan on December 23, 2003. In September 2001, we received proceeds of \$135 million, net of repayment of then outstanding bank debt and closing costs, from the sale of the majority of our antibody collection business and testing laboratory. These funds were invested in the financial instruments described above in 2002. In April 2002, a portion of these funds was utilized to redeem our \$78.5 million 6.5% Convertible Subordinated Notes.

*Interest expense.* Interest expense for 2003 was \$1.4 million compared to \$2.1 million for 2002. Interest expense in 2003 includes interest expense incurred under our credit facility entered into on June 20, 2003, amortization of loan origination fees and unused limit fees related to the credit agreement and non-cash interest expense imputed to our non interest bearing notes payable entered into in connection with the acquisition of PhosLo on August 4, 2003. Interest expense in 2002 relates to interest on the 6.5% Convertible Subordinated Notes which were redeemed in April 2002. Capitalized interest related to construction of our laboratory and cold storage facility in Boca Raton, Florida was \$0.1 million for 2003.

*Income taxes.* The provision for income taxes reflected a benefit of \$6.1 million for 2003, compared to a provision of \$0.3 million for 2002. The 50% effective tax rate for 2003 differs from the statutory rate of 34% due to the recognition of research and development tax credits as a result of our European strategy and our determination that it is more likely than not that this strategy will result in realization of these tax credits because of the completion of our equity financing in December 2003.

### **Liquidity and Capital Resources**

Net cash provided by operating activities for the year ended December 25, 2004 was \$8.7 million. The total of our cash and cash equivalents and marketable securities balances at December 25, 2004 was \$103.1 million compared to cash and cash equivalents of \$115.8 million at December 27, 2003.

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In conjunction with the acquisition of PhosLo in August 2003, we entered into an obligation to pay the seller \$30.0 million over the period ending March 1, 2007. As of December 25, 2004, our remaining obligation, net of discount, was \$23.3 million. We will repay \$10.9 of this obligation in 2005. During 2004, we repaid \$5.3 million of this obligation.

Under terms of an agreement entered into in October 2003 with Cambrex Bio Science, at December 25, 2004 we have a remaining commitment of \$0.2 million including costs to acquire the rights to future commercial manufacturing capacity for StaphVAX at Cambrex Bio Science's facility and to transfer commercial scale manufacture of StaphVAX to this facility. Through December 25, 2004, we have incurred \$9.6 million in costs, of which a total of \$3.0 million has been capitalized as a Manufacturing Right and included in intangible assets.

In April 2004, we entered into an agreement to construct a commercial scale vaccine manufacturing facility and install equipment within available space in our Boca Raton, Florida manufacturing plant. Under the terms of the agreement, as of December 25, 2004 we have a remaining commitment of \$0.7 million that we expect to complete before the end of 2005. To date, we have incurred a total of \$17.8 million to construct this vaccine manufacturing facility, including \$14.7 million under our contractual commitment. We anticipate the total cost for the facility, including equipment, to be approximately \$18.5 million to \$20 million.

Capital expenditures were \$22.6 million for 2004. Our capital expenditures are primarily related to the construction of commercial scale vaccine manufacturing facility at our Boca Raton, Florida manufacturing plant. In addition, capital expenditures included costs to complete our laboratory and cold storage facilities in Boca Raton, Florida as well as fixed assets to support our research and development activities in Rockville, Maryland. During 2005, we expect capital expenditures to be between \$10 million to \$11 million, primarily to support research and development activities, manufacturing and information technology.

In connection with an agreement related to the retirement of our former Chief Executive Officer as of December 25, 2004 we have a remaining net obligation of \$1.9 million in cash payments through December 2006. The current portion of this obligation totaling \$1.0 million is recorded in accrued expenses and the long-term portion is recorded in other liabilities at December 25, 2004.

During 2004, we received \$9.8 million from the exercise of employee stock options.

Although we incurred income tax expense for 2004 due to the U.S. taxable gain arising from licensing of product rights to one of our non-U.S. subsidiaries, we do not anticipate a significant cash outflow for income taxes. We anticipate realizing deferred tax assets related to net operating loss carryforwards incurred in prior periods and deduction of employee stock option exercises for income tax reporting purposes to offset cash payment of income taxes on the reported U.S. taxable gain in 2004.

On December 7, 2004, we filed a shelf registration statement on Form S-3 with the U.S. Securities and Exchange Commission. Once declared effective by the SEC, this registration statement will permit us, from time to time, to offer and sell up to \$175 million of equity or debt securities. We plan to use net proceeds from sales of securities under this shelf registration statement to provide additional funds for general corporate purposes, including but not limited to clinical trials, research, development and marketing expenses, and new acquisition and licensing costs.

On March 26, 2004, we ended our credit facility with Wells Fargo Foothill, part of Wells Fargo & Company.



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

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

The following table provides information as of December 25, 2004 with respect to the amounts and timing of our known contractual obligations as specified below.

### Contractual Obligations

	2005	2006	2007	2008	2009	After 2010	Total
<b>(In Thousands)</b>							
Open purchase orders	\$ 3,866	\$ —	\$ —	\$ —	\$—	\$—	\$ 3,866
Operating leases	2,625	2,059	1,447	1,233	155	378	7,897
Capital leases	240	240	109	—	—	—	589
Notes Payable, PhosLo acquisition	10,856	8,877	4,934	—	—	—	24,667
Retirement obligations	1,329	1,184	—	—	—	—	2,513
Contractual obligations to purchase inventory	636	636	636	636	424	—	2,968
Cambrex Bio Science	220	—	—	—	—	—	220
Capital commitments for vaccine manufacturing facility	666	—	—	—	—	—	666
<b>Total</b>	<b>\$20,438</b>	<b>\$12,996</b>	<b>\$7,126</b>	<b>\$1,869</b>	<b>\$579</b>	<b>\$378</b>	<b>\$43,386</b>

The preceding table does not include information with respect to the following contractual obligations because the amounts of the obligations are currently not determinable: contractual obligations in connection with clinical trials, which are payable on a per-patient basis and royalty obligations, which are payable based on the sales levels of some of our biopharmaceutical products. In addition, the payment terms provided in the PhosLo acquisition agreement are a combination of fixed semi-annual payments and variable annual payments calculated as a percentage of net revenue, and therefore, the PhosLo notes payable amounts in 2006 and 2007 are based on our current estimates.

### Critical Accounting Policies

#### Accounting Estimates

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

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### *Intangible Assets – PhosLo Intangibles*

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

Management believes the estimated remaining useful lives of the acquired intangible assets are as follows:

<u>(Dollars in Thousands)</u>	<u>December 25, 2004</u>	<u>Estimated Remaining Useful Life</u>
<b>PhosLo Intangibles</b>		
Trademark/tradename	\$ 1,423	16.3 years
Tablet patent	11,381	2.3 years
Gelcap patent	80,670	16.3 years
Customer relationships	2,337	3.6 years
Covenant-not-to-compete	508	13.6 years
	<hr/>	
Total PhosLo intangible assets	96,319	
Accumulated amortization	(11,690)	
	<hr/>	
<b>Total PhosLo Related Intangible Assets</b>	<b>\$ 84,629</b>	

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

### *Intangible Assets – Manufacturing Right*

In October 2003, we entered into a contract manufacturing agreement with Cambrex Bio Science. Under our agreement with Cambrex Bio Science, at December 25, 2004 we are committed to make future payments of at least \$0.2 million including costs to acquire the rights to commercial manufacturing capacity for StaphVAX vaccine. We have commenced amortization of the Manufacturing Right. Due to StaphVAX being a new product and the exact period of future economic benefit that will be derived from the sale of StaphVAX being difficult to determine, we have elected to amortize the Manufacturing Right on a straight-line basis over the extended term of our contract manufacturing agreement with Cambrex Bio Science, which may be extended, at our option, through October 2013. The contract extension is permitted under terms of the agreement with notice from us to Cambrex Bio Science. At December 25, 2004, we have capitalized \$2.9 million, net million as a Manufacturing Right on our balance

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sheet. If we determine that the manufacture of StaphVAX will not occur at Cambrex Bio Science's facility, or we assess that circumstances have resulted in changes to the carrying value of the intangible asset, we will write off this Manufacturing Right in the period of that determination.

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

We incurred costs of \$90.3 million to construct our biopharmaceutical manufacturing facility in Boca Raton, Florida and received approval to manufacture our own antibody-based biopharmaceutical product, Nabi-HB, at this facility from the FDA in October 2001. In constructing the facility for its intended use, we incurred approximately \$26.8 million in direct costs of acquiring the building, building systems, manufacturing equipment and computer systems. We also incurred a total of \$63.5 million of costs related to validation of the facility to operate in an FDA approved environment and capitalized interest. Costs related to validation and capitalized interest have been allocated to the building, building systems, manufacturing equipment and computer systems. Buildings and building systems are depreciated on a straight-line basis over 39 years and 20 years, respectively, the estimated useful lives of these assets. The specialized manufacturing equipment and computer systems are depreciated using the units-of-production method of depreciation subject to a minimum level of depreciation based on straight-line depreciation. The units-of-production method of depreciation is based on management's estimate of production levels. Management believes the units-of-production method is appropriate for these specialized assets. Use of the units-of-production method of depreciation may result in significantly different financial results of operation than straight-line depreciation in periods of lower than average or higher than average production levels. However, this differential is limited in periods of lower than average production, as we record a minimum of 60% of the depreciation that would have otherwise been recorded had we used the straight-line method. In 2004, 2003 and 2002, we recorded additional depreciation of \$2.5 million, \$1.6 million and \$2.3 million, respectively, under this policy.

### *Accounts Receivable and Revenue Recognition*

In the year ended December 25, 2004, we had biopharmaceutical product sales of \$131.8 million. At December 25, 2004 we had \$32.4 million of accounts receivable including \$25.4 million from biopharmaceuticals sales.

Our primary customers for biopharmaceutical products are pharmaceutical wholesalers. In accordance with our revenue recognition policy, revenue from biopharmaceutical product sales is recognized when title and risk of loss are transferred to the customer. Reported sales are net of estimated customer prompt pay discounts, contractual allowances in accordance with managed care agreements known as chargebacks, government payer rebates, customer returns of PhosLo and other wholesaler fees. At December 25, 2004, we had \$8.6 million recorded in other current liabilities related to these contractual obligations as accrued sales deductions. Our policy regarding sales to customers is that we do not recognize revenue from, or the cost of, such sales where we believe the customer has more than a demonstrably reasonable level of inventory. We make this assessment based on historical demand, historical customer ordering patterns for purchases and estimated inventory levels. If our actual experience was greater than our assumptions we would then record additional expenses in that period.

We estimate allowances for revenue dilution items using a combination of information received from third parties, including market data, inventory reports from our major U.S. wholesaler customers, historical information and analysis that we perform. The key assumptions used to arrive at our best estimate of revenue dilution reserves are estimated customer inventory levels, contractual prices and related terms. Our estimates of inventory at wholesaler customers and in the distribution channels are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates, and reflect other limitations. Provisions for estimated rebates and other allowances, such as discounts, promotional and other credits are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels

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and contract terms and actual discounts offered. We believe that such provisions are determinable due to the limited number of assumptions involved and the consistency of historical experience. Provision for chargebacks involves more subjective judgments and are more complex in nature. This provision is discussed in further detail below.

*Chargebacks* - The provision for chargebacks is a significant and complex estimate used in the recognition of revenue. We market products directly to wholesalers, distributors and homecare companies. We also market products indirectly to group purchasing organizations, managed care organizations, physician practice management groups and hospitals, collectively referred to as indirect customers. We enter into agreements with indirect customers to establish contract pricing for certain products. The indirect customers then select wholesalers from which to actually purchase the products at these contracted prices. Under this arrangement, we will provide credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler's invoice price. Such credit is called a chargeback. The provision for chargebacks is based on our historical chargeback experience and estimated wholesaler inventory levels, as well as expected sell-through levels by our wholesaler customers to indirect customers. Our estimates of inventory at wholesaler customers and in the distribution channels are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates, and reflect other limitations. We continually monitor our provision for chargebacks and make adjustments when we believe that actual chargebacks may differ from established reserves.

The following table represents the amounts we have accrued for sales deductions as of:

<u>(In Thousands)</u>	<u>Accrued chargebacks</u>	<u>Accrued rebates</u>	<u>Accrued sales discounts</u>	<u>Other accrued sales deductions</u>	<u>Total sales deductions</u>
Balance at December 28, 2002	\$ 2,496	\$ 200	\$ 894	\$ 313	\$ 3,903
Provision for sales	6,287	2,238	4,331	808	13,664
Actual credits utilized during 2003	(4,286)	(571)	(4,573)	(804)	(10,234)
Balance at December 27, 2003	4,497	1,867	652	317	7,333
Provision for sales	7,831	3,819	7,266	1,087	20,003
Actual credits utilized during 2004	(7,911)	(3,106)	(6,851)	(916)	(18,784)
Balance at December 25, 2004	\$ 4,417	\$ 2,580	\$ 1,067	\$ 488	\$ 8,552

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

At December 25, 2004, we had inventory, net on hand of \$20.2 million. In the year ended December 25, 2004, we recorded a provision for inventory valuation allowance of \$4.0 million. We review inventory on hand at each reporting period to assess that inventory is stated at the lower of cost or market and that inventory on hand is saleable. Our assessment of inventory includes review of selling price compared to inventory carrying cost, recent sales trends and our expectations for sales trends in future periods, ongoing validation that inventory is maintained within established product specifications and product shelf life expiration. Based on these assessments, we provide for an inventory valuation allowance in the period in which the requirement is identified. If our actual experience is greater than our assumptions we will record additional expenses in that period.

We have made, are in the process of making and/or will scale-up and make commercial quantities of certain of our product candidates prior to the date we anticipate that such products will receive final EU regulatory or FDA marketing approval (i.e., pre-launch inventories). The scale-up and commercial production of pre-launch inventories involves the risk that such products may not be approved for marketing by the governmental agencies on a timely basis, or ever. This risk notwithstanding, we plan to continue to scale-up and build pre-launch inventories of certain products that have not yet received final governmental approval. As of December 25, 2004, we had approximately \$2.3 million of inventories, primarily work-in-process, related to StaphVAX and Nabi-HB Intravenous pending final regulatory approval.

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We record pre-launch inventory once the product has attained a stage in the development process of having been subject to a Phase III clinical trial, or its equivalent, or a MAA or BLA filing. Further, the product must have a well-characterized manufacturing process. In addition, we must have an internal sales forecast that includes an assessment whereby anticipated future sales exceed the manufacturing costs plus the expected cost to distribute the product. Finally, product stability data must exist so that we can assert that capitalized inventory is anticipated to be sold, based on the sales projections noted above, prior to anticipated expiration of product shelf life.

If approval for these product candidates is not received, or approval is not received timely compared to our estimates for product shelf life, we will write the related amounts of pre-launch inventory off in the period of that determination. If we were required to write off the \$2.3 million recorded as pre-launch inventory at December 25, 2004, this amount would be considered by us to be material to our operating results.

### *Income Taxes*

We follow Statement of Financial Accounting Standards, or SFAS No. 109, *Accounting for Income Taxes*, which requires, among other things, recognition of future tax benefits and liabilities measured at enacted rates attributable to temporary differences between financial statement and income tax bases of assets and liabilities and to tax net operating loss carryforwards to the extent that realization of these benefits is more likely than not. We periodically evaluate the realizability of our net deferred tax assets. As a result of licensing the right to market StaphVAX and PhosLo in the EU to one of our ex-U.S. subsidiaries and in recognition of the value of the product rights developed and acquired by us, we realized a gain for U.S. tax reporting purposes of approximately \$55 million. Although we recognized a consolidated operating loss on a GAAP basis during the 2004, we nevertheless incurred income tax expense due to the U.S. taxable gain arising from licenses of these product rights to our non-U.S. subsidiary. We anticipate realizing deferred tax assets from net operating loss carryforwards incurred in prior periods and the exercise of employee stock options to offset this income tax expense. As a result, we do not anticipate making a U.S. income tax payment for 2004. For 2004, the provision for income taxes reflected a provision of \$10.4 million due to the recognition of this gain. We determined that we do not require a valuation allowance for research and development tax credits and net operating losses as a result of our European strategy and our determination that it is more likely than not that this strategy will result in realization of these tax assets. We have recorded \$4.4 million as a tax contingency reserve against certain of our deferred tax assets that is included in other long-term liabilities.

### **New Accounting Pronouncements**

In December 2004, the FASB announced that SFAS No. 123R, *Share-Based Payment*, which requires all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value, is effective for public companies for interim or annual periods beginning after June 15, 2005. SFAS 123R requires companies to expense the fair value of all stock options that have future vesting provisions, are modified, or are newly granted

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beginning on the grant date of such options. We believe implementation of SFAS No. 123R will be material to our reported results of operations. Using the Black-Scholes model for valuating stock options under FAS 148 would result in expense for options granted in prior years in the amount of \$9.0 million, \$9.4 million and \$7.3 million for the years ending in 2005, 2006 and 2007, respectively.

In December 2004, the FASB announced that SFAS 151, *Inventory Costs* is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. This statement clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). This Statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal", as defined in Accounting Principal Board 43. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. We will evaluate the requirements of the final standard to determine the impact on our financial condition, results of operations or cash flows.

### Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined effective could provide only reasonable assurance with respect to financial statement preparation and presentation.

An internal control significant deficiency is a control deficiency, or combination of control deficiencies, that adversely affects the company's ability to initiate, authorize, record, process, or report external financial data reliably in accordance with generally accepted accounting principles such that there is more than a remote likelihood that a misstatement of the company's annual or interim financial statements that is more than inconsequential will not be prevented or detected. An internal control material weakness is a significant deficiency, or combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Our management assessed the effectiveness of our internal control over financial reporting as of December 25, 2004, and this assessment identified one material weakness in our internal control over financial reporting as of that date related to the controls that ensure that the selection and approval of periods for certain intangible assets is in accordance with SFAS No. 142 *Goodwill and Other Intangible Assets* for the periods ended December 27, 2003 and December 28, 2002. As a result of this assessment, we have restated our financial statements. Refer to footnote 17 of the Consolidated Financial Statements.

Based on our evaluation under the framework in Internal Control, Integrated Framework, our management concluded that our internal control over financial reporting was not effective as of December 25, 2004.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 25, 2004 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

### Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during our fiscal quarter ended December 25, 2004 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting. During the first quarter of 2005, management implemented steps to address the material weakness more fully described below.

### Remediation Steps to Address Material Weakness

We have implemented additional review procedures to ensure that upon entry into an agreement, under which we create a manufacturing right intangible asset we will select and approve an amortization period beginning immediately from the point we generate a direct or indirect economic benefit consistent with the provisions of SFAS No. 142 *Goodwill and Other Intangible Assets*.

**ITEM 7a. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

*Foreign Currency Exchange Risk.* We have two wholly owned Irish subsidiaries and one Luxembourg subsidiary. During the year ended December 25, 2004, we did not record any sales by our foreign subsidiaries. Two of our subsidiaries incurred expenses during this period, primarily relating to our initial activities to obtain regulatory approval in the EU for our pipeline products and products that we currently market in the U.S. If the U.S. dollar weakens relative to a foreign currency, any losses generated in the foreign currency will, in effect, increase when converted into U.S. dollars and vice versa. We do not speculate in the foreign exchange market and do not manage exposures that arise in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. We also do not engage in derivative activities.

*Interest Rate Risk.* At December 25, 2004, we had cash and cash equivalents and marketable securities in the amount of \$94.8 million and \$8.4 million, respectively. In addition, we had notes payable for the acquisition of PhosLo of \$23.3 million, net of imputed discount and capital lease obligations of \$0.6 million.

Cash equivalents consist of money market funds and qualified purchaser funds with maturities of three months or less placed with major financial institutions. Marketable securities consist of auction rate securities placed with major financial institutions.

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

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

<u>Dollars in Millions</u>	<u>Fair Value at December 25, 2004</u>
<b>Assets:</b>	
Cash equivalents	\$ 94.8
Marketable securities	8.4
Average interest rate	1.4%
<b>Liabilities:</b>	
Notes payable and capital lease obligations	\$ 23.9
Average interest rate	4.9%

**Nabi Biopharmaceuticals**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of Nabi Biopharmaceuticals

We have audited the accompanying consolidated balance sheets of Nabi Biopharmaceuticals as of December 25, 2004 and December 27, 2003, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 25, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Nabi Biopharmaceuticals at December 25, 2004 and December 27, 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 25, 2004 in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule referred to above, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in note 17, the Company's December 27, 2003 and December 28, 2002 financial statements referred to above have been restated for the correction of an error.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Nabi Biopharmaceuticals' internal control over financial reporting as of December 25, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2005 expressed an unqualified opinion on management's assessment and an adverse opinion on the effectiveness of internal control over financial reporting.

/s/ Ernst & Young LLP  
Certified Public Accountants

West Palm Beach, Florida  
March 8, 2005



## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of Nabi Biopharmaceuticals

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, that Nabi Biopharmaceuticals did not maintain effective internal control over financial reporting as of December 25, 2004, because of the effect of ineffective controls over the Company's accounting for amortization expense related to certain intangible assets for the periods ending December 27, 2003 and December 28, 2002, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Nabi Biopharmaceuticals' management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The following material weakness has been identified and included in management's assessment. Certain intangible assets related to manufacturing rights were not being properly amortized in accordance with SFAS No. 142 Goodwill and Other Intangible Assets. As a result, Nabi Biopharmaceuticals restated its financial statements for the years ended December 27, 2003 and December 28, 2002 for the effects of amortizing intangible manufacturing rights. This material weakness was considered in determining the nature,

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timing, and extent of audit tests applied in our audit of the December 25, 2004 financial statements, and this report does not affect our report dated March 8, 2005 on those financial statements.

In our opinion, management's assessment that Nabi Biopharmaceuticals did not maintain effective internal control over financial reporting as of December 25, 2004, is fairly stated, in all material respects, based on the COSO control criteria. Also, in our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, Nabi Biopharmaceuticals has not maintained effective internal control over financial reporting as of December 25, 2004, based on the COSO control criteria.

Ernst & Young LLP  
Certified Public Accountants

West Palm Beach, Florida  
March 8, 2005

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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**Nabi Biopharmaceuticals**

**CONSOLIDATED BALANCE SHEETS**

Amounts in Thousands, Except Share and Per Share Data	December 25, 2004	December 27, 2003
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 94,759	\$ 115,756
Marketable securities	8,350	—
Restricted cash	672	689
Trade accounts receivable, net	32,405	37,062
Inventories, net	20,175	23,483
Prepaid expenses and other current assets	6,227	4,971
<b>Total current assets</b>	<b>162,588</b>	<b>181,961</b>
<b>Property, plant and equipment, net</b>	<b>115,406</b>	<b>101,831</b>
<b>Other assets:</b>		
Intangible assets, net	89,728	94,991
Other, net	449	8,518
<b>Total assets</b>	<b>\$ 368,171</b>	<b>\$ 387,301</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Trade accounts payable	\$ 21,943	\$ 10,874
Accrued expenses	32,290	23,956
Notes payable and capital lease obligations	10,173	4,226
<b>Total current liabilities</b>	<b>64,406</b>	<b>39,056</b>
<b>Notes payable and capital lease obligations</b>	<b>13,671</b>	<b>23,167</b>
<b>Other liabilities</b>	<b>5,773</b>	<b>5,762</b>
<b>Total liabilities</b>	<b>83,850</b>	<b>67,985</b>
<b>Stockholders' equity:</b>		
Convertible preferred stock, par value \$.10 per share: 5,000 shares authorized; no shares outstanding	—	—
Common stock, par value \$.10 per share: 125,000,000 and 75,000,000 shares authorized, respectively; 59,428,941 and 57,723,019 shares issued, respectively	5,943	5,772
Capital in excess of par value	313,494	297,910
Treasury stock, 803,811 and 800,315 shares, respectively, at cost	(5,297)	(5,240)
(Accumulated deficit) retained earnings	(29,516)	20,874
Other accumulated comprehensive loss	(303)	—
<b>Total stockholders' equity</b>	<b>284,321</b>	<b>319,316</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 368,171</b>	<b>\$ 387,301</b>

See accompanying notes to consolidated financial statements.

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## Nabi Biopharmaceuticals

## CONSOLIDATED STATEMENTS OF OPERATIONS

Amounts in Thousands, Except Per Share Data	For the Years Ended		
	December 25, 2004	December 27, 2003 (as restated)	December 28, 2002 (as restated)
<b>Sales</b>	\$ 179,763	\$ 176,570	\$ 195,966
<b>Costs and expenses:</b>			
Costs of products sold, excluding amortization of intangible assets	76,345	81,354	119,170
Royalty expense	17,569	18,387	12,883
<b>Gross margin, excluding amortization of intangible assets</b>	<b>85,849</b>	<b>76,829</b>	<b>63,913</b>
Selling, general and administrative expense	55,286	43,867	38,380
Research and development expense	61,003	29,040	21,096
Amortization of intangible assets	8,673	5,393	1,116
Other operating expenses, principally freight	521	477	583
Write-off of manufacturing right	—	9,735	—
<b>Operating (loss) income</b>	<b>(39,634)</b>	<b>(11,683)</b>	<b>2,738</b>
<b>Interest income</b>	<b>1,628</b>	<b>614</b>	<b>1,287</b>
<b>Interest expense</b>	<b>(2,199)</b>	<b>(1,350)</b>	<b>(2,130)</b>
<b>Other income (expenses), net</b>	<b>213</b>	<b>204</b>	<b>(157)</b>
<b>(Loss) income before (provision) benefit for income taxes</b>	<b>(39,992)</b>	<b>(12,215)</b>	<b>1,738</b>
<b>(Provision) benefit for income taxes</b>	<b>(10,398)</b>	<b>6,149</b>	<b>(264)</b>
<b>Net (loss) income</b>	<b>\$ (50,390)</b>	<b>\$ (6,066)</b>	<b>\$ 1,474</b>
<b>Basic (loss) earnings per share</b>	<b>\$ (0.86)</b>	<b>\$ (0.14)</b>	<b>\$ 0.04</b>
<b>Diluted (loss) earnings per share</b>	<b>\$ (0.86)</b>	<b>\$ (0.14)</b>	<b>\$ 0.04</b>
<b>Basic weighted average shares outstanding</b>	<b>58,800</b>	<b>42,888</b>	<b>38,670</b>
<b>Diluted weighted average shares outstanding</b>	<b>58,800</b>	<b>42,888</b>	<b>39,641</b>

See accompanying notes to consolidated financial statements.

**Nabi Biopharmaceuticals**
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (as restated)**

In Thousands	Common Stock		Common Stock Warrants		Capital in Excess of Par Value	Treasury Stock		Retained Earnings (Accumulated deficit)	Other accumulated comprehensive loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount		Shares	Amount			
<b>Balance at December 29, 2001</b>	38,445	\$3,845	133	\$ —	\$158,687	(174)	\$ (977)	\$ 25,466	\$ —	\$ 187,021
Stock options exercised	317	32	—	—	1,199	—	—	—	—	1,231
Delivery of shares upon exercise of options	60	6	—	—	208	(40)	(246)	—	—	(32)
Compensation expense related to modified stock options	—	—	—	—	(13)	—	—	—	—	(13)
Adjustment relating to tax effect from stock options exercised in 2001	—	—	—	—	(1,133)	—	—	—	—	(1,133)
Net income for the year	—	—	—	—	—	—	—	1,474	—	1,474
Stock issued under Employee Stock Purchase Plan	117	12	—	—	572	—	—	—	—	584
Purchase of treasury stock at cost	—	—	—	—	—	(172)	(917)	—	—	(917)
Directors fees paid in stock	8	—	—	—	48	—	—	—	—	48
<b>Balance at December 28, 2002</b>	38,947	3,895	133	—	159,568	(386)	(2,140)	26,940	—	188,263
Stock options exercised	1,165	117	—	—	5,288	—	—	—	—	5,405
Delivery of shares upon exercise of options	644	64	—	—	2,586	(414)	(3,100)	—	—	(450)
Compensation expense related to modified stock options	—	—	—	—	350	—	—	—	—	350
Common shares issued for product acquisition	1,500	150	—	—	8,250	—	—	—	—	8,400
Net loss for the year	—	—	—	—	—	—	—	(6,066)	—	(6,066)
Issuance of common stock in private placement and underwritten offering, net of issuance costs	15,352	1,536	—	—	121,188	—	—	—	—	122,724
Stock issued under Employee Stock Purchase Plan	112	11	—	—	657	—	—	—	—	668
Directors fees paid in stock	3	—	—	—	22	—	—	—	—	22
<b>Balance at December 27, 2003</b>	57,723	5,773	133	—	297,909	(800)	(5,240)	20,874	—	319,316
Comprehensive loss	—	—	—	—	—	—	—	(50,390)	—	(50,390)
- Net loss for the year	—	—	—	—	—	—	—	(50,390)	—	(50,390)
- Currency translation adjustment	—	—	—	—	—	—	—	—	(303)	(303)
Comprehensive loss	—	—	—	—	—	—	—	—	—	(50,693)
Stock options exercised	1,534	153	—	—	9,667	—	—	—	—	9,820
Delivery of shares upon exercise of options	6	1	—	—	44	(4)	(57)	—	—	(12)
Compensation expense related to modified stock options	—	—	—	—	150	—	—	—	—	150
Stock issued under Employee Stock Purchase Plan	91	9	—	—	950	—	—	—	—	959
Tax benefit of stock option exercises	—	—	—	—	4,761	—	—	—	—	4,761
Warrants exercised	74	7	(133)	—	(7)	—	—	—	—	—
Directors fees paid in stock	1	—	—	—	20	—	—	—	—	20
<b>Balance at December 25, 2004</b>	59,429	\$5,943	—	\$ —	\$313,494	(804)	\$(5,297)	\$ (29,516)	\$ (303)	\$ 284,321

See accompanying notes to consolidated financial statements.

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**Nabi Biopharmaceuticals**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

Dollars in Thousands	For the Years Ended		
	December 25, 2004	December 27, 2003 (as restated)	December 28, 2002 (as restated)
<b>Cash flow from operating activities:</b>			
Net (loss) income	\$ (50,390)	\$ (6,066)	\$ 1,474
Adjustments to reconcile net (loss) income to net cash provided by Operating activities:			
Depreciation and amortization	18,178	15,854	11,009
Write-off of manufacturing right	—	9,735	—
Loan origination fees	539	232	400
Interest expense on non-interest bearing notes	1,338	589	—
Provision for doubtful accounts	428	39	751
Provision for slow moving or obsolete inventory	3,950	1,044	169
Non-cash compensation	1,129	1,040	619
Deferred income taxes	4,714	(5,753)	131
Tax benefit from stock option exercises	4,761	—	—
Write-off of fixed assets	259	23	269
Other, primarily foreign currency translation	(422)	—	—
Changes in assets and liabilities:			
Trade accounts receivable	4,229	(775)	(1,037)
Inventories	(685)	(4,983)	(1,419)
Prepaid expenses and other assets	2,323	170	2,098
Other assets	88	1,167	(33)
Income taxes payable	262	—	—
Accounts payable and accrued expenses	18,037	(4,774)	(3,511)
	59,128	13,608	9,446
<b>Net cash provided by operating activities</b>	<b>8,738</b>	<b>7,542</b>	<b>10,920</b>
<b>Cash flow from investing activities:</b>			
Purchases of marketable securities	(83,950)	—	(86,350)
Proceeds from sales of marketable securities	75,600	—	86,350
Proceeds from sale of assets, net of closing costs	179	—	—
Capital expenditures	(22,633)	(8,050)	(6,021)
Expenditures for Aloprim	(750)	—	—
Expenditures for other assets – PhosLo	—	(61,255)	—
Expenditures for other assets – Dow	—	(2,024)	(6,136)
Expenditures for other assets – Cambrex Bio Science	(2,668)	(323)	—
	(34,222)	(71,652)	(12,157)
<b>Net cash used in investing activities</b>	<b>(34,222)</b>	<b>(71,652)</b>	<b>(12,157)</b>
<b>Cash flow from financing activities:</b>			
Repayments of notes payable, PhosLo acquisition	(5,333)	—	—
Redemption of Convertible Subordinated Debt	—	—	(78,500)
Borrowings of term debt	—	10,000	—
Repayments of term debt	—	(10,000)	—
Purchase of treasury stock	—	—	(917)
Proceeds from exercise of employee stock options	9,820	5,405	1,199
Issuance of common stock, net	—	122,724	—
	4,487	128,129	(78,218)
<b>Net cash provided by (used in) financing activities</b>	<b>4,487</b>	<b>128,129</b>	<b>(78,218)</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(20,997)</b>	<b>64,019</b>	<b>(79,455)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>115,756</b>	<b>51,737</b>	<b>131,192</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 94,759</b>	<b>\$ 115,756</b>	<b>\$ 51,737</b>

See accompanying notes to consolidated financial statements.

**Nabi Biopharmaceuticals**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1 BUSINESS AND ORGANIZATION**

We leverage our experience and knowledge in powering the immune system to develop and market products that fight serious medical conditions. We are poised to capture the large, commercial opportunities in our four core business areas: Gram-positive bacterial infections; hepatitis; kidney disease (nephrology); and nicotine addiction. We have four products on the market today and a number of products in various stages of clinical and preclinical development. We invest the gross margins we earn from sales of our marketed products toward funding the development of our product pipeline.

We are incorporated in Delaware. Our U.S. operations are headquartered in Boca Raton, Florida and our European offices are located in Bray, Ireland; we maintain our commercial and manufacturing operations in Boca Raton, Florida and research and development operations in Rockville, Maryland. In addition to our biopharmaceutical business, we also collect specialty and non-specific antibodies for use in our products and sell our excess production to pharmaceutical and diagnostic customers for the subsequent manufacture of their products.

**NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Principles of consolidation:* The consolidated financial statements include the accounts of Nabi Biopharmaceuticals and our wholly owned subsidiaries. All significant inter-company accounts and transactions are eliminated in consolidation.

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

*Basis of presentation:* We have restated our balance sheet as of December 28, 2002 and our statements of operations, changes in stockholders' equity and cash flows for the years ended December 27, 2003 and December 28, 2002. In addition, certain items in the 2003 and 2002 consolidated financial statements have been reclassified to conform to the current year's presentation.

*Revenue recognition:* Our primary customers for biopharmaceutical products are pharmaceutical wholesalers. In accordance with our revenue recognition policy, revenue from biopharmaceutical product sales is recognized when title and risk of loss are transferred to the customer. Reported sales are net of estimated customer prompt pay discounts, contractual allowances in accordance with managed care agreements or chargebacks, government payer rebates, customer returns of PhosLo and other wholesaler fees. Our policy regarding sales to customers is that we do not recognize revenue from, or the cost of, such sales where we believe the customer has more than a demonstrably reasonable level of inventory. We make this assessment based on historical demand, historical customer ordering patterns for purchases and estimated inventory levels. If our actual experience were greater than our assumptions we would then adjust such allowances accordingly.

We estimate allowances for revenue dilution items using a combination of information received from third parties, including market data, inventory reports from our major U.S. wholesaler customers, historical information and analysis that we perform. The key assumptions used to arrive at our best estimate of revenue dilution reserves are estimated customer inventory levels, contractual prices and related terms. Our estimates of inventory at wholesaler customers and in the distribution channels are subject to the inherent limitations of estimates that rely on third-party

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data, as certain third-party information may itself rely on estimates, and reflect other limitations. Provisions for estimated rebates and other allowances, such as discounts, promotional and other credits are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels and contract terms and actual discounts offered. We believe that such provisions are determinable due to the limited number of assumptions involved and the consistency of historical experience. Provisions for chargebacks involve more subjective judgments and are more complex in nature. These provisions are discussed in further detail below.

*Chargebacks* - The provision for chargebacks is a significant and complex estimate used in the recognition of revenue. We market products directly to wholesalers, distributors and homecare companies. We also market products indirectly to group purchasing organizations, managed care organizations, physician practice management groups and hospitals, collectively referred to as "indirect customers." We enter into agreements with indirect customers to establish contract pricing for certain products. The indirect customers then select wholesalers from which to actually purchase the products at these contracted prices. Under this arrangement, we will provide credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler's invoice price. Such credit is called a chargeback. The provision for chargebacks is based on our historical chargeback experience and estimated wholesaler inventory levels, as well as expected sell-through levels by our wholesale customers to indirect customers. Our estimates of inventory at wholesale customers and in the distribution channels are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates, and reflect other limitations. We continually monitor our provision for chargebacks and make adjustments when we believe that actual chargebacks may differ from established reserves.

*Research and development expense:* Research and development costs are expensed as incurred. Amounts payable to third parties under collaborative product development agreements are recorded at the earlier of the milestone achievement or as payments become contractually due. Funding from third party grants are applied directly to related expenses. For the years ended December 25, 2004, December 27, 2003 and December 28, 2002, we received grants from the National Institute on Drug Addition, or NIDA, in the amounts of \$0.3 million, \$1.3 million, and \$1.2 million, respectively and have recorded the funding as a reduction of Research and Development expense.

*Advertising expenses:* Advertising costs are expensed as incurred as set forth in Statement of Position 93-7, *Reporting on Advertising Costs*. Advertising expenses for the years ended December 25, 2004, December 27, 2003 and December 28, 2002 amounted to \$3.8 million, \$3.3 million and \$3.4 million, respectively.

*Shipping and Handling Costs:* We report costs related to the shipment of our product as part of other operating expenses, principally freight. We incurred \$0.5 million, \$0.5 million, and \$0.6 million in the years ended December 25, 2004, December 27, 2003 and December 28, 2002, respectively.

*Comprehensive Loss:* We follow SFAS No. 130, *Reporting Comprehensive Income*, which computes comprehensive income as the total of net income and all other changes in shareholders' equity. For the year ended December 25, 2004, comprehensive loss included our net loss and the effect of foreign currency translation adjustments. As of December 25, 2004, \$0.3 million of foreign currency loss was included on our balance sheet in addition to net loss. The foreign currency loss primarily related to intercompany balances we have classified as intercompany debt. It is our intent for the amounts paid on behalf of our subsidiaries to be repaid once we begin generating revenue in the markets the subsidiaries operate in, primarily Europe.

*(Loss) earnings per share:* Basic (loss) earnings per share are computed by dividing consolidated net (loss) earnings by the weighted average number of common shares outstanding during the year. Diluted earnings per share are computed by dividing consolidated net earnings by the weighted average number of common shares outstanding, and the impact of all potential dilutive common shares, primarily stock options. The dilutive impact of stock options is determined by applying the treasury stock method. In 2004 and 2003, we did not apply this method as there



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would have been an anti-dilutive effect on earnings per share. There were 2,101,279 and 1,172,833 potential dilutive shares excluded in the calculation of diluted weighted average shares outstanding in 2004 and 2003, respectively.

*Financial instruments:* The carrying amounts of financial instruments including cash equivalents, short-term investments, accounts receivable and accounts payable approximated fair value as of December 25, 2004 and December 27, 2003, because of the relatively short-term maturity of these instruments. Total debt and capital leases obligations were \$23.9 million as of December 25, 2004 and \$27.4 million as of December 27, 2003. The carrying value of long-term debt at December 25, 2004 is consistent with its estimated fair value. Information regarding long-term debt is included in Note 11.

*Cash and cash equivalents:* Cash equivalents consist of money market funds and qualified purchaser funds with maturities of three months or less placed with major financial institutions.

*Marketable securities:* Short-term investments in marketable debt securities consist of auction rate securities with final maturities longer than three years, but with interest rate auctions occurring every 28 or 35 days. These short-term marketable securities consist primarily of taxable municipal bonds, corporate bonds, government agency securities and commercial paper. It is our intent to maintain a liquid portfolio to take advantage of investment opportunities; therefore, these securities are deemed short-term, are classified as available for sale securities and are recorded at market value using the specific identification method. Realized gains and losses are included in "Other income" in the accompanying consolidated statements of operations using the specific identification method. Unrealized gains and losses are included in "Other comprehensive income" in the accompanying consolidated balance sheet and consolidated statement of changes in stockholders' equity.

*Trade Accounts Receivable:* We sell a significant portion of our products through pharmaceutical wholesalers and distributors and to major pharmaceutical companies and, as a result, maintain individually significant receivable balances with major customers. Those customers include McKesson Drug Co., AmerisourceBergen, Cardinal Health, Inc. and Bayer Corporation, representing 31%, 28% 12% and 9% of our total accounts receivable, respectively at December 25, 2004. If the financial condition or operations of these customers were to deteriorate, our results could be adversely affected. Credit terms to these customers generally range from 30 to 60 days. We evaluate and monitor the credit worthiness of each customer on a case-by-case basis and do not require collateral on specific accounts receivable. Allowances are maintained for potential credit losses. Accounts receivable allowances are recorded in the segment operating results in which the applicable sale was originally reported.

*Inventories:* Inventories are stated at the lower of cost or market with cost determined on the first-in first-out or FIFO method.

The scale-up and commercial production of pre-launch inventories involves the risk that such products may not be approved for marketing by the governmental agencies on a timely basis, or ever. This risk notwithstanding, we plan to continue to scale-up and build pre-launch inventories of certain products that have not yet received final governmental approval. As of December 25, 2004, we had approximately \$2.3 million of inventories, primarily work-in-process, related to StaphVAX and Nabi-HB Intravenous, pending final regulatory approval.

We record pre-launch inventory once the product has attained a stage in the development process of having been subject to a Phase III clinical trial, or its equivalent, or a MAA or BLA filing. Further, the product must have a well-characterized manufacturing process. In addition, we must have an internal sales forecast that includes an assessment whereby anticipated future sales exceed the manufacturing costs plus the expected cost to distribute the product. Finally, product stability data must exist so that we can assert that capitalized inventory is anticipated to be sold, based on the sales projections noted above, prior to anticipated expiration of product shelf life.

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If approval for these product candidates is not received, or approval is not received timely compared to our estimates for product shelf life, we will write-off the related amounts of pre-launch inventory in the period of that determination. If we were required to write off the \$2.3 million recorded as pre-launch inventory at December 25, 2004, this amount would be considered by us to be material to our operating results.

*Property, plant and equipment:* Property, plant and equipment are carried at cost. Depreciation is generally recognized on the straight-line method over the estimated useful lives of the assets.

Depreciation for certain specialized production equipment in our Boca Raton, Florida biopharmaceutical manufacturing facility is calculated over its remaining useful life using the units-of-production method. In quarters of lower production, we record a minimum of 60% of the depreciation that would have otherwise been recorded had we used the straight-line method. We evaluate the remaining life and recoverability of this equipment periodically based on the appropriate facts and circumstances.

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Depreciable lives of property and equipment are as follows:

<u>Asset</u>	<u>Initial Useful Life</u>
Buildings	39 years
Building systems	20 years
Furniture and fixtures	8 years
Information systems	3 – 7 years
Machinery and equipment	3 – 8 years
Leasehold improvements and capital leases	Lesser of lease term or economic life

*Intangible assets:* Intangible assets represent the fair values of certain assets acquired in product acquisitions including trademarks and trademark registrations and the cost to acquire the right to use manufacturing capacity at our contract manufacturer's facility for StaphVAX in future periods. The carrying costs of intangible assets are amortized ratably from the date acquired over periods ranging from 3 to 25 years.

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

<u>Asset</u>	<u>Estimated Remaining Useful Life</u>
PhosLo trademark/tradename	16.3 years
PhosLo tablet patent	2.3 years
PhosLo gelcap patent	16.3 years
PhosLo customer relationships	3.6 years
PhosLo covenant not to compete	13.6 years
Manufacturing right	8.8 years
Other intangible assets	1.0 to 12.8 years

### PhosLo Intangibles

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

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

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*Manufacturing Right Intangible:* In October 2003, we entered into a contract manufacturing agreement with Cambrex Bio Science. Under our agreement with Cambrex Bio Science, at December 25, 2004 we are committed to make future payments of at least \$0.2 million including costs to acquire the rights to commercial manufacturing capacity for StaphVAX vaccine. We have commenced amortization of the Manufacturing Right. Due to StaphVAX being a new product and the exact period of future economic benefit that will be derived from the sale of StaphVAX being difficult to determine, we have elected to amortize the Manufacturing Right on a straight-line basis over the extended term of our contract manufacturing agreement with Cambrex Bio Science, which may be extended, at our option, through October 2013. At December 25, 2004, we have capitalized \$2.9 million, net as a Manufacturing Right on our balance sheet. If we determine that the manufacture of StaphVAX will not occur at Cambrex Bio Science's facility, or we assess that circumstances have resulted in changes to the carrying value of the intangible asset, we will write off this Manufacturing Right in the period of that determination.

*Impairment of Long-Lived Assets:* Pursuant to the provisions of Statement of Financial Accounting Standards, or SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, we review long-lived assets for impairment at least annually, or whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. If this review reveals indications of impairment, as generally determined based on estimated undiscounted cash flows, the carrying amount of the related long-lived assets are adjusted to fair value.

*Stock-Based Compensation:* We grant stock options for a fixed number of common shares to employees and directors from time to time. We account for employee stock options using the intrinsic value method as prescribed by APB Opinion No. 25, *Accounting for Stock Issued to Employees*, which provides that no compensation expense is recognized for stock option grants when the exercise price of the options equals, or is greater than, the market value of the underlying stock on the date of grant. Accordingly, we did not recognize any compensation cost during each of the years ended December 25, 2004, December 27, 2003 and December 28, 2002 for stock-based employee awards at the market price. We did recognize expense related to modification of stock option terms related to the retirement of certain employees. Refer to Note 18. We follow the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123* (SFAS 148), for stock options issued to non-employees.

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The effect of applying the fair value method prescribed by SFAS 123 to our options would have us recording the following pro forma net (loss) income and net (loss) income per share amounts:

Dollars in Thousands, Except Per Share Data	For the Years Ended		
	December 25, 2004	December 27, 2003 (as restated)	December 28, 2002 (as restated)
<b>Net (loss) income:</b>			
As reported	\$ (50,390)	\$ (6,066)	\$ 1,474
Add: Stock-based employee compensation expense included in reported net (loss) income, net of tax	150	350	13
Deduct: Total stock-based employee compensation expense determined under fair value based method, net of tax	(4,567)	(3,977)	(5,984)
Pro forma	<u>\$ (54,807)</u>	<u>\$ (9,693)</u>	<u>\$ (4,497)</u>
<b>Basic (loss) earnings per share:</b>			
As reported	\$ (0.86)	\$ (0.14)	\$ 0.04
Net compensation expense, net of tax	(0.08)	(0.08)	(0.15)
Pro forma	<u>\$ (0.94)</u>	<u>\$ (0.22)</u>	<u>\$ (0.11)</u>
<b>Diluted (loss) earnings per share:</b>			
As reported	\$ (0.86)	\$ (0.14)	\$ 0.04
Net compensation expense, net of tax	(0.08)	(0.08)	(0.15)
Pro forma	<u>\$ (0.94)</u>	<u>\$ (0.22)</u>	<u>\$ (0.11)</u>

Pro forma information regarding net income or loss is required by SFAS 123 and has been determined as if we had accounted for our employee stock options under the fair value method of that statement. The fair value of options granted was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions: expected term of two to five years; expected volatility of 60 – 67%; and expected risk-free interest rates of 2.73 – 4.15%. The weighted-average estimated fair value of options granted during 2004, 2003 and 2002 was \$8.31, \$4.45 and \$5.76, respectively.

### *Income Taxes*

We follow Statement of Financial Accounting Standards, or SFAS No. 109, *Accounting for Income Taxes*, which requires, among other things, recognition of future tax benefits and liabilities measured at enacted rates attributable to temporary differences between financial statement and income tax bases of assets and liabilities and to tax net operating loss carryforwards to the extent that realization of these benefits is more likely than not. We periodically evaluate the realizability of our net deferred tax assets. As a result of licensing the right to market StaphVAX and PhosLo in the EU to one of our ex-U.S. subsidiaries and in recognition of the value of the product rights developed and acquired by us, we realized a gain for U.S. tax reporting purposes of approximately \$55 million. Although we recognized a consolidated operating loss on accounting principles generally accepted in the U.S., or GAAP, basis during 2004, we nevertheless incurred income tax expense due to the U.S. taxable gain arising from the licensing of these product rights to our non-U.S. subsidiary. We anticipate realizing deferred tax assets from net operating loss carryforwards incurred in prior periods and the exercise of employee stock options to offset this income tax expense. As a result, we do not

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anticipate making a U.S. income tax payment for 2004. For 2004, the provision for income taxes reflected a provision of \$10.4 million due to the recognition of this gain. We determined that we do not require a valuation allowance for research and development tax credits and net operating losses as a result of our European strategy and our determination that it is more likely than not that this strategy will result in realization of these tax assets. Our policy is to establish accruals for tax contingencies that may arise in future years as a result of examination by tax authorities, despite our belief that our tax return positions are correct. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment.

*Foreign Currency Translation.* In accordance with SFAS No. 52, Foreign Currency Translation, assets and liabilities denominated in foreign currencies are translated into U.S. dollars at the rate of exchange at the balance sheet date, while revenue and expenses are translated at the weighted average rates prevailing during the respective years. Components of stockholders' equity are translated at historical rates. Translation adjustments are deferred in accumulated other comprehensive loss, which is a separate component of stockholders' equity. Our foreign subsidiaries use the Euro and U.S. dollar as their functional currencies. Gains and losses resulting from changes in exchange rates from year to year are included in the accompanying consolidated statements of operations as other operating expenses.

*New Accounting Pronouncements:* In December 2004, the FASB announced that SFAS No. 123R, *Share-Based Payment*, which requires all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value, is effective for public companies for interim or annual periods beginning after June 15, 2005. SFAS 123R requires companies to expense the fair value of all stock options that have future vesting provisions, are modified, or are newly granted beginning on the grant date of such options. We believe implementation of SFAS No. 123R will be material to our reported results of operations. Using the Black-Scholes model for valuing stock options under SFAS No. 123R would result in pre-tax expense for options granted in prior years in the amount of \$9.0 million, \$9.4 million and \$7.3 million for the years ending in 2005, 2006 and 2007, respectively.

In December 2004, the FASB announced that SFAS No. 151, *Inventory Costs*, is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. This statement clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). This Statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal" as defined in Accounting Principal Board 43. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. We will evaluate the requirements of the final standard to determine the impact on our financial condition, results of operations or cash flows.

### **NOTE 3 TRADE ACCOUNTS RECEIVABLE**

Trade accounts receivable are composed of the following:

<u>Dollars in Thousands</u>	<u>December 25, 2004</u>	<u>December 27, 2003</u>
Trade accounts receivable	\$ 32,838	\$ 37,708
Allowance for doubtful accounts	(433)	(646)
<b>Total</b>	<b>\$ 32,405</b>	<b>\$ 37,062</b>

**NOTE 4 INVENTORIES, NET**

The components of inventories, net are as follows:

<u>Dollars in Thousands</u>	<u>December 25, 2004</u>	<u>December 27, 2003</u>
Finished goods	\$ 11,475	\$ 12,746
Work in process	7,826	9,955
Raw materials	874	782
<b>Total</b>	<b>\$ 20,175</b>	<b>\$ 23,483</b>

Work in process inventory at December 25, 2004 and December 27, 2003 primarily consisted of Nabi-HB for which manufacture was in process or that was awaiting release to the market from the U.S. Food and Drug Administration, or FDA, in accordance with the normal course of our business. In addition, we have made, are in the process of making and/or will scale-up and make commercial quantities of certain of our product candidates prior to the date we anticipate that such products will receive final EU regulatory or FDA marketing approval (i.e., pre-launch inventories). The scale-up and commercial production of pre-launch inventories involves the risk that such products may not be approved for marketing by the governmental agencies on a timely basis, or ever. This risk notwithstanding, we plan to continue to scale-up and build pre-launch inventories of certain products that have not yet received final governmental approval. As of December 25, 2004, we had approximately \$2.3 million of inventories of StaphVAX and Nabi-HB Intravenous, pending final regulatory approval.

We record pre-launch inventory once the product has attained a stage in the development process of having been subject to a Phase III clinical trial, or its equivalent, or a MAA or a BLA filing, and has a well characterized manufacturing process. In addition, we must have an internal sales forecast that includes an assessment that sales will exceed the manufacturing costs plus the expected cost to distribute the product. Finally, product stability data must exist so that we can assert that capitalized inventory is anticipated to be sold, based on the sales projections noted above, prior to anticipated expiration of a product shelf life.

If approval for these product candidates is not received, or approval is not received timely compared to our estimates for product shelf life, we will write-off the related amounts of pre-launch inventory in the period of that determination. If we were required to write off the \$2.3 million recorded as pre-launch inventory at December 25, 2004, this amount would be considered by us to be material to our 2004 operating results.

**NOTE 5 PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment and related allowances for depreciation are summarized below:

<u>Dollars in Thousands</u>	<u>December 25, 2004</u>	<u>December 27, 2003</u>
Information systems	\$ 25,065	\$ 23,334
Leasehold improvements	8,064	7,825
Machinery and equipment	51,926	48,947
Land and buildings	50,099	45,188
Building systems	8,415	8,039
Furniture and fixtures	3,332	3,191
Capital leased property	674	—
Construction in progress	19,170	7,459
	<hr/>	<hr/>
Property, plant and equipment, gross	166,745	143,983
Less accumulated depreciation	(51,339)	(42,152)
	<hr/>	<hr/>
<b>Property, plant and equipment, net</b>	<b>\$ 115,406</b>	<b>\$ 101,831</b>

We received FDA licensure to manufacture Nabi-HB at our biopharmaceutical manufacturing facility in Boca Raton, Florida in October 2001. Capitalization of interest and other costs ceased at that time, which was the point at which the facility was ready for the manufacture of Nabi-HB in an FDA approved environment, its intended use, and the facility was placed into service. Total costs of construction of the Boca Raton facility, including the building, building systems, plant equipment and information systems were approximately \$90.3 million. Validation costs and capitalized interest related directly to preparing the facility for its intended use totaled \$63.5 million.

Depreciation expense of property, plant and equipment during 2004, 2003 and 2002 was \$9.5 million, \$10.3 million and \$9.6 million, respectively. Depreciation expense related to the initial operation of our biopharmaceutical manufacturing facility in Boca Raton, Florida commenced in October 2001. In accordance with our depreciation policy for certain specialized equipment in our biopharmaceutical facility, we recorded additional depreciation expense of \$2.5 million, \$1.6 million and \$2.3 million in 2004, 2003 and 2002, respectively, due to the units-of-production method of depreciation resulting in depreciation less than at least 60% of depreciation expense that would be recorded using the straight-line method of depreciation for this equipment. In addition, depreciation expense included depreciation of assets under capital leases of \$0.1 million.

Construction in progress primarily consisted of costs related to the construction of a vaccine manufacturing plant within our Boca Raton, Florida facility at December 25, 2004. At December 27, 2003 construction in progress primarily consisted of costs related to the construction of a laboratory and cold storage facility in Boca Raton, Florida. Interest capitalized in connection with construction of our vaccine manufacturing plant was \$0.3 million in 2004 and in connection with construction of our cold storage facility \$0.1 million in 2003.



[Table of Contents](#)**NOTE 6 INTANGIBLE ASSETS**

Intangible assets consist of the following:

<u>Dollars in Thousands</u>	<u>December 25, 2004</u>	<u>December 27, 2003</u>
PhosLo related:		
Trademark/tradename	\$ 1,423	\$ 1,423
Tablet patent	11,381	11,381
Gelcap patent	80,670	80,680
Customer relationships	2,337	2,337
Covenant-not-to-compete	508	508
Manufacturing right – Cambrex	2,992	323
Other intangible assets	4,389	3,639
	<hr/>	<hr/>
Total intangible assets	103,700	100,291
Less accumulated amortization	(13,972)	(5,300)
	<hr/>	<hr/>
<b>Total</b>	<b>\$ 89,728</b>	<b>\$ 94,991</b>

On August 4, 2003, we acquired PhosLo from Braintree Laboratories Inc. or Braintree. PhosLo is currently approved for the control of elevated phosphate levels, or hyperphosphatemia, for patients with end-stage kidney (renal) failure. Under the terms of the acquisition, we purchased patent rights, trade secrets, the PhosLo trademarks, regulatory approvals and licenses, certain customer and regulatory data and finished product inventory and did not assume any liabilities. All assets purchased, except for inventory, have been recorded at their estimated fair value, adjusted by a pro rata portion of the excess of purchase price, and are included in intangible assets.

On October 9, 2003, we announced we had entered into a contract manufacturing agreement for an initial term of up to ten years with Cambrex Bio Science for the commercial manufacture of StaphVAX. Vaccine manufactured at Cambrex Bio Science was used to support our Marketing Approval Application or MAA for StaphVAX in the EU that we filed in December of 2004. As a result of entering into this agreement with Cambrex Bio Science, we ended our contract manufacturing agreement with Dow on October 9, 2003. We recorded a charge of approximately \$9.7 million for the write-off of the Dow manufacturing right during 2003, the period in which we determined that we would not manufacture commercial StaphVAX vaccine at Dow.

Amortization of intangible assets during 2004, 2003 and 2002 was \$8.7 million, \$5.4 million and \$1.1 million. Amortization expense for intangible assets currently subject to amortization is expected to be \$8.9 million, \$8.8 million, \$6.5 million, \$5.5 million, and \$5.2 million in each of the five fiscal years subsequent to December 25, 2004.

**NOTE 7 ACCRUED EXPENSES**

Accrued expenses consist of the following:

<u>In Thousands</u>	<u>December 25, 2004</u>	<u>December 27, 2003</u>
Sales deductions		
Accrued chargebacks	\$ 4,417	\$ 4,497
Accrued rebates	2,580	1,867
Accrued discounts	1,067	652
Other accrued sales deductions	488	317
	<hr/>	<hr/>
Total accrued sales deductions	8,552	7,333
Employee compensation and benefits	8,411	6,448
Accrued royalties and product costs	5,236	6,486
Accrued clinical trial expenses	5,152	822
Accrued construction services fees	873	—
Accrued professional services	883	554
Accrued European expenses	222	—
Other	2,961	2,313
	<hr/>	<hr/>
<b>Total</b>	<b>\$ 32,290</b>	<b>\$ 23,956</b>

**NOTE 8 CREDIT FACILITIES**

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

**NOTE 9 STOCKHOLDERS' EQUITY***Warrants*

In July 2000, we issued a warrant to purchase 133,333 shares of common stock to our agent in connection with the private placement of common stock for which we realized \$9.3 million, net of issuance costs. On April 15, 2004, the holder of a warrant to purchase 133,333 shares of our common stock at \$7.50 per share exercised the warrant using the net exercise provision of the warrant. As a result of the net exercise, we issued 74,070 shares of our common stock to the holder of the warrant. The estimated fair value of the warrant at the date of grant was \$0.9 million. This fair value was calculated using the Black-Scholes model with the following assumptions: expected term of five years, expected volatility of 104% and expected risk-free interest rate of 6%.

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### *Treasury Stock*

In September 2001, our Board of Directors approved the expenditure of up to \$5.0 million to purchase our common stock in the open market or in privately negotiated transactions. We acquired no shares under this program during 2004 or 2003. To date, we have acquired 345,883 shares of our common stock for a total of \$1.9 million since the inception of this buy back program. Repurchased shares have been accounted for as treasury stock.

In various transactions, a member of our Board of Directors exercised stock options for 6,250 shares in 2004, two members of our Board of Directors exercised stock options for 639,311 shares and 4,500 shares, respectively, in 2003, and one member of our Board of Directors exercised stock options for 60,000 shares of our common stock in 2002. These purchases were paid for by delivery of 3,496 shares of common stock in 2004, 411,956 and 2,371 shares of common stock in 2003 and 40,107 shares, respectively, in 2002, which were valued at \$57 thousand, \$3.1 million, \$16 thousand and \$0.2 million for the respective transactions. In each of the transactions, the shares delivered had been acquired more than six months earlier by the members of our Board of Directors. These shares have been accounted for as treasury stock.

### *Stock Options*

We maintain four stock option plans for our employees. Under these plans, we have granted options to certain employees entitling them to purchase shares of common stock within ten years. The options vest over periods ranging from zero to five years from the date of grant and have been granted at exercise prices equal to the fair market value of the underlying common stock on the date of grant.

During 2004, we modified stock options for certain of our employees and, as a result, incurred a charge of \$0.2 million. On June 20, 2003, we entered into a retirement agreement with David J. Gury, our former Chief Executive Officer. As a result, we incurred a charge of \$0.3 million of costs related to modification of certain of his outstanding stock options. Refer to Note 18.

In May 2004, our shareholders approved the 2004 Stock Plan for Non-Employee Directors, or the Directors Plan, that succeeded the Stock Plan for Non-Employee Directors that was then in effect. Under the Directors Plan we have granted options to certain directors entitling them to purchase shares of common stock within ten years, vesting six months after the date of grant, at an exercise price equal to the fair market value of the underlying common stock at the date of grant. Under the plan, non-employee directors may also elect to be paid their annual retainer as a director in whole or in part in shares of our common stock if approved in advance by our Board of Directors. The number of shares issued if this election is made is the annual retainer divided by the market value of a share of common stock on the date the annual retainer is paid. In 2004, one director elected to receive his annual retainer in common shares, receiving 1,201 shares of common stock.

In May 2004, our shareholders approved an amendment to our 2000 Equity Incentive Plan adding 4,500,000 shares of our common stock to the plan.

At December 25, 2004, there were options outstanding under our various stock plans to acquire a total of 8.0 million shares of our common stock of which options for 4.0 million shares were then exercisable. Additionally, 4.6 million shares of common stock are reserved for future grants under the plans.

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Stock options granted and outstanding under these plans as of December 25, 2004 are presented below:

	Options	Exercise Price per Share	Weighted Average Exercise Price
	In Thousands		
<b>Balance at December 29, 2001</b>	7,392	\$ 1.63 - \$ 13.75	\$ 5.99
Granted	1,470	3.60 - 10.18	8.69
Exercised	(379)	5.30 - 11.28	3.76
Canceled	(495)	2.69 - 13.75	7.38
<b>Balance at December 28, 2002</b>	7,988	1.63 - 13.75	6.51
Granted	1,937	5.09 - 11.25	6.00
Exercised	(1,808)	1.63 - 11.13	4.46
Canceled	(1,003)	2.88 - 13.75	8.22
<b>Balance at December 27, 2003</b>	7,114	2.63 - 13.75	6.68
Granted	2,567	8.88 - 17.15	15.04
Exercised	(1,540)	2.69 - 13.75	6.40
Canceled	(150)	4.69 - 17.08	9.13
<b>Balance at December 25, 2004</b>	7,991	\$ 2.63 - \$ 17.15	\$ 9.38

Exercise Price Range	Outstanding			Exercisable	
	Options	Average Years Remaining	Average Exercise Price	Options	Average Exercise Price
	(In Thousands)			(In Thousands)	
\$ 2.63 - \$4.25	592	3.8	\$ 3.08	591	\$ 3.08
\$ 4.35 - \$7.47	3,494	6.6	5.99	2,375	6.11
\$ 8.00 - \$11.25	1,176	6.1	9.64	738	9.81
\$ 11.69 - \$17.15	2,729	8.7	14.97	296	14.38
<b>Total</b>	7,991			4,000	

### *Employee Stock Purchase Plan*

In May 2000, the stockholders approved the Nabi Employee Stock Purchase Plan. The terms of the ESPP, as amended, allow for qualified employees as defined therein to participate in the purchase of up to 1,000,000 shares of our common stock at a price equal to 85% of the lower of the closing price at the beginning or end of each semi-annual stock purchase period. We issued 90,382, 112,494 and 116,940 shares of common stock during 2004, 2003 and 2002, respectively, pursuant to this plan at an average price per common share of \$10.60, \$5.94 and \$4.99, respectively.

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### *Nabi Savings and Retirement Plan*

In May 2000, the stockholders approved the issuance of up to 425,000 shares of our common stock to our employees participating in the Nabi Savings and Retirement Plan. To date no shares have been issued under this plan.

### *Shareholders Rights Plan*

Effective July 1997, our Board of Directors adopted a shareholders rights plan under which a dividend of one preferred share purchase right, or Right, was distributed for each outstanding share of common stock. Each Right entitles the holder to purchase one one-hundredth of a share of Series One Preferred Stock at a price of \$70, subject to adjustment. The Rights expire in August 2007, and are exercisable only if an individual or group has acquired or obtained the right to acquire, or has announced a tender or exchange offer that if consummated would result in such individual or group acquiring beneficial ownership of 15% or more of the common stock. Such percentage may be lowered at the Board's discretion. If the Rights become exercisable, the holder (other than the individual or group who triggered the exercisability) may be entitled to receive upon exercise shares of our common stock having a market value of two times the exercise price of the Rights, or the number of shares of the acquiring company which have a market value of two times the exercise price of the Rights. The Rights separate from the common stock if they become exercisable. We are entitled to redeem the Rights in whole for \$0.01 per Right under certain circumstances.

### *Shares of Common Stock*

In May 2004, our shareholders approved an amendment to our Restated Certificate of Incorporation increasing the number of authorized common stock to 125 million shares from 75 million shares.

As of December 25, 2004, a total of 12.6 million shares of common stock in the aggregate were reserved for issuance under our stock options, warrants and employee benefit plans.

## **NOTE 10 OFFERING REGISTRATIONS**

On December 7, 2004, we filed a Form S-3 with the Securities and Exchange Commission, or SEC to register the offer and sale of equity or debt securities up to \$175 million from time to time. We plan to use net proceeds from sales of securities under this shelf registration statement to provide additional funds for general corporate purposes, including but not limited to clinical trials, research, development and marketing expenses, and new acquisition and licensing costs.

**NOTE 11 PRODUCT ACQUISITIONS**

In a transaction dated June 29, 2004, we exercised our right under our distribution agreement to acquire Aloprim from DSM Pharmaceuticals, Inc., or DSM. We paid a total of \$1.0 million for the acquisition of Aloprim including payment of \$0.8 million for the Aloprim product license at the closing of the purchase. We had previously paid \$0.2 million in the fourth quarter of 2003. As a result of acquiring the Aloprim product license, future product royalties were set at 15% of net sales for five years. Previously, we were obligated to share net profits, as defined, equally with DSM from net sales of Aloprim up to \$4.0 million and to pay DSM 30% of net profits from net sales in excess of \$4.0 million. In conjunction with acquiring Aloprim, we entered into a manufacturing agreement with DSM to continue to supply product to us for a term of up to five years. We are obligated to purchase \$3.0 million of Aloprim product under this agreement. Refer to Note 20.

On August 4, 2003, we acquired the worldwide rights to PhosLo from Braintree. PhosLo is currently approved for the control of elevated phosphate levels, or hyperphosphatemia, for patients with end-stage kidney failure. Under the terms of the agreement, we acquired the worldwide rights to PhosLo for payment of \$60.3 million in cash and issuance of 1.5 million shares of our common stock at the closing date and the payment of \$30.0 million cash over the period ending March 1, 2007. In addition, we paid professional fees and closing costs totaling \$0.9 million in connection with the acquisition. The discounted value of the notes payable on December 25, 2004 was \$23.3 million of which \$9.9 million has been reported as a current liability under the caption, Notes payable, and the balance of \$13.3 million has been reported as a long-term liability. The notes were discounted at 4.5%, our estimated rate of interest under our credit facility on August 4, 2003, the date of the closing of the agreement. Braintree will continue to manufacture the product for us under a long-term manufacturing agreement with an initial term of seven years. The manufacturing agreement also provides us access to an independent third party manufacturer and is renewable at our option for an additional eight years.

The following table is a reconciliation of notes payable for the acquisition of PhosLo:

<u>Dollars in Thousands</u>	<u>December 25, 2004</u>
Notes payable, PhosLo acquisition	\$ 23,289
Less current maturities	(9,949)
Notes payable, PhosLo acquisition, long-term	<u>\$ 13,340</u>

The repayment terms for the notes payable provided in the acquisition agreement are a combination of fixed semi-annual payments and variable annual payments calculated as a percentage of net revenue. We anticipate the repayment of the Notes Payable, PhosLo acquisition, to be \$10.9 million, \$8.9 million and \$4.9 million for the years ended 2005, 2006 and 2007, respectively.

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The following table is a reconciliation of the consideration paid for PhosLo:

<u>Dollars in Thousands</u>	<u>August 4, 2003</u>
Cash paid at closing	\$60,325
Closing costs, including professional fees	920
<b>Total cash paid</b>	<b>61,245</b>
Common shares issued	8,400
Notes payable, PhosLo acquisition, net	26,860
Inventory received	(186)
<b>Total purchase price of PhosLo</b>	<b>\$96,319</b>

### NOTE 12 DISTRIBUTION AGREEMENT

On July 15, 2004, Cangene Corporation informed us that it would not renew the WinRho SDF license and distribution agreement with us at its expiration in March 2005. We will continue to distribute WinRho SDF exclusively in the U.S. through March 2005. We reported sales of WinRho SDF of \$47.9 million, \$50.0 and \$34.0 million for the years ended December 25, 2004, December 27, 2003 and December 28, 2002, respectively.

### NOTE 13 INCOME TAXES

Income before income taxes was taxed domestically only.

The provision (benefit) for income taxes consists of the following:

<u>In Thousands</u>	<u>For the Years Ended</u>		
	<u>December 25, 2004</u>	<u>December 27, 2003 (as restated)</u>	<u>December 28, 2002 (as restated)</u>
<b>Current:</b>			
Federal	\$ 5,413	\$ —	\$ —
State	271	(396)	133
<b>Subtotal</b>	<b>5,684</b>	<b>(396)</b>	<b>133</b>
<b>Deferred:</b>			
Federal	4,511	(5,465)	131
State	203	(288)	—
<b>Subtotal</b>	<b>4,714</b>	<b>(5,753)</b>	<b>131</b>
<b>Total</b>	<b>\$ 10,398</b>	<b>\$ (6,149)</b>	<b>\$ 264</b>

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Deferred tax assets and liabilities are comprised of the following:

Dollars in Thousands	For the Years Ended	
	December 25, 2004	December 27, 2003
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 3,076	\$ 8,663
Capitalized research and development	—	724
Research and development tax credit	12,464	10,754
Inventory reserve and capitalization	2,639	2,424
Amortization	2,555	1,751
Bad debt reserve	162	239
Depreciation	1,296	1,296
Alternative minimum tax credit	1,117	900
Deferred income	—	5
Accrued retirement	849	1,477
Other	498	880
Deferred tax assets	24,656	29,113
<b>Deferred tax liabilities:</b>		
Depreciation	(19,733)	(17,511)
Other	(1,332)	(3,957)
Deferred tax liabilities	(21,065)	(21,468)
Net deferred tax assets	\$ 3,591	\$ 7,645

We have net operating loss carryforwards of approximately \$20.3 million that expire at various dates through 2023. Approximately \$12.1 million of our net operating loss carryforwards are related to the exercise of employee stock options, and we will record a tax benefit of approximately \$4.5 million through capital in excess of par value when such losses are realized.

We have research and development tax credit carryforwards of \$12.5 million that expire in varying amounts through 2024. We have alternative minimum tax credit carryforwards of \$1.1 million that are available to offset future regular tax liabilities, and do not expire.

The ultimate realization of the net deferred tax assets is largely dependent on our ability to generate sufficient future taxable income. As a result of our tax planning strategies we believe that the realization of our tax assets is more likely than not to be realized and our tax planning strategies are prudent and feasible. We have determined that no valuation allowance is necessary as of December 25, 2004. We have recorded \$4.4 million as a tax contingency reserve against certain of our deferred tax assets, which is included in other long-term liabilities.

The following table reconciles our losses before income taxes by jurisdiction:

In Thousands	For the Years Ended		
	December 25, 2004	December 27, 2003 (as restated)	December 28, 2002 (as restated)
<b>Pre-tax (loss) income:</b>			
U.S.	\$ (29,908)	\$ (12,215)	\$ 1,738
Ex-U.S.	(10,084)	—	—
<b>Total</b>	<b>\$ (39,992)</b>	<b>\$ (12,215)</b>	<b>\$ 1,738</b>

Our ex-U.S. losses are primarily in no tax jurisdictions, and as such, we did not record a provision for income taxes on those losses.

The significant elements contributing to the difference between the federal statutory tax rate and the effective tax rate are as follows:

	For the Years Ended		
	December 25, 2004	December 27, 2003	December 28, 2002
Federal statutory rate	(34.0)%	(34.0)%	34.0%
State income taxes, net of federal benefit	(3.3)	(3.3)	5.0
Foreign tax rate differential	(12.1)	—	—
Foreign sales benefit and nondeductible items	0.1	(2.2)	(3.2)
Tax credits	(3.0)	(10.8)	(27.3)
Gain on sale of intellectual property	75.8	—	—
Other	2.5	—	6.8
<b>Total</b>	<b>26.0%</b>	<b>(50.3)%</b>	<b>15.3%</b>



[Table of Contents](#)**NOTE 14 EARNINGS PER SHARE**

The following reconciles basic and diluted (loss) earnings per share for net (loss) income for the years ended December 25, 2004, December 27, 2003 and December 28, 2002:

Amounts in Thousands, Except Per Share Data	Basic (Loss) Earnings Per Share	Effect of Dilutive Securities:	
		Stock options and other dilutive Securities	Diluted (Loss) Earnings Per Share
<b>2004</b>			
Net loss	\$ (50,390)	—	\$ (50,390)
Shares	58,800	—	58,800
Per share amount	\$ (0.86)	—	\$ (0.86)
<b>2003</b>			
Net loss (as restated)	\$ (6,066)	—	\$ (6,066)
Shares	42,888	—	42,888
Per share amount	\$ (0.14)	—	\$ (0.14)
<b>2002</b>			
Net income (as restated)	\$ 1,474	—	\$ 1,474
Shares	38,670	971	39,641
Per share amount	\$ 0.04	—	\$ 0.04

**NOTE 15 EMPLOYEE BENEFIT PLANS**

Effective January 1, 2003, the Nabi Savings and Retirement Plan, or the Plan, permits employees to contribute up to 92% of pre-tax annual compensation up to annual statutory limitations. Effective December 31, 2001, the discretionary company match for employee contributions to the Plan was changed to 100% of up to the first 4% of the participant's earnings contributed to the Plan commencing in 2002. Our matching contributions to the plan were approximately \$1.4 million in 2004, \$1.1 million in 2003 and \$1.0 million in 2002.

**NOTE 16 LEASES**

We conduct certain of our operations under operating lease agreements. The majority of these lease agreements contain renewal options, which enable us to renew the leases for periods of two to ten years at the then fair rental value at the end of the initial lease term.

Rent expense was approximately \$3.5 million, \$3.3 million and \$3.4 million for the years ended December 25, 2004, December 27, 2003 and December 28, 2002, respectively.

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As of December 25, 2004, the aggregate future minimum lease payments under all non-cancelable operating leases with initial or remaining lease terms in excess of one year are as follows:

<u>Year Ending</u>	<u>In Thousands</u>
2005	\$ 2,625
2006	2,059
2007	1,447
2008	1,233
2009	155
Thereafter	378
<b>Total minimum lease commitments</b>	<b>\$ 7,897</b>

During 2004, we have recorded assets under capital leases that are included in property, plant and equipment totaling \$0.7 million. The following schedule summarizes future minimum lease payments under capital leases with terms greater than one year as of December 25, 2004:

<u>Year Ending</u>	<u>In Thousands</u>
2005	\$ 240
2006	240
2007	109
<b>Total minimum lease payments</b>	<b>589</b>
Imputed interest	(34)
<b>Present value of net minimum lease payments</b>	<b>555</b>
Current portion	(224)
<b>Long-term portion</b>	<b>\$ 331</b>

### NOTE 17 RESTATEMENT OF PRIOR YEAR FINANCIAL STATEMENTS

During the process of preparing our consolidated financial statements for 2004, we determined that we had received a benefit from our intangible manufacturing right asset related to our right to manufacture Staph VAX at Dow Biopharmaceutical Contract Manufacturer of Dow's, site in the prior fiscal years 2003, 2002 and 2001 when we had recorded no amortization expense. This determination led to our decision to restate the financial statements for these periods for additional amortization expense in accordance with SFAS No. 142 *Goodwill and Other Intangible Assets*. The following table summarizes the impact of the restatement on our statements of operations:

<u>(In thousands)</u>	<u>December 27, 2003</u>	<u>December 28, 2002</u>	<u>December 29, 2001</u>
Increase in amortization expense	\$ (1,618)	\$ (932)	\$ (290)
Decrease in write-off manufacturing right	2,840		
<b>Decrease net operating loss/(decrease net operating income)</b>	<b>\$ 1,222</b>	<b>\$ (932)</b>	<b>\$ (290)</b>
Increase (decrease) in (provision) benefit for income taxes	(456)	351	105
<b>Decrease net loss/(decrease net income)</b>	<b>\$ 766</b>	<b>\$ (581)</b>	<b>\$ (185)</b>

Net (loss) income originally reported as \$(6.8) million or \$(0.16) per share for the year ended December 27, 2003, \$2.1 million or \$0.05 per share for the year ended December 28, 2002 and \$104.7 million or \$2.36 per share for the year ended December 29, 2001 have been restated as \$(6.1) million or \$(0.14) per share, \$1.5 million or \$0.04 per share and \$104.5 million or \$2.36 per share, respectively.

In October 2003 we made a decision to establish a new manufacturing relationship with Cambrex Bio Science to support an opportunity for earlier commercialization of our vaccine against *S. aureus* infections, StaphVAX in Europe. As a result, we terminated our contract manufacturing agreement with Dow on October 9, 2003 and reported a non-cash write off equal to the recorded value of the manufacturing right asset as of that date. As restated, this write off amount totals \$9.7 million versus \$12.6 million reported previously. The restatement of amortization expense related to this asset will not require restatement of the previously reported balance sheet as of December 27, 2003.

**NOTE 18 RELATED PARTY TRANSACTIONS**

On June 20, 2003, we entered into a retirement agreement with David J. Gury, our former Chief Executive Officer. As a result we incurred a charge of \$3.3 million comprising approximately \$3.0 million in future cash payments and \$0.3 million of costs related to modification of certain of his outstanding stock options. The liability for future cash payments is included in accrued expenses for the current portion, and in other liabilities for the long-term portion, as of December 25, 2004 and December 27, 2003. Cash payments are being paid over three years commencing January 2004.

In October 2001, we engaged Stonebridge Associates, LLC or Stonebridge, an investment bank, the president of which is a member of our Board of Directors, to provide financial advisory services in connection with our review and implementation of a corporate expansion strategy. The agreement, as amended in October 2002, provided for a monthly retainer of \$30 thousand plus, in certain circumstances, hourly charges. If the engagement resulted in transactions by us involving aggregate consideration paid in excess of a specified level, Stonebridge received additional fees based upon the consideration paid. Stonebridge acted as our financial adviser in connection with our acquisition of the worldwide rights to PhosLo from Braintree in August 2003 and received a fee of approximately \$0.3 million for its services upon consummation of this transaction. Refer to Note 11. We believe that the terms of the engagement with Stonebridge were no less favorable to us than would have been obtained from an unrelated party. Upon completion of the PhosLo transaction, we concluded our agreement with Stonebridge. We did not incur any fees during the year ended December 25, 2004 and during the years ended December 27, 2003 and December 28, 2002, we paid \$0.5 million and \$0.6 million, respectively, to Stonebridge, pursuant to the financial advisory services agreement.

There are no amounts receivable from corporate officers at December 25, 2004 or December 27, 2003.

**NOTE 19 STRATEGIC ALLIANCES, LICENSES AND ROYALTY AGREEMENTS**

In October 2003, we entered into a contract manufacturing agreement with Cambrex Bio Science to produce commercial quantities of StaphVAX. During 2004 the manufacturing process for StaphVAX was transferred to Cambrex Bio Science from a previous contract manufacturer, as well as from our pilot plant in Rockville, Maryland. We have completed the transfer of the manufacturing process to Cambrex Bio Science and completed manufacturing of consistency lots of StaphVAX at the facility in August 2004. The contract manufacturing agreement requires us to make certain payments to Cambrex Bio Science to secure future access to commercial vaccine manufacturing capacity and to enable Cambrex Bio Science to ready its facility for the future commercial scale manufacture of StaphVAX. The payments to secure future access to commercial vaccine manufacturing capacity have been recorded as a Manufacturing Right and included in Intangible Assets. Amortization of the Manufacturing Right has commenced in 2004.

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Under a license and distribution agreement with Cangene, we have exclusive rights to distribute and market WinRho SDF in the U.S. Cangene, which holds the FDA licenses for the product, is required to supply the necessary quantities of WinRho SDF to support such sales and shares equally in the profits from sales after accounting for the costs of production and selling and marketing expenses. The current license and distribution agreement ends in March 2005. Cangene has informed us that it will not renew the agreement. We will continue to distribute WinRho SDF exclusively in the U.S. through March 2005.

Under a license agreement with the Public Health Services/National Institute of Health, or PHS/NIH, we have exclusive rights to a U.S. patent relating to a carbohydrate/protein conjugate vaccine against *Staphylococcus* for the term of the patent and are obligated to pay PHS a royalty based on net sales of products using this technology. The licensed patent rights, which expire in 2010, cover staphylococcal vaccines including StaphVAX.

We have an agreement with Chiron Corporation, or Chiron, that grants us an exclusive supply agreement for four vaccines, including hepatitis C. In addition, we have rights to 10 additional Chiron vaccines for use in humans to produce immunotherapeutic products. The agreement may also grant us access to a vaccine adjuvant, MF 59. We will be responsible for all development, manufacturing and worldwide distribution of these products. We may terminate the agreement on a product-by-product basis in which event we shall transfer to Chiron all of our rights with respect to the product as to which the agreement has been terminated. Similarly, Chiron may terminate its obligations to supply immunizing agents to us on a product-by-product basis, in which event Chiron shall grant to us a license of the technology necessary for us to manufacture the applicable immunizing agent and the financial arrangements in the Chiron Agreement with respect to such agent shall continue.

In April 2003, we licensed the worldwide rights to our whole cell vaccine technology for the prevention and treatment of *Staphylococcus aureus* infections in cattle to Pfizer. In a letter dated March 2, 2005, Pfizer notified us that they would not pursue further development of a product to address infections in cattle and were terminating the license agreement with us. Pursuant to the license agreement we retain our full rights to information and data generated under this agreement and have no further obligations to Pfizer.

### **NOTE 20 COMMITMENTS AND CONTINGENCIES**

Under the terms of our agreement with DSM, we have a minimum purchase requirement of \$3.0 million to purchase Aloprim over the period ending June 29, 2009. Our purchase commitment requires us to purchase \$0.6 million in 2005, \$0.6 million in 2006, \$0.7 million in 2007, \$0.7 million in 2008 and \$0.4 million in 2009.

Under the terms of the Cambrex Bio Science contract manufacturing agreement at December 25, 2004, we have a commitment of \$0.2 million related to acquiring the right to future commercial manufacturing capacity for StaphVAX and establishing commercial manufacturing of the vaccine at their facility.

In April 2004, we entered into an agreement with a general contractor for the construction of a vaccine manufacturing facility and the installation of equipment. At December 25, 2004, we had a commitment of \$0.7 million remaining under this agreement.

As of December 25, 2004, we had open purchase order commitments of \$3.9 million.

See lease commitments discussed at Note 16 for other commitments.

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

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We have employment agreements with certain members of our senior management that include certain cash payments in the event of termination of employment, and cash payments and stock option modifications in the event of a change in control of the Company.

**NOTE 21 INDUSTRY SEGMENT INFORMATION**

We manage our operations in two reportable segments, the biopharmaceutical products and antibody products segments. The biopharmaceutical products segment consists of the production and sale of proprietary biopharmaceutical products and research and development efforts for the biopharmaceutical product lines. The write-off of the manufacturing right relating to our previous contract manufacturer of StaphVAX of \$9.7 million is included in the biopharmaceutical products segment results for the year ended December 27, 2003. The antibody products segment consists of the collection and sale of non-specific and specialty antibody products to other biopharmaceutical manufacturers and the production and sale of antibody-based control products.

The accounting policies for each of the segments are the same as those described in the summary of significant accounting policies. There are no inter-segment sales. Antibody product used to manufacture Nabi-HB is transferred from our antibody segment to our biopharmaceutical segment at cost. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

Information regarding our operations and assets for the two industry segments is as follows:

Dollars in Thousands	For the Years Ended		
	December 25, 2004	December 27, 2003 (as restated)	December 28, 2002 (as restated)
<b>Sales:</b>			
Biopharmaceutical products	\$ 131,813	\$ 109,459	\$ 89,466
Antibody products	47,950	67,111	106,500
	\$ 179,763	\$ 176,570	\$ 195,966
<b>Gross margin:</b>			
Biopharmaceutical products	\$ 82,086	\$ 72,104	\$ 54,764
Antibody products	3,763	4,725	9,149
	\$ 85,849	\$ 76,829	\$ 63,913
<b>Operating (loss) income:</b>			
Biopharmaceutical products	\$ (35,361)	\$ (6,712)	\$ 5,800
Antibody products	(4,273)	(4,971)	(3,062)
	\$ (39,634)	\$ (11,683)	\$ 2,738
<b>Depreciation and amortization expense:</b>			
Biopharmaceutical products	\$ 15,771	\$ 12,893	\$ 7,898
Antibody products	2,090	2,655	2,744
	\$ 17,861	\$ 15,548	\$ 10,642
<b>Capital expenditures:</b>			
Biopharmaceutical products	\$ 20,274	\$ 3,594	\$ 2,285
Antibody products	450	1,555	2,290
	\$ 20,724	\$ 5,149	\$ 4,575
<b>Assets:</b>			
Biopharmaceutical products	\$ 309,467	\$ 305,745	
Antibody products	50,997	74,406	
	\$ 360,464	\$ 380,151	

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A reconciliation of reportable segment selected financial information to the total combined amounts of the selected financial information is as follows:

Dollars in Thousands	For the Years Ended		
	December 25, 2004	December 27, 2003 (as restated)	December 28, 2002 (as restated)
<b>(Loss) income before income taxes:</b>			
Reportable segment operating (loss) income	\$ (39,634)	\$ (11,683)	\$ 2,738
Unallocated interest expense	(2,199)	(1,350)	(2,130)
Unallocated other income and expense, net	1,841	818	1,130
<b>Consolidated (loss) income before income taxes</b>	<b>\$ (39,992)</b>	<b>\$ (12,215)</b>	<b>\$ 1,738</b>
<b>Depreciation and amortization expense:</b>			
Reportable segment depreciation and amortization expense	\$ 17,861	\$ 15,548	\$ 10,642
Unallocated corporate depreciation and amortization expense	317	306	367
<b>Consolidated depreciation and amortization expense</b>	<b>\$ 18,178</b>	<b>\$ 15,854</b>	<b>\$ 11,009</b>
<b>Capital expenditures:</b>			
Reportable segment capital expenditures	\$ 20,724	\$ 5,149	\$ 4,575
Unallocated corporate capital expenditures	1,909	2,901	1,446
<b>Consolidated capital expenditures</b>	<b>\$ 22,633</b>	<b>\$ 8,050</b>	<b>\$ 6,021</b>
<b>Assets:</b>			
Reportable segment assets	\$ 360,464	\$ 380,151	
Unallocated corporate assets	7,707	7,150	
<b>Consolidated assets</b>	<b>\$ 368,171</b>	<b>\$ 387,301</b>	

Information regarding sales by geographic area for the years ended December 25, 2004, December 27, 2003 and December 28, 2002 and information regarding long-lived assets at December 28, 2002, December 27, 2003 and December 28, 2002 is as follows:

Dollars in Thousands	For the Years Ended		
	December 25, 2004	December 27, 2003 (as restated)	December 28, 2002 (as restated)
<b>Sales:</b>			
U.S.	\$ 167,363	\$ 161,595	\$ 174,291
Ex-U.S.	12,400	14,975	21,675
<b>Total</b>	<b>\$ 179,763</b>	<b>\$ 176,570</b>	<b>\$ 195,966</b>
<b>Operating (loss) income:</b>			
U.S.	\$ (29,550)	\$ (11,683)	\$ 2,738
Ex-U.S.	(10,084)	—	—
<b>Total</b>	<b>\$ (39,634)</b>	<b>\$ (11,683)</b>	<b>\$ 2,738</b>
<b>Long-lived assets:</b>			
U.S.	\$ 205,573	\$ 205,340	\$ 119,770
Ex-U.S.	10	—	—
<b>Total</b>	<b>\$ 205,583</b>	<b>\$ 205,340</b>	<b>\$ 119,770</b>

Ex-U.S. sales are determined based upon customer location. The majority of our sales are generated from the U.S. Our principal ex-U.S. markets were South Korea, Israel and Canada in 2004. In the years ended December 25, 2004, December 27, 2003 and December 28, 2002, sales to ex-U.S. markets were derived wholly from antibody products.

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Sales for the year ended December 25, 2004 included three customers of our biopharmaceutical product segment, Cardinal Health, Inc., McKesson Drug Co. and AmerisourceBergen and one customer of our antibody products segment, Bayer Corporation, representing 26%, 25%, 23% and 15% of sales, respectively. Sales for the year ended December 27, 2003 included three customers of our biopharmaceutical product segment, AmerisourceBergen, Cardinal Health, Inc., and McKesson Drug Co. and one customer of our antibody products segment, Bayer Corporation, representing 20%, 19%, 18% and 21% of sales, respectively. Sales for the year ended December 28, 2002 included two customers of our biopharmaceutical product segment, Cardinal Health, Inc. and AmerisourceBergen and one customer of our antibody products segment, Bayer Corporation, representing 15%, 14% and 35% of sales respectively.

**NOTE 22 SUPPLEMENTAL CASH FLOW INFORMATION**

(In thousands)	For the Years Ended		
	December 25, 2004	December 27, 2003	December 28, 2002
Interest paid	\$ 615	\$ 331	\$ 3,677
Income taxes paid (refunded)	\$ 703	\$ (550)	\$ (1,035)
Discount paid on non-interest bearing notes	\$ 654	—	—
<b>Supplemental non-cash financing and investing activities:</b>			
Stock options exercised in exchange for common stock	\$ 101	\$ 3,100	\$ 246
Warrants exercised in exchange for common stock	\$ 1,000	—	—
Intangible and other PhosLo assets acquired, net of cash paid of \$61.3 million	—	\$ 35,260	—
Consideration issued in PhosLo product acquisition:			
- Notes Payable	—	\$ 26,860	—
- Common Stock	—	\$ 8,400	—
Capital lease obligations	\$ 555	—	—

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Dollars in Thousands, Except Per Share Data	Sales	Gross Profit Margin	Net (Loss) Income	Basic (Loss) Earnings Per Share	Diluted (Loss) Earnings Per Share
<b>2004</b>					
1 <sup>st</sup> Quarter ended March 27, 2004	\$ 46,349	\$ 22,574	\$ (4,839)	\$ (0.08)	\$ (0.08)
2 <sup>nd</sup> Quarter ended June 26, 2004	47,992	24,635	(17,578)	(0.30)	(0.30)
3 <sup>rd</sup> Quarter ended September 25, 2004	43,774	22,948	(10,921)	(0.18)	(0.18)
4 <sup>th</sup> Quarter ended December 25, 2004	41,648	15,692	(17,052)	(0.30)	(0.30)
<b>Year ended December 25, 2004</b>	<b>\$ 179,763</b>	<b>\$ 85,849</b>	<b>\$ (50,390)</b>	<b>\$ (0.86)</b>	<b>\$ (0.86)</b>
<b>2003 (as restated)</b>					
1 <sup>st</sup> Quarter ended March 29, 2003	\$ 51,511	\$ 16,642	\$ 259	\$ 0.01	\$ 0.01
2 <sup>nd</sup> Quarter ended June 28, 2003	34,649	14,539	(3,355)	(0.09)	(0.09)
3 <sup>rd</sup> Quarter ended September 27, 2003	42,435	20,911	1,824	0.04	0.04
4 <sup>th</sup> Quarter ended December 27, 2003	47,975	24,737	(4,794)	(0.10)	(0.10)
<b>Year ended December 27, 2003</b>	<b>\$ 176,570</b>	<b>\$ 76,829</b>	<b>\$ (6,066)</b>	<b>\$ (0.14)</b>	<b>\$ (0.14)</b>

The results for the quarters ended March 29, 2003, June 28, 2003, September 27, December 27, 2003 and year ended December 27, 2003 have been restated. Net income (loss) was reported as \$0.5 million or \$0.1 per share, \$(3.0) million or \$(0.8) per share, \$2.2 million or \$0.5 per share and \$(6.6) million or \$(0.14) per share and was restated to \$0.3 million or \$0.1 per share, \$(3.3) million or \$(0.9) per share, \$1.2 million or \$0.4 per share and \$(4.8) million or \$(0.11) per share, respectively, for the quarters ended March 29, 2003, June 28, 2003, September 27, 2003 and December 27, 2003. Refer to Note 17. As a result, net (loss) income, basic (loss) earning per share and diluted (loss) earning per share have been restated. There were no changes to sales or gross profit margin.

The results of the second quarter of 2003 include the impact of a \$3.3 million charge related to a retirement agreement entered into with our former Chief Executive Officer, David J. Gury. Refer to Note 18. The results of the fourth quarter of 2003 included the impact of a \$9.7 million charge related to the write-off of a manufacturing right asset at Dow.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9a. CONTROLS AND PROCEDURES**

## Disclosure Controls and Procedures

Our management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures, as of December 25, 2004. Because we identified one weakness in our internal control over financial reporting for amortization expense related to an intangible asset for the periods ending December 27, 2003 and December 28, 2002, our management concluded that as of December 25, 2004, our disclosure controls and procedures were not effective to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Refer to Item 7 for Management's Annual Report on Internal Control Over Financial Reporting.



**ITEM 9b. OTHER INFORMATION**

We entered into a Development and License Agreement with Pharmacia and Upjohn Company (now Pfizer) dated April 3, 2003, which licensed the worldwide rights to our whole cell vaccine technology for the prevention and treatment of *S. aureus* infections in cattle to Pfizer. In a letter dated March 2, 2005, Pfizer notified us that they would not pursue further development of a product to address *S. aureus* infections in cattle and were terminating the license agreement with us. Pursuant to the license agreement, we retain our full rights to information and data generated under the agreement and have no further obligations to Pfizer.

**Nabi Biopharmaceuticals**

**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The information called for by this Item and not already provided in Item 4A will be contained in our Proxy Statement, which we intend to file within 120 days following our fiscal year end, December 25, 2004, and such information is incorporated herein by reference.

**ITEM 11. EXECUTIVE COMPENSATION**

The information called for by this Item will be contained in our Proxy Statement, which we intend to file within 120 days following our fiscal year end, December 25, 2004, and such information is incorporated herein by reference.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information called for by this Item will be contained in our Proxy Statement, which we intend to file within 120 days following our fiscal year end, December 25, 2004, and such information is incorporated herein by reference.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The information called for by this Item will be contained in our Proxy Statement, which we intend to file within 120 days following our fiscal year end, December 25, 2004, and such information is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTANTS FEES AND SERVICES**

The information called for by this Item will be contained in our Proxy Statement, which we intend to file within 120 days following our fiscal year end, December 25, 2004, and such information is incorporated herein by reference.

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### **Nabi Biopharmaceuticals**

#### **PART IV**

#### **ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

##### **(a) (1) FINANCIAL STATEMENTS**

The following consolidated financial statements are filed as part of this report:

	<u>Page No.</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	63
<a href="#">Consolidated Balance Sheets at December 25, 2004 and December 27, 2003</a>	66
<a href="#">Consolidated Statements of Operations for the years ended December 25, 2004, December 27, 2003 and December 28, 2002</a>	67
<a href="#">Consolidated Statements of Stockholders' Equity for the years ended December 25, 2004, December 27, 2003 and December 28, 2002</a>	68
<a href="#">Consolidated Statements of Cash Flows for the years ended December 25, 2004, December 27, 2003 and December 28, 2002</a>	69
<a href="#">Notes to Consolidated Financial Statements</a>	70
<b>(2) FINANCIAL STATEMENT SCHEDULES</b>	
<a href="#">Schedule II - Valuation and Qualifying Accounts and Reserves</a>	102

All other schedules omitted are not required, inapplicable or the information required is furnished in the financial statements or notes thereto.

##### **(3) EXHIBITS**

- 3.1 Restated Certificate of Incorporation of Nabi, as amended (incorporated by reference to Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 26, 2004)
- 3.2 By-Laws of Nabi Biopharmaceuticals (incorporated by reference to Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 28, 2003)
- 4.1 Form of Common Stock Certificate (incorporated by reference to Exhibit 4.4 to our Current Report on Form 8-K filed on August 21, 1997)
- 4.2 Rights Agreement dated August 1, 1997, as amended, between Nabi and Registrar and Transfer Company (incorporated by reference to Exhibit 10.28 to our 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, between Nabi Biopharmaceuticals, Registrant and Transfer Company, and American Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.4 to our Annual Report on Form 10-K for the year ended December 28, 2002)

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- 10.1 1990 Equity Incentive Plan (incorporated by reference to Appendix A to our Definitive Proxy Statement dated April 22, 1997)
- 10.2 2004 Stock Plan for Non-Employee Directors (incorporated by reference to Appendix C to our Definitive Proxy Statement dated April 9, 2004)
- 10.3 1998 Non-Qualified Employee Stock Option Plan (incorporated by reference to Exhibit 10.22 to our Annual Report on Form 10-K for the year ended December 31, 1998)
- 10.4 2000 Equity Incentive Plan, as amended (incorporated by reference to Appendix B to our Definitive Proxy Statement dated April 9, 2004)
- 10.5 1990 Equity Incentive Plan Award Letter\*
- 10.6 1998 Non-Qualified Employee Stock Option Plan Award Letter\*
- 10.7 1998 Non-Qualified Employee Stock Option Plan Anniversary Award Letter\*
- 10.8 2000 Equity Incentive Plan Award Letter\*
- 10.9 2000 Equity Incentive Plan Special Award Letter\*
- 10.10 Change of Control Severance Agreement dated April 1, 2004 between Thomas H. McLain and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)
- 10.11 Employment Agreement dated April 1, 2004 between Thomas H. McLain and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)
- 10.12 Change of Control Severance Agreement dated April 1, 2004 between Gary Siskowski and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)
- 10.13 Employment Agreement dated April 1, 2004 between Gary Siskowski and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)
- 10.14 Change of Control Severance Agreement dated April 1, 2004 between Henrik Rasmussen, Ph.D., MD and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)
- 10.15 Employment Agreement dated April 1, 2004 between Henrik Rasmussen, Ph.D., MD and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.6 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)
- 10.16 Change of Control Severance Agreement dated April 1, 2004 between Mark L. Smith and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.7 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)

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- 10.17 Employment Agreement dated April 1, 2004 between Mark L. Smith and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.8 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)
- 10.18 Change of Control Severance Agreement dated April 1, 2004 between Raafat E.F. Fahim, Ph.D. and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.9 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)
- 10.19 Employment Agreement dated April 1, 2004 between Raafat E.F. Fahim, Ph.D. and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.10 to our Quarterly Report on Form 10-Q for the quarter ended September 25, 2004)
- 10.20 Change of Control Severance Agreement dated December 20, 2004 between H. Le Roux Jooste and Nabi Biopharmaceuticals\*
- 10.21 Employment Agreement dated December 20, 2004 between H. Le Roux Jooste and Nabi Biopharmaceuticals\*
- 10.22 Change of Control Severance Agreement dated May 3, 2004 between Richard G. Clark and Nabi Biopharmaceuticals\*
- 10.23 Employment Agreement dated May 3, 2004 between Richard G. Clark and Nabi Biopharmaceuticals\*
- 10.24 Form of Director/Officer Indemnification Agreement\*
- 10.25 Summary of Director Compensation\*
- 10.26 2003 VIP Management Incentive Plan\*
- 10.27 Letter agreement between Nabi Biopharmaceuticals and David J. Gury dated June 20, 2003 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended September 27, 2003)
- 10.28 Asset Purchase Agreement between Nabi Biopharmaceuticals and Braintree Laboratories, Inc. dated June 23, 2003 (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended June 28, 2003)
- 23. Consent of Independent Registered Public Accounting Firm
- 31.1 Rule 13a-14(a)/15d-14(a) Certification
- 31.2 Rule 13a-14(a)/15d-14(a) Certification
- 32.1 Section 1350 Certification

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\* Filed herewith

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**Nabi Biopharmaceuticals**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 10th day of March, 2005.

**Nabi Biopharmaceuticals**

By: /s/ Thomas H. McLain

**Thomas H. McLain**

Chairman, Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
/s/ Thomas H. McLain _____ Thomas H. McLain	Chairman, Chief Executive Officer and President	March 10, 2005
/s/ Mark L. Smith _____ Mark L. Smith	Senior Vice President, Finance, Chief Financial Officer, Chief Accounting Officer and Treasurer	March 10, 2005
/s/ David L. Castaldi _____ David L. Castaldi	Director	March 10, 2005
/s/ Geoffrey F. Cox, PhD _____ Geoffrey F. Cox, PhD	Director	March 10, 2005
/s/ George W. Ebright _____ George W. Ebright	Director	March 10, 2005
/s/ Richard A. Harvey, Jr. _____ Richard A. Harvey, Jr.	Director	March 10, 2005
/s/ Linda Jenckes _____ Linda Jenckes	Director	March 10, 2005
/s/ Stephen G. Sudovar _____ Stephen G. Sudovar	Director	March 10, 2005

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## Nabi Biopharmaceuticals

## SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Classification	Balance at Beginning of Period	Additions		Deductions	Balance at End of Period
		Charged to Costs and Expenses	Charged to Other Accounts	Write-Offs Charged Against Reserve	
<b>Year ended December 25, 2004:</b>					
Allowance for doubtful accounts	\$ 646	\$ 428	\$ —	\$ (641)	\$ 433
Inventory valuation allowance	5,219	3,950	(577)	(2,171)	6,421
<b>Year ended December 27, 2003:</b>					
Allowance for doubtful accounts	\$ 647	\$ 39	\$ —	\$ (40)	\$ 646
Inventory valuation allowance	4,489	1,044	(7)	(307)	5,219
<b>Year ended December 28, 2002:</b>					
Allowance for doubtful accounts	\$ 962	\$ 751	\$ 19	\$ (1,085)	\$ 647
Inventory valuation allowance	4,152	683	(69)	(277)	4,489

Exhibit Index (Exhibits filed herewith)

<u>Exhibit No.</u>	<u>Description.</u>
10.5	1990 Equity Incentive Plan Award Letter
10.6	1998 Non-Qualified Employee Stock Option Plan Award Letter
10.7	1998 Non-Qualified Employee Stock Option Plan Anniversary Award Letter
10.8	2000 Equity Incentive Plan Award Letter
10.9	2000 Equity Incentive Plan Special Award Letter
10.20	Change of Control Severance Agreement dated December 20, 2004 between H. Le Roux Jooste and Nabi Biopharmaceuticals
10.21	Employment Agreement dated December 20, 2004 between H. Le Roux Jooste and Nabi Biopharmaceuticals
10.22	Change of Control Severance Agreement dated May 3, 2004 between Richard G. Clark and Nabi Biopharmaceuticals
10.23	Employment Agreement dated May 3, 2004 between Richard G. Clark and Nabi Biopharmaceuticals
10.24	Form of Director/Officer Indemnification Agreement
10.25	Summary of Non-Employee Director Fees
10.26	2003 VIP Management Incentive Plan
23.	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a)/15d-14(a) Certification
31.2	Rule 13a-14(a)/15d-14(a) Certification
32.1	Section 1350 Certification



Nabi

## NON-STATUTORY STOCK OPTION

For good and valuable consideration, receipt of which is hereby acknowledged, Nabi, a Delaware corporation (the "Company"), does hereby grant to \_\_\_\_\_ (the "Grantee") an option to purchase \_\_\_\_\_ (\_\_\_\_\_) shares of Common Stock of the Company (the "Option"), pursuant to the terms of the Company's 1990 Equity Incentive Plan (the "Plan"). A copy of the Plan is annexed hereto and is incorporated herein in its entirety by reference.

The Grantee hereby accepts the Option subject to all of the provisions of the Plan, and upon the following additional terms and conditions:

1. The price at which the shares of Common Stock may be purchased pursuant to the Option is \_\_\_\_\_ per share, subject to adjustment as provided in the Plan.

2. (a) The Option shall expire at the close of business on the tenth anniversary of the date hereof. Subject to the following provisions of this Section 2 and to the provisions of the Plan, the Option shall be exercisable before said date as follows: (i) if the Optionee is employed by the Company on the first anniversary of the date hereof, to the extent of 25% of the number of shares covered hereby; (ii) if the Optionee is employed by the Company on the second anniversary of the date hereof, to the extent of 50% of the number of shares covered hereby, less the number of shares as to which the Option has been exercised previously; (iii) if the Optionee is employed by the Company on the third anniversary of the date hereof, to the extent of 75% of the shares covered hereby, less the number of shares as to which the Option has been exercised previously; and (iv) if the Optionee is employed by the Company on the fourth anniversary of the date hereof, to the extent of the full number of shares covered hereby. The Option may not be exercised at all during the first year after the date hereof (except to the extent provided in the Plan) or after the tenth anniversary of the date hereof.

(b) If the Optionee ceases to be employed by the company for "cause", the Option shall terminate automatically and without notice to the Optionee on the date the Optionee's employment so ceases. For purposes hereof, "cause" shall mean (i) illegal or disreputable conduct which impairs the reputation, good will or business of the Company or involves the misappropriation of funds or other property of the Company, (ii) refusal or failure to carry out any employment duties reasonably assigned to the Optionee other than by reason of death or disability or (ii) demonstrated negligence or gross inefficiency in the execution of the Optionee's employment duties for the Company. Any resignation in anticipation of discharge for cause or accepted by the Company in lieu of a formal discharge for cause shall be deemed a cessation of employment for cause for purposes hereof.

(c) If the Optionee ceases to be employee by the Company because of death or disability, the Option shall be exercisable by him (or by his legal representative if he shall cease to be so employed by reason of his death or if he shall have died within ninety (90) days

after he shall have ceased to be so employed because of disability) during the twelve (12) months following such cessation but only as to the number of shares, if any, as to which the Option was exercisable immediately prior to such cessation and in no event after the tenth anniversary of the date hereof.

(d) If the Optionee ceases to be employed by the Company for any reason other than cause, death or disability, the Option shall be exercisable by him during the ninety (90) days following such cessation but only as to the number of shares, if any, as to which the Option was exercisable immediately prior to such cessation and in no event after the tenth anniversary of the date hereof.

(e) In the event exercise of the Option shall require the Company of issue a fractional share of Common Stock of the Company, such fraction shall be disregarded and the purchase price payable in connection with such exercise shall be disregarded and the purchase price payable in connection with such exercise shall be appropriately reduced. Any such fractional share shall be carried forward and added to any shares covered by future exercise(s) of the Option.

3. The Option shall not be transferable other than by will or by the laws of descent and distribution and shall be exercisable during the Optionee's lifetime only by the Optionee.

4. This Option may be exercised by the giving of written notice, in person or by mail, to the Company, marked "Attention: Chief Financial Officer", at its principal place of business, of the election to purchase shares pursuant hereto accompanied by the full payment for all shares being so purchased.

5. This Option shall not be treated as an incentive stock option.

WITNESS the execution hereof as of this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

Nabi

By \_\_\_\_\_  
Chief Executive Officer

The foregoing Option is hereby accepted on the terms and conditions set forth herein and is expressly subject to all the provisions set forth in the Nabi 1990 Equity Incentive Plan, a copy of which is annexed hereto.

\_\_\_\_\_  
Grantee Signature

\_\_\_\_\_  
Print Name

XXXXXX XX, 200X

XXXXXXXXXXXXXX  
XXXXXXXXXXXXXX  
XXXXXXXXXXXXXX

Re: Letter Agreement for Stock Option Grant and Acceptance Between Nabi Biopharmaceuticals and XXXXXXXXXXXXXXXX

Dear XXXXXXXXXXXXXXXX:

I am pleased to report that for good and valuable consideration, receipt of which is hereby acknowledged, Nabi Biopharmaceuticals, a Delaware corporation (the "Company"), does hereby grant to you (the "Optionee") an option to purchase XXXXXXXXXXXXXXXX (XXXXXX) shares of Common Stock of the Company (the "Option"), pursuant to the terms of the Company's 1998 Non-Qualified Employee Stock Option Plan (the "Plan") and the terms and conditions set forth below. A copy of the Plan is attached hereto and is incorporated herein in its entirety by reference.

The Optionee hereby accepts the Option subject to all of the provisions of the Plan, and upon the following additional terms and conditions:

1. The price at which the shares of Common Stock may be purchased pursuant to the Option is \$XXXX per share, subject to adjustment as provided in the Plan.

2. (a) The Option shall expire at the close of business on the tenth anniversary of the date hereof (the "Expiration Date"). Subject to the following provisions of this Section 2 and to the provisions of the Plan, the Option shall be exercisable before said Expiration Date as follows: (i) if the Optionee is employed by the Company on the first anniversary of the date hereof, to the extent of 25% of the number of shares covered hereby; (ii) if the Optionee is employed by the Company on the second anniversary of the date hereof, to the extent of 50% of the number of shares covered hereby, less the number of shares covered hereby, less the number of shares as to which the Option has been exercised previously; (iii) if the Optionee is employed by the Company on the third anniversary of the date hereof, to the extent of 75% of the number of shares covered hereby, less the number of shares as to which the Option has been exercised previously; and (iv) if the Optionee is employed by the Company on the fourth anniversary of the date hereof, to the extent of the full number of shares covered hereby, less the number of shares as to which the Option has been exercised previously. The Option may not be exercised at all during the first year after the date hereof (except to the extent provided in the Plan) or after the Expiration Date.

(b) If the Optionee's employment is terminated by the Company for "cause", the Option shall terminate automatically and without notice to the Optionee on the date the Optionee's employment is terminated. For purposes hereof, "cause" shall mean (i) illegal or disreputable conduct which impairs the reputation, good will or business of the Company or involves the misappropriation of funds or other property of the Company, (ii) willful misconduct by the Optionee or willful failure to perform his or her responsibilities in the best interests of the Company (including, without limitation, breach by the Optionee of any provision of any employment, advisory, consulting, nondisclosure, non-competition or other agreement between the Optionee and the Company or any subsidiary of the Company, (iii) refusal or failure to carry out any employment duties reasonably assigned to the Optionee other than by reason of death or employment duties for the Company, or (iv) demonstrated negligence or gross inefficiency in the execution of the Optionee's employment duties for the Company. Any resignation in anticipation of discharge for cause that is accepted by the Company in lieu of a formal discharge for cause shall be deemed a termination of employment for cause for purposes hereof.

(c) If the Optionee dies while employed by the Company or within ninety (90) days after the Optionee ceases active employment due to disability, each option held by the Optionee immediately prior to death may be exercised, to the extent it was exercisable immediately prior to death, by the Optionee's executor or administrator or by the person or persons to whom the option is transferred by will or the applicable laws of descent and distribution, at any time within a one-year period beginning with the date of the Optionee's death, but in no event beyond the Expiration Date.

(d) If the Optionee's employment with the Company terminates for any reason other than cause or death, all options held by the Optionee that are not then exercisable, shall terminate. Options that are exercisable as of the date employment terminates shall be exercisable by the Optionee during the ninety (90) days following such termination, but only as to the number of shares, if any, as to which the Option was exercisable immediately prior to such termination and in no event after the Expiration Date.

(e) In the event exercise of the Option shall require the Company to issue a fractional share of Common Stock of the Company, such fraction shall be disregarded and the purchase price payable in connection with such exercise shall be appropriately reduced. Any such fractional share shall be carried forward and added to any shares covered by future exercise(s) of the Option.

3. The Option shall not be transferable other than by will or by the laws of descent and distribution and shall be exercisable during the Optionee's lifetime only by the Optionee.

4. Options may be exercised only in writing and in the manner described in the Nabi Stock Options Information Brochure and the Salomon Smith Barney Automated Stock Access Program brochure, copies of which are attached hereto.

5. This Option shall not be treated as an incentive stock option.

6. Any brokerage fees or commissions, and all taxes are the responsibility of the Optionee.

WITNESS the execution hereof as of XXXXXXXX XXX of 200X.

Nabi Biopharmaceuticals

By \_\_\_\_\_

Thomas H. McLain, Chairman  
Chief Executive Officer & President

**By signing this Letter Agreement below, the Optionee hereby acknowledges and agrees that he/she has read, understands and accepts all of the terms and conditions set forth herein and set forth in the Nabi 1998 Non-Qualified Employee Stock Option Plan.**

\_\_\_\_\_  
Optionee Signature

\_\_\_\_\_  
Print Name

1998 Non-Qualified Employee Stock Option Plan

XXXXXX XX, 200X

XXXXXXXXXXXXXX  
XXXXXXXXXXXXXX  
XXXXXXXXXXXXXX

Re: Letter Agreement for Stock Option Grant and Acceptance Between Nabi Biopharmaceuticals and XXXXXXXXXXXXXXXX

Dear XXXXXXXXXXXX:

I am pleased to report that for good and valuable consideration, receipt of which is hereby acknowledged, Nabi Biopharmaceuticals, a Delaware corporation (the "Company"), does hereby grant to you (the "Optionee") an option to purchase XXXXXXXXXXX (XXXXX) shares of Common Stock of the Company (the "Option"), pursuant to the terms of the Company's 1998 Non-Qualified Employee Stock Option Plan (the "Plan") and the terms and conditions set forth below. A copy of the Plan is attached hereto and is incorporated herein in its entirety by reference. These options are issued in recognition of your years of service with Nabi Biopharmaceuticals.

The Optionee hereby accepts the Option subject to all of the provisions of the Plan, and upon the following additional terms and conditions:

1. The price at which the shares of Common Stock may be purchased pursuant to the Option is \$XXXXXX per share, subject to adjustment as provided in the Plan.

2. (a) The Option shall expire at the close of business on the tenth anniversary of the date hereof (the "Expiration Date"). Subject to the following provisions of the Section 2 and to the provisions of the Plan, the Option shall be fully exercisable as of the date of this award.

(b) If the Optionee's employment is terminated by the Company for "cause", the Option shall terminate automatically and without notice to the Optionee on the date the Optionee's employment is terminated. For purposes hereof, "cause" shall mean (i) illegal or involves the misappropriation of funds or other property of the Company, (ii) willful misconduct by the Optionee or willful failure to perform his or her responsibilities In the best interests of the Company (including, without limitation, breach by the Optionee of any provision of any employment, advisory, consulting, nondisclosure, non-competition or other agreement between the Optionee and the Company or any subsidiary of the Company, (iii) refusal or failure to carry out any employment duties reasonably assigned to the Optionee other than by reason of death or disability, or (iv) demonstrated negligence or gross inefficiency in the execution of the Optionee's employment duties for the Company. Any resignation in anticipation of discharge for cause that is accepted by the Company in lieu of a formal discharge for cause shall be deemed a termination of employment for cause for purposes hereof.

(c) If the Optionee dies while employed by the Company or with ninety (90) days after the Optionee ceases active employment due to disability, each option held by the Optionee immediately prior to death may be exercised, to the extent it was exercisable immediately prior to death, by the Optionee's executor or administrator or by the person or persons to whom the option is transferred by will or applicable laws of decent and distribution, at any time within a one-year period beginning with the date of the Optionee's death, but in no event beyond the Expiration Date.

(d) If the Optionee's employment with the Company terminates for any reason other than cause or death, all options held by the Optionee shall be exercisable by the Optionee during the ninety (90) days following such termination, but in no event after the Expiration Date.

(e) In the event exercise of the Option shall require the Company to issue a fractional share of Common Stock of the Company, such fraction shall be disregarded and the such fractional share shall be carried forward and added to any shares covered by future exercise(s) of the Option.

3. The Option shall not be transferable other than by will or by the laws of descent and distribution and shall be exercisable during the Optionee's lifetime only by Optionee.

4. Options may be exercised only in writing and in the manner described in the Nabi Stock Options Information Brochure and the Salomon Smith Barney Automated Stock Access Program brochure, copies of which are attached hereto.

5. This Option shall not be treated as an incentive stock option.

6. Any brokerage fees or commissions, and all taxes are the responsibility of the Optionee.

WITNESS the execution hereof as of XXXXXXXXXX XX of 200X.

Nabi Biopharmaceuticals

By \_\_\_\_\_

Thomas H. McLain, Chairman  
Chief Executive Officer & President

**By signing this Letter Agreement below, the Optionee hereby acknowledges and agrees that he/she has read, understands and accepts all of the terms and conditions set forth herein and set forth in the Nabi 1998 Non-Qualified Employee Stock Option Plan.**

\_\_\_\_\_  
Optionee Signature

\_\_\_\_\_  
Print Name

1998 Non-Qualified Employee Stock Option Plan

XXXXXX XX, 200X

XXXXXXXXXXXXXX

XXXXXXXXXXXXXX

XXXXXXXXXXXXXX

Re: Letter Agreement for Stock Option Grant and Acceptance Between  
Nabi Biopharmaceuticals and XXXXXXXXX

Dear XXXXXXXXXXXXXXXX:

I am pleased to report that for good and valuable consideration, receipt of which is hereby acknowledged, Nabi Biopharmaceuticals, a Delaware corporation (the "Company"), does hereby grant to you (the "Optionee") an option to purchase XXXXXXXX (XXXXXX) shares of Common Stock of the Company (the "Option"), pursuant to the terms of the Company's 2000 Equity Incentive Plan (the "Plan") and the terms and conditions set forth below. A copy of the Plan is attached hereto and is incorporated herein in its entirety by reference.

The Optionee hereby accepts the Option subject to all of the provisions of the Plan, and upon the following additional terms and conditions:

1. The price at which the shares of Common Stock may be purchased pursuant to the Option is \$XXXXXX per share, subject to adjustment as provided in the Plan.
2. (a) The Option shall expire at the close of business on the tenth anniversary of the date hereof (the "Expiration Date"). Subject to the following provisions of this Section 2 and to the provisions of the Plan, the Option shall be exercisable before said Expiration Date as follows: (i) if the Optionee is employed by the Company on the first anniversary of the date hereof, to the extent of 25% of the number of shares covered hereby; (ii) if the Optionee is employed by the Company on the second anniversary of the date hereof, to the extent of 50% of the number of shares covered hereby, less the number of shares as to which the Option has been exercised previously; (iii) if the Optionee is employed by the Company on the third anniversary of the date hereof, to the extent of 75% of the number of shares covered hereby, less the number of shares as to which the Option has been exercised previously; and (iv) if the Optionee is employed by the Company on the fourth anniversary of the date hereof, to the extent of the full number of shares covered hereby, less the number of shares as to which the Option has been exercised previously. The Option may not be exercised at all during the first year after the date hereof (except to the extent provided in the Plan) or after the Expiration Date.

(b) If the Optionee's employment is terminated by the Company for "cause", the Option shall terminate automatically and without notice to the Optionee on the date the Optionee's employment is terminated. For purposes hereof, "cause" shall mean (i) illegal or disreputable conduct which impairs the reputation, good will or business of the Company or involves the misappropriation of funds or other property of the Company, (ii) willful misconduct by the Optionee or willful failure to perform his or her responsibilities in the best interests of the Company (including, without limitation, breach by the Optionee of any provision of any employment, advisory, consulting, nondisclosure, non-competition or other agreement between the Optionee and the Company or any subsidiary of the Company, (iii) refusal or failure to carry out any employment duties reasonably assigned to the Optionee other than by reason of death or disability, or (iv) demonstrated negligence or gross inefficiency in the execution of the Optionee's employment duties for the Company. Any resignation in anticipation of discharge for cause that is accepted by the Company in lieu of a formal discharge for cause shall be deemed a termination of employment for cause for purposes hereof.

2000 Equity Incentive Plan

(c) If the Optionee dies while employed by the Company or within ninety (90) days after the Optionee ceases active employment due to disability, each option held by the Optionee immediately prior to death may be exercised, to the extent it was exercisable immediately prior to death, by the Optionee's executor or administrator or by the person or persons to whom the option is transferred by will or the applicable laws of descent and distribution, at any time within a one-year period beginning with the date of the Optionee's death, but in no event beyond the Expiration Date.

(d) If the Optionee's employment with the Company terminates for any reason other than cause or death, all options held by the Optionee that are not then exercisable, shall terminate. Options that are exercisable as of the date employment terminates shall be exercisable by the Optionee during the ninety (90) days following such termination, but only as to the number of shares, if any, as to which the Option was exercisable immediately prior to such termination and in no event after the Expiration Date.

(e) In the event exercise of the Option shall require the Company to issue a fractional share of Common Stock of the Company, such fraction shall be disregarded and the purchase price payable in connection with such exercise shall be appropriately reduced. Any such fractional share shall be carried forward and added to any shares covered by future exercise(s) of the Option.

3. The Option shall not be transferable other than by will or by the laws of descent and distribution and shall be exercisable during the Optionee's lifetime only by the Optionee.

4. Options may be exercised only in writing and in the manner described in the Nabi Biopharmaceuticals Stock Options Information Brochure and the Salomon Smith Barney Automated Stock Access Program brochure, copies of which are attached hereto.

5. This Option shall not be treated as an incentive stock option.

6. Any brokerage fees or commissions, and all taxes are the responsibility of the Optionee.

WITNESS the execution hereof as of this XXX day of XXXXX, 200X.

Nabi Biopharmaceuticals

By \_\_\_\_\_

Thomas H. McLain, Chairman,  
Chief Executive Officer and President

By signing this Letter Agreement below, the Optionee hereby acknowledges and agrees that he/she has read, understands and accepts all of the terms and conditions set forth herein and set forth in the Nabi 2000 Equity Incentive Plan.

\_\_\_\_\_  
Optionee Signature – XXXXXXXXXXXXXXXXXXXX

\_\_\_\_\_  
Print Name

2000 Equity Incentive Plan



XXXXXXX XX, 200X

XXXXXXXXXXXXXX  
XXXXXXXXXXXXXX  
XXXXXXXXXXXXXX

Re: Letter Agreement for Stock Option Grant and Acceptance Between  
Nabi Biopharmaceuticals and XXXXXXXXXXXX

Dear XXXXXXXXXXXXXXXX:

I am pleased to report that for good and valuable consideration, receipt of which is hereby acknowledged, Nabi Biopharmaceuticals, a Delaware corporation (the "Company"), does hereby grant to you (the "Optionee") an option to purchase XXXXXXXXXX shares of Common Stock of the Company (the "Option"), pursuant to the terms of the Company's 2000 Equity Incentive Plan (the "Plan") and the terms and conditions set forth below. A copy of the Plan is attached hereto and is incorporated herein in its entirety by reference.

The Optionee hereby accepts the Option subject to all of the provisions of the Plan, and upon the following additional terms and conditions:

1. The price at which the shares of Common Stock may be purchased pursuant to the Option is \$XXXXX per share, subject to adjustment as provided in the Plan.

2. (a) The Option shall expire at the close of business on the tenth anniversary of the date hereof (the "Expiration Date"). Subject to the following provisions of this Section 2 and to the provisions of the Plan, the Option shall be exercisable before said Expiration Date as follows: (i) if the Optionee is employed by the Company on the third anniversary of the date hereof, to the extent of 50% of the number of shares covered hereby; (ii) if the Optionee is employed by the Company on the fourth anniversary of the date hereof, to the extent of 75% of the number of shares covered hereby, less the number of shares as to which the Option has been exercised previously; and (iii) if the Optionee is employed by the Company on the fifth anniversary of the date hereof, to the extent of the full number of shares covered hereby, less the number of shares as to which the Option has been exercised previously. The Option may not be exercised at all during the first three years after the date hereof (except to the extent provided in the Plan) or after the Expiration Date.

(b) If the Optionee's employment is terminated by the Company for "cause", the Option shall terminate automatically and without notice to the Optionee on the date the Optionee's employment is terminated. For purposes hereof, "cause" shall mean (i) illegal or disreputable conduct which impairs the reputation, good will or business of the Company or involves the misappropriation of funds or other property of the Company, (ii) willful misconduct by the Optionee or willful failure to perform his or her responsibilities in the best interests of the Company (including, without limitation, breach by the Optionee of any provision of any employment, advisory, consulting, nondisclosure, non-competition or other agreement between the Optionee and the Company or any subsidiary of the Company, (iii) refusal or failure to carry out any employment duties reasonably assigned to the Optionee other than by reason of death or disability, or (iv) demonstrated negligence or gross inefficiency in the execution of the Optionee's employment duties for the Company. Any resignation in anticipation of discharge for cause that is accepted by the Company in lieu of a formal discharge for cause shall be deemed a termination of employment for cause for purposes hereof.

2000 Equity Incentive Plan

(c) If the Optionee dies while employed by the Company or within ninety (90) days after the Optionee ceases active employment due to disability, each option held by the Optionee immediately prior to death may be exercised, to the extent it was exercisable immediately prior to death, by the Optionee's executor or administrator or by the person or persons to whom the option is transferred by will or the applicable laws of descent and distribution, at any time within a one-year period beginning with the date of the Optionee's death, but in no event beyond the Expiration Date.

(d) Notwithstanding the provisions of Section 8(D) of Optionee's Employment Agreement effective as of XXXXXXXXXXXX but subject to the provisions of Section 2(d) of Optionee's Change of Control Severance Agreement effective as of XXXXXXXXXXXX, if the Optionee's employment with the Company terminates for any reason other than cause or death, all options held by the Optionee that are not then exercisable, shall terminate. Options that are exercisable as of the date employment terminates shall be exercisable by the Optionee during the ninety (90) days following such termination, but only as to the number of shares, if any, as to which the Option was exercisable immediately prior to such termination and in no event after the Expiration Date.

(e) In the event exercise of the Option shall require the Company to issue a fractional share of Common Stock of the Company, such fraction shall be disregarded and the purchase price payable in connection with such exercise shall be appropriately reduced. Any such fractional share shall be carried forward and added to any shares covered by future exercise(s) of the Option.

3. The Option shall not be transferable other than by will or by the laws of descent and distribution and shall be exercisable during the Optionee's lifetime only by the Optionee.

4. Options may be exercised only in writing and in the manner described in the Nabi Biopharmaceuticals Stock Options Information Brochure and the Salomon Smith Barney Automated Stock Access Program brochure, copies of which are attached hereto.

5. This Option shall not be treated as an incentive stock option.

6. Any brokerage fees or commissions, and all taxes are the responsibility of the Optionee.

WITNESS the execution hereof as of this XXXX day of XXXXX, 200X.

Nabi Biopharmaceuticals

By \_\_\_\_\_

Thomas H. McLain, Chairman,  
Chief Executive Officer and President

By signing this Letter Agreement below, the Optionee hereby acknowledges and agrees that he/she has read, understands and accepts all of the terms and conditions set forth herein and set forth in the Nabi 2000 Equity Incentive Plan and, without limitation, expressly agrees to the provisions of paragraph 2(d) set forth above.

\_\_\_\_\_  
Optionee Signature – XXXXXXXXXXXX

\_\_\_\_\_  
Print Name

2000 Equity Incentive Plan

Nabi Biopharmaceuticals

5800 Park of Commerce Boulevard, N.W.  
Boca Raton, FL 33487**Change of Control Severance Agreement**  
**Effective as of December 20, 2004**H. Le Roux Jooste  
xxxxx  
xxxxx

Dear Le Roux:

The Board of Directors of Nabi Biopharmaceuticals (the "Corporation") and the Compensation Committee (the "Committee") of the Board have determined that it is in the best interests of the Corporation and its shareholders for the Corporation to agree, as provided herein, to pay you termination compensation in the event you should leave the employ of the Corporation under the circumstances described below.

The Board and the Committee recognize that the continuing possibility of a sale or change of control of the Corporation is unsettling to you and other key employees of the Corporation. Therefore, these arrangements are being made to help assure a continuing dedication by you to your duties to the Corporation by diminishing the inevitable distraction to you from the personal uncertainties and risks created by a pending sale or change of control of the Corporation. In particular, the Board and the Committee believe it important, should the Corporation receive proposals from third parties with respect to its future, to enable you, without being influenced by the uncertainties of your own situation, to assess and advise the Board whether such proposals would be in the best interests of the Corporation and its shareholders and to take such other action regarding such proposals as the Board might determine to be appropriate, including being available to assist in any transition should there be a sale or change of control of the Corporation. The Board and the Committee also wish to demonstrate to executives of the Corporation that the Corporation is concerned with the welfare of its executives and intends to see that loyal executives are treated fairly.

1. In view of the foregoing and in further consideration of your continued employment with the Corporation, the Corporation will pay you as termination compensation a lump sum amount, determined as provided below, in the event that (a) within six months after a Change of Control of the Corporation you terminate your employment with the Corporation for Good Reason or you die or you become disabled, or (b) within twelve months after a Change of Control of the Corporation your employment with the Corporation is terminated by the Corporation for any reason, or (c) within the period beginning on the sixth monthly anniversary of a Change of Control of the Corporation and ending on the twelfth monthly anniversary thereof, you terminate your employment with the Corporation for any reason

(including, without limitation, death or disability). The lump sum compensation so payable (hereinafter referred to as the "Lump Sum Amount") shall be an amount equal to two times the sum of (a) the higher of (i) your current annual base salary or (ii) your base salary immediately prior to the Change of Control plus (b) the target Bonus you could have earned for the fiscal year in which the Change of Control occurred. The Lump Sum Amount shall be paid to you within five days after the date of termination of your employment (hereinafter referred to as the "Termination Date").

2. In addition, in the event your employment with the Corporation terminates under circumstances entitling you to receive the Lump Sum Amount:

(a) Any compensation and other amounts previously deferred by you, together with accrued interest thereon, if any, to which you are entitled, and any accrued vacation pay and accrued paid leave bank amounts not yet paid by the Corporation, shall be paid to you within five days of such termination.

(b) All other amounts accrued or earned by you through the date of such termination and amounts otherwise owing under the Corporation's plans and policies shall be paid to you within five days of such termination.

(c) The Corporation shall maintain in full force and effect, for the continued benefit of you and/or your family for twenty-four months after the Termination Date, all employee welfare benefit plans and any other employee benefit programs or arrangements (including, without limitation, medical and dental insurance plans, disability and life insurance plans and car allowance programs) in which you were entitled to participate immediately prior to the Change of Control, provided that your continued participation is possible under the general terms and provisions of such plans and programs. In the event that your participation in any such plan or program is barred, the Corporation shall arrange to provide you with benefits substantially similar to those which you are entitled to receive under such plans and programs. To the extent permissible, all such benefits shall be assignable by you.

(d) All outstanding stock options which you hold shall vest immediately upon a Change of Control and shall be exercisable for (i) the remainder of the option term(s) or (ii) a period of five years from the Termination Date, whichever is shorter.

(e) The Corporation shall provide outplacement services for you by its designated organization at a level consistent with the Corporation's career transition policy.

(f) You shall not be required to mitigate the amount of any payment provided for in this Agreement by seeking other employment or otherwise, nor shall the amount of any payment provided for in this Agreement be reduced by any compensation earned by you as the result of employment by another employer after the Termination Date, or otherwise. The Corporation's obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall not be affected by any set-off, counterclaim, recoupment, defense or other claim, right or action which it may have against you or others.

3. Any termination by you for Good Reason shall be communicated by a written notice given within 120 days of your having actual notice of the events giving rise to a right to terminate for Good Reason and which (i) sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination for Good Reason and (ii), if the Termination Date is other than the date of receipt of such notice, specifies the Termination Date (which date shall not be more than 15 days after the giving of such notice). Your failure to set forth in the notice of termination any fact or circumstance which contributes to a showing of Good Reason shall not waive any right of yours hereunder or preclude you from asserting such fact or circumstance in enforcing your rights hereunder.

4. For purposes of this Agreement:

(a) "Bonus" means bonus or incentive compensation payable by the Corporation to you pursuant to plans which the Corporation now or hereafter maintains.

(b) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(c) A "Change of Control" shall be deemed to have taken place if (i) any "person" (as such term is used in Sections 13(d) and 14(d)(2) of the Exchange Act) is or becomes the beneficial owner (within the meaning of Rule 13d-3 promulgated under the Exchange Act), directly or indirectly, of securities of the Corporation representing 25% or more of the combined voting power of the Corporation's then outstanding securities; (ii) (A) a reorganization, merger or consolidation, in each case, with respect to which persons who were shareholders of the Corporation immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities or (B) a liquidation or dissolution of the Corporation; or (iii) as the result of a tender offer, exchange offer, merger, consolidation, sale of assets or contested solicitation of proxies or stockholder consents or any combination of the foregoing transactions (a "Transaction"), the persons who were directors of the Corporation immediately before the Transaction shall cease to constitute a majority of the Board of Directors of the Corporation or of any parent of or successor to the Corporation immediately after the Transaction occurs.

(d) "Good Reason" means:

(i) The assignment to you of any duties inconsistent in any material adverse respect with your position (including status, offices, titles and reporting requirements), authority, duties or responsibilities as in effect on the date of the Change of Control, or any other action by the Corporation which results in a diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Corporation promptly after receipt of notice from you;

(ii) Any reduction of your base salary or the failure by the Corporation to provide you with an incentive compensation program, welfare benefits, retirement benefits and other benefits which in the aggregate are no less favorable than the benefits to which you were entitled prior to the Change of Control;

(iii) The Corporation's requiring you to be based at any office or location more than 15 miles from that location at which you are employed on the date of the Change of Control, except for travel reasonably required in the performance of your responsibilities;

(iv) Any action taken or suffered by the Corporation as of or following the Change of Control (such as, without limitation, transfer or encumbrance of assets or incurring of indebtedness) which materially impairs the ability of the Corporation to make any payments due or which may become due to you under this Agreement; or

(v) any failure by the Corporation to obtain the assumption and agreement to perform this Agreement by a successor as contemplated by Section 10.

5.(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Corporation to you or for your benefit, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "Payment"), would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code") or any interest or penalties with respect to such excise tax (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then you shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount such that after payment by you of all taxes (including any interest or penalties imposed with respect to such taxes), including any Excise Tax, imposed upon the Gross-Up Payment, you retain an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments.

(b) Subject to the provisions of Section 5(c), all determinations required to be made under this Section 5, including whether a Gross-Up Payment is required and the amount of such Gross-Up Payment, shall be made by a nationally recognized accounting firm (the "Accounting Firm") which shall provide detailed supporting calculations both to the Corporation and you within 15 business days of the date your employment with the Corporation terminates, or such earlier time as is requested by the Corporation. If the Accounting Firm determines that no Excise Tax is payable to you, it shall furnish you with an opinion that you have substantial authority not to report any Excise Tax on your federal income tax return. Any determination by the Accounting Firm shall be binding upon the Corporation and you. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have

been made by the Corporation should have been made (“Underpayment”), consistent with the calculations required to be made hereunder. In the event that the Corporation exhausts its remedies pursuant to Section 5(c) and you thereafter are required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Corporation to you or for your benefit.

(c) You shall notify the Corporation in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Corporation of the Gross-Up Payment. Such notification shall be given as soon as practicable but no later than ten business days after you know of such claim and shall apprise the Corporation of the nature of such claim and the date on which such claim is requested to be paid. You shall not pay such claim prior to the expiration of the thirty-day period following the date on which you give such notice to the Corporation (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Corporation notifies you in writing prior to the expiration of such period that it desires to contest such claim, you shall:

- (i) give the Corporation any information reasonably requested by the Corporation relating to such a claim,
- (ii) take such action in connection with contesting such claim as the Corporation shall reasonably request in writing from time to time, including, without limitation, accepting legal representation with regard to such claim by an attorney reasonably selected by the Corporation,
- (iii) cooperate with the Corporation in good faith in order effectively to contest such claim, and
- (iv) permit the Corporation to participate in any proceedings relating to such claim;

provided, however, that the Corporation shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest and shall indemnify and hold you harmless, on an after-tax basis, for an Excise Tax or income tax, including interest and penalties with respect thereto, imposed as a result of such representation and payment of costs and expenses. Without limitation of the foregoing provisions of this Section 5(c), the Corporation shall control all proceedings taken in connection with such contest and, at its sole option, may pursue or forgo any and all administrative appeals, proceedings, hearings and conferences with the taxing authority in respect of such claim and may, at its sole option, either direct you to pay the tax claimed and sue for a refund or contest the claim in any permissible manner, and you agree to prosecute such contest to a determination before any administrative tribunal, in a court of initial jurisdiction and in one or more appellate courts, as the Corporation shall determine; provided, however, that if the Corporation directs you to pay such claim and sue for a refund, the Corporation shall advance the amount of such payment to you, on an interest-free basis and shall indemnify and hold you harmless, on an after-tax basis, from any Excise Tax or income tax, including interest or penalties with respect thereto, imposed

with respect to such advance or with respect to any imputed income with respect to such advance; and further provided that any extension of the statute of limitations related to payment of taxes for your taxable year with respect to which such contested amount is claimed to be due is limited solely to such contested amount. Furthermore, the Corporation's control of the contest shall be limited to issues with respect to which a Gross-Up Payment would be payable hereunder and you shall be entitled to settle or contest, as the case may be, any other issue raised by the Internal Revenue Service or any other taxing authority.

(d) If, after the receipt by you of an amount advanced by the Corporation pursuant to Section 5(c), you become entitled to receive any refund with respect to such claim, you shall (subject to the Corporation's complying with the requirements of Section 5(c)) promptly pay to the Corporation the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto). If, after the receipt by you of an amount advanced by the Corporation pursuant to Section 5(c), a determination is made that you shall not be entitled to any refund with respect to such claim and the Corporation does not notify you in writing of its intent to contest such denial of refund prior to the expiration of thirty days after such determination, then such advance shall be forgiven and shall not be required to be repaid and the amount of such advance shall offset, to the extent thereof, the amount of Gross-Up Payment required to be paid.

6. Anything in this Agreement to the contrary notwithstanding, if your employment with the Corporation is terminated prior to the date on which a Change of Control occurs, and it is reasonably demonstrated by you that such termination (a) was at the request of a third party who has taken steps reasonably calculated to effect a Change of Control or (b) otherwise arose in connection with or in anticipation of a Change of Control, then for all purposes of this Agreement, a Change of Control shall be deemed to have occurred the date immediately prior to the date of such termination.

7. This Agreement shall be binding upon and inure to the benefit of you, your estate and the Corporation and any successor or assign of the Corporation, but neither this Agreement nor any rights arising hereunder may be assigned or pledged by you. If you should die while any amount would still be payable to you hereunder if you had continued to live, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to your devisee, legatee, or other designee or, if there be no such designee, to your estate.

8. For purposes of this Agreement, notices and all other communications provided for in the Agreement shall be in writing and shall be deemed to have been duly given when delivered or mailed by United States registered mail, return receipt requested, postage prepaid, addressed, in your case, to the address set forth on the first page of this Agreement and, in the Corporation's case, to the address of its principal office (all notices to the Corporation to be directed to the attention of the President of the Corporation with a copy to the Secretary of the Corporation) or to such other address as either party may have furnished to the other in writing in accordance herewith, except that notices of change of address shall be effective only upon receipt.



9. No provisions of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing signed by you and such officer as may be specifically designated by the Board of Directors of the Corporation. No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the time or at any prior or subsequent time. No agreements or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by either party which are not set forth expressly in this Agreement. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of Florida without regard to principles of conflicts of laws.

10. The Corporation will require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Corporation to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Corporation would be required to perform it if no such succession had taken place. As used in this Agreement, "Corporation" shall mean the Corporation as hereinbefore defined and any successor to its business and/or assets as aforesaid which assumes and agrees to perform this Agreement by operation of law, or otherwise.

11. Nothing in this Agreement shall prevent or limit your continuing or future participation in any benefit, bonus, incentive or other plan or program provided by the Corporation and for which you may qualify, nor shall anything herein limit or otherwise prejudice such rights as you may have under any other agreements with the Corporation. Amounts which are vested benefits or which you are otherwise entitled to receive under any plan or program of the Corporation at or subsequent to any Change of Control shall be payable in accordance with such plan or program. To the extent the terms of any other agreements you may have with the Corporation are inconsistent with this Agreement, the terms of this Agreement shall control.

12. If you assert any claim in any contest (whether initiated by you or by the Corporation) as to the validity, enforceability or interpretation of any provision of this Agreement, the Corporation shall pay your legal expenses (or cause such expenses to be paid), including, without limitation, your reasonable attorneys' fees, on a quarterly basis, upon presentation of proof of such expenses in a form reasonably acceptable to the Corporation, provided that you shall reimburse the Corporation for such amounts, plus simple interest thereon at the 90-day United States Treasury Bill rate as in effect from time to time, compounded annually, if a court of competent jurisdiction shall find that you did not have a good faith and reasonable basis to believe that you would prevail as to at least one material issue presented to such court.

13. The invalidity or unenforceability of any provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

14. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instrument.

If you are in agreement with the foregoing, please so indicate by signing and returning to the Corporation the enclosed copy of this letter, whereupon this letter shall constitute a binding agreement under seal between you and the Corporation.

Very truly yours,

Nabi Biopharmaceuticals

By /s/ Thomas H. McLain

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Thomas H. McLain  
Chairman, CEO and President

Agreed:

/s/ H. Le Roux Jooste

---

H. Le Roux Jooste

XXXXX

XXXXX

**NABI BIOPHARMACEUTICALS**  
**5800 PARK OF COMMERCE BOULEVARD, N.W.**  
**BOCA RATON, FLORIDA 33487**

**Effective as of December 20, 2004**

H. Le Roux Jooste

XXXXX

XXXXX

Dear Le Roux:

You have agreed to serve as Senior Vice-President (SVP) Global Sales and Marketing for Nabi Biopharmaceuticals ("Nabi") which term for purposes of this Agreement shall include affiliates of Nabi Biopharmaceuticals. The following are the terms of such employment:

1. **TERM:** You will serve as a SVP Global Sales and Marketing for a period beginning as of the date hereof and ending on January 1, 2008, unless your employment is sooner terminated as provided below (the "Employment Period"). In the event that your employment by the Company continues beyond the Employment Period, the terms and conditions of this Agreement shall continue except that your continued employment by the Company may be terminated by either party upon thirty (30) days' prior notice unless you and the Company shall have entered into a written agreement to the contrary.
2. **SALARY:** Your salary will be \$290,000 per year, payable bi-weekly during the Employment Period. Your salary will be subject to discretionary annual increases as determined by Nabi's Board of Directors.
3. **BONUS:** You will be entitled to participate in Nabi's VIP Management Incentive Program or any comparable bonus plan maintained by Nabi ("Bonus Plan"). Your participation in the Bonus Plan shall be subject to the terms and conditions of the Bonus Plan.

Unless the Employment Period is terminated for "cause" pursuant to Section 7(B) (b) below, if the Employment Period ends during a calendar year, your bonus compensation opportunity shall be pro rated based upon the number of full calendar months you were employed and the amount of bonus compensation which would have been payable with respect to such year pursuant to the Bonus Plan. If the Employment Period is terminated pursuant to Section 7 (B)(b) below, no bonus compensation shall be payable with respect to the calendar year during which the Employment Period is terminated. Bonus payments, if applicable, shall be payable within 120 days after the end of the relevant calendar year.

4. **AUTO ALLOWANCE:** While an employee under the terms of this Agreement, you shall receive an auto allowance of not less than \$1200.00 per month.

5. **BENEFITS:** During the Employment Period, you will be eligible to participate in such fringe benefits programs as are accorded to other similarly situated Nabi employees. In addition, Nabi shall pay you an Executive Bonus, grossed up for taxes, so that you can make a \$12,000 contribution to your Supplemental Executive Retirement Plan (the "SERP") and provide you at Nabi's cost with term life insurance of \$500,000 in excess of the term life insurance coverage Nabi provides to its employees generally. Nabi shall cover the cost of financial planning services up to \$3000.00/year. Nabi shall also pay your reasonable social dues at a single club.

6. **DUTIES AND EXTENT OF SERVICES:**

(A) During the Employment Period, you agree to devote substantially all of your working time, and such energy, knowledge, and efforts as is necessary to the discharge and performance of your duties provided for in this Agreement and such other reasonable duties and responsibilities consistent with your position as are assigned to you from time to time by the person to whom you report. You shall be located primarily in Nabi's Boca Raton, Florida facilities, but shall travel to other locations from time to time as shall be reasonably required in the course of performance of your duties.

(B) During the Employment Period, you shall serve as a SVP Global Sales and Marketing. You shall have such duties as are delegated to you by the person to whom you report provided that such duties shall be reasonably consistent with those duties assigned to executive officers having similar titles in organizations comparable to Nabi.

7. **TERMINATION:**

(A) The Employment Period shall terminate upon your death. You may also terminate the Employment Period upon thirty (30) days' prior written notice to Nabi. Any termination pursuant to this Section 7(A) shall not affect any bonus compensation applicable to the year of such termination, provided that, if applicable, any bonus compensation payable pursuant to Section 3 of this Agreement shall be pro rated as provided for in Section 3.

(B) Nabi may terminate the Employment Period (a) in the event Nabi reasonably determines that you are unable to perform the essential functions of your position, with or without reasonable accommodation, for any three (3) consecutive months as the result of mental or physical incapacity or (b) for "cause", which is defined as (i) acts of fraud or embezzlement or other felonious acts by you, (ii) your refusal to comply with reasonable directions in connection with the performance of your duties as provided for in Section 6 of this Agreement after notice of such failure is delivered to you, (iii) failure to comply with the provisions of Section 9 or 10 of this

Agreement or (iv) your gross negligence in connection with the performance of your duties as provided for in this Agreement, provided that, in the event of a proposed termination under clause (ii) or clause (iv) of this clause (B), you shall receive ten (10) days' prior written notice of such proposed termination and within such period you shall be afforded an opportunity to be heard by Nabi's Board of Directors or a duly appointed committee of the Board as to whether grounds for termination under these clauses exists.

(C) Nabi may otherwise terminate the Employment Period upon thirty (30) days' prior notice to you.

(D) Your confidentiality and non-competition agreements set forth in Sections 9 and 10 below and your agreement to cooperate set forth in Section 11 below shall survive the termination of your employment regardless of the reasons therefor.

#### **8. SEVERANCE**

(A) In the event that (a) your employment terminates pursuant to Section 7C or (b) after the expiration of the Employment Period, if your employment continues as provided in Section 1, either you give notice of termination of employment to the Company or the Company gives you notice of termination of employment other than for cause (as defined above) or disability, and provided that (i) within thirty (30) days prior to the expiration of the Employment Period Nabi had not offered to renew this Agreement on terms no less favorable to you than the terms then in effect, and (ii) within ninety (90) days following the expiration of the Employment Period Nabi has not tendered to you a new employment agreement executed on behalf of Nabi and containing such no less favorable terms, you shall receive the benefits set forth in Sections 8B, 8C and 8D. In the event your employment terminates pursuant to Section 7B (a), or as a result of your death, you shall receive the benefit set forth in Section 8D. Notwithstanding the foregoing provisions of this Section 8A, in the event your employment terminates under circumstances that entitle you to receive compensation and other benefits pursuant to the December 20, 2004 Change of Control Severance Agreement between you and Nabi (the "Change of Control Severance Agreement"), you shall not receive the benefits set forth in Section 8B, 8C and 8D.

(B) Based on the effective date of such termination and subject to the following provisions of this Section 8(B), Nabi will pay you severance pay as defined in (i) and (ii) below ("Severance Pay") and maintain in effect such fringe benefits as are accorded to other similarly situated employees (to the extent allowed under, and subject to the limitations of, applicable plans) for the following periods: (i) if at the date of termination you shall have been employed by Nabi for less than twelve months, you shall receive Severance Pay equal to your monthly base salary as in effect at the time of such termination and benefit continuation for nine (9) months and (ii) if at the date of termination you shall have been employed by Nabi for twelve months or more, you shall receive Severance Pay equal to your monthly base salary and benefit continuation for eighteen months. Severance Pay shall be made in equal bi-weekly installments.

(C) The Company shall pay for executive outplacement services up to \$18,000 by an organization selected by Nabi in its sole discretion.

(D) Provided that at the date your employment terminates you shall have been employed by Nabi for a period of at least twelve months, all of your non-vested stock options, restricted stock or similar incentive equity instruments ("Options") shall immediately vest. All such "Options" shall be exercisable for twelve (12) months past your termination date, except that no "Options" shall be exercisable beyond the original "Option" expiration date. To the extent the terms of any "Options" are inconsistent with this Agreement, the terms of this Agreement shall control.

(E) All payments or benefits to you under this Section 8 (other than payments or benefits already accrued and otherwise due under Nabi's employee benefit plans or programs, or as a result of your death) will not be given unless you execute (and do not rescind) a written employment termination agreement in a form prescribed by Nabi, containing terms consistent with this Agreement as well as a general release of all claims against Nabi and related parties with respect to all matters occurring prior to or on the date of the release, including (but not limited to) employment matters or matters in connection with your termination.

(F) It is the intent of you and Nabi that the provisions of this Section 8 and all amounts payable to you hereunder meet the requirements of Section 409A of the Internal Revenue Code of 1986, as amended, to the extent applicable to this Agreement and such payments. Recognizing such intent and the lack of guidance currently available under Section 409A, you and Nabi agree to cooperate in good faith in preparing and executing, at such time as sufficient guidance is available under Section 409A and from time to time thereafter, such amendments to this Section 8 as may reasonably be necessary solely for the purpose of assuring that this Section 8 and all amounts payable to you hereunder meet the requirements of Section 409A.

9. **CONFIDENTIALITY:** You acknowledge that your duties with Nabi will give you access to trade secrets and other confidential information of Nabi and/or its affiliates, including but not limited to information concerning production and marketing of their respective products, customer lists, and other information relating to their present or future operations (all of the foregoing, whether or not it qualifies as a "trade secret" under applicable law, is collectively called "Confidential Information"). You recognize that Confidential Information is proprietary to each such entity and gives each of them significant competitive advantage.

Accordingly, you shall not use or disclose any of the Confidential Information during or after the Employment Period, except for the sole and exclusive benefit of the relevant company. Upon any termination of the Employment Period, you will return to the relevant company's office all documents, computer electronic information and files, e.g., diskettes, floppies etc. and other tangible embodiments of any Confidential Information. You agree that Nabi would be irreparably injured by any breach of your confidentiality agreement, that such injury would not be adequately compensable by monetary damages, and that, accordingly, the offended company may specifically enforce the provisions of this Section by injunction or similar remedy by any court of competent jurisdiction without affecting any claim for damages.

**10. NON-COMPETITION:**

(A) You acknowledge that your services to be rendered are of a special and unusual character and have a unique value to Nabi the loss of which cannot adequately be compensated by damages in an action at law. In view of the unique value of the services, and because of the Confidential Information to be obtained by or disclosed to you, and as a material inducement to Nabi to enter into this Agreement and to pay to you the compensation referred to above and other consideration provided, you covenant and agree that, during the term of your employment by Nabi and for a period of one (1) year after termination of such employment for any reason whatsoever, you will not, directly or indirectly, (a) engage or become interested, as owner, employee, consultant, partner, through stock ownership (except ownership of less than five percent of any class of equity securities which are publicly traded), investment of capital, lending of money or property, rendering of services, or otherwise, either alone or in association with others, in the operations, management or supervision of any type of business or enterprise engaged in any business which is competitive with any business of Nabi (a "Competitive Business"), (b) solicit or accept orders from any current or past customer of Nabi for products or services offered or sold by, or competitive with products or services offered or sold by, Nabi, (c) induce or attempt to induce any such customer to reduce such customer's purchase of products or services from Nabi, (d) disclose or use for the benefit of any Competitive Business the name and/or requirements of any such customer or (e) solicit any of Nabi's employees to leave the employ of Nabi or hire or negotiate for the employment of any employee of Nabi. By way of clarification, a "Competitive Business" is not any business or enterprise in the health care industry; it is only a business or enterprise in the health care industry that is competitive with any business of Nabi. Notwithstanding the foregoing, nothing contained in this Section 10A shall be deemed to prohibit you from being employed by or providing services to a Competitive Business following a "Change of Control" (as defined in the Change of Control Agreement) and termination of your employment if the nature of such employment or services do not compete with any business engaged in by Nabi immediately prior to the Change in Control.

(B) You have carefully read and considered the provisions of this Section and Section 9 and having done so, agree that the restrictions set forth (including but not limited to the time period of restriction and the world wide areas of restriction) are fair and reasonable (even if termination is at our request and without cause) and are reasonably required for the protection of the interest of Nabi, its officers, directors, and other employees. You acknowledge that upon termination of this Agreement for any reason, it may be necessary for you to relocate to another area, and you agree that this restriction is fair and reasonable and is reasonably required for the protection of the interests of Nabi, their officers, directors, and other employees.

(C) In the event that, notwithstanding the foregoing, any of the provisions of this Section or Section 9 shall be held to be invalid or unenforceable, the remaining provisions thereof shall nevertheless continue to be valid and enforceable as though invalid or unenforceable parts had not been included therein. In the event that any provision of this Section relating to time period and/or areas of restriction shall be declared by a court of competent jurisdiction to exceed the maximum time period or areas such court deems reasonable and enforceable, said time period and/or areas of restriction shall be deemed to become, and thereafter be, the maximum time period and/or area which such court deems reasonable and enforceable.

(D) With respect to the provisions of this Section, you agree that damages, by themselves, are an inadequate remedy at law, that a material breach of the provisions of this Section would cause irreparable injury to the aggrieved party, and that provisions of this Section 10 may be specifically enforced by injunction or similar remedy in any court of competent jurisdiction without affecting any claim for damages.

11. **LITIGATION AND REGULATORY COOPERATION:** During and after your employment with Nabi, you shall reasonably cooperate with Nabi in the defense or prosecution of any claims now in existence or which may be brought in the future against or on behalf of Nabi which relate to events or occurrences that transpired while you were employed by Nabi; provided, however, that such cooperation shall not materially and adversely affect you or expose you to an increased probability of civil or criminal litigation. Your cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of Nabi at mutually convenient times. During and after your employment with Nabi, you also shall cooperate fully with Nabi in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by Nabi. Nabi shall reimburse you for all out-of-pocket costs and expenses incurred in connection with your performance under this Section 11, including, but not limited to, reasonable attorneys' fees and costs.

12. **MISCELLANEOUS:** This Agreement and the rights and obligations of the parties pursuant to it and any other instruments or documents issued pursuant to it shall be construed, interpreted and enforced in accordance with the laws of the State of Florida, exclusive of its choice-of-law principles. This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their respective successors and assigns. The provisions of this Agreement shall be severable and the illegality, unenforceability or invalidity of any provision of this Agreement shall not affect or impair the remaining provisions hereof, and each provision of this Agreement shall be construed to be valid and enforceable to the full extent permitted by law. In any suit, action or proceeding arising out of or in connection with this Agreement, the prevailing party shall be entitled to receive an award of the reasonable related amount of attorneys' fees and disbursements incurred by such party, including fees and disbursements on appeal. This Agreement and the Change of Control Severance Agreement are a complete expression of all agreements of the parties relating to the subject matter hereof, and all prior or contemporaneous oral or written understandings or agreements shall be null and void except to the extent set forth in this Agreement.



This Agreement cannot be amended orally, or by any course of conduct or dealing, but only by a written agreement signed by the party to be charged therewith. All notices required and allowed hereunder shall be in writing, and shall be deemed given upon deposit in the Certified Mail, Return Receipt Requested, first-class postage and registration fees prepaid, and correctly addressed to the party for whom intended at its address set forth under its name below, or to such other address as has been most recently specified by a party by one or more counterparts, each of which shall constitute one and the same agreement. All references to genders or number in this Agreement shall be deemed interchangeably to have a masculine, feminine, neuter, singular or plural meaning, as the sense of the context required.

If the foregoing confirms your understanding of our agreements, please so indicate by signing in the space provided below and returning a signed copy to us.

Nabi Biopharmaceuticals  
5800 Park of Commerce Boulevard, N.W.  
Boca Raton, Florida 33487

BY: /s/ Thomas H. McLain

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Thomas H. McLain  
CEO and President

Accepted and agreed:

/s/ H. Le Roux Jooste

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H. Le Roux Jooste

xxxxx

xxxxx

Nabi Biopharmaceuticals

5800 Park of Commerce Boulevard, N.W.  
Boca Raton, FL 33487**Change of Control Severance Agreement**  
**Effective as of May 3, 2004**Mr. Richard G. Clark  
xxxxx  
xxxxx

Dear Dick:

The Board of Directors of Nabi Biopharmaceuticals (the "Corporation") and the Compensation Committee (the "Committee") of the Board have determined that it is in the best interests of the Corporation and its shareholders for the Corporation to agree, as provided herein, to pay you termination compensation in the event you should leave the employ of the Corporation under the circumstances described below.

The Board and the Committee recognize that the continuing possibility of a sale or change of control of the Corporation is unsettling to you and other key employees of the Corporation. Therefore, these arrangements are being made to help assure a continuing dedication by you to your duties to the Corporation by diminishing the inevitable distraction to you from the personal uncertainties and risks created by a pending sale or change of control of the Corporation. In particular, the Board and the Committee believe it important, should the Corporation receive proposals from third parties with respect to its future, to enable you, without being influenced by the uncertainties of your own situation, to assess and advise the Board whether such proposals would be in the best interests of the Corporation and its shareholders and to take such other action regarding such proposals as the Board might determine to be appropriate, including being available to assist in any transition should there be a sale or change of control of the Corporation. The Board and the Committee also wish to demonstrate to executives of the Corporation that the Corporation is concerned with the welfare of its executives and intends to see that loyal executives are treated fairly.

1. In view of the foregoing and in further consideration of your continued employment with the Corporation, the Corporation will pay you as termination compensation a lump sum amount, determined as provided below, in the event that (a) within six months after a Change of Control of the Corporation you terminate your employment with the Corporation for Good Reason or you die or you become disabled, or (b) within twelve months after a Change of Control of the Corporation your employment with the Corporation is terminated by the Corporation for any reason, or (c) within the period beginning on the sixth monthly anniversary of a Change of Control of the Corporation and ending on the twelfth monthly anniversary thereof, you terminate your employment with the Corporation for any reason (including, without limitation, death or disability). The lump sum compensation so payable

(hereinafter referred to as the "Lump Sum Amount") shall be an amount equal to two times the sum of (a) the higher of (i) your current annual base salary or (ii) your base salary immediately prior to the Change of Control plus (b) the target Bonus you could have earned for the fiscal year in which the Change of Control occurred. The Lump Sum Amount shall be paid to you within five days after the date of termination of your employment (hereinafter referred to as the "Termination Date").

2. In addition, in the event your employment with the Corporation terminates under circumstances entitling you to receive the Lump Sum Amount:

(a) Any compensation and other amounts previously deferred by you, together with accrued interest thereon, if any, to which you are entitled, and any accrued vacation pay and accrued paid leave bank amounts not yet paid by the Corporation, shall be paid to you within five days of such termination.

(b) All other amounts accrued or earned by you through the date of such termination and amounts otherwise owing under the Corporation's plans and policies shall be paid to you within five days of such termination.

(c) The Corporation shall maintain in full force and effect, for the continued benefit of you and/or your family for twenty-four months after the Termination Date, all employee welfare benefit plans and any other employee benefit programs or arrangements (including, without limitation, medical and dental insurance plans, disability and life insurance plans and car allowance programs) in which you were entitled to participate immediately prior to the Change of Control, provided that your continued participation is possible under the general terms and provisions of such plans and programs. In the event that your participation in any such plan or program is barred, the Corporation shall arrange to provide you with benefits substantially similar to those which you are entitled to receive under such plans and programs. To the extent permissible, all such benefits shall be assignable by you.

(d) All outstanding stock options which you hold shall vest immediately upon a Change of Control and shall be exercisable for (i) the remainder of the option term(s) or (ii) a period of five years from the Termination Date, whichever is shorter.

(e) The Corporation shall provide outplacement services for you by its designated organization at a level consistent with the Corporation's career transition policy.

(f) You shall not be required to mitigate the amount of any payment provided for in this Agreement by seeking other employment or otherwise, nor shall the amount of any payment provided for in this Agreement be reduced by any compensation earned by you as the result of employment by another employer after the Termination Date, or otherwise. The Corporation's obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall not be affected by any set-off, counterclaim, recoupment, defense or other claim, right or action which it may have against you or others.

3. Any termination by you for Good Reason shall be communicated by a written notice given within 120 days of your having actual notice of the events giving rise to a right to terminate for Good Reason and which (i) sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination for Good Reason and (ii), if the Termination Date is other than the date of receipt of such notice, specifies the Termination Date (which date shall not be more than 15 days after the giving of such notice). Your failure to set forth in the notice of termination any fact or circumstance which contributes to a showing of Good Reason shall not waive any right of yours hereunder or preclude you from asserting such fact or circumstance in enforcing your rights hereunder.

4. For purposes of this Agreement:

(a) "Bonus" means bonus or incentive compensation payable by the Corporation to you pursuant to plans which the Corporation now or hereafter maintains.

(b) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(c) A "Change of Control" shall be deemed to have taken place if (i) any "person" (as such term is used in Sections 13(d) and 14(d)(2) of the Exchange Act) is or becomes the beneficial owner (within the meaning of Rule 13d-3 promulgated under the Exchange Act), directly or indirectly, of securities of the Corporation representing 25% or more of the combined voting power of the Corporation's then outstanding securities; (ii) (A) a reorganization, merger or consolidation, in each case, with respect to which persons who were shareholders of the Corporation immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities or (B) a liquidation or dissolution of the Corporation; or (iii) as the result of a tender offer, exchange offer, merger, consolidation, sale of assets or contested solicitation of proxies or stockholder consents or any combination of the foregoing transactions (a "Transaction"), the persons who were directors of the Corporation immediately before the Transaction shall cease to constitute a majority of the Board of Directors of the Corporation or of any parent of or successor to the Corporation immediately after the Transaction occurs.

(d) "Good Reason" means:

(i) The assignment to you of any duties inconsistent in any material adverse respect with your position (including status, offices, titles and reporting requirements), authority, duties or responsibilities as in effect on the date of the Change of Control, or any other action by the Corporation which results in a diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Corporation promptly after receipt of notice from you;

(ii) Any reduction of your base salary or the failure by the Corporation to provide you with an incentive compensation program, welfare benefits, retirement benefits and other benefits which in the aggregate are no less favorable than the benefits to which you were entitled prior to the Change of Control;

(iii) The Corporation's requiring you to be based at any office or location more than 15 miles from that location at which you are employed on the date of the Change of Control, except for travel reasonably required in the performance of your responsibilities;

(iv) Any action taken or suffered by the Corporation as of or following the Change of Control (such as, without limitation, transfer or encumbrance of assets or incurring of indebtedness) which materially impairs the ability of the Corporation to make any payments due or which may become due to you under this Agreement; or

(v) any failure by the Corporation to obtain the assumption and agreement to perform this Agreement by a successor as contemplated by Section 10.

5.(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Corporation to you or for your benefit, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "Payment"), would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code") or any interest or penalties with respect to such excise tax (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then you shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount such that after payment by you of all taxes (including any interest or penalties imposed with respect to such taxes), including any Excise Tax, imposed upon the Gross-Up Payment, you retain an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments.

(b) Subject to the provisions of Section 5(c), all determinations required to be made under this Section 5, including whether a Gross-Up Payment is required and the amount of such Gross-Up Payment, shall be made by a nationally recognized accounting firm (the "Accounting Firm") which shall provide detailed supporting calculations both to the Corporation and you within 15 business days of the date your employment with the Corporation terminates, or such earlier time as is requested by the Corporation. If the Accounting Firm determines that no Excise Tax is payable to you, it shall furnish you with an opinion that you have substantial authority not to report any Excise Tax on your federal income tax return. Any determination by the Accounting Firm shall be binding upon the Corporation and you. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have

been made by the Corporation should have been made (“Underpayment”), consistent with the calculations required to be made hereunder. In the event that the Corporation exhausts its remedies pursuant to Section 5(c) and you thereafter are required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Corporation to you or for your benefit.

(c) You shall notify the Corporation in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Corporation of the Gross-Up Payment. Such notification shall be given as soon as practicable but no later than ten business days after you know of such claim and shall apprise the Corporation of the nature of such claim and the date on which such claim is requested to be paid. You shall not pay such claim prior to the expiration of the thirty-day period following the date on which you give such notice to the Corporation (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Corporation notifies you in writing prior to the expiration of such period that it desires to contest such claim, you shall:

- (i) give the Corporation any information reasonably requested by the Corporation relating to such a claim,
- (ii) take such action in connection with contesting such claim as the Corporation shall reasonably request in writing from time to time, including, without limitation, accepting legal representation with regard to such claim by an attorney reasonably selected by the Corporation,
- (iii) cooperate with the Corporation in good faith in order effectively to contest such claim, and
- (iv) permit the Corporation to participate in any proceedings relating to such claim;

provided, however, that the Corporation shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest and shall indemnify and hold you harmless, on an after-tax basis, for an Excise Tax or income tax, including interest and penalties with respect thereto, imposed as a result of such representation and payment of costs and expenses. Without limitation of the foregoing provisions of this Section 5(c), the Corporation shall control all proceedings taken in connection with such contest and, at its sole option, may pursue or forgo any and all administrative appeals, proceedings, hearings and conferences with the taxing authority in respect of such claim and may, at its sole option, either direct you to pay the tax claimed and sue for a refund or contest the claim in any permissible manner, and you agree to prosecute such contest to a determination before any administrative tribunal, in a court of initial jurisdiction and in one or more appellate courts, as the Corporation shall determine; provided, however, that if the Corporation directs you to pay such claim and sue for a refund, the Corporation shall advance the amount of such payment to you, on an interest-free basis and shall indemnify and hold you harmless, on an after-tax basis, from any Excise Tax or income tax, including interest or penalties with respect thereto, imposed

with respect to such advance or with respect to any imputed income with respect to such advance; and further provided that any extension of the statute of limitations related to payment of taxes for your taxable year with respect to which such contested amount is claimed to be due is limited solely to such contested amount. Furthermore, the Corporation's control of the contest shall be limited to issues with respect to which a Gross-Up Payment would be payable hereunder and you shall be entitled to settle or contest, as the case may be, any other issue raised by the Internal Revenue Service or any other taxing authority.

(d) If, after the receipt by you of an amount advanced by the Corporation pursuant to Section 5(c), you become entitled to receive any refund with respect to such claim, you shall (subject to the Corporation's complying with the requirements of Section 5(c)) promptly pay to the Corporation the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto). If, after the receipt by you of an amount advanced by the Corporation pursuant to Section 5(c), a determination is made that you shall not be entitled to any refund with respect to such claim and the Corporation does not notify you in writing of its intent to contest such denial of refund prior to the expiration of thirty days after such determination, then such advance shall be forgiven and shall not be required to be repaid and the amount of such advance shall offset, to the extent thereof, the amount of Gross-Up Payment required to be paid.

6. Anything in this Agreement to the contrary notwithstanding, if your employment with the Corporation is terminated prior to the date on which a Change of Control occurs, and it is reasonably demonstrated by you that such termination (a) was at the request of a third party who has taken steps reasonably calculated to effect a Change of Control or (b) otherwise arose in connection with or in anticipation of a Change of Control, then for all purposes of this Agreement, a Change of Control shall be deemed to have occurred the date immediately prior to the date of such termination.

7. This Agreement shall be binding upon and inure to the benefit of you, your estate and the Corporation and any successor or assign of the Corporation, but neither this Agreement nor any rights arising hereunder may be assigned or pledged by you. If you should die while any amount would still be payable to you hereunder if you had continued to live, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to your devisee, legatee, or other designee or, if there be no such designee, to your estate.

8. For purposes of this Agreement, notices and all other communications provided for in the Agreement shall be in writing and shall be deemed to have been duly given when delivered or mailed by United States registered mail, return receipt requested, postage prepaid, addressed, in your case, to the address set forth on the first page of this Agreement and, in the Corporation's case, to the address of its principal office (all notices to the Corporation to be directed to the attention of the President of the Corporation with a copy to the Secretary of the Corporation) or to such other address as either party may have furnished to the other in writing in accordance herewith, except that notices of change of address shall be effective only upon receipt.

9. No provisions of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing signed by you and such officer as may be specifically designated by the Board of Directors of the Corporation. No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the time or at any prior or subsequent time. No agreements or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by either party which are not set forth expressly in this Agreement. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of Florida without regard to principles of conflicts of laws.

10. The Corporation will require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Corporation to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Corporation would be required to perform it if no such succession had taken place. As used in this Agreement, "Corporation" shall mean the Corporation as hereinbefore defined and any successor to its business and/or assets as aforesaid which assumes and agrees to perform this Agreement by operation of law, or otherwise.

11. Nothing in this Agreement shall prevent or limit your continuing or future participation in any benefit, bonus, incentive or other plan or program provided by the Corporation and for which you may qualify, nor shall anything herein limit or otherwise prejudice such rights as you may have under any other agreements with the Corporation. Amounts which are vested benefits or which you are otherwise entitled to receive under any plan or program of the Corporation at or subsequent to any Change of Control shall be payable in accordance with such plan or program. To the extent the terms of any other agreements you may have with the Corporation are inconsistent with this Agreement, the terms of this Agreement shall control.

12. If you assert any claim in any contest (whether initiated by you or by the Corporation) as to the validity, enforceability or interpretation of any provision of this Agreement, the Corporation shall pay your legal expenses (or cause such expenses to be paid), including, without limitation, your reasonable attorneys' fees, on a quarterly basis, upon presentation of proof of such expenses in a form reasonably acceptable to the Corporation, provided that you shall reimburse the Corporation for such amounts, plus simple interest thereon at the 90-day United States Treasury Bill rate as in effect from time to time, compounded annually, if a court of competent jurisdiction shall find that you did not have a good faith and reasonable basis to believe that you would prevail as to at least one material issue presented to such court.

13. The invalidity or unenforceability of any provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.



14. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instrument.

If you are in agreement with the foregoing, please so indicate by signing and returning to the Corporation the enclosed copy of this letter, whereupon this letter shall constitute a binding agreement under seal between you and the Corporation.

Very truly yours,

Nabi Biopharmaceuticals

By /s/ Thomas H. McLain

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Thomas H. McLain  
Chairman, CEO and President

Agreed:

/s/ Richard G. Clark

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Richard G. Clark

XXXXX

XXXXX

**NABI BIOPHARMACEUTICALS**  
**5800 PARK OF COMMERCE BOULEVARD, N.W.**  
**BOCA RATON, FLORIDA 33487**

**Effective as of May 3, 2004**

Mr. Richard G. Clark

xxxxx

xxxxx

Dear Dick:

You have agreed to serve as Senior Vice President Administration/Chief Administrative Officer (CAO) for Nabi Biopharmaceuticals ("Nabi") which term for purposes of this Agreement shall include affiliates of Nabi Biopharmaceuticals. The following are the terms of such employment:

1. **TERM:** You will serve as a Senior Vice President Administration/CAO for a period beginning as of the date hereof and ending on March 31, 2007, unless your employment is sooner terminated as provided below (the "Employment Period"). In the event that your employment by the Company continues beyond the Employment Period, the terms and conditions of this Agreement shall continue except that your continued employment by the Company may be terminated by either party upon thirty (30) days' prior notice unless you and the Company shall have entered into a written agreement to the contrary.
2. **SALARY:** Your salary will be \$235,000 per year, payable bi-weekly during the Employment Period. Your salary will be subject to discretionary annual increases as determined by Nabi's Board of Directors.
3. **BONUS:** You will be entitled to participate in Nabi's VIP Management Incentive Program or any comparable bonus plan maintained by Nabi ("Bonus Plan"). Your participation in the Bonus Plan shall be subject to the terms and conditions of the Bonus Plan.

Unless the Employment Period is terminated for "cause" pursuant to Section 7(B) (b) below, if the Employment Period ends during a calendar year, your bonus compensation opportunity shall be pro rated based upon the number of full calendar months you were employed and the amount of bonus compensation which would have been payable with respect to such year pursuant to the Bonus Plan. If the Employment Period is terminated pursuant to Section 7 (B)(b) below, no bonus compensation shall be payable with respect to the calendar year during which the Employment Period is terminated.

Bonus payments, if applicable, shall be payable within 120 days after the end of the relevant calendar year.

4. **AUTO ALLOWANCE:** While an employee under the terms of this Agreement, you shall receive an auto allowance of not less than \$1200.00 per month.

5. **BENEFITS:** During the Employment Period, you will be eligible to participate in such fringe benefits programs as are accorded to other similarly situated Nabi employees. In addition, Nabi shall pay you an Executive Bonus, grossed up for taxes, so that you can make a \$12,000 contribution to your Supplemental Executive Retirement Plan (the "SERP") and provide you at Nabi's cost with term life insurance of \$500,000 in excess of the term life insurance coverage Nabi provides to its employees generally. Nabi shall cover the cost of financial planning services up to \$3000.00/year. Nabi shall also pay your reasonable social dues at a single club.

6. **DUTIES AND EXTENT OF SERVICES:**

(A) During the Employment Period, you agree to devote substantially all of your working time, and such energy, knowledge, and efforts as is necessary to the discharge and performance of your duties provided for in this Agreement and such other reasonable duties and responsibilities consistent with your position as are assigned to you from time to time by the person to whom you report. You shall be located primarily in Nabi's Boca Raton, Florida facilities, but shall travel to other locations from time to time as shall be reasonably required in the course of performance of your duties.

(B) During the Employment Period, you shall serve as a Senior Vice President Administration/CAO. You shall have such duties as are delegated to you by the person to whom you report provided that such duties shall be reasonably consistent with those duties assigned to executive officers having similar titles in organizations comparable to Nabi.

7. **TERMINATION:**

(A) The Employment Period shall terminate upon your death. You may also terminate the Employment Period upon thirty (30) days' prior written notice to Nabi. Any termination pursuant to this Section 7(A) shall not affect any bonus compensation applicable to the year of such termination, provided that, if applicable, any bonus compensation payable pursuant to Section 3 of this Agreement shall be pro rated as provided for in Section 3.

(B) Nabi may terminate the Employment Period (a) in the event Nabi reasonably determines that you are unable to perform the essential functions of your position, with or without reasonable accommodation, for any three (3) consecutive months as the result of mental or physical incapacity or (b) for "cause", which is defined as (i) acts of fraud or embezzlement or other felonious acts by you, (ii) your refusal to comply with reasonable directions in connection with the performance of your duties as provided for in Section 6 of this Agreement after notice of such failure is delivered to you, (iii) failure to comply with the provisions of Section 9 or 10 of this Agreement or (iv) your gross negligence in connection with the performance of your duties as provided for in this Agreement, provided that, in the event of a proposed termination under

clause (ii) or clause (iv) of this clause (B), you shall receive ten (10) days' prior written notice of such proposed termination and within such period you shall be afforded an opportunity to be heard by Nabi's Board of Directors or a duly appointed committee of the Board as to whether grounds for termination under these clauses exists.

(C) Nabi may otherwise terminate the Employment Period upon thirty (30) days' prior notice to you.

(D) Your confidentiality and non-competition agreements set forth in Sections 9 and 10 below and your agreement to cooperate set forth in Section 11 below shall survive the termination of your employment regardless of the reasons therefor.

## **8. SEVERANCE**

(A) In the event that (a) your employment terminates pursuant to Section 7C or (b) after the expiration of the Employment Period, if your employment continues as provided in Section 1, either you give notice of termination of employment to the Company or the Company gives you notice of termination of employment other than for cause (as defined above) or disability, and provided that (i) within thirty (30) days prior to the expiration of the Employment Period Nabi had not offered to renew this Agreement on terms no less favorable to you than the terms then in effect, and (ii) within ninety (90) days following the expiration of the Employment Period Nabi has not tendered to you a new employment agreement executed on behalf of Nabi and containing such no less favorable terms, you shall receive the benefits set forth in Sections 8B, 8C and 8D. In the event your employment terminates pursuant to Section 7B (a), or as a result of your death, you shall receive the benefit set forth in Section 8D. Notwithstanding the foregoing provisions of this Section 8A, in the event your employment terminates under circumstances that entitle you to receive compensation and other benefits pursuant to the May 3, 2004 Change of Control Severance Agreement between you and Nabi (the "Change of Control Severance Agreement"), you shall not receive the benefits set forth in Section 8B, 8C and 8D.

(B) Based on the effective date of such termination, Nabi will pay you your base salary as of the effective date of such termination ("Severance Pay") and maintain in effect such fringe benefits (including auto allowance) as are accorded to other similarly situated employees (to the extent allowed under, and subject to the limitations of, applicable plans) for eighteen (18) months. Severance Pay shall be made in equal bi-weekly installments.

(C) The Company shall pay for executive outplacement services up to \$18,000 by an organization selected by Nabi in its sole discretion.

(D) All of your non-vested stock options, restricted stock or similar incentive equity instruments ("Options") shall immediately vest. All such "Options" shall be exercisable for twelve (12) months past your termination date, except that no "Options" shall be exercisable beyond the original "Option" expiration date. To the extent the terms of any "Options" are inconsistent with this Agreement, the terms of this Agreement shall control.

(E) All payments or benefits to you under this Section 8 (other than payments or benefits already accrued and otherwise due under Nabi's employee benefit plans or programs, or as a result of your death) will not be given unless you execute (and do not rescind) a written employment termination agreement in a form prescribed by Nabi, containing terms consistent with this Agreement as well as a general release of all claims against Nabi and related parties with respect to all matters occurring prior to or on the date of the release, including (but not limited to) employment matters or matters in connection with your termination.

9. **CONFIDENTIALITY:** You acknowledge that your duties with Nabi will give you access to trade secrets and other confidential information of Nabi and/or its affiliates, including but not limited to information concerning production and marketing of their respective products, customer lists, and other information relating to their present or future operations (all of the foregoing, whether or not it qualifies as a "trade secret" under applicable law, is collectively called "Confidential Information"). You recognize that Confidential Information is proprietary to each such entity and gives each of them significant competitive advantage.

Accordingly, you shall not use or disclose any of the Confidential Information during or after the Employment Period, except for the sole and exclusive benefit of the relevant company. Upon any termination of the Employment Period, you will return to the relevant company's office all documents, computer electronic information and files, e.g., diskettes, floppies etc. and other tangible embodiments of any Confidential Information. You agree that Nabi would be irreparably injured by any breach of your confidentiality agreement, that such injury would not be adequately compensable by monetary damages, and that, accordingly, the offended company may specifically enforce the provisions of this Section by injunction or similar remedy by any court of competent jurisdiction without affecting any claim for damages.

10. **NON-COMPETITION:**

(A) You acknowledge that your services to be rendered are of a special and unusual character and have a unique value to Nabi the loss of which cannot adequately be compensated by damages in an action at law. In view of the unique value of the services, and because of the Confidential Information to be obtained by or disclosed to you, and as a material inducement to Nabi to enter into this Agreement and to pay to you the compensation referred to above and other consideration provided, you covenant and agree that, during the term of your employment by Nabi and for a period of one (1) year after termination of such employment for any reason whatsoever, you will not, directly or indirectly, (a) engage or become interested, as owner, employee, consultant, partner, through stock ownership (except ownership of less than five percent of any class of equity securities which are publicly traded), investment of capital, lending of money or property, rendering of services, or otherwise, either alone or in association with others, in the operations, management or supervision of any type of business or enterprise engaged in any business which is competitive with any business of Nabi (a "Competitive Business"), (b) solicit or accept orders from any current or past customer of Nabi for products or services offered or sold by, or competitive with products or services offered or sold by, Nabi, (c) induce or attempt to induce

any such customer to reduce such customer's purchase of products or services from Nabi, (d) disclose or use for the benefit of any Competitive Business the name and/or requirements of any such customer or (e) solicit any of Nabi's employees to leave the employ of Nabi or hire or negotiate for the employment of any employee of Nabi. By way of clarification, a "Competitive Business" is not any business or enterprise in the health care industry; it is only a business or enterprise in the health care industry that is competitive with any business of Nabi. Notwithstanding the foregoing, nothing contained in this Section 10A shall be deemed to prohibit you from being employed by or providing services to a Competitive Business following a "Change of Control" (as defined in the Change of Control Agreement) and termination of your employment if the nature of such employment or services do not compete with any business engaged in by Nabi immediately prior to the Change in Control.

(B) You have carefully read and considered the provisions of this Section and Section 9 and having done so, agree that the restrictions set forth (including but not limited to the time period of restriction and the world wide areas of restriction) are fair and reasonable (even if termination is at our request and without cause) and are reasonably required for the protection of the interest of Nabi, its officers, directors, and other employees. You acknowledge that upon termination of this Agreement for any reason, it may be necessary for you to relocate to another area, and you agree that this restriction is fair and reasonable and is reasonably required for the protection of the interests of Nabi, their officers, directors, and other employees.

(C) In the event that, notwithstanding the foregoing, any of the provisions of this Section or Section 9 shall be held to be invalid or unenforceable, the remaining provisions thereof shall nevertheless continue to be valid and enforceable as though invalid or unenforceable parts had not been included therein. In the event that any provision of this Section relating to time period and/or areas of restriction shall be declared by a court of competent jurisdiction to exceed the maximum time period or areas such court deems reasonable and enforceable, said time period and/or areas of restriction shall be deemed to become, and thereafter be, the maximum time period and/or area which such court deems reasonable and enforceable.

(D) With respect to the provisions of this Section, you agree that damages, by themselves, are an inadequate remedy at law, that a material breach of the provisions of this Section would cause irreparable injury to the aggrieved party, and that provisions of this Section 10 may be specifically enforced by injunction or similar remedy in any court of competent jurisdiction without affecting any claim for damages.

11. **LITIGATION AND REGULATORY COOPERATION:** During and after your employment with Nabi, you shall reasonably cooperate with Nabi in the defense or prosecution of any claims now in existence or which may be brought in the future against or on behalf of Nabi which relate to events or occurrences that transpired while you were employed by Nabi; provided, however, that such cooperation shall not materially and adversely affect you or expose you to an increased probability of civil or criminal litigation. Your cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of Nabi at mutually

convenient times. During and after your employment with Nabi, you also shall cooperate fully with Nabi in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by Nabi. Nabi shall reimburse you for all out-of-pocket costs and expenses incurred in connection with your performance under this Section 11, including, but not limited to, reasonable attorneys' fees and costs.

12. **MISCELLANEOUS:** This Agreement and the rights and obligations of the parties pursuant to it and any other instruments or documents issued pursuant to it shall be construed, interpreted and enforced in accordance with the laws of the State of Florida, exclusive of its choice-of-law principles. This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their respective successors and assigns. The provisions of this Agreement shall be severable and the illegality, unenforceability or invalidity of any provision of this Agreement shall not affect or impair the remaining provisions hereof, and each provision of this Agreement shall be construed to be valid and enforceable to the full extent permitted by law. In any suit, action or proceeding arising out of or in connection with this Agreement, the prevailing party shall be entitled to receive an award of the reasonable related amount of attorneys' fees and disbursements incurred by such party, including fees and disbursements on appeal. This Agreement, the Change of Control Severance Agreement and the Indemnification Agreement dated September 11, 2000 are a complete expression of all agreements of the parties relating to the subject matter hereof, and all prior or contemporaneous oral or written understandings or agreements shall be null and void except to the extent set forth in this Agreement.

This Agreement cannot be amended orally, or by any course of conduct or dealing, but only by a written agreement signed by the party to be charged therewith. All notices required and allowed hereunder shall be in writing, and shall be deemed given upon deposit in the Certified Mail, Return Receipt Requested, first-class postage and registration fees prepaid, and correctly addressed to the party for whom intended at its address set forth under its name below, or to such other address as has been most recently specified by a party by one or more counterparts, each of which shall constitute one and the same agreement. All references to genders or number in this Agreement shall be deemed interchangeably to have a masculine, feminine, neuter, singular or plural meaning, as the sense of the context required.

If the foregoing confirms your understanding of our agreements, please so indicate by signing in the space provided below and returning a signed copy to us.

Nabi Biopharmaceuticals  
5800 Park of Commerce Boulevard, N.W.  
Boca Raton, Florida 33487

BY: /s/ Thomas H. McLain

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Thomas H. McLain  
CEO and President

Accepted and agreed:

/s/ Richard G. Clark

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Mr. Richard G. Clark

XXXXX

XXXXX



## INDEMNIFICATION AGREEMENT

This Indemnification Agreement is made and entered into this \_\_\_\_\_ day of \_\_\_\_\_, between Nabi Biopharmaceuticals (the “Company”) and \_\_\_\_\_ (the “Indemnitee”), and is effective retroactively to the date of hire of the Indemnitee by Company.

## PRELIMINARY STATEMENT

The board of directors of the Company has determined that highly competent persons will be difficult to retain unless they are adequately protected against liabilities incurred in performance of their services on behalf of the Company, and the Company’s By-laws authorize the Company to enter into and perform Indemnification Agreements for this purpose.

Therefore, the board of directors has determined that it is in the best interests of the Company to attract and retain persons such as the Indemnitee by providing adequate protection against such liabilities by means of Indemnification Agreements with persons such as the Indemnitee.

NOW, THEREFORE, in consideration of the promises and covenants contained herein and as an inducement to the Indemnitee to continue as an employee of the Company, the Company and the Indemnitee, intending to be legally bound, do hereby agree as follows:

1. The Indemnitee agrees to serve as an employee of the Company until the Indemnitee’s resignation by written notice to the Company or the Indemnitee’s removal, whichever occurs earliest.
2. The Company agrees to indemnify and hold harmless the Indemnitee, with respect to any action taken or omitted by the Indemnitee while serving as an employee of the Company, to the fullest extent permissible under applicable law, as such law may be amended or supplemented from time to time. The Indemnitee’s indemnification rights shall include but not be limited to the rights contained in the following paragraphs, except to the extent expressly prohibited by applicable law.
3. The Company shall indemnify and hold harmless the Indemnitee from and against expenses (including attorneys’ fees and disbursements), judgments, damages, fines (including any excise taxes assessed on a person with respect to an employee benefit plan) and amounts paid in settlement actually and reasonably incurred by the Indemnitee in connection with any threatened, pending or contemplated action, suit or proceeding, or appeal thereof, whether civil, criminal or administrative, or in connection with any internal or external investigation (other than an action by or in the right of the Company) if the Indemnitee was or is a “party” (as used in this Agreement, “party” shall include the giving of testimony or similar involvement) or threatened to be made a party to such action, suit or proceeding by reason of the fact that the Indemnitee is or was a director, officer, employee or agent of the Company, or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise (including employee benefit plans); provided, however, that the Indemnitee shall be entitled to such indemnification only if the Indemnitee acted in good faith

and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, the Indemnitee had no reasonable cause to believe such conduct was unlawful. The term “serving at the request of the Company” shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants, or beneficiaries. A person who acted in good faith and in a manner he reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the Company.”

4. The Company shall indemnify and hold harmless the Indemnitee from and against expenses (including attorneys’ fees and disbursements), and amounts paid in settlement, actually and reasonably incurred by the Indemnitee in connection with the defense or settlement of any threatened, pending or completed action or suit, or appeal thereof, by or in the right of the Company to procure a judgment in its favor if the Indemnitee was or is a party or threatened to be a party to such action or suit by reason of the fact that the Indemnitee is or was a director, officer, employee or agent of the Company, or is or was serving at the request of the Company as a director, officer, employer or agent of another corporation, partnership, joint venture, trust or other enterprise; provided, however, that the Indemnitee shall be entitled to such indemnification only if the Indemnitee acted in good faith and in a manner reasonably believed by the Indemnitee to be in or not opposed to the best interests of the Company and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable in the performance of such person’s duty to the Company if and to the extent that the court in which such action or suit was brought shall determine that the Indemnitee is not entitled to such indemnification.

5. The Company currently has in force policies of Directors and Officers Liability Insurance (the “D&O Policy”). The Company shall not be liable under this Indemnification Agreement for any amount of any claim for which the Indemnitee has been paid under the D&O Policy or under any other valid insurance policies maintained in the future by the Company for Indemnitee’s benefit. The Company shall not be required to maintain the D&O Policy presently in effect or to replace such policy if, in the judgment of the board of directors of the Company, the cost of such policy is not reasonable in relation to the coverage provided. If the Company so decides not to maintain the current D&O Policy or replace it with policies with similar coverage, the Company agrees, in addition to and not in limitation of the indemnification otherwise provided for by this Indemnification Agreement, to indemnify and hold harmless the Indemnitee to the extent of coverage which would have been provided by the D&O Policy to the fullest extent permissible under applicable law.

6. Expenses incurred by the Indemnitee in connection with any action, suit, proceeding, or appeal thereof, described in Paragraphs 3 and 4 above, shall be paid by the Company in advance of the final disposition of such action, suit or proceeding within twenty (20) days of receipt of an undertaking by the Indemnitee to repay such amount if it is ultimately determined by the board of directors, Independent Counsel (as defined below), the shareholders or a court, as provided in Paragraph 9 of this Indemnification Agreement, that the Indemnitee is not entitled to be indemnified by the Company or not entitled to full indemnification by the Company.

7. The Indemnitee’s right to indemnification and advancement of expenses as set forth in this Indemnification Agreement shall not be exclusive of other rights the Indemnitee may have under applicable law, other agreements between the Company and the Indemnitee, the Certificate of Incorporation or By-laws of the Company, by vote of disinterested directors of the Company or by vote of the shareholders of the Company.

8. The indemnification and advancement of expenses provided by, or granted pursuant to, this Indemnification Agreement shall continue after the Indemnitee has ceased to be an employee of the Company and shall inure to the benefit of the heirs, executors and administrators of the Indemnitee.

9. Upon written request by the Indemnitee for indemnification under Paragraphs 3 and 4 above, a determination regarding the Indemnitee's entitlement to such indemnification shall be made by (1) the board of directors of the Company by a majority vote of a quorum consisting of directors who are not parties to the action, suit, settlement or proceeding, or (2) if such a quorum is not obtainable, or, even if obtainable, a quorum consisting of disinterested directors so directs, by Independent Counsel, as defined below, in a written opinion, or (3) by the shareholders of the Company. "Independent Counsel" shall mean a law firm or member of a law firm that has not within the last five (5) years represented the Company or the Indemnitee in a matter material to either or in a matter material to any other party to the action, suit or proceeding giving rise to the Indemnitee's claim for indemnification under this Indemnification Agreement. Independent Counsel shall not include any member of a law firm who would have a conflict of interest under applicable standards of professional conduct in representing the Company or the Indemnitee in an action hereunder. Such Independent Counsel shall be chosen by the board of directors of the Company and approved by the Indemnitee. Upon failure of the board of directors to choose, or the Indemnitee to approve, Independent Counsel, Independent Counsel shall be selected by the Chancellor of the State of Delaware or by an appointee of the Chancellor. Determination of entitlement to indemnification shall be made within thirty (30) days of receipt by the Company of a written request for indemnification by the Indemnitee. The Indemnitee's request to the Company shall be accompanied by any documentation reasonably available to the Indemnitee relating to the Indemnitee's entitlement to be indemnified. All reasonable expenses (including attorneys' fees and disbursements) relating to the Indemnitee's request for indemnification under this Indemnification Agreement shall be paid by the Company regardless of the outcome of the determination as to the Indemnitee's entitlement to indemnification. If such determination is unfavorable to the Indemnitee or if the Indemnitee has made no request for indemnification hereunder or no determination is otherwise made, the Indemnitee may within two (2) years after such determination, or, if no determination has been made, within two (2) years after the Indemnitee has incurred the expense or otherwise made a payment for which the Indemnitee seeks indemnification, petition the Court of Chancery of the State of Delaware or any other court of competent jurisdiction to determine whether the Indemnitee is entitled to indemnification under the terms of this Indemnification Agreement or otherwise. The Indemnitee shall not be prejudiced in such judicial proceeding by a prior determination that the Indemnitee is not entitled to indemnification. The Company shall be precluded from asserting in such judicial proceeding that it is not bound by the provisions of this Indemnification Agreement. The Company shall pay all expenses (including attorneys' fees and disbursements incurred or at trial or on one or more appeals) actually and reasonably incurred by the Indemnitee in connection with such judicial determination.

10. If any action, suit or proceeding described in Paragraphs 3 and 4 above shall be terminated by judgment, order, settlement or conviction or upon a plea of *nolo contendere* or its equivalent, no presumption shall be created that the Indemnitee did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, that the Indemnitee had reasonable cause to believe that his conduct was unlawful.

11. In each request made by Indemnitee for indemnity or advancement of expenses under this Indemnification Agreement, the Indemnitee shall be presumed to have satisfied the required standard of conduct and any and all other conditions precedent to such indemnity and/or advancement, unless and until the contrary is established.

12. Notwithstanding any other provision of the Indemnification Agreement, the Company shall not be liable to indemnify the Indemnitee under this Indemnification Agreement in connection with any claim against Indemnitee:

(a) for which the Indemnitee is indemnified by the Company other than under this Indemnification Agreement;

(b) if a court of competent jurisdiction has rendered a final decision that indemnification relating to the claim would be unlawful;

(c) if pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of any state or federal statutory law, the claim is for an accounting of profits made from the purchase and sale by the Indemnitee of securities of the Company;

(d) if a final decision by a court of competent jurisdiction shall adjudge the Indemnitee's conduct to have been knowingly fraudulent or deliberately dishonest and to be material to the claim adjudicated by the court; or

(e) if the claim was based upon the Indemnitee's deriving an unlawful personal benefit and a court of competent jurisdiction adjudges that such benefit was unlawful in a final decision.

13. If any provision of this Indemnification Agreement or the application thereof to any particular facts or circumstances shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions (including portions of any paragraph of this Indemnification Agreement containing an invalid, illegal or unenforceable provision) and the application thereof to facts or circumstances other than those as to which it is held invalid, illegal, or unenforceable shall not be impaired or affected thereby. This Indemnification Agreement shall be construed to be valid and enforceable to the full extent allowed by law, and any invalid, illegal or unenforceable provision of this Indemnification Agreement shall be modified as necessary to comply with all applicable laws.

14. This Indemnification Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

15. This Indemnification Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware applicable to contracts made and wholly performed in such state.

16. All notices or other communication hereunder shall be in writing and shall be deemed to be effective and to have been duly given if delivered by certified mail postage prepaid, return receipt requested, to the respective parties, as follows:

If to the Company:

Nabi Biopharmaceuticals  
5800 Park of Commerce Boulevard, N.W.  
Boca Raton, FL 33487  
Attention: CEO & President

If to Indemnitee:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

or to such other address as a party may have furnished to the other in writing in accordance with this paragraph, except that notices of change of address shall only be effective upon receipt.

17. This Indemnification Agreement shall be binding upon the Company and its successors and assigns and shall inure to the benefit of (and be enforceable against the Company by) the Indemnitee and the Indemnitee's heirs, executors and administrators.

18. No amendment of this Indemnification Agreement shall be binding unless executed in writing by both parties hereto. No waiver of any provision of this Indemnification Agreement shall constitute a waiver of any other provision hereof.

19. The Indemnitee shall notify the Company in writing within thirty days after being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any matter concerning which the Indemnitee may be entitled to indemnification hereunder, but the failure to give such notice shall not affect the Company's obligation to indemnify the Indemnitee to the extent provided for herein or otherwise.

IN WITNESS WHEREOF, the parties hereto have caused this Indemnification Agreement to be duly executed and signed as of the day and year first above written.

Nabi Biopharmaceuticals:

Indemnitee:

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

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

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

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

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

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

Date: \_\_\_\_\_

Date: \_\_\_\_\_

NABI BIOPHARMACEUTICALS  
SUMMARY OF NON-EMPLOYEE DIRECTOR FEES

Under Nabi Biopharmaceuticals' compensation policy for non-employee directors, each non-employee director receives an annual retainer of \$20,000 plus a fee of \$1,000 for each Board and committee meeting attended by the director (whether the meeting is in person or by conference telephone). Currently, each chairperson of a standing Board committee receives an annual retainer of \$3,000. Effective May 2005, each member of a standing Board committee will receive an annual retainer of \$2,500, and each chairperson of a standing Board committee will receive an annual retainer of \$5,000, except that the chairman of the Audit Committee will receive an annual retainer of \$7,500. Fees are paid for attendance at committee meetings even if they are held on the same day as Board meetings. Directors are reimbursed for out-of-pocket expenses incurred in connection with attendance at Board and committee meetings. Under Nabi Biopharmaceuticals' 2004 Stock Plan for Non-Employee Directors, each non-employee director may elect to be paid his or her annual retainer, in whole or in part, in shares of Common Stock in lieu of cash

SUMMARY OF  
VIP MANAGEMENT INCENTIVE PLAN

Nabi Biopharmaceuticals executive officers are eligible to receive cash bonus rewards under the VIP Management Incentive Plan which is summarized below. The company's vice president, senior director and director level personnel also are eligible to participate in the VIP Plan, although the summary below focuses on the aspects of the VIP Plan applicable to executive officers.

The objective of the VIP Plan is to provide an effective tool to help motivate managers high performance in achieving the company's long-term value drivers and other objectives of the company's strategy by aligning measurement and accountability with rewards.

Rewards under the VIP Plan are based on performance as measured by two balanced scorecards, the corporate scorecard and an individual scorecard for each participant's functional area (except the Chief Executive Officer, who is measured on the corporate scorecard only). Both scorecards view organizational performance from four equally-weighted perspectives: financial, customer, internal, and employee learning and growth. Each perspective is divided into strategic objectives and corresponding measures, which are organized and weighted differently on each scorecard. The weighting may vary significantly from corporate to individual scorecards where increased focus is necessary. Both corporate and individual scorecards define threshold, target, and maximum performance levels. The structure and performance levels of the corporate scorecard are designed by our Chief Executive Officer and the other executive officers and approved by the Compensation Committee of the Board of Directors. Each individual scorecard is designed by the appropriate executive officer, reviewed by our human resources department, and approved by our Chief Executive Officer.

The three performance levels under each scorecard are defined as follows:

- **Threshold** – This is the minimum level of performance for which the VIP Plan provides compensation that still builds value for the organization, but falls short of the stretch target. If the threshold level only is achieved, the weighting for a particular objective is reduced by 50% of its original value.
- **Target** – This is achieved when a performance target is met. If the target level is achieved, the weighting for a particular objective is maintained at 100% of its original value.
- **Maximum** – This is the maximum level of performance for which the VIP Plan provides compensation. If the maximum level is achieved, the weighting for a particular objective is increased to 150% of its original value.

In order for any reward to be payable a minimum corporate qualifier established for each bonus year must be achieved. In 2004, the minimum qualifier was based on free cash flow, as defined. Assuming achievement of the minimum corporate qualifier, the amount of reward that is paid is determined by using a two-step process.

First, the percentage scores from each of the corporate and individual scorecards (which will range between 50% and 150% in the aggregate) are multiplied by the bonus potential for each participant. The bonus potential for each participant is a percentage of the participant's base salary as set forth in the following table.

<u>Position</u>	<u>Percentage of Base Salary</u>
CEO	83%
Sr. VP	55%
VP	37.5%
Sr. Director	37.5%
Director	15%

Second, the resulting corporate and individual bonus components are combined based on a weighting depending on the level of the participant as defined in the following table.

<u>Position</u>	<u>Corporate</u>	<u>Individual</u>
CEO	100%	0%
Sr. VP	80%	20%
VP	60%	40%
Sr. Director	50%	50%
Director	50%	50%

The bonus potential, the relative weights of the corporate and individual scores, and all other elements of the VIP Plan are subject to change at the discretion of the Compensation Committee.



## Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Forms S-3 No. 333-42188, No. 333-107134, No. 333-108086, No. 333-112006, and No. 333-121050; Forms S-8 No. 333-109017, No. 333-38868, No. 333-95269, No. 333-81009, No. 333-56037, No. 333-56071, No. 033-65069, No. 033-60795, No. 333-115691 and No. 333-115688) of Nabi Biopharmaceuticals and in the related Prospectus of our reports dated March 8, 2005, with respect to the consolidated financial statements and schedule of Nabi Biopharmaceuticals, Nabi Biopharmaceuticals management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Nabi Biopharmaceuticals, included in this Annual Report (Form 10-K) for the year ended December 25, 2004.

/s/ Ernst & Young LLP

Certified Public Accountants

West Palm Beach, Florida  
March 8, 2005

**Nabi Biopharmaceuticals****CERTIFICATIONS**

I, Thomas H. McLain, certify that:

1. I have reviewed this annual report on Form 10-K of Nabi Biopharmaceuticals;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2005

By: /s/ Thomas H. McLain

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Thomas H. McLain  
Chief Executive Officer and President

**Nabi Biopharmaceuticals****CERTIFICATIONS**

I, Mark L. Smith, certify that:

1. I have reviewed this annual report on Form 10-K of Nabi Biopharmaceuticals;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which could adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2005

By: /s/ Mark L. Smith

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

**Nabi Biopharmaceuticals****SECTION 1350 CERTIFICATION**

The undersigned officers of Nabi Biopharmaceuticals (the "Company") hereby certify that, as of the date of this statement, the Company's annual report on Form 10-K for the year ended December 25, 2004 (the "Report") fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 and that, to the best of their knowledge, information contained in the Report fairly presents, in all material respects, the financial condition of the Company as of December 25, 2004 and the results of operations of the Company for the year ended December 25, 2004.

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

Date: March 10, 2005

/s/ Thomas H. McLain

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Name: Thomas H. McLain

Title: Chairman, Chief Executive Officer and President

Date: March 10, 2005

/s/ Mark L. Smith

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Name: Mark L. SmithTitle: Chief Financial Officer, Chief Accounting Officer  
and Treasurer