# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

# **FORM 10-K**

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

For the fiscal year ended December 31, 2005

Commission File Number: 000-04829

# **Nabi Biopharmaceuticals**

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of

(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)

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

Common Stock, par value \$.10 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. 🛛 Yes 🛛 No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. 🗆 Yes 🛛 No

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 12 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 a large accelerated filer, an accelerated filer or a non-accelerated filer (as defined in Exchange Act Rule 12b-2).

Large accelerated filer  $\Box$  Accelerated filer  $\boxtimes$  Non-accelerated filer  $\Box$ 

Indicate by check mark whether the registrant is a shell company  $\Box$  Yes  $\boxtimes$  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: \$871,777,005

As of February 27, 2006, 59,517,041 shares of the registrant's common stock were outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement for its Annual Meeting of Shareholders, which will be filed within 120 days after the close of the registrant's fiscal year ended December 31, 2005, are incorporated by reference into Part III.

# Nabi Biopharmaceuticals

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#### Nabi Biopharmaceuticals

## 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 focused on developing products addressing the large commercial opportunities within our core business areas: Gram-positive bacterial infections, hepatitis, kidney disease (nephrology), and nicotine addiction. We have three products on the market today: Nabi-HB<sup>®</sup> [Hepatitis B Immune Globulin (Human)], Aloprim<sup>TM</sup> [Allopurinol sodium (for injection)] and PhosLo<sup>®</sup> (calcium acetate), and a number of products in various stages of clinical and pre-clinical development. We have also filed Marketing Authorization Applications, or MAAs, in Europe to market Nabi-HB<sup>TM</sup> Intravenous [Hepatitis B Immune Globulin (Human) Intravenous] under the trade name HEBIG<sup>TM</sup>, for the prevention of hepatitis B disease in HBV-positive liver transplant patients, and to market PhosLo in Europe, which is already marketed in the U.S. for the treatment of hyperphosphatemia in patients with end-stage renal disease.

Our products in clinical development include vaccines and antibody-based therapies that target healthcare-associated and community acquired *S. aureus* and *S. epidermidis* infections, Civacir<sup>®</sup> [Hepatitis C Immune Globulin (Human)], an antibody for preventing re-infection with hepatitis C disease in liver transplant patients and NicVAX<sup>®</sup> (Nicotine Conjugate Vaccine), a vaccine to treat nicotine addiction.

Within the area of Gram-positive infections we are applying our core technology to the development of next-generation products that will address the major strains of healthcare-associated and community acquired bacterial infections. Gram-positive bacteria are the leading cause of serious hospital-acquired infections and, according the U.S. Centers for Disease Control and Prevention, or CDC, these infections are the fourth-leading cause of death in the U.S. today. Gram-positive infections are demonstrating an increased resistance to current antibiotic treatment options, resulting in increased healthcare costs and mortality rates worldwide. Collectively, our vaccine and antibody products currently in development would provide new treatment and prevention options for the majority of these dangerous pathogens.

In 2005, we initiated separate Phase I clinical trials for novel vaccines targeting *S. epidermidis* and *S. aureus* Type 336 infections. We believe *S. aureus* Type 336 infections account for approximately 20% of all *S. aureus* infection isolates from the US and Europe. We also have two investigational vaccines in preclinical development for the prevention of infections caused by *Enterococcus*, representing approximately 10-12% of all bloodstream infections infections worldwide and Community-Associated Methicillin-resistant *S. aureus*, or CA-MRSA, infections, an increasingly common and deadly form of infection.

In November 2005, we announced the results of our Phase III clinical trial for StaphVAX<sup>®</sup> [*Staphylococcus aureus* Polysaccharide Conjugate Vaccine], which did not meet its defined end point of protecting end-stage renal disease, or ESRD, patients from *S. aureus* Types 5 and 8 infections for eight months following vaccination. These results are in contrast with the results of a previously reported Phase III clinical trial. In conjunction with a panel of outside experts, we are investigating the factors that could explain these different outcomes and expect to announce our findings in the first half of 2006. Until we have reached a conclusion based on these investigations, we have placed our StaphVAX and Altastaph<sup>®</sup> [*Staphylococcus aureus* Immune Globulin Intravenous (Human)] clinical programs on hold.

Our operating focus in the near term is directed to generating an increased cash return from our operations, concentrating on the period from 2006 through 2008 and advancing key product

development programs. These efforts are aligned with our multi-year strategic plan. In order to accomplish this goal we are pursuing three major objectives:

- Optimizing the value of current operations;
- Building value through strategic partnerships and commercial alliances; and
- Proving value in key research and development programs through "proof-of-concept" clinical studies.

We define optimizing the value of current operations as maximizing the cash return on the operating assets we currently own. These assets include our marketed products and our sales force. They also include the manufacturing capacity in our plant in Florida and our plasma collection centers. Leveraging our core competencies and manufacturing capacity we plan to pursue development of new products including Intravenous Immune Globulin, or IVIG, and plasma proteins. Our goal is to realize an increased cash return on our investment in these assets in the period from 2006 to 2008.

Our focus on building incremental value through strategic partnerships and commercial alliances may include marketing of our PhosLo and HEBIG products outside of the U.S. We will also pursue in-licensing opportunities in our core commercial areas of nephrology, transplantation and hospital specialty products. We also are pursuing partnership opportunities for our vaccine programs and other product development programs outside North America.

We plan to demonstrate "proof-of-concept" clinical evidence for key programs by following a common development process that is well designed, focused and cost-effective. We intend to work in consultation with an external scientific and clinical advisory panel on design, execution and results from each development program; to conduct Phase II "proof-of-concept" studies that will follow a design similar to the design we expect to use in future Phase III clinical trials; to use clinical material manufactured in our plant on a scale capable of supporting commercial launch; and to analyze relevant pharmacoeconomic data that support the cost benefit of our treatment approach. We have identified three program areas where we believe value can be demonstrated through these "proof-of-concept" trials between now and 2008: nicotine addiction, hepatitis C and Gram- positive infections.

We are incorporated in Delaware in 1969. We maintain our commercial and manufacturing operations in Boca Raton, Florida and our research and development operations in Rockville, Maryland.



The following table shows our currently marketed and development products:

Products	Indication/Intended Use	Status
Transplants		
Nabi-HB®	Post-exposure prevention of hepatitis B infection	Marketed in U.S.
Nabi-HB™ Intravenous (HEBIG™ in the Europe)	Prevention of re-infection with hepatitis B in HBV- positive liver transplant patients	MAA approval expected in Europe in 2006 or 2007; U.S. BLA filed in November 2002
Civacir®	Prevention of re-infection with hepatitis C in HCV- positive liver transplant patients	Orphan Drug Designation and Fast Track Status in the U.S.; Orphan Medicinal Product Designation in Europe; Phase II clinical trial planned for 2006
IVIG and other Plasma fractions	Various immune deficiencies and coagulation disease	Pre-clinical development
Nephrology		
PhosLo®	Treatment of hyperphosphatemia in end-stage renal failure patients;	Marketed in U.S.; MAA approval expected in Europe during first half of 2006; CARE2 study ongoing and results expected during 2006
	Treatment of hyperphosphatemia in pre- dialysis Chronic Kidney Disease patients	Phase IIIb clinical trial in Stage 4 chronic kidney disease patients initiated in May 2005
Hospital acquired infections		
StaphVAX®	Protection against Types 5 and 8 <i>S. aureus</i> infections	Clinical development on hold pending results from ongoing assessment
Altastaph®	Treatment and/or protection of Types 5 and 8 <i>S. aureus</i> infections	Clinical development on hold pending results from ongoing assessment
S. aureus Type 336 and S. epidermidis Vaccine and corresponding antibodies	Protection against <i>S</i> . <i>epidermidis</i> and Type 336 <i>S</i> . <i>aureus</i> infections	Phase II clinical trial planned for 2007
Panton- Valentine Leukocidin (PVL)	Protection and/or treatment against the PVL toxin	Phase I clinical trial planned for 2006/2007
S007A	Eradication of <i>S. aureus</i> in nasal passages	Phase I clinical trial planned for 2006
Nicotine addiction		
NicVAX <sup>®</sup> Other	Treatment of nicotine addiction	Phase IIb clinical trial planned for 2006
Aloprim®	Chemotherapy-induced hyperuricemia	Marketed in U.S.

# PRODUCTS AND PRODUCTS IN DEVELOPMENT

## TRANSPLANTS

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

Nabi-HB is a human polyclonal antibody product indicated to prevent hepatitis B infection 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 virus in HBV-positive liver transplant patients. We filed our MAA in Europe for Nabi-HB™ Intravenous under the tradename HEBIG in June 2005 under the Mutual Recognition Process, or MRP, and expect approval by

regulators in the country in which we applied, during 2006 or 2007. This approval in one country will be the basis for submission to additional countries within the EU. The EU filing was also prepared in the Common Technical Document, or CTD, format, which is widely accepted on a global basis facilitating our ability to file for marketing approval of Nabi-HB beyond the U.S. and the EU.

In November 2002 we filed a Biologics License Application, or BLA, with the Federal Drug Administration, or FDA, for Nabi-HB Intravenous, to prevent reinfection with hepatitis B disease in HBV-positive liver transplant patients. The FDA has requested additional information and longer-term patient follow-up data. We are currently in discussions with the FDA regarding our BLA.

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 to HBV liver transplant patients. We collect the anti-HBV plasma raw material at our FDA approved antibody collection centers and we manufacture Nabi-HB in our state-of-the-art fractionation and purification facility in Florida.

Nabi-HB is a purified human polyclonal antibody product collected from plasma donors who 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. The CDC estimated that, as of 2003, there were approximately 1.25 million chronic hepatitis B carriers in the U.S. In addition, the CDC estimated that there were approximately 73,000 new hepatitis B infections in 2003. 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, or ESLD, and according to the United Network for Organs Sharing, or UNOS, approximately 2.7% of 2005 liver transplants through November 2005 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 is almost inevitable after surgery in HBV-positive patients without treatment with a hepatitis B immunoglobulin product such as Nabi-HB.

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.

Civacir is aligned with our commercial model for Nabi-HB. The product applies our clinical, regulatory, manufacturing and commercial expertise in antibody technology and our knowledge of the transplant market to the treatment of HCV liver transplant patients. We have manufactured clinical lots of Civacir in our state-of-the-art fractionation and purification facility and intend to market the product through our own sales force.

Civacir is derived from human plasma enriched with HCV antibodies collected from screened donors at our 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 an HCV-positive patient.

HCV is a major cause of acute hepatitis C and chronic liver diseases, 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 two to four 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 ESLD, resulting in the need for liver transplantation. In the U.S. approximately 34% of all liver transplants, or approximately 2,000 liver transplants per year, are due to HCV infections. We believe the proportion of liver transplants due to HCV infection is expected to reach 40%-50% as patients mature and other reasons for ESLD decline. Each year approximately 1,000 liver transplants due to HCV are conducted in the EU, with an expected increase of 1%-3% annually. 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 certain within weeks to months following 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.

During 2005, we initiated important steps in defining the clinical and regulatory program for Civacir including the development of an advisory panel to assist us in defining the design of a clinical plan. In discussions with the FDA and the European Medicines Agency, or EMEA, we were able to confirm a clinical plan for this product, including the end points for a Phase II "proof of concept" study that we plan to initiate during the second half of 2006. The timing for beginning the trial is dependent on collecting plasma and manufacturing a clinical lot of Civacir in our manufacturing facility in Florida.

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 National Institutes of Health, or 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 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 Alanine Aminotransferase 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 doses of Civacir. We will use these data as we define our continued clinical 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. In 2005 Civacir was also granted Fast Track Designation by the FDA. Civacir was granted Orphan Medicinal Product Designation in Europe in 2005 for its use in prevention of re-infection with HCV in HCV-positive liver transplant patients. This designation entitles us to 10 years marketing exclusivity in the EU if Civacir is the first product to receive marketing authorization in the EU for this indication.

### Intravenous Immune Globulin (IVIG) and Plasma-based Proteins

Demand for IVIG in the U.S. has increased significantly and exceeds the capacity of currently licensed manufacturers. This led the FDA to issue a notice encouraging potential manufacturers to enter the IVIG market. The FDA indicated in this notification that they have simplified and streamlined the pivotal clinical development program to license new IVIGs. This is expected to greatly expedite the review of such applications. We believe that Nabi has both the core competencies and the facilities to participate in this market, including our nine plasma collection centers and state-of-the-art manufacturing facility. During 2006 we plan to pursue changes to the manufacturing process to reduce the production cost and maximize the yield for IVIG products and a number of niche plasma proteins that can be extracted from plasma. We will then manufacture clinical lots of IVIG. Finally, before the end of 2006 we expect to initiate a pivotal clinical trial according to these recent guidelines and after consultation with the FDA.

### NEPHROLOGY

### PhosLo (calcium acetate)

PhosLo is a first line prescription phosphate binder indicated for the control of elevated blood, or serum, phosphorus levels, or hyperphosphatemia, in End-Stage Renal Disease, or ESRD, patients. The Kidney Disease Outcome Quality Initiative, or K/DOQI, guidelines issued by the National Kidney Foundation, or NKF, specify 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.

We currently market PhosLo in the U.S. We expect approval of our MAA for PhosLo filed in Germany under the MRP during the first half of 2006. This approval will be the basis of submission to additional countries within the EU. Further, the filing was prepared in the CTD format, facilitating our ability to expand the marketing of PhosLo in markets beyond the U.S. and the EU. We anticipate PhosLo will be approved in up to seven additional countries in the EU during 2006.

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's calcium acetate formulation is more effective than calcium carbonate phosphate binders due to its higher phosphate binding activity. 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 their inferior activity.

Kidney disease is the ninth-leading cause of death in the U.S. The NKF estimates that approximately 20 million people in the U.S. suffer from chronic kidney disease. Of those 20 million people, the NKF further estimates that there are at least eight million patients with moderate to severe kidney disease defined as Chronic Kidney Disease, or CKD, Stages 3 and 4, and that there are an additional 450,000 ESRD patients. ESRD, Stage 5 kidney failure typically requires dialysis treatment.

According to the U.S. Renal Data System, or USRDS, in December 2003 approximately 325,000 patients were undergoing dialysis. 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 likely will require phosphate binder therapy to control their serum phosphorus levels for a period of time.

According to the European Renal Association-European Dialysis & Transplant Association, or ERA-EDTA, in Germany, France, Italy, Spain and the UK alone, there are currently approximately 176,000 patients undergoing chronic renal dialysis. This figure increases to almost 230,000 patients in all of Europe. This patient population is expected to grow due to increased incidence of diabetes, hypertension and the overall aging of the European 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 \$107 million and is primarily served by sevelamer hydrochloride (Renagel) as well as a number of calcium acetate and calcium carbonate products.

In the May 2004 issue of Kidney International, the study "Treatment of Hyperphosphatemia in Hemodialysis Patients: The Calcium Acetate Renagel Evaluation", or CARE, was published as a full original paper. This is the only double-blinded, randomized controlled comparison study of PhosLo and Renagel. The results of the study showed that patients treated with PhosLo were able to control serum phosphorus levels more effectively than patients treated with Renagel throughout the eight-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 Renagel. In addition, the CARE study identified significant differences in the cost of treatment between PhosLo and Renagel.

At the American Society of Nephrology's Annual meeting in November 2005, data from the Dialysis Outcomes Practice Pattern Study, or DOPPS, was presented that reported that calcium-containing phosphate binders such as PhosLo result in superior control of serum phosphorus levels and calcium phosphate product as compared to Renagel (sevelamer hydrochloride). PhosLo is the only prescription phosphate binder containing calcium available in the U.S. Mean serum phosphorus levels for patients on calcium-containing phosphate binders were 5.37 mg/dL as compared to 6.11 mg/dL on sevelamer. The K/DOQl guidelines recommend maintaining serum phosphorus levels below 5.5 mg/dL. Serum calcium levels were comparable between the two treatment groups. Patients on calcium-based binders were 9.59 mg/dL versus 9.66 mg/dL for patients treated with sevelamer. As expected, calcium-phosphorous product was demonstrated to be superior in patients treated with calcium-containing phosphate binders, with a value of 49.3 mg2/dL2 as compared to 56.8 mg2/dL2 in patients on sevelamer. The K/DOQI guidelines recommend keeping the calcium-phosphorus product below 55. The DOPPS study also showed that there was no mortality benefit associated with sevelamer as compared to PhosLo and other calcium-containing phosphate binders reported in the study. DOPPS was an independent study of patient outcomes among ESRD patients being treated for hyperphosphatemia.

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 an ESRD patient's cardiac health, including the control of serum phosphorus to prevent hyperphosphatemia, 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 Renagel is due to the lipid-lowering benefit associated with Renagel. The CARE 2 study, which will compare efficacy, safety and arterial calcification in patients treated with PhosLo plus Lipitor (atorvastatin calcium), and Renagel plus Lipitor, was fully enrolled during 2005. Lipitor will be provided to patients in each treatment regimen as appropriate to secure Low Density Lipoprotein, or LDL, levels in accordance with the guidelines 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 Renagel, a known lipid lowering drug, 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 Renagel alone. We expect that preliminary data evaluating serum phosphorus levels, serum calcium levels, calcium phosphorus product and lipid levels will be available in the first half of 2006. Final data evaluating arterial calcification using electron beam computer tomography, or EBCT, is expected to be available in the second half of 2006.

In line with recommendations included in the K/DOQI guidelines that pre-dialysis CKD patients may benefit from phosphate binder therapy, in May 2005 we initiated and finally enrolled a study using PhosLo in CKD patients suffering from Stage 4 kidney disease entitled "Effect of PhosLo in Chronic Kidney Disease", or EPICK. The EPICK study, which is following a randomized, double blinded, placebo-controlled design, will evaluate patients at approximately 15 U.S. sites who have Stage 4 pre-dialysis CKD and develop hyperphosphatemia. The study is designed to evaluate PhosLo's ability to safely and effectively control serum phosphorus levels, parathyroid, or PTH, levels, serum calcium levels and calcium phosphorus product in these CKD patients. Data from the study are expected in second half of 2006. We believe PhosLo is well positioned for the CKD patient, as it is likely to control serum phosphorus and a secondary end point of parathyroid hormone levels without causing very low calcium levels, or hypocalcemia, high levels of acidity in the blood, or metabolic acidosis. This possible extension of the labeled use for PhosLo is significant because, as previously mentioned, it is estimated that there are approximately 400,000 CKD patients suffering from Stage 4 kidney failure in the U.S. alone.

# HOSPITAL-ACQUIRED INFECTIONS

The 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 healthcare setting. Collectively, *S. epidermidis* and *S. aureus* represent approximately 80% of all Gram-positive hospital-acquired bacterial infections. These bacteria often live transiently or permanently in the nasal passages or on the skin of humans, and can spread to the blood through breaks in the nasal membranes or skin. For example, it is estimated that over 30% of the adult population at any given time is colonized in the nasal passages with *S. aureus*. With their capacity to cause serious complications and their increasing resistance to most antibiotics, *S. epidermidis and S. aureus* have become critically dangerous pathogens and global health concerns. *S. epidermidis* frequently colonizes catheters and surgical implants and form an impenetrable biofilm. It can then spread to the bloodstream and cause serious and life-threatening infections. *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, infections from all sites of infection has risen from 22% in 1995 to 57% in 2002 in the U.S. Methicillin-resistant *S. epidermidis*, or MRSE, rates have reached approximately 80%, and over 50% of *S. epidermidis* infections are also resistant to other currently administered antibiotics.

*S. aureus* infection rates in patient populations at high risk for *S. aureus* infection can be as high as 40%. These infections result in longer hospital stays, higher death rates, increased illness and significantly higher medical costs.

Of the approximately 2.6 to 2.8 million hospital-associated infections reported in the U.S. annually, the mean cost is estimated at \$13,973 per infection for a range of total costs estimated at \$36.3 - \$39.1 billion annually. The overall mortality rate associated with hospital-associated (nosocomial) bloodstream infections and pneumonia are 27% and 27% to 50%, respectively.

As an example of the costs associated with these infections, in 2004 investigators from Duke Clinical Research Institute, Duke University Medical Center, Durham, North Carolina and Health Economics Consulting, Annapolis, Maryland completed a study sponsored by us evaluating heart disease patients with implanted cardiovascular devices who developed *S. aureus* bacteremia. 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 showing individual patients incurring a mean cost of \$82,300 for a hospital-acquired infection. It is estimated that healthcare-associated treatment costs associated with *S. epidermidis* infections total almost \$600 million in the U.S. each year.

Three clinically significant *S. aureus* serotypes have been identified: *S. aureus* Types 5 and 8, which are responsible for approximately 80% of *S. aureus* infections and Type 336. We identified and patented the antigen to Type 336, found in some *S. aureus* bacteria, independent of serotypes 5 and 8.

We have identified and patented two clinically significant *S. epidermidis* strains, PS-1 and GP-1. We believe PS-1 serotype is responsible for approximately 70% of *S. epidermidis* infections. GP-1 is present in approximately 20% of *S. epidermidis* infections. Combined, it is believed that these two antigens may provide protection for up to 90% of *S. epidermidis* infections.

Depending on the results from an ongoing assessment of our lead program, StaphVAX, our next-generation vaccine and antibody products, may contain the *S. epidermidis* PS-1 and *S. aureus* Type 336 antigen combined with *S. aureus* Types 5 and 8 antigens. We believe that these next-generation products would have the ability to provide protection against virtually all clinically significant *S. epidermidis* and *S. aureus* infections known today.

*Enterococcus* is the other clinically significant Gram-positive bacterium that causes hospital-acquired infections, representing approximately 10-12% of all bloodstream infections. We intend to extend our product coverage to this third type of Gram-positive bacteria in separate vaccine and antibody products.

### Gram-positive vaccines

Vaccines and antibody therapies represent a new and innovative approach in broadening the available clinical tools against the global health problem of healthcare-associated bacterial infections. This approach is focused on effective prevention whenever possible and using a combination approach of antibiotics with antibodies to treat serious infection.

For example, we advanced the development of StaphVAX for use in patients who are at high risk of *S*. aureus infection and who are able to respond to a vaccine by producing their own antibodies. StaphVAX is an investigational polysaccharide conjugate vaccine based on patented technology that we have licensed on an exclusive basis from the Public Health Service/NIH. In its initial formulation, it contains surface polysaccharides found in the outer coating of Types 5 and 8 *S*. *aureus* bacteria. To produce the vaccine, 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 should bind to *S. aureus* upon subsequent exposure to the bacteria. These antibodies should 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.

A third strain of *S. aureus*, Type 336, accounts for approximately 20% of *S. aureus* infections that do not form a polysaccharide capsule in the human bloodstream. In addition, approximately 30% of *S. aureus* bacteria are partially encapsulated and Type 336 may also have benefit in preventing and treating infections caused by those bacteria. We believe that the mechanism of action of the Type 336 vaccine is independent of the polysaccharide capsule targeted by our *S. aureus* Types 5 and 8 vaccine approach, in that it attacks a structure in the cell wall of the bacteria, not the polysaccharide capsule outside the cell wall. Research has supported that the target in *S. aureus* Type 336 is cross-reactive to *S. epidermidis*. As an example, data already support that Type 336 antibodies are cross-reactive with the majority of *S. epidermidis* bacteria.

Our patented PS-1 antigen is found on approximately 70% of all *S. epidermidis* strains. We believe that the PS-1 antigen targets a taichoic acid-like structure in the cell wall of the bacteria and that immunization with PS-1 results in the production of antibodies that attack this cell wall structure. This would make the mechanism of action of this vaccine independent of the polysaccharide capsule approach targeted by StaphVAX. We also are advancing our GP-1 antigen through pre-clinical development. It also targets a component of the bacterial cell wall. Additionally, this antigen may be effective in preventing the bacteria from colonizing catheters and implanted devices.

Potential at-risk populations who may benefit from the use of vaccines to prevent Gram-positive bacterial infections include:

- patients with indwelling catheters, including patients in intensive care units, patients receiving cancer chemotherapy and premature babies;
- 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 bacterial 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 November 2005, we announced the results of our second Phase III clinical trial of StaphVAX. The study, a randomized, double-blinded, placebo-controlled trial among 3,976 patients on hemodialysis did not meet its defined end point of reduction in *S. aureus* Types 5 and 8 infections in the StaphVAX group as compared to the placebo group through eight months following initial vaccination. As these results are in contrast with the results of our analysis of a Phase III clinical trial among 1,804 ESRD patients previously reported in 2000, we have initiated an assessment in consultation with an outside panel of experts, including scientists and clinicians with expertise in immunology, vaccines, bacterial infections and nephrology. This assessment is focused in five areas: changes in the bacteria itself, changes in the care of dialysis patients, the manufacture of the vaccine, the quality of antibodies produced by the vaccine, and the conduct of the clinical trial,

in an attempt to understand the results. We expect to announce the findings from our work with the panel in the first half of 2006. While this investigation is ongoing, we have placed further clinical development of StaphVAX and Altastaph on hold pending the outcome.

A significant finding from the second Phase III trial of StaphVAX was that the vaccine was highly immunogenic, both after the initial vaccination as well as following a booster dose administered at a primary end point of the trial of eight months following vaccination, confirming that our vaccine conjugation technology is effective in producing and sustaining high levels of specific antibodies. This finding is significant for the development of our next-generation vaccines targeted at prevention of Gram-positive infections.

Our initial Phase III double-blinded, placebo-controlled and randomized clinical trial for StaphVAX was conducted in hemodialysis patients with ESRD. We selected these patients because of their high infection rate and their 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 eight months, where a 63% reduction in *S. aureus* event rate was observed. After the eight-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 results of this trial were reported in the New England Journal of Medicine in February 2002.

In 2005, we completed a Phase I study with our Type 336 vaccine. The trial was a double-blinded, placebo-controlled study evaluating safety and antibody responses of the vaccine in 48 patients at four different dosage levels. Within each of these four dose groups there were 12 patients, nine receiving the Type 336 vaccine and three receiving a placebo. The doses were administered in an escalating manner. The data support that escalating doses of the vaccine were well-tolerated and resulted in significant dose-related increases in levels of antibodies against *S. aureus* Type 336. The results of these studies also support that our conjugation technology stimulates antibody responses. High antibody titers against specific targets are critical in conferring protection to patients against these infections.

In 2005, we also conducted a Phase I double-blinded, placebo-controlled study evaluating safety and antibody responses of our *S. epidermidis* PS-I vaccine in 36 patients at three different dosage levels. Within each of these three dose groups there were 12 patients, nine receiving the *S. epidermidis* vaccine and three receiving a placebo. The doses were administered in an escalating manner. The data support that escalating doses of the vaccines was well tolerated and resulted in significant dose-related increases in levels of antibodies against *S. epidermidis* PS-1 and *S. aureus* Type 336. The results of this study also support that our vaccine conjugation technology stimulates antibody responses.

During 2006, we will further study these vaccine candidates as stimulating agents to produce antibody products active against these bacteria. Antibodies can be used for prevention in patients at immediate risk for infection and may act synergistically with antibiotics in the treatment of active infections.

We intend to advance our *S. epidermidis* PS-1 and *S. aureus* Type 336 programs into a Phase II clinical trial designed as a "proof-of-concept" study. We expect to initiate this clinical trial in the first half of 2007 and plan to evaluate the benefit of a multi-valent product in reducing or treating *S. epidermidis* infections in patient populations at-risk for infection. We will work with our Gram-positive infections advisory panel to both define the study population and advise whether the vaccine or antibody product should first advance into late-stage clinical study. Based on the outcome of the StaphVAX assessment, this trial may or may not involve combination with the capsular polysaccharide antigens, Types 5 and 8. We anticipate that the next Phase II clinical trial will be conducted in both U.S. and EU sites.

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

A prototypical enterococcal vaccine produced by us has been shown to induce antibodies that are protective in animal models and to facilitate elimination of bacteria with the same type of immune system response as StaphVAX. We will continue to advance this product through pre-clinical testing during 2006.

#### Gram-positive Antibody Products

Altastaph [*Staphylococcus aureus Immune Globulin Intravenous (Human)*] is an investigational human polyclonal antibody product that in its current formulation 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. Next generation formulations of Altastaph, if we continue with its development, are expected to contain antibodies to *S. aureus* Type 336 and *S. epidermidis*. We believe Altastaph can be used to treat patients with active *S. epidermidis* and *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 seven to 14 days necessary to respond to the vaccine, prior to being at risk of infection.

Because the mechanism of action for the current formulation of Altastaph is the same as for StaphVAX, we have placed this program on hold for further clinical development pending the outcome of our evaluation of the StaphVAX clinical trials results. Based on the outcome of the StaphVAX assessment, the next generation product may or may not involve combination with *S. aureus* capsular polysaccharide Types 5 and 8.

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

We believe patients with active *S. aureus* infections could benefit from a combination therapy of Altastaph initially plus a dose of 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.

# 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 likely be primary care physicians 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 bloodbrain barrier. Once in the brain, the nicotine binds to specific nicotine receptors, which results 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 blocking the effects of nicotine, including effects that can lead to addiction or can reinforce and maintain addiction.

Smoking is a global healthcare problem. The WHO estimates that there are 1.3 billion smokers worldwide today and nearly five million tobacco-related deaths each year. If current smoking patterns continue, smoking will cause some 10 million deaths each year by 2020. According to the CDC, tobacco use is the single leading preventable cause of death in the U.S. responsible for approximately 438,000 deaths each year. In addition, it is estimated that smoking results in an annual health-related economic cost of approximately \$157 billion. The CDC estimates that, among the 45 million adult smokers in the U.S., 70% want to quit, but less than five percent of those who try to quit remain smoke-free at 12 months.

Nicotine addiction is difficult to treat effectively. We believe NicVAX has advantages over existing treatment therapies because its 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, smokers being treated for nicotine addiction can stop using their therapy and resume their addiction.

In September 2005, we were awarded a \$4.1 million grant by the U.S. National Institute on Drug Abuse, or NIDA, partially offsetting our funding requirements for the NicVAX development program.

Following the award of the NIDA grant, we formed a scientific advisory panel to provide us guidance on clinical trial design and clinical development plans for NicVAX.

We have advanced the NicVAX clinical program through completion of a second Phase II dose-ranging clinical trial in smokers in 2005. The clinical trial was an open-label randomized dose-ranging clinical trial in smokers designed to evaluate the safety and antibody response to a new formulation of NicVAX. The four NicVAX dose levels, 100, 200, 300 and 400 mcg per injection, were given over a six-month period with 20 patients receiving the 200 mcg dose and with 10 patients in each of the 100, 300 and 400 mcg dose groups. Initial findings from the study showed that NicVAX was well-tolerated. The vaccine in this study was manufactured with a lower level of adjuvant, an additive often used in vaccines to enhance the immune response, in an attempt to optimize its formulation. Based on this Phase II dose-ranging study and in line with our product development strategy, we plan to conduct a Phase II "proof-of-concept" study in 2006 that will evaluate the vaccine manufactured with an optimized formulation at commercial scale at our facility in Florida.

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 indicated a 33% quit rate in smokers who

received NicVAX at the highest dose level versus 9% in the placebo group, however, given the limited number of smokers included in the trial this result was not statistically significant. 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 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 and to measure nicotine specific antibody titers and 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

#### 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 who 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 were 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.

# CONTRACT MANUFACTURING

We have a state-of-the-art facility located in Florida for the fractionation and purification of human immunoglobulin. Our facility was designed to accommodate manufacture of Nabi-HB, as well as our polyclonal antibody-based products in development, including Civacir and Altastaph. 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 of maintaining the facility.

During 2005, we completed the construction of a vaccine plant within our manufacturing facility in Florida. During 2006, we will complete the validation of this plant and, once validated, it will be available for commercial manufacture of the vaccine products in our research pipeline, including NicVAX, and for contract manufacturing.

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.

#### 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 (normal source) antibodies to our worldwide 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 achieve licensure for antibody-based biopharmaceutical products in our research and development pipeline, we anticipate a strategic shift in our antibody segment by converting production of antibodies for use in the 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 or to prevent and treat viral and bacterial diseases as well as to develop diagnostic products.

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. Our fully integrated expertise in antibody collection capabilities, operational expertise in donor immunization programs, clinical and medical experience in conducting clinical trials under Investigational New Drug Applications, or INDs, and access to a diverse antibody donor base provides us with the ability to produce competitive specialty antibodies.

Our specialty antibody products include hepatitis B, Rh<sub>o</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 \$62.1 million in 2005 compared to \$131.8 million in 2004 and \$109.5 million in 2003. Sales of biopharmaceutical products in 2005, 2004 and 2003 included sales of WinRho SDF totaling \$6.2 million, \$47.9 million and \$50.0 million, respectively, which we ceased to distribute on March 24, 2005. In 2005, biopharmaceutical products accounted for 58% of our sales and 83% of our gross margin. Total sales of our antibody products were \$45.9 million in 2005 compared to \$48.0 million in 2004 and \$67.1 million in 2003. In 2005, antibody products accounted for 42% of our sales and 17% of our gross margin.

# RESEARCH AND DEVELOPMENT PROGRAMS

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

		For the Years Ended					
Dollars in Thousands		December 31, 2005		December 25, 2004		December 27, 2003	
StaphVAX	\$	50,026	\$	47,391	\$	15,031	
Altastaph		3,322		3,073		1,849	
Other Gram-positive products		1,139		483		390	
Total Gram-positive		54,487		50,947		17,270	
Other clinical programs, including Civacir and NicVAX, net of reimbursed amounts		1,996		5,803		6,219	
Other, pre-clinical programs		263		271		446	
PhosLo, including PhosLo CKD		9,512		2,506		533	
Nabi-HB and Nabi-HB Intravenous and other currently marketed products		578		1,476		4,572	
Total	\$	66,836	\$	61,003	\$	29,040	

Research and development expenses of approximately \$0.3 million, \$0.3 million and \$1.3 million related to the NicVAX program were reimbursed by NIDA for fiscal years 2005, 2004 and 2003, 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.

### 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 earlier of the expiration of the last-to-expire licensed patent, which is April 20, 2010, and no further royalties will be due to PHS/NIH for use of the subject technology after that date. 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 for four vaccines, including the vaccine for 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-byproduct 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 for 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.

# **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 virtually all our biopharmaceutical products to AmerisourceBergen Corporation, 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 2005, we extended a distribution service agreement with one of our major wholesaler customers under which this customer 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 for the 2006 fiscal year will exceed to any material extent the negotiated discounts that have been provided to this customer in prior periods.

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 2006 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 to significant customers for the year ended December 31, 2005 included sales to three customers of our biopharmaceutical products segment, AmerisourceBergen Corporation, Cardinal Health, Inc., McKesson Drug Co. and one customer of our antibody products segment, Telecris Biotherapeutics Inc., representing 25%, 21%, 15% and 17% of total consolidated 2005 sales, respectively.

# SUPPLY AND MANUFACTURING

#### **Biopharmaceutical Products**

We manufacture Nabi-HB in our FDA approved biopharmaceutical manufacturing facility in Florida. Our facility has been licensed by the FDA for the manufacture of Nabi-HB since 2001 and, as such, is among the most recently licensed fractionation and purification facilities in the U.S. Additionally, we manufacture clinical lots of our investigational products, Altastaph and Civacir, in the same facility.

During 2005, we completed the construction of a vaccine plant within our manufacturing facility in Florida. During 2006, we will complete the validation of this plant, and once validated, it will be available for commercial manufacture of our own products in clinical development as well as contract manufacturing. We have manufactured clinical lots of NicVAX in this facility at commercial scale for use in a clinical trial and this facility may be used for the commercial manufacture of our vaccines in development including our Gram-positive vaccines and NicVAX. We designed this vaccine manufacturing capacity to be flexible and expandable so as to support the manufacture of our vaccines and possibly other products in our research and development pipeline.

Third parties manufacture PhosLo and Aloprim for us. PhosLo is manufactured for us by Braintree Laboratories, Inc. under an agreement that can be extended until 2018. 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 FDA licensed antibody collection centers located in six states across the U.S. These centers are also licensed and approved for collection by a German regulatory agency, on behalf of the EU.

# 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 licensed the right to three patents granted in the U.S. and one patent granted in Canada relating to PhosLo. One U.S. patent and the Canadian patent 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. The two other U.S. patents contain 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. These second-generation U.S. patents expire in April 2021.

In September 2005, we filed a lawsuit in the United States District Court for the Southern District of Ohio against Roxane Laboratories, Inc., or Roxane, for infringement of our PhosLo Gelcap patent. We filed this lawsuit under the Hatch-Waxman Act in response to a Paragraph IV Certification letter we received from Roxane concerning Roxane's filing of an Abbreviated New



Drug Application, or ANDA, with the FDA to market a generic version of PhosLo Gelcaps, on the basis that Roxane's submission of its ANDA and its proposed generic product infringe a patent held by the Company. The patent expires in 2021. Under the Hatch-Waxman Act, FDA approval of Roxane Laboratories' proposed generic product will be stayed until the earlier of 30 months or resolution of the patent infringement lawsuit.

### Products in development

We have 37 patents issued, including nine U.S. patents, 15 patents in European countries and 13 patents in other countries, and 50 patent applications 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 Type 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.

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 U.S. and ex-U.S. patent applications covering methods directed to the use of StaphVAX, among other compositions. These 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 patents that have been in 15 European countries. The patents contain claims to vaccines and hyperimmune globulins against *S. epidermidis* surface antigen. Most of these patents expire in 2016.

Also in this portfolio is 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. Another related U.S. patent application has been allowed with claims to a pharmaceutical composition containing a glucan and antibody.

# 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 a nicotine-like molecule linked to a carrier protein and to the methods for the use of these conjugates to treat or prevent nicotine addiction. In particular, we hold three issued U.S. patents relating to our conjugates, antibodies against the conjugates, and methods for using the conjugates and antibodies against nicotine addiction. These U.S. patents expire in 2018. We also have pending U.S. applications

relating to our conjugates and their use. We hold granted patents in the following countries, relating to our conjugates and antibodies against our conjugates, for use in treating nicotine addiction: Europe (18 countries), Australia, China, Eurasia (Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgzstan, Moldova, Russian Federation, Tajikistan, Turkmenistan), Hong Kong, Indonesia, New Zealand and Turkey. We also have 12 pending foreign patent applications relating to our conjugate technology (Brazil, Canada, Hungary, India, Israel, Japan, Korea, Mexico, Norway, Poland, Serbia-Montenegro and Yugoslavia).

We have received correspondence alleging that our plans to commercialize NicVAX infringe certain U.S. and European patent rights. Based upon our current plans for NicVAX we do not believe that any valid U.S. or European patent rights will be infringed.

#### 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 products and product candidates.

#### **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 authorities in the U.S., Canada, 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.

#### **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 formalized U.S. FDA mechanism for allowing competitors to seek approval of generic versions.

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 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 the MAA. There are two different procedures to file a MAA, the Centralized Registration Procedure and the Mutual Recognition Procedure. A third process (the decentralized procedure) was put info effect recently. 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.

Our fractionation and purification facility is licensed by the FDA for the manufacture of Nabi-HB and an application for licensure of this product under the tradename HEBIG manufactured at this facility has been submitted to EMEA in 2005. As such, the facility has to comply with the current Good Manufacturing Practices, or cGMP, regulatory requirements of both regulatory authorities. This entails strict requirements and guidelines for the state of physical facility and its air supply, the associated utilities such as water for injection, the flow of personnel and materials as well as the quality systems policies and procedures that govern the conduct of all aspects related to manufacturing. Maintenance and upkeep of this asset demands substantial resources by several disciplines and functions, including, manufacturing, quality control, quality assurance, facilities and regulatory personnel. In addition, management oversight of all quality system is a strict requirement under the cGMP regulation. We are regularly audited by the FDA and other regulatory agencies as required, to ensure compliance with regulatory expectations.

#### Product specific reimbursement expectations

When Nabi-HB is administered peri-operatively in the hospital setting the cost of Nabi-HB is reimbursed under the established Diagnosis Related Group, or DRG. When Nabi-HB is administered as part of the patient's follow-up care in a physician's office or out-patient setting, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, establishes the reimbursement rate average sales price plus 6%. 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 vendor who will be responsible for securing reimbursement from the government or other third party payers.

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. In the EU, RPS is expected to be applied to Nabi-HB Intravenous (HEBIG in Europe) and PhosLo as certain EU countries currently reimburse for similar products that would compete with each product.

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

In the U.S., dialysis providers are primarily reimbursed by the Federal government through the ESRD Program. 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 MMA, includes an outpatient prescription drug benefit, under Part D, that contemplates beneficiary access to PhosLo and other prescription phosphate binders. Under this benefit, beneficiaries must pay a premium, which is expected to average of \$32.20 per month, with the patient responsible for the following co-payment structure:

Prescription costs	]	Patient Responsibility	
\$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 is being administered through a combination of Prescription Drug Plans, or PDP's, and 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.

#### 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 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 also 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.

#### Orphan Medicinal Product Designation

During 2005, Civacir and Altastaph were granted Orphan Medicinal Product Designation, or OMP, in Europe. The OMP designation will result in reduced MAA fees, free access to scientific advice from the EMEA and other potential research and development incentives. If a product with OMP designation is the first to receive marketing authorization in Europe for its designated indication, the product will be entitled to a 10-year marketing exclusivity, which means that a similar drug is prevented from receiving authorization for the same indication during this period.

Under Regulation (EC) No 141/2000, the EMEA through its Committee for Orphan Medicinal Products (COMP) is responsible for reviewing designation applications from sponsors who intend to develop medicines for rare diseases, or orphan medicines. Orphan medicines are designated diagnosing, preventing or treating life-threatening or very serious conditions that affect not more than five people in 10,000 in the EU. In addition to market exclusivity for a period of 10 years, products designated as orphan medicines received the following incentives; protocol assistance and medical advice from EMEA, access to the Centralized Procedure for regulatory filings and fee reductions.

#### Fast Track Designation

Civacir has received Fast Track Designation from the FDA for use in prevention of re-infection with HCV in HCV-positive liver transplant patients and Altastaph has been granted Fast Track review designation for use in very low birth-weight neonate patients. StaphVAX has been granted Fast Track review designation for protection from infection with *S. aureus* for the ESRD patient indication.

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 end points. 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 and Fosrenol prescription products marketed by Genzyme Corporation and Shire Pharmaceuticals, respectively, and over-thecounter 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 and DOPPS studies. As compared to Renagel and Fosrenol, PhosLo also competes on the basis of a favorable cost of treatment. Review of third-party prescription data indicates that PhosLo currently is prescribed at a slightly greater rate than Renagel among ESRD patients while Fosrenol is prescribed to a lesser number of patients than PhosLo.

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.

During 2005, there was one antibody-based therapy for prevention of hepatitis B post-exposure that competes with Nabi-HB in the U.S. In January 2006, a second competitive product developed by Cangene Corporation received approval for this indication 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 B disease in HBV-positive liver transplant patients of the U.S. B disease in HBV-positive liver transplant patients of the U.S. market. We believe the majority of our 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 an 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.

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

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. Another intravenous allopurinol product formulation is available in the U.S. market and competes 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 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 776 employees at December 31, 2005.

### 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 22 to our consolidated financial statements set forth in Part II of this Annual Report on Form 10-K.

# AVAILABLE INFORMATION

Our Internet address is <u>http://www.nabi.com</u>. 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**

Statements in this document that are not strictly historical are forward-looking statements and include statements about our marketed products, products in development, demand for our products, clinical trials and studies, licensure applications and approvals, assessment of the StaphVAX phase III trial results, and alliances and partnerships. You can identify these forward-looking statements because they involve our expectations, beliefs, projections, anticipations, or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements as a result of any number of factors. These factors include, but are not limited to, risks relating to our ability to: advance the development of products currently in our pipeline or in clinical trials; complete the assessment of the StaphVAX Phase III clinical trials during the first half of 2006; maintain the human and financial resources to commercialize current products and bring to market products in development; obtain regulatory approval for our products in the U.S. or other markets; successfully develop manufacture and market our products; utilize the full capacity of our manufacturing facility; successfully partner with third parties to develop, manufacture and distribute our existing and pipeline products; announce preliminary safety and immunogenicity results from our Phase IIb NicVAX study by early 2006; manufacture NicVAX in our own vaccine facility; realize the value of our acquisition of PhosLo; realize safes from Nabi-HB due to patient treatment protocols and the number of liver transplants performed in HBV-positive patients; effectively and profitability use our vaccine manufacturing facility; generate future sales growth for our biopharmaceutical products; comply with reporting and payment obligations under government rebate and pricing programs; prevail in pat

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

We may not continue to commercialize or be able to successfully commercialize our Gram-positive infections products in development.

In November 2005, we announced the results of our Phase III trial of StaphVAX, which did not meet its defined clinical end point that StaphVAX prevents *S. aureus* infections in patients on hemodialysis. The study, a randomized, double-blinded, placebo-controlled trial of 3,976 patients on hemodialysis, found no reduction in *S. aureus* Types 5 and 8 infections in the StaphVAX group as compared to the placebo group. Following these results, in conjunction with a panel of outside experts, we initiated an internal assessment in an effort to determine the factors causing this outcome. This assessment will review, among other things, the vaccine target (*S. aureus* polysaccharide capsule), changes in the care of dialysis patients, manufacture of the vaccine and the quality of the antibody generated by the vaccine as well as the design and conduct of the clinical trial and will involve initiating a series of scientific experiments to help interpret the trial results. Our advisory panel of outside experts formed in December 2005 includes experts in immunology, vaccines, bacterial infections and nephrology to help us assess the future development of our Gram-positive infections programs and to advise us on the most appropriate steps to advance the clinical development of our Gram-positive infections with external experts in the U.S. and Europe, including some members of the advisory panel. We expect to complete our internal assessment incorporating the work of the panel of outside experts during the first six months of 2006.

We have invested a significant portion of our efforts and financial resources in the development of our Gram-positive infections products and our willingness to continue to develop these products will depend on our understanding of the efficacy of their underlying technology. Our inability to timely assess and understand with certainty the factors causing the unfavorable results of the StaphVAX trial, our decision not to further commercialize some or all of the products in our Gram-positive infections portfolio or our ultimate inability to successfully commercialize some or all of these products could adversely affect our future business, operating results and financial condition.

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.

A number of our product candidates or products in development are in or will undergo clinical trials. These trials may not meet their defined end points, and, even if they do achieve their end points, we cannot be certain that results from future clinical trials will be positive. The results of our Phase III trial of StaphVAX announced in November 2005 were not positive. Unfavorable clinical trial results at any stage could adversely affect our business plans and have an adverse effect on our market valuation and our future business.

In 2005, we completed enrollment of the CARE 2 study, initiated in 2004, 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.

We are currently enrolling pre-dialysis Level 4 CKD patients in the EPICK study, to determine if PhosLo can control serum phosphorus in pre-dialysis patients with moderate to severe impairment of kidney function. If the results are favorable we will seek to broaden our labeled indication for PhosLo to CKD patients. Unfavorable clinical trial results or our inability to attain regulatory approval for the expansion of our labeled indication for PhosLo to CKD patients could adversely affect our business plans and have an adverse effect on our market valuation and our future business.

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

Regulatory approvals for any of our marketed products 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, post-marketing studies, which may be sponsored by us or 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. Finally, claims and concerns may arise regarding the safety or efficacy of one of our marketed products, which could lead to a product recall. 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, HEBIG, and PhosLo in the EU may not be successful.

Using the Mutual Recognition Process, we filed MAA's for Nabi-HB Intravenous, HEBIG, 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 any country in the EU that the approval is commercially feasible, or that such approval will be timely. If we receive approval, our focus will be on the launch of these two products through a sales distributor or commercialization partner, there can be no assurance that we will be able to find a suitable distributor or partner. Following approval in each country, we or our distributor or commercialization partner will then need to seek reimbursement in that country. There can be no assurance reimbursement approval will be obtained from any or all of the countries where such approval is sought 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 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 may not generate sufficient cash flow from our biopharmaceutical and antibody products or obtain financing necessary to fund our research and development and commercialization activities at an appropriate level.

We generate revenues from sales of our biopharmaceutical and antibody products. We ceased to generate revenues from sales of one of these products, WinRho SDF, in March 2005 when our exclusive distribution agreement in the U.S. ended. 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 and other commercialization expenses. Our current revenues from sales of biopharmaceutical and antibody products are insufficient to fund our products under development. In addition, our 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. Therefore, 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 and to obtain external financing or commercial partners. 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 expect that our existing capital resources and our ability to control expenditures will enable us to maintain our operations for at least the next twelve months based on current activities; however, to fully fund ongoing and planned activities beyond the next twelve months we may need to raise additional funds. Our operations will require significant additional funding in large part due to our current and future commercialization efforts. The amount of funds needed largely depends on our commercialization strategy concerning our Gram-positive products in development and on the timing and structure of potential future collaborations.

The following are illustrations of potential impediments to our ability to successfully secure additional funds:

- the current trading price of our common stock will materially and adversely affect our ability to raise funds through the issuance of equity;
- our Phase III trial for StaphVAX did not meet its defined primary end point; and
- the outstanding indebtedness from our 2.875% convertible senior notes issued in 2005 and the terms of the related indenture may discourage additional financing.

We may seek additional funding through public or private equity or debt financing, collaborative arrangements with strategic partners or from other sources. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates or to grant licenses on terms that are not favorable to us. 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 or effectively use our nephrology sales force.

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 23% of the total assets reflected on our balance sheet at December 31, 2005. PhosLo is marketed to physicians caring for ESRD patients who have developed elevated phosphorus levels in their blood. This is a competitive market in which we use our own sales force to sell 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.

In September 2005, we filed a lawsuit in the United States District Court for the Southern District of Ohio against Roxane Laboratories, Inc. for infringement of our PhosLo Gelcap patent. We filed this lawsuit under the Hatch-Waxman Act in response to a Paragraph IV Certification letter we received from Roxane concerning Roxane's filing of an ANDA with the FDA to market a generic version of PhosLo Gelcaps, on the basis that Roxane's submission of its ANDA and its proposed generic product infringe a patent held by the Company. The patent expires in 2021. Under the Hatch-Waxman Act, FDA approval of Roxane's proposed generic product will be stayed until the earlier of 30 months or resolution of the patent infringement lawsuit. If we are not successful in protecting our PhosLo Gelcap patent other companies may develop lower cost generic versions of PhosLo, negatively affecting our ability to compete.

PhosLo is currently the only nephrology product that we sell. When we acquired PhosLo we expected that we would be able to also sell StaphVAX to the nephrology community after its initial licensure for use with ESRD patients. Since the further development of StaphVAX is currently on

hold, we are uncertain when, if ever, it might be available for sale. We would like to acquire or in-license one or more other products for sale by our sales force to the nephrology community, but there can be no assurance that we will be successful in doing so on commercially advantageous terms, if at all. Our inability to acquire or in-license other nephrology products could adversely affect the effectiveness of our nephrology sales force.

If we are unable to maintain an effective nephrology sales force or otherwise unable to successfully market PhosLo at current or higher prices, we may not recover the value of the PhosLo intangible assets we acquired, we will be required to write down or write off some or all of the PhosLo intangible assets, and 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 and Aloprim. At times, contract manufacturers have failed to meet our needs. 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. 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;
- results of clinical studies conducted by our competitors;
- 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 our vaccine manufacturing plant.

We have constructed a vaccine plant in our Boca Raton, Florida manufacturing facility designed to allow us to produce vaccines in our product pipeline. The new plant is designed to process several vaccines on a commercial scale. We have not previously owned or operated such a plant and have no direct experience in commercial, large-scale manufacturing of vaccine products. There can be no assurance that we will be successful in licensing the plant or, if FDA and EU licensures are received, that the costs to validate the plant will be reasonable or that we can operate the plant efficiently and profitably. Our failure to successfully operate our new vaccine plant could 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 Boca Raton, Florida manufacturing facility.

We began commercial manufacture of Nabi-HB at our Boca Raton, Florida manufacturing facility in the fourth quarter of 2001. For the foreseeable future, we will 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. Our failure to fully utilize the capacity of the plant or to manufacture products successfully could require us to write down or write off some or all of the tangible and intangible assets related to the facility and could have a material adverse effect on our future business, financial condition and results of operations.

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

Currently, Nabi-HB is only manufactured at our manufacturing facility in Boca Raton, Florida. 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;
- 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 or Civacir or to fulfill contractual obligations.

Our ability to manufacture Nabi-HB today and Nabi-HB Intravenous, HEBIG, 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 to third parties other specialty antibodies 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, or HEBIG in the EU 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 2005, three such customers accounted for 61% of our total consolidated sales. A loss of any of the customers or a material reduction in such customers' 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 non-specific antibody sales in 2005 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.

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

We intend to pursue strategic alliances with third parties to develop, commercialize and/or market 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 and effective manner. If we are not successful in our efforts, our ability to continue to develop, commercialize and market our products may be affected adversely. Even if we are successful, if any of our collaborative partners violates or terminates its agreements with us or otherwise fails to conduct its 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 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
- lack of 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 and 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 three years. Certain contracts do not permit us to increase prices during the contract term except to reflect changes in customer specifications and new governmental regulations. If our costs of collecting antibodies under these contracts rise for reasons other than changes in customer specifications and new governmental regulations, we are unable to pass on these cost increases to our antibody product customers except with the customer's consent.

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

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

If we fail to comply with extensive regulations enforced by the FDA, the EMEA, the Paul Ehrlich 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, 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.

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, the 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 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 nonspecific 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 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. There can be 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.

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 use and produce hazardous materials. Any claims relating to improper handling, storage or disposal of these materials could be costly.

Our research and development operations involve the use of hazardous materials. Our operations also produce hazardous waste products. We are currently classified as a large quantity generator of hazardous waste. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to damages, fines and penalties in the event of an improper or unauthorized release of, or exposure of individuals to, these hazardous materials and waste. Compliance with current and future environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research and development and manufacturing efforts.

#### 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. The ultimate degree of patent protection that will be afforded to biotechnology products and processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. 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 patents or patent applications or received patents relating to products or processes competitive with or similar to ours. Some of these applications or patents may compete with our applications or conflict in certain respects with claims made under our applications. Such a conflict could result in a significant reduction of the coverage of our patents, if issued. In addition, if patents that contain competitive or conflicting claims are issued to others and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative technology.

If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all. Our failure to obtain a license to any technology that we may require in order to commercialize our products could have a material adverse effect on our future business, financial condition and results of operations.

In September 2005, we filed a lawsuit in the United States District Court for the Southern District of Ohio against Roxane Laboratories, Inc., or Roxane, for infringement of our PhosLo Gelcap patent. We filed this lawsuit under the Hatch-Waxman Act in response to a Paragraph IV Certification letter we received from Roxane concerning Roxane's filing of an Abbreviated New Drug Application, or ANDA, with the FDA to market a generic version of PhosLo Gelcaps, on the basis that Roxane's submission of its ANDA and its proposed generic product infringe a patent held by us. The patent expires in 2021. Under the Hatch-Waxman Act, FDA approval of Roxane's proposed generic product will be stayed until the earlier of 30 months or resolution of the patent infringement lawsuit.

We have received correspondence alleging that our research and plans to commercialize NicVAX infringe certain U.S. and European patent rights. Based upon our current plans for NicVAX we do not believe that any valid U.S. or European patent rights will be infringed on, however, there can be no assurance that we will prevail in our belief if challenged.

Additional litigation may be necessary to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights and to defend against any claims that our business infringes on third-party proprietary rights. Patent litigation is expensive and will result in substantial cost to us. The costs of patent litigation and our ability to prevail in such litigation will have a material adverse effect on our future business, financial condition and results of operations.

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, that are capable of developing and marketing products more effectively than we are able to so.

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 and marketing staffs and budgets than we have, as well as substantially greater experience in developing products and marketing, obtaining regulatory approvals, and manufacturing and marketing biopharmaceutical products. Some of our competitors are able to price their competitive products, such as Renagel and Fosrenol, at prices that are substantially higher than our product, which provides them with greater gross margins to invest in development and marketing. We compete with our competitors:

- to develop and market 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 or marketing technologies and products that are more effective, affordable or profitable than those that we are developing and marketing. In addition, one or more of our competitors may achieve product commercialization of or patent protection for competitive products earlier than us, which would preclude or substantially limit sales of our products. 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, commercialization or marketing by any of our competitors of any such products could have a material adverse effect on our future business, financial condition and results of operations.

# If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be required to make additional payments or be subject to penalties, fines and other sanctions that could have a material adverse effect on our business.

We participate in the Federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program based upon sales of our products that are reimbursed by those programs. Rebate calculations are complex and, in certain respects, subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to the Centers for Medicare and Medicaid Services or, CMS, at the Department of Health and Human Services, or DHHS, of our current average manufacturer price and best price for each of our products. Governmental agencies may make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the PHS pharmaceutical pricing program. The PHS pricing program extends discounts comparable to the Medicaid rebates to a variety of community health clinics and other entities that receive health services grants from the PHS, as well as hospitals that serve a disproportionate share of poor Medicare and Medicaid beneficiaries.

In addition, we make our products available to authorized users of the Federal Supply Schedule, or FSS, of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs, or DVA. The Veterans Health Care Act of 1992, or VHCA, imposes a requirement that the prices we charge to agencies under the FSS be discounted by a minimum of 24% off the average manufacturer price charged to non-federal customers. Our computation of the average manufacturer price to non-federal customers is used in establishing the FSS price for federal purchasers. The government maintains the right to audit the accuracy of our computations. Among the remedies available to the government for failure to accurately calculate FSS pricing and the average manufacturer price charged to non-federal customers is recoupment of any overpayments made by FSS purchasers as a result of errors in computations that affect the FSS price.

In 2005, we engaged an outside consultant to assess our pricing programs and in connection with that assessment it was determined that we may have inadvertently underpaid certain rebates due under Medicaid and likely other governmental pricing programs during the period from 2003 to 2005 due to the extension of best prices to ineligible entities. As a result we have established an accrual of approximately \$5.0 million in our financial statements for the future payment of those rebates. This amount represents our best estimate of the extent to which we underpaid amounts due under Medicaid and other governmental pricing programs during the period from 2003 to 2005, including amounts owing to the DVA and PHS. We expect to make the requisite payments during 2006. The amount also assumes that we will be successful in rebilling ineligible entities that improperly received best prices. We believe we have properly estimated the underpaid amounts due under Medicaid and other governmental pricing programs. However, if we are unable to effectively rebill and collect proper prices from ineligible entities we may be required to make additional payments to Medicaid and other similarly affected governmental pricing programs, all of which could have a material adverse effect on our future business, operating results and financial condition.

In connection with the determination that we have underpayments and overcharges under the Medicaid, PHS and FSS programs, we expect to engage in discussions with representatives of the Centers for Medicare and Medicaid Services, the DVA, the PHS and the Department of Defense. These discussions could include a detailed review by these agencies of our calculations of our underpayments and overcharges, and it is possible that this review could result in material changes to our calculations. Resolving the amounts owed to governmental agencies in connection with the underpayments has resulted, and is expected to continue to result, in a significant diversion of management's attention and resources and an increase in professional fees which could have a material adverse effect on our future business, results of operations and financial condition.

There are potential limitations on third-party reimbursement, complex regulations for reimbursement of our products 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. Further, there are high levels of regulatory complexity related to reimbursement from U.S. and government payers that can significantly limit available reimbursement for market products.

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

Within the EU, a number of countries use price controls to limit 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.

#### Current healthcare laws and future legislative changes to the healthcare system may affect our ability to distribute our products profitably.

The primary prescription drug benefit under the MMA, enacted in December 2003, the new Medicare Part D coverage, began in January 2006. The Part D program will be administered through a combination of PDP's and Medicare Advantage Plans. The plan design is for the PDP's to assume 100% of the financial risk for the relevant 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. PhosLo is the lowest cost prescription phosphate binder currently market in the U.S. As a result, we believe that the Part D program may provide us an opportunity to grow sales and increase market share of PhosLo but there can be no assurance of this growth and our inability to comply with the requirements of the Part D program in a timely manner could have an adverse effect on our ability to distribute PhosLo profitably.

Our operations are also subject to federal and state anti-kickback laws. Certain provisions of the Social Security Act prohibit entities such as us from knowingly and willingly offering, paying, soliciting or receiving any form of remuneration (including any kickbacks, bribe or rebate) in return for the referral of items or services for which payment may be made under a federal health care program, or in return for the recommendation, arrangement, purchase, lease or order of items or services for which payment may be made under a federal health care program. Violation of the federal anti-kickback law is a felony, punishable by criminal fines and imprisonment for up to five years or both. In addition, the DHHS may impose civil penalties and exclude violators from participation in federal health care programs such as Medicare and Medicaid. Many states have adopted similar prohibitions against payments intended to induce referrals of products or services paid by Medicaid or other third party payers. Because of the far-reaching nature of these laws and their lack of uniformity, there can be no assurance that the occurrence of one or more violations of these laws would not result in a material adverse effect on our business, financial condition and results of operations.

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

We may conduct business directly, or with partners, in countries outside of the U.S., which could 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.

#### We may not have the ability to raise the funds necessary to repay our convertible senior notes upon maturity or to repurchase them.

After giving effect to the 2.875% convertible senior notes offering we completed in May 2005, we had outstanding debt of approximately \$112.4 million as of December 31, 2005. Our annual interest expense, including the interest payable on the notes, is approximately \$4.1 million.

At maturity in 2025, the entire outstanding principal amount of the notes will become due and payable by us. In addition, holders of the notes may require us to repurchase the notes on April 15, 2010, April 15, 2012, April 15, 2015 and April 15, 2020 or upon the occurrence of a fundamental change as described in the indenture governing the notes. If we are unable to generate significant revenue from our products or are unable to raise additional capital we may not be able to make required payments on the notes or our other obligations, resulting in our default under the terms of the notes and the related indenture, which would permit holders of the notes to accelerate maturity. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the principal amount or repurchase price when due. Our failure to pay the principal amount or repurchase price when due would result in an event of default with respect to the notes. Prior to the notes coming due, we may engage in

restructuring or other strategic initiatives that could affect the rate at which the notes convert into our common stock, resulting in the issuance of additional shares of common stock upon conversion of the notes that may dilute or be adverse to the value of our common stock.

#### Conversion of the notes will dilute the ownership interest of existing stockholders.

The conversion of some or all of the notes will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issued upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the notes may encourage short selling by market participants because the conversion of the notes could depress the price of our common stock.

#### 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.

## 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 Florida. We also own a 46,000 square foot facility in Florida 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 lease a facility in Bray, Ireland with a term through 2030. We have the right to terminate the lease under certain circumstances in 2015. We do not currently occupy this facility and are attempting to sublease it.

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

On September 27, 2005, we filed a lawsuit in the United States District Court for the Southern District of Ohio against Roxane Laboratories, Inc., or Roxane, for infringement of our U.S. Patent Number 6,576,665 for PhosLo Gelcaps. We filed this lawsuit under the Hatch-Waxman Act in response to a Paragraph IV Certification letter we received from Roxane concerning Roxane's filing of an ANDA with the FDA to market a generic version of PhosLo Gelcaps, on the basis that Roxane's submission of its ANDA and its proposed generic product infringe the referenced patent that expires in 2021. Under the Hatch-Waxman Act, FDA approval of Roxane's proposed generic product will be stayed until the earlier of 30 months or resolution of the patent infringement lawsuit.

We remain committed to protecting our intellectual property and will take all appropriate steps to vigorously protect our patent rights.

## 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 31, 2005.

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

The executive officers of Nabi Biopharmaceuticals are as follows:

Name	Age	Position
Thomas H. McLain	48	Chairman, Chief Executive Officer and President
Joseph Johnson	49	Senior Vice President, People, Process and Technology
Raafat E.F. Fahim, Ph.D.	52	Senior Vice President, Research, Technical and Production Operations
Henrik S. Rasmussen, M.D., Ph.D.	47	Senior Vice President, Clinical, Medical and Regulatory Affairs
Mark L. Smith	44	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. Johnson* has served as Senior Vice President, People, Process and Technology since September 2005. From July 2004 to August 2005, Mr. Johnson led the Pharmaceutical Practice in Organizational Strategy at IBM's Business Consulting Services, overseeing a range of global engagements in organization strategy, change management, sales force effectiveness, lean discovery, and lean Six Sigma. From October 2003 to June 2004, Mr. Johnson served as Chief Operating Officer of P-Tech Inc. From March 2001 to September 2003, Mr. Johnson was the Managing Partner at Arthur D. Little, and worked as a turnaround specialist managing several biotech concerns that were absorbed into larger pharmaceutical companies. From September 2000 to March 2001, Mr. Johnson was the Chief Operating Officer of Cayenta, Corporation. Prior to consulting, Mr. Johnson began his career at Lehman Brothers in their biotech investment banking practice.

*Dr. Fahim* has served as Senior Vice President, Research, 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.

*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 Senior Vice President/ 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 Senior Vice President of Clinical Research/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. In January 2006, Mr. Smith tendered his resignation to the company effective on or about March 3, 2006. 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.

# Nabi Biopharmaceuticals

## PART II

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

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.

		High	Low
2005			
	First Quarter ending March 26, 2005	\$15.300	\$11.030
	Second Quarter ending June 25, 2005	15.000	10.230
	Third Quarter ending September 24, 2005	16.000	12.650
	Fourth Quarter ending December 31, 2005	13.640	3.060

2004

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

The closing price of our common stock on February 28, 2006 was \$4.11 per share. The number of record holders of our common stock on February 28, 2006 was 999.

No cash dividends have been previously paid on our common stock and none are anticipated in 2006.

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

Period	Total Number of Shares Purchased	Average Price Paid per share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (1)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (1)
9/25/05-10/29/05	0	N/A	0	\$ 3.1 million
10/30/05-11/26/05	0	N/A	0	\$ 3.1 million
11/27/05-12/31/05	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

The following table sets forth selected consolidated financial data for the five years ended December 31, 2005 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.

Total stockholders' equity

	For the Years Ended								
	December 31, 2005		ember 25, 2004	De	cember 27, 2003	De	cember 28, 2002		cember 29, 2001 (a)
Statements of Operations Data:									
Sales	\$ 108,055	<b>\$</b> 1	179,763	\$	176,570	\$	195,966	\$	234,829
Costs of products sold, excluding amortization of intangible assets	67,217		76,345		81,354		119,170		152,613
Royalty expense	3,623		17,569		18,387		12,883		12,093
Gross margin, excluding amortization of intangible assets	37,215		85,849		76,829		63,913		70,123
Selling, general and administrative expense	68,448		55,286		43,867		38,380		40,501
Research and development expense	66,836		61,003		29,040		21,096		15,330
Amortization of intangible assets	8,928		8,673		5,393		1,116		1,075
Other operating expenses, principally freight	349		521		477		583		715
Impairment of vaccine manufacturing facility	19,842		_		—		—		—
Write-off of manufacturing right	2,684		—		9,735		—		—
Gain on disposition of assets			_		_		<u> </u>		<u>(104,219</u> )
Operating (loss) income	(129,872)		(39,634)	)	(11,683)		2,738		116,721
Interest income	4,094		1,628		614		1,287		1,204
Interest expense	(3,097)		(2,199)	)	(1,350)		(2,130)		(2,128)
Other (expense) income, net	(482)		213		204		(157)		(28)
(Loss) income before benefit (provision) for income taxes	(129,357)		(39,992)	)	(12,215)		1,738		115,769
Benefit (provision) for income taxes	908		(10,398)	)	6,149		(264)		(11,272)
Net (loss) income	\$ (128,449)	\$	(50,390)	\$	(6,066)	\$	1,474	\$	104,497
Basic (loss) earnings per share:	\$ (2.15)	\$	(0.86)	\$	(0.14)	\$	0.04	\$	2.75
Diluted (loss) earnings per share:	\$ (2.15)	\$	(0.86)	\$	(0.14)	\$	0.04	\$	2.36
	De	cember 31, 2005		ember 25, 2004	Decemb 2003		December 28, 2002	D	ecember 29, 2001 (a)
Balance Sheet Data:									
Working capital	\$	108,965	\$	98,182	\$ 142	,905	\$ 74,495	\$	154,425
Total assets		328,397		368,171	387	,301	231,595		314,334
Notes payable and capital lease obligations, including current maturitie	s	122,702		23,844	27	,393	—		78,500

(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.

\$ 161,827

\$ 284,321

\$ 319,316

\$ 188,263

\$ 187,021

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

# **OUR STRATEGY**

Our operating focus in the near term is directed to generating an increased cash return from our operations, concentrating on the period from 2006 through 2008 and advancing key product development programs. These efforts are aligned with our multi-year strategic plan. In order to accomplish this goal we are pursuing three major objectives:

- Optimizing the value of current operations;
- Building value through strategic partnerships and commercial alliances; and
- Proving value in key research and development programs through "proof-of-concept" clinical studies.

We define optimizing the value of current operations as maximizing the cash return on the operating assets we currently own. These assets include our marketed products and our sales force. They also include the manufacturing capacity in our plant in Florida and our plasma collection centers. Leveraging our core competencies and manufacturing capacity we plan to pursue development of new products including Intravenous Immune Globulin, or IVIG, and plasma proteins. Our goal is to realize an increased cash return on our investment in these assets in the period from 2006 to 2008.

Our focus on building incremental value through strategic partnerships and commercial alliances may include marketing of our PhosLo and HEBIG products outside of the U.S. We will also pursue in-licensing opportunities in our core commercial areas of nephrology, transplantation and hospital specialty products. We also are pursuing partnership opportunities for our vaccine programs and other product development programs outside North America.

We plan to demonstrate "proof-of-concept" clinical evidence for key programs by following a common development process that is well designed, focused and cost-effective. We intend to work in consultation with an external scientific and clinical advisory panel on design, execution and results from each development program; to conduct Phase II "proof-of-concept" studies that will follow a design similar to the design we expect to use in future Phase III clinical trials; to use clinical material manufactured in our plant on a scale capable of supporting commercial launch; and to analyze relevant pharmacoeconomic data that support the cost benefit of our treatment approach. We have identified three program areas where we believe value can be demonstrated through these "proof-of-concept" trials between now and 2008: nicotine addiction, hepatitis C and Gram- positive infections.

## **KEY OPERATING ACTIVITIES**

On November 1, 2005, we announced that our Phase III clinical trial of StaphVAX did not meet its primary end point of a clinically significant reduction in *S. aureus* Types 5 and 8 infections among ESRD patients. These results are in contrast with the results of a previously reported Phase III clinical trial. In conjunction with an outside panel of experts, we are investigating these outcomes and expect to announce our findings in the first half of 2006. While this investigation is ongoing, we have placed our StaphVAX and Altastaph [*Staphylococcus aureus* Immune Globulin Intravenous (Human)] clinical programs on hold.

Following the announcement of the outcome of the Phase III StaphVAX clinical trial and the resulting uncertainties we assessed the recoverability of certain assets supporting our StaphVAX Types 5 and 8 programs. As a result of this assessment, we recorded several charges totaling \$27.4 million in the fourth quarter. This includes charges for impairment of our vaccine manufacturing facility totaling \$19.8 million, write off of pre-launch StaphVAX inventory totaling \$4.9 million and impairment of our intangible manufacturing right asset totaling \$2.7 million. In addition, as a result of our withdrawing our Marketing Authorization Application, or MAA, for StaphVAX in Europe pursuant to the Phase III trial results, we changed our strategy for commercialization of PhosLo and HEBIG in Europe and plan to distribute these products through third party marketing partners. In conjunction with this change in operations, in December 2005 we cancelled our pre-launch marketing activities for StaphVAX and made the decision to close our European office resulting in severance related costs for our European employees of \$0.6 million and other related costs of \$0.6 million. Further, in connection with placing our Altastaph clinical program on hold, we recorded a valuation allowance against all the deferred tax assets we had planned to utilize in a tax planning transaction for the European rights to this product between our U.S. entity and our non-U.S. subsidiary. As a result, we recorded a valuation allowance against all deferred tax assets in the amount of \$78.6 million.

## **KEY FINANCING ACTIVITIES**

On April 19, 2005, we issued \$100.0 million of 2.875% Convertible Senior Notes, or the Notes, due 2025. The Notes were issued through a private offering to qualified institutional buyers as defined under Rule 144A of the Securities Act. On May 13, 2005, the initial purchasers of the Notes exercised \$12.4 million of their option to purchase additional Notes to cover over allotments. A \$3.4 million discount was granted to the initial purchasers and an additional \$0.3 million in deferred charges were recorded for professional fees related to the issuance. Net cash proceeds from the offering totaled \$108.7 million. Interest on the Notes is payable on each April 15 and October 15, and commenced October 15, 2005. We can redeem the Notes at 100% of their principal amount, or \$112.4 million, plus accrued and unpaid interest, any time on or after April 18, 2010. Holders of Notes may require us to repurchase the Notes for 100% of their principal amount, plus accrued and unpaid interest, on April 15, 2010, April 15, 2012, April 15, 2015 and April 15, 2020, or following the occurrence of a fundamental change as defined in the indenture governing the Notes.

## **Results of Operations**

The following discussion and analysis of our financial condition and results of operations for each of the three years ended December 31, 2005, December 25, 2004 and December 27, 2003, 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.

	For the Years Ended					
(In the user to execute reverte geo)	Decembe 2005			Decembe 2003		
(In thousands, except percentages)	2003	·	2004		2003	
Segment						
Biopharmaceutical Products:						
- Nabi-HB	\$ 39,185	36.3%	\$ 40,176	22.3%	\$ 37,638	21.3%
- PhosLo	13,906	12.9	37,580	20.9	12,875	7.3
- WinRho SDF	6,172	5.7	47,882	26.7	49,957	28.3
- Other Biopharmaceuticals	2,874	2.6	6,175	3.4	8,989	5.1
	\$ 62,137	57.5	131,813	73.3	109,459	62.0
Antibody Products:						
- Specialty antibodies	22,936	21.2	23,270	13.0	21,425	12.1
- Non-specific antibodies	22,982	21.3	24,680	13.7	45,686	25.9
	45,918	42.5	47,950	26.7	67,111	38.0
Total	\$108,055	100.0%	\$179,763	100.0%	\$176,570	100.0%

#### 2005 as Compared to 2004

Sales. Total sales for 2005 were \$108.1 million compared to sales of \$179.8 million for 2004.

Biopharmaceutical sales. Biopharmaceutical sales for 2005 were \$62.1 million compared to \$131.8 million for 2004.

*Nabi-HB.* [*Hepatitis B Immune Globulin (Human)*] Sales of Nabi-HB were \$39.2 in 2005 compared to \$40.2 in 2004. Based on our review of internal tracking data, we believe that HBV liver transplant activity for HBV-positive patients during the 2005 was below 2004 levels and is reflected in sales of Nabi-HB. The effect of lower HBV liver transplant activity in 2005 has been partially offset by increased use of Nabi-HB among patients receiving maintenance therapy following liver transplant. Patient use of Nabi-HB in 2005, as reported in our internal tracking data, is consistent with reported sales to wholesalers and distributors. Sales of Nabi-HB in 2004 benefited from an initial buy-in of product from Novation LLC, or Novation, under a contract entered into during the first quarter of 2004. Under the terms of the agreement, we supply finished Nabi-HB product to Novation for distribution through their Novaplus<sup>®</sup> Private Label Program. Sales reported for 2005 benefited from product backorders of \$3.8 million at December 25, 2004, that were filled in 2005.

*PhosLo (calcium acetate).* Sales of PhosLo were \$13.9 million for 2005 compared to \$37.6 million for 2004. During 2005, patient use of PhosLo exceeded shipments to wholesalers resulting in wholesaler inventory levels being reduced. During our closing process for 2005, we identified an error in the calculation of rebates payable under certain Federal programs related to 2003 and 2004 totaling \$1.4 million. This error is considered immaterial to those periods and has been recorded as a reduction to 2005 PhosLo sales. Patient prescriptions for PhosLo in 2005 have remained consistent with 2004 based on our review of third party prescription data despite the introduction of a third prescription product in 2005 and an intense competitive environment. In addition, during 2005, we completed the transition to our gelcap formulation of PhosLo, which began in 2004. We believe that the gelcap formulation of PhosLo. Because of the timing of prescription drug provider contract renewals, we anticipate that the impact from the price increase will be only partially realized in early 2006. Sales of PhosLo in 2004 included stocking of the gelcap formulation by our wholesaler customers in the first quarter as we increased manufacturing capacity for PhosLo Gelcaps as part of the transition to this formulation as well as purchases by our wholesaler customer made in anticipation of price increases

*WinRho SDF* [*Rho* (*D*) *Immune Globulin Intravenous (Human)*]. Sales of WinRho SDF were \$6.2 million in 2005 compared to \$47.9 million in 2004. The decrease is due to the expiration of our agreement to distribute this product on March 24, 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 \$2.9 million in 2005 compared to \$6.2 million in 2004. Sales of Aloprim were lower in 2005 compared to 2004 due to the impact from the introduction of a new competitive product. Sales of Autoplex T were lower in 2005 due to our contract with the manufacturer of Autoplex T ending on May 11, 2004 and sales subsequent to that date being limited to existing inventory on hand. Contract manufacturing revenue increased in 2005 compared to 2004 due to sales under a new contract manufacturing agreement. Sales of intermediate products, which are not a strategic focus for us, were lower in 2005 compared to 2004.

Antibody products. Total antibody product sales for 2005 were \$45.9 million compared to \$48.0 million for 2004.

*Specialty antibodies.* Specialty antibody sales were \$22.9 million for 2005 compared to \$23.3 million for 2004. The decrease in specialty antibodies primarily reflects decreased sales of Rh<sub>o</sub>D antibodies substantially offset by increased sales of tetanus, rabies and anti-HBs antibodies. Throughout 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 at a low gross margin. This contract ended on December 31, 2004.

Hepatitis B antibodies produced at our antibody collection centers are primarily retained by us to support the manufacture of Nabi-HB, limiting the amount of these antibodies available for sale. Hepatitis B antibodies are the primary raw material in the manufacture of Nabi-HB.

*Non-specific antibodies.* Total non-specific antibody sales were \$23.0 million in 2005 compared to \$24.7 million in 2004. In December 2003, we entered into a long-term supply contract for the sale of non-specific antibodies, which is expected to generate a consistent cash flow from the excess non-specific antibody production in our centers.

*Gross margin*. Gross margin for 2005 was \$37.2 million, or 34% of sales, compared to \$85.8 million, or 48% of sales, for 2004. The decrease in gross margin for 2005 compared to 2004 reflects decreased biopharmaceutical product sales in 2005, primarily WinRho SDF and PhosLo. As well, during 2005 we wrote-off \$4.9 million of pre-launch StaphVAX inventory following the withdrawal of our MAA for StaphVAX, \$1.0 million of Nabi-HB inventory damaged at our contract fill and finisher, \$0.8 million of Nabi-HB pre-launch inventory due to our assessment of pre-launch inventory shelf life not being sufficient compared to our projected timing for sales of the product and \$0.4 million of PhosLo tablet inventory not planned for sale. In the comparable period of 2004 we reserved Nabi-HB inventory valued at \$3.0 million in 2005 compared to \$3.7 million in 2004, primarily reflecting increased gross margin on specialty antibody product sales following expiration of the low gross margin Rh<sub>o</sub>D supply contract in December 2004. During 2005, we had \$2.8 million in excess plant capacity compared to \$6.6 million in 2004 when our manufacturing facility underwent renovations related to compliance with EU regulations and routine maintenance that limited utilization of the facility. Gross margin for 2004 benefited from a non-performance penalty from the manufacture of Autoplex T of \$2.0 million.

Royalty expense was \$3.6 million, or 6% of biopharmaceutical sales, for 2005 compared to \$17.6 million, or 13% of biopharmaceutical sales, for 2004. The decrease in royalty expense as a percentage of biopharmaceutical sales reflects the decrease in total biopharmaceutical sales, as well as the expiration of the WinRho SDF distribution agreement and an associated royalty obligation based on product sales. 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 \$68.4 million for 2005 compared to \$55.3 million for 2004. Increased selling, general and administrative expenses for 2005 was primarily related to the planned launch of StaphVAX, including market research, costs incurred to establish commercial operations in Europe prior to our decision to close our European operations in December 2005 and pre-launch marketing activities.

*Research and development expense*. Research and development expense was \$66.8 million for 2005 compared to \$61.0 million for 2004. The majority of research and development expense in 2005 and 2004 was incurred to support our Gram-positive infections program primarily composed of StaphVAX and Altastaph as well as our next generation Gram-positive products. In 2005, these activities included our Phase III clinical trial for StaphVAX that concluded during the third quarter of 2005, seeking to establish StaphVAX vaccine manufacturing capability, supporting our MAA filed for StaphVAX in the EU, immunogenicity studies in orthopedic patients in both the U.S. and the UK, the completion of an immunogenicity study among cardiac surgery patients, bridging and consistency lot studies, initiation of Phase I clinical trials for a *S. aureus* Type 336 vaccine and a *S. epidermidis* vaccine and a study evaluating the ability of StaphVAX to provide long-term protection against *S. aureus*. During 2005 and 2004, we incurred approximately \$14.2 million and \$17.9 million, respectively, in outside clinical trial costs for the Phase III clinical trial for StaphVAX.

Within our NicVAX program, during 2005 we completed enrollment of our open-labeled Phase II dose ranging clinical trial for NicVAX in the EU. In addition during 2005, we were granted a \$4.1 million grant from the National Institute on Drug Addiction for the further development of NicVAX. In 2005, \$0.3 million of the grant was utilized to offset NicVAX clinical trials expense and \$3.8 million remains available to offset future NicVAX clinical trials expense.

Research and development expense during 2005 and 2004 also included costs to support our currently marketed products as well as the other products in our development pipeline. In support of our PhosLo product, during 2005 we completed enrollment in the Effect of PhosLo in Chronic Kidney Disease, or EPICK. EPICK is a Phase IIIb study of PhosLo among pre-dialysis Stage 4 Chronic Kidney Disease patients. Also in support of PhosLo, we completed enrollment in the Calcium Acetate Renagel Evaluation 2, or CARE2, study in 2005. Results of EPICK and CARE2 are expected to be reported in the second half of 2006. In addition, during 2005 we incurred ongoing expenses to support our MAA's filed during 2004 in the EU for PhosLo and HEBIG. And we incurred costs to support our Biologics License Application, or BLA, filed for Nabi-HB Intravenous seeking an indication for the prevention of re-infection with hepatitis B in HBV-positive liver transplant patients in the U.S.

Amortization of intangible assets. Amortization expense was \$8.9 million for 2005 compared to \$8.7 million for 2004. This amortization is primarily related to the intangible assets recorded as part of the acquisition of PhosLo.

*Impairment of vaccine manufacturing facility:* We incurred \$21.5 million in total costs to construct our vaccine manufacturing plant in Boca Raton, Florida in support of the anticipated global launch of StaphVAX. This plant was placed into service in February 2005 and depreciation of this facility for financial reporting purpose began on that date. As a result of not meeting the primary end point of the Phase III clinical trial for StaphVAX, we concluded that the carrying value of the asset was impaired and should be reduced to \$0.5 million, its estimated current fair market value as determined by an outside valuation firm. As a result, we recorded a \$19.8 million impairment charge during 2005.

*Write-off of Manufacturing Right.* In connection with our decision in December 2005 to cancel our contract manufacturing relationship to manufacture StaphVAX in a facility owned by Cambrex Bio Science Baltimore, Inc. we wrote-off the unamortized asset balance at that date totaling \$2.7 million.

*Interest income.* Interest income for 2005 was \$4.1 million compared to \$1.6 million for 2004. Interest income is earned from investing cash and cash equivalents on hand in money market funds and marketable securities with maturities or reset periods of three months or less. The increase in interest income in 2005 compared to 2004 is due to higher average cash balances in 2005 as a result of the issuance of \$112.4 million of our 2.875% Convertible Senior Notes due 2025 during the second quarter of 2005.

*Interest expense*. Interest expense for 2005 was \$3.1 million compared to \$2.2 million for 2004. Included in interest expense for 2005 was \$2.3 million of interest expense associated with our 2.875% Convertible Senior Notes due 2025. In addition, interest expense included \$0.6 million and \$1.2 million in 2005 and 2004, respectively, for amortization of the discount on the notes payable entered into in connection with the acquisition of PhosLo. On 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. Capitalized interest relating to construction of our vaccine manufacturing facility and our laboratory and cold storage facility that was completed in 2004 was \$0.1 million in 2005 and \$0.3 million for 2004,

*Income taxes.* We had an income tax benefit of \$0.9 million in 2005, compared to a provision of \$10.4 million for 2004. As of December 31, 2005, we had a valuation allowance of \$78.6 million against all our deferred tax assets because there is not sufficient evidence to conclude that we would "more likely than not" realize all or a portion of those assets prior to their

expiration. The valuation allowance is equal to the total net carrying value of all of our deferred tax assets, primarily composed of net operating losses and research and development tax credits. In 2004, as a result of licensing the right to market StaphVAX and PhosLo in the EU to one of our foreign 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 realized deferred tax assets related to net operating loss carryforwards incurred in prior periods and the exercise of employee stock options to offset cash payment of income taxes on the reported U.S. taxable gain in 2004.

*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 year ending December 31, 2005 was a 53-week year with the additional week included in the fourth quarter of 2005. The fiscal years ended December 25, 2004 and December 27, 2003 were 52-week years.

*Stock option expensing.* We will have an expense in 2006 related to our equity compensation plans as a result of the implementation of Statement on Financial Accounting Standards, or SFAS 123(R): *Share-Based Payment* that is effective for our accounting periods beginning January 1, 2006. On December 20, 2005, the Compensation Committee of our Board of Directors approved the acceleration of vesting of all unvested options to purchase our common stock having an exercise price of \$6.00 or higher, effective for all outstanding options as of December 20, 2005 to avoid compensation expense as a result of the adoption of FAS 123(R). The closing price of our common stock on December 20, 2005 was \$3.35 per share. Using the Black-Scholes model for valuing stock options under FAS 123(R) that were not subject to acceleration will result in expense for options granted in prior years on a pre-tax basis in the amounts of \$1.7 million, \$1.7 million and \$2.0 million for the years ending in 2006, 2007 and 2008, respectively.

#### 2004 as Compared to 2003

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 2004, we made the strategic decision to convert patients from the PhosLo tablet formulation to the PhosLo Gelcap formulation. In line with this decision and orders received from wholesaler customers, we significantly reduced our inventory of PhosLo tablet formulation in 2004. 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 also 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 increases that went into effect in January 2004 and September 2003 based on a 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.

*Nabi-HB*. Sales of Nabi-HB were \$40.2 million in 2004 compared to sales of \$37.6 million reported in 2003. Sales of Nabi-HB in 2004 benefited from initial sales under our agreement with Novation LLC, or Novation, entered into during the first quarter of 2004. Under the terms of the agreement, we supply finished Nabi-HB product to Novation for distribution through their Novaplus<sup>®</sup> Private Label Program. 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 indicated that the number of liver transplants for hepatitis B patients for 2004 increased by approximately 20% compared to the number for 2003. Sales of Nabi-HB 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 resulted in lower doses of antibody 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 \$47.9 million in 2004 compared to sales of \$50.0 million in 2003. Based on internally generated patient use data, we believe patient demand for WinRho SDF in 2004 decreased in-line with the decrease in reported sales in 2004 as compared to 2003. Our agreement with Cangene to distribute WinRho SDF ended 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. 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 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.

*Specialty antibodies*. Specialty antibody sales were \$23.3 million for 2004 compared to \$21.4 million for the comparable period of 2003. The increase in specialty antibodies primarily reflected 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 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 from non-performance penalty amounts from the manufacturer of Autoplex T of \$2.0 million and \$8.1 million, respectively. During 2004, our 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 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 reflected 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 included a 4% patent usage royalty related to the manufacturing process of Nabi-HB and a royalty related to Aloprim that was 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 expenses 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 comprising StaphVAX and Altastaph as well as our next generation Gram-positive products. These activities included our Phase III clinical trial for StaphVAX that was fully enrolled in August 2004, transferring the StaphVAX manufacturing process to our contract manufacturer, Cambrex Bio Science, establishing StaphVAX vaccine manufacturing capability within our 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 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 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.

Amortization of intangible assets. Amortization expense was \$8.7 million for 2004 compared to \$5.4 million for 2003. The increase in 2004 was 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 was 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 was 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 Florida was \$0.3 million for 2004 and related to construction of our laboratory and cold storage facility in 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. 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.

#### Liquidity and Capital Resources

The total of our cash and cash equivalents and marketable securities balances at December 31, 2005 was \$106.9 million compared to cash and cash equivalents of \$103.1 million at December 25, 2004. Cash used by operations for the year ended December 31, 2005 was \$89.8 million reflecting our net loss in 2005, the reduction in accounts payable and accruals following conclusion of our Phase III clinical trial for StaphVAX, activities in anticipation of our planned launch of StaphVAX in Europe, royalties due to Cangene Corporation for the distribution of WinRho SDF in the fourth quarter of 2004 and increased inventories offset by reduced accounts receivable balances due to lower sales levels of our biopharmaceutical products.

On April 19, 2005, we issued \$100.0 million of 2.875% Convertible Senior Notes due 2025, or the Notes. The Convertible Senior Notes were issued through a private offering to qualified institutional buyers as defined under Rule 144A of the Securities Act. On May 13, 2005, the initial purchasers of the Notes exercised \$12.4 million of their option to purchase additional Notes to cover over allotments. A \$3.4 million discount was granted to the initial purchasers and an additional \$0.3 million in deferred charges were recorded for professional fees related to the issuance. Net cash

proceeds from the offering totaled \$108.7 million. Interest on the Notes is payable on each April 15 and October 15, and commenced on October 15, 2005. We can redeem the Notes at 100% of their principal amount, or \$112.4 million, plus accrued and unpaid interest, any time on or after April 18, 2010. Holders of the Notes may require us to repurchase the Notes for 100% of their principal amount, plus accrued and unpaid interest, on April 15, 2010, April 15, 2012, April 15, 2015 and April 15, 2020, or following the occurrence of a fundamental change as defined in the indenture governing the Notes.

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 31, 2005, our remaining obligation, net of discount, was \$13.1 million. We will repay \$3.1 of this obligation in 2006. During 2005, we repaid \$10.8 million of this obligation.

Capital expenditures were \$8.7 million for 2005. Capital expenditures were primarily related to investments in our information technology systems, the completion of our vaccine manufacturing facility and laboratory equipment for use in research and development. During 2006, we expect capital expenditures to be approximately \$6 million to \$9 million, primarily to support research and development activities, information technology systems and maintenance of our facilities.

In connection with an agreement related to the retirement of our former Chief Executive Officer entered into in 2003, at December 31, 2005, we had a remaining net obligation of \$0.9 million in cash payments through December 2006, which is recorded in accrued expenses.

During 2005, we received \$4.65 million from the exercise of employee stock options.

On December 7, 2004, we filed a shelf registration statement on Form S-3 with the U.S. Securities and Exchange Commission. This registration statement will permit us, from time to time, to offer and sell up to \$175 million of equity or debt securities. If we elect to sell securities under this registration statement, we anticipate using net proceeds from such sales 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 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 2005, 2004 and 2003. 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 also may seek approval of our Board of Directors to repurchase from time to time our Convertible Senior Notes in the open market or in privately negotiated transactions.

We believe that cash flow from operations, cash and cash equivalents and marketable securities on hand at December 31, 2005 will be sufficient to meet our anticipated cash requirements for operations and debt service for at least the next 12 months.

The following table provides information as of December 31, 2005 with respect to the amounts and timing of our known contractual obligations as specified below.

## **Contractual Obligations**

						After	
(in thousands)	2006	2007	2008	2009	2010	2011	Total
Open purchase orders	\$ 5,532	\$ —	\$ —	\$—	\$ —	\$—	\$ 5,532
Operating leases	2,300	1,746	1,777	493	277	484	7,077
Capital leases	437	401	—		—		838
Notes Payable, PhosLo acquisition	3,059	10,841					13,900
Retirement obligations	2,006	76	—		—		2,082
Contractual obligations to purchase inventory	892	669	669	446	—	—	2,676
Senior Convertible notes					112,400		112,400
Total	\$14,226	\$13,733	\$2,446	\$939	\$112,677	\$484	\$144,505

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. Although the holders of the Notes can require us to repurchase them in April 2010, the Notes are due in 2025.

## **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.

#### Accounts Receivable and Revenue Recognition

In the year ended December 31, 2005, we had biopharmaceutical product sales of \$62.1 million. At December 31, 2005, we had \$22.3 million of accounts receivable including \$12.8 million from biopharmaceutical sales.

Our primary customers for biopharmaceutical products are pharmaceutical wholesalers. In accordance with our revenue recognition policy, revenue from biopharmaceutical product sales is recognized when title and risk of loss are transferred to the customer. Reported sales are net of contractual allowances in accordance with managed care agreements known as chargebacks, government payer rebates, estimated customer prompt pay discounts, customer returns and other wholesaler fees. At December 31, 2005, we had \$11.4 million recorded in other current liabilities related to these items 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, business considerations for customer purchases and estimated inventory levels. If our actual experience is different than our assumptions we record the impact of such differences in the appropriate 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, 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. 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 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 to the extent the contracted price with the indirect party is less than the 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:

(in thousands)	Accrued chargebacks	Accrued rebates	Accrued sales discounts	Other accrued sales deductions	Total sales deductions
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
Provision for sales	4,336	8,303	5,849	1,027	19,515
Actual credits utilized during 2005	(6,673)	(3,526)	(5,566)	(883)	(16,648)
Balance at December 31, 2005	\$ 2,080	\$ 7,357	\$ 1,350	\$ 632	\$ 11,419

Inventory and Reserves for Slow Moving or Obsolete Inventory

At December 31, 2005, we had inventory, net of \$22.3 million. In the year ended December 31, 2005, we recorded a provision for inventory valuation allowance of \$8.6 million. We review inventory on hand at each reporting period to assess whether 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 different than our assumptions we will record the impact of such differences in the appropriate period.

We have made and in future periods we expect to scale-up and make commercial quantities of certain of our product candidates prior to the date we anticipate that such product will receive final regulatory 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, if based on future circumstances we assess that it is appropriate, we will scale-up and build pre-launch inventories of products that have not yet received final governmental approval in future periods.

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 if a regulatory filing has been made for licensure for marketing the product and the product 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's shelf life. If approval for these product candidates is not received, or approval is not timely compared to our estimates for product shelf life, we write the related amounts of pre-launch inventory off in the period of that determination. During 2005, we wrote off \$4.9 million of StaphVAX pre-launch inventory based on the outcome of our Phase III clinical trial for StaphVAX that did not meet its primary end point and the withdrawal of our MAA for StaphVAX from consideration by EMEA. In addition, we wrote off \$0.8 million of Nabi-HB Intravenous during 2005 as a result of the shelf life of such product being inadequate compared to the timing of our sales projections. At December 31, 2005, we did not have any pre-launch inventories on hand.

#### 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:

(in thousands)	December 31, 2005	Estimated Remaining Useful Life
PhosLo Intangibles		
Trademark/tradename	\$ 1,423	15.3 years
Tablet patent	11,381	1.3 years
Gelcap patent	80,670	15.3 years
Customer relationships	2,337	2.6 years
Covenant-not-to-compete	508	12.6 years
Total PhosLo intangible assets	96,319	
Accumulated amortization	(19,942)	
Total PhosLo Related Intangible Assets	\$ 76,377	

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 from the date of acquisition. We have established an initial 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 marketplace. 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.

On September 27, 2005, we filed a lawsuit in the United States District Court for the Southern District of Ohio against Roxane Laboratories, Inc., or Roxane, for infringement of our PhosLo Gelcaps patent. We filed this lawsuit under the Hatch-Waxman Act in response to a Paragraph IV Certification notice letter we received from Roxane concerning Roxane's filing of an ANDA with the FDA to market a generic version of PhosLo Gelcaps, on the basis that Roxane's submission of its ANDA and its proposed generic product infringe the patent held by us. The patent expires in 2021. Under the Hatch-Waxman Act, FDA approval of Roxane proposed generic product will be stayed until the earlier of 30 months or resolution of the patent infringement lawsuit.

Based on our assessment of this matter, we do not believe that the carrying values of our PhosLo related intangible assets are impaired at December 31, 2005 or that the estimates useful lives of the assets are changed.

#### Intangible Assets - Manufacturing Right

In October 2003, we entered into a contract manufacturing agreement with Cambrex Bio Science Baltimore, Inc., or Cambrex Bio Science, pursuant to which we acquired a manufacturing right, which we began amortizing in 2004. In December 2005, we determined that the manufacture of StaphVAX at commercial scale would not occur at Cambrex Bio Science's facility. Our determination was based on the outcome of our Phase III clinical trial for StaphVAX that did not meet its primary end point and the withdrawal of our MAA for StaphVAX from consideration by EMEA. In accordance with our stated policy, we wrote-off the remaining unamortized intangible asset balance of \$2.7 million.

#### Property, Plant and Equipment and Depreciation

We incurred costs of \$90.3 million to construct our biopharmaceutical manufacturing facility in Florida and received approval to manufacture our own antibodybased 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-ofproduction 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 2005, 2004 and 2003, we recorded additional depreciation of \$2.1 million, \$2.5 million and \$1.6 million, respectively, under this policy.

We incurred \$21.5 million in total costs to construct our vaccine manufacturing facility in Boca Raton, Florida in support of the anticipated global launch of StaphVAX. This facility was placed into service in February 2005 and began depreciating on that date. As a result of the Phase III clinical trial for StaphVAX not meeting its primary end point, we impaired the carrying value to its estimated current fair market value as determined by an outside valuation firm to \$0.5 million. As a result, we recorded a \$19.8 million impairment charge during 2005.

#### 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. During 2005, we generated significant operating losses and generated additional research and development tax credits. We have recorded a \$78.6 million valuation allowance against all deferred tax assets that we have assessed will not be utilized by deferred tax liabilities that reverse with the passage of time. If in the future, circumstances change such that realization of the deferred tax assets is more likely than not, the valuation allowance will be reversed and a benefit will be recorded in that period. As a result, for 2005 we recorded a benefit for income taxes of \$0.9 million, compared to a provision of \$10.4 million during the year ended December 25, 2004.

#### **New Accounting Pronouncements**

In April 2005, the SEC announced that SFAS No. 123(R), *Share-Based Payment*, which requires all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value, has been deferred. SFAS 123(R) 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.

Statement 123(R) permits public companies to adopt its requirements using one of two methods:

A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123(R) for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date.

A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate, based on the amounts previously recognized under Statement 123(R) for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

We plan to adopt Statement 123(R) using the modified prospective method.

On December 20, 2005, the Compensation Committee of our Board of Directors approved the acceleration of vesting of all unvested options to purchase our common stock having an exercise price of \$6.00 or higher, effective for all outstanding options as of December 20, 2005. The closing price of our common stock on December 20, 2005 was \$3.35 per share. All other terms and conditions applicable to such options, including the exercise prices, remain unchanged. The affected options were previously granted to our employees, including our executive officers, under the Company's 2000 Equity Incentive Plan and its 1998 Non-Qualified Employee Stock Option Plan. Options to purchase 3,962,159 shares of our common stock or 96% of our outstanding unvested options are subject to this acceleration and such options have exercise prices ranging from \$6.00 to \$17.15 per share and a weighted average exercise price of \$12.51 per share. Of the accelerated options, approximately 778,099 are held by our Named Executive Officers included in the Summary Compensation Table in the Company's 2005 Definitive Proxy Statement filed with the Securities and Exchange Commission on April 8, 2005.

Our decision to accelerate the vesting of the affected options was based primarily upon the issuance of SFAS No. 123(R), which will require us to treat all unvested stock options as compensation expense effective January 1, 2006. We believe that the acceleration of vesting of the affected options will enable us to avoid recognizing stock-based compensation expense associated with these options in future periods. We estimate this compensation expense, before tax, would total \$26.7 million (excluding the impact of forfeitures), which would have been recognized over approximately the next 3 years from the date of the acceleration. Compensation expense for options not subject to the acceleration of vesting described above, at fair value is expected to be approximately \$1.7 million, \$1.7 million and \$2.0 million in 2006, 2007 and 2008, 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 do not expect the adoption of SFAS No. 151 to have a material impact on our financial condition, results of operations or cash flows.

In October 2005, the FASB announced that FSP No. 13-1, *Accounting for Rental Costs Incurred during a Construction Period*, is effective for reporting periods beginning after December 15, 2005. This Position concludes that rental costs incurred during and after a construction period are for the right to control the use of a leased asset during and after construction of a lessee asset, and that there is no distinction between the right to use a leased asset during the construction period and the right to use that asset after the construction period. This Position requires that rental costs associated with ground or building operating leases that are incurred during a construction period be recognized as rental expense, included in income from continuing operations. We do not expect the adoption of FSP No. 13-1 to have an 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 31, 2005, and this assessment identified no material weaknesses in our internal control over financial reporting as of that date.

Based on our evaluation under the framework in Internal Control, Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2005.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 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 31, 2005 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

## 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, one United Kingdom subsidiary and one Luxembourg subsidiary. During the year ended December 31, 2005, we did not record any sales by our foreign subsidiaries. One subsidiary incurred expenses during this period, primarily relating to our initial activities to obtain regulatory approval in the EU for our products in development and products that we currently market in the U.S. only. 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 31, 2005, we had cash and cash equivalents and marketable securities in the amount of \$101.7 million and \$5.2 million, respectively. In addition, we had outstanding Convertible Senior Notes that incur interest at 2.875% with a face value of \$112.4 million, notes payable for the acquisition of PhosLo of \$13.1 million, net of imputed discount, and capital lease obligations of \$0.5 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 closing date of the acquisition.

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:

(in millions, except for percentages)	Fair Value at r 31, 2005
Assets:	
Cash, cash equivalents and marketable securities	\$ 106.9
Average interest rate	3.1%
Liabilities:	
2.875% Convertible Senior Notes due 2025	\$ 109.1
Notes payable and capital lease obligations	\$ 13.6
Average interest rate	3.3%

#### Nabi Biopharmaceuticals

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Nabi Biopharmaceuticals

#### To the Board of Directors and Stockholders of Nabi Biopharmaceuticals

We have audited the accompanying consolidated balance sheets of Nabi Biopharmaceuticals as of December 31, 2005 and December 25, 2004, 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 31, 2005. 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 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 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 and subsidiaries at December 31, 2005 and December 25, 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

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 31, 2005, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP Certified Public Accountants

West Palm Beach, Florida February 28, 2006

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

The Board of Directors

and Stockholders 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 maintained effective internal control over financial reporting as of December 31, 2005, 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.

In our opinion, management's assessment that Nabi Biopharmaceuticals maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Nabi Biopharmaceuticals maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Nabi Biopharmaceuticals as of December 31, 2005 and December 25, 2004, 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 31, 2005 of Nabi Biopharmaceuticals and our report dated February 28, 2006 expressed an unqualified opinion thereon.

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/s/ Ernst & Young LLP Certified Public Accountants

West Palm Beach, Florida February 28, 2006

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

# Nabi Biopharmaceuticals CONSOLIDATED BALANCE SHEETS

Amounts in thousands, except share and per share data	December 31, 2005	December 25, 2004
Assets		
Current assets:		
Cash and cash equivalents	\$ 101,762	\$ 94,759
Marketable securities	5,172	8,350
Restricted cash	816	672
Trade accounts receivable, net	22,322	32,405
Inventories, net	22,323	20,175
Prepaid expenses and other current assets	2,672	6,227
Total current assets	155,067	162,588
Property, plant and equipment, net	94,084	115,406
Other assets:		
Intangible assets, net	78,332	89,728
Other	914	449
Total assets	\$ 328,397	\$ 368,171
Liabilities and stockholders' equity		
Current liabilities:		
Trade accounts payable	\$ 17,584	\$ 21,943
Accrued expenses	25,906	32,290
Notes payable, net and capital lease obligations, net	2,612	10,173
Total current liabilities	46,102	64,406
2.875% Convertible Senior Notes, net	109,145	
Notes payable, net and capital lease obligations, net	10,945	13,671
Other liabilities	378	5,773
Total liabilities	166,570	83,850
Stockholders' equity:		
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		
shares authorized; 60,322,763 and 59,428,941		
shares issued, respectively	6,032	5,943
Capital in excess of par value	318,910	313,494
Treasury stock, 805,769 and 803,811, respectively, at cost	(5,321)	(5,297)
Accumulated deficit	(157,965)	(29,516)
Other accumulated comprehensive income (loss)	171	(303)
Total stockholders' equity	161,827	284,321
Total liabilities and stockholders' equity	\$ 328,397	\$ 368,171

See accompanying notes to consolidated financial statements.

# Nabi Biopharmaceuticals CONSOLIDATED STATEMENTS OF OPERATIONS

		For the Years Ended	
In thousands	December 31, 2005	December 25, 2004	December 27, 2003
Sales	\$ 108,055	\$ 179,763	\$ 176,570
Costs and expenses:			
Costs of products sold, excluding amortization of intangible assets	67,217	76,345	81,354
Royalty expense	3,623	17,569	18,387
Gross margin, excluding amortization of intangible assets	37,215	85,849	76,829
Selling, general and administrative expense	68,448	55,286	43,867
Research and development expense	66,836	61,003	29,040
Amortization of intangible assets	8,928	8,673	5,393
Other operating expenses, principally freight	349	521	477
Impairment of vaccine manufacturing facility	19,842	—	_
Write-off of manufacturing right	2,684		9,735
Operating loss	(129,872)	(39,634)	(11,683)
Interest income	4,094	1,628	614
Interest expense	(3,097)	(2,199)	(1,350)
Other (expense) income, net	(482)	213	204
Loss before benefit (provision) for income taxes	(129,357)	(39,992)	(12,215)
Benefit (provision) for income taxes	908	(10,398)	6,149
Net loss	\$ (128,449)	\$ (50,390)	\$ (6,066)
Basic and diluted loss per share	\$ (2.15)	\$ (0.86)	\$ (0.14)
Basic and diluted weighted average shares outstanding	59,862	58,800	42,888

See accompanying notes to consolidated financial statements.

# Nabi Biopharmaceuticals CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Commo	Common mmon Stock Warra			Capital in Excess of	Treasu	ry Stock	Retained Earnings (Accumulated	Other Accumulated Comprehensive	Total Stockholders'
In thousands	Shares	Amount	Shares	Amount	Par Value	Shares	Amount	Deficit)	Income (Loss)	Equity
Balance at December 28, 2002	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	,	, i i i i i i i i i i i i i i i i i i i			,					,
Purchase Plan	112	11		_	657	_		_	_	668
Directors fees paid in stock	3			_	22	_			_	22
Balance at December 27, 2003	57,723	5,773	133		297,909	(800)	(5,240)	20,874		319,316
Comprehensive loss	07,720	0,770	100		207,000	(000)	(0,210)	20,071		515,510
- Net loss for the year				_				(50,390)	_	(50,390)
- Currency translation adjustment					_		_	(50,550)	(303)	(303)
Comprehensive loss		_							(505)	(50,693)
Stock options exercised	1,534	153		_	9,667					9,820
1	1,554	155		_	9,007					9,020
Delivery of shares upon exercise of options	6	1			44	(A)	(57)			(17)
Compensation expense related to modified	0	1		_	44	(4)	(37)			(12)
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
Balance at December 25, 2004	59,429	5,943	—	_	313,494	(804)	\$(5,297)	(29,516)	(303)	284,321
Comprehensive loss										
- Net loss for the year	_	_		_	_			(128,449)		(128,449)
- Currency translation adjustment									474	474
Comprehensive loss	—	—	—	—		—	—			(127,975)
Stock options exercised	717	71			4,547			—	—	4,618
Delivery of shares upon exercise of										
options	8	1	—	—	23	(2)	(24)			
Compensation expense related to modified stock options					62					62
Stock options Stock issued under Employee Stock	_	_		_	02			_	_	02
Purchase Plan	167	17	—	_	765	_		—	—	782
Tax benefit of stock option exercises	_	_	_		_				_	
Warrants exercised	_	_	_	_	—	_	_	—	_	_
Directors fees paid in stock	2			_	19					19
Balance at December 31, 2005	60,323	\$6,032	_		\$318,910	(806)	\$(5,321)	\$ (157,965)	\$ 171	\$ 161,827

See accompanying notes to consolidated financial statements.

# Nabi Biopharmaceuticals CONSOLIDATED STATEMENTS OF CASH FLOWS

	<u> </u>		
In thousands	December 31, 2005	December 25, 2004	December 27, 2003
Cash flow from operating activities:	2005	2004	2003
Net loss	\$ (128,449)	\$ (50,390)	\$ (6,066
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:	¢ (1=0,110)	\$ (00,000)	¢ (0,000
Depreciation and amortization	18,985	18,294	15,854
Write-off of manufacturing right	2,684		9,735
Write down of vaccine plant	19,842	_	
Write-off of loan origination fees		539	232
Accretion of discount on Convertible Senior Notes	117	_	
Interest expense on non-interest bearing notes	652	1,222	589
Provision for doubtful accounts	9	428	39
Provision for slow moving or obsolete inventory	8,580	3,950	1,044
Non-cash compensation	863	1,129	1,040
Gain on sale of assets	(74)		
Deferred income taxes	(3,591)	4,714	(5,753
Tax benefit of stock option exercises	(0,001)	4,761	(0,700
Write-off of fixed assets	438	259	23
Other, primarily foreign currency translation	474	(422)	
Changes in assets and liabilities:	., .	()	
Trade accounts receivable	10,074	4,229	(775
Inventories	(10,728)	(685)	(4,983
Prepaid expenses and other current assets	7,207	2,323	170
Other assets	(178)	88	1,167
Income taxes payable	(1/0)	262	
Trade accounts payable and accrued expenses	(16,619)	18,153	(4, 784
Total adjustments	38,735	59,244	13,598
5			
Net cash (used in) provided by operating activities	(89,714)	8,854	7,532
Cash flow from investing activities:		(00.050)	
Purchases of marketable securities	(203,297)	(83,950)	_
Proceeds from sales of marketable securities	206,475	75,600	
Proceeds from sale of assets	74	179	
Capital expenditures	(8,712)	(22,633)	(8,050
Expenditures for Aloprim		(750)	
Expenditures for PhosLo	—	—	(61,245
Expenditures for manufacturing right – Dow	(24.0)		(2,024
Expenditures for manufacturing right – Cambrex Bio Science	(216)	(2,668)	(323
Net cash used in investing activities	(5,676)	(34,222)	(71,642
Cash flow from financing activities:			
Repayments of notes payable and capital leases	(10,955)	(5,449)	_
Borrowings of term debt	_	—	10,000
Repayments of term debt	_	—	(10,000
Proceeds from exercise of employee stock options	4,618	9,820	5,405
Proceeds from issuance of convertible debt, net	108,730		_
Issuance of common stock, net			122,724
Net cash provided by financing activities	102,393	4,371	128,129
Net increase (decrease) in cash and cash equivalents	7,003	(20,997)	64,019
Cash and cash equivalents at beginning of period	94,759	115,756	51,737
Cash and cash equivalents at end of period	\$ 101,762	\$ 94,759	\$ 115,756
con and cash equivalence at end of period	¢ 101,702	φ 34,705	φ 110,700

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 focused on developing products addressing the large commercial opportunities within our core business areas: Gram-positive bacterial infections, hepatitis, kidney disease (nephrology), and nicotine addiction. We have three products on the market today: Nabi-HB<sup>®</sup> [Hepatitis B Immune Globulin (Human)], Aloprim<sup>TM</sup> [Allopurinol sodium (for injection)], and PhosLo<sup>®</sup> (calcium acetate), and a number of products in various stages of clinical and pre-clinical development. We have also filed Marketing Authorization Applications, or MAAs, in Europe to market Nabi-HB<sup>TM</sup> Intravenous [Hepatitis B Immune Globulin (Human) Intravenous] under the trade name HEBIG<sup>TM</sup>, for the prevention of hepatitis B disease in HBV-positive liver transplant patients, and to market PhosLo in Europe, which is already marketed in the U.S. for the treatment of hyperphosphatemia in patients with end-stage renal disease.

Following the announcement of the outcome of the Phase III StaphVAX clinical trial and the resulting uncertainties we assessed the recoverability of certain assets supporting our StaphVAX Types 5 and 8 programs. As a result of this assessment, we recorded several charges totaling \$27.4 million in the fourth quarter. This includes charges for impairment of our vaccine manufacturing facility totaling \$19.8 million, write off of pre-launch StaphVAX inventory totaling \$4.9 million and impairment of our intangible manufacturing right asset totaling \$2.7 million. In addition, as a result of our withdrawing our Marketing Authorization Application, or MAA, for StaphVAX in Europe pursuant to the Phase III trial results, we changed our strategy for commercialization of PhosLo and HEBIG in Europe and plan to distribute these products through third party marketing partners. In conjunction with this changes in operations, in December 2005 we cancelled our pre-launch marketing activities for StaphVAX and made the decision to close our European office resulting in severance related costs for our European employees of \$0.6 million and other related costs of \$0.6 million. Further, in connection with placing our Altastaph clinical program on hold, we recorded a valuation allowance against all the deferred tax assets we had planned to utilize in a tax planning transaction for the European rights to this product between our U.S. entity and our non-U.S. subsidiary . As a result, we recorded a valuation allowance against all deferred tax assets in the amount of \$78.2 million. Refer to Note 14.

#### 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:* Certain items in the 2004 and 2003 consolidated financial statements have been reclassified to conform to the current year's presentation including payments of \$0.1 million under capital leases reclassified as financing activities previously included in operating activities on the Consolidated Statements of Cash Flows.

*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 year ending December 31, 2005 was a 53-week year with the additional week included in the fourth quarter of 2005. The fiscal years ended December 25, 2004 and December 27, 2003 were 52-week years.

*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 known as chargebacks, government payer rebates, customer returns 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, business considerations for customer purchases and estimated inventory levels. If our actual experience proves to be different 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 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 reasonably ascertainable 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 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.

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 31, 2005, December 25, 2004 and December 27, 2003 amounted to \$4.0 million, \$3.8 million and \$3.3 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 \$0.3 million, \$0.5 million and \$0.5 million of such costs, in the years ended December 31, 2005, December 25, 2004 and December 27, 2003, respectively.

*Comprehensive Loss:* We follow Statement of Financial Accounting Standards, or SFAS, No. 130, *Reporting Comprehensive Income*, which computes comprehensive income as the total of net income and all other non-owner changes in shareholders' equity. For the year ended December 31, 2005, comprehensive loss included our net loss and the effect of foreign currency translation adjustments, net of tax. As of December 31, 2005 and December 25, 2004, \$0.2 million and \$0.3 million of foreign currency income (loss), respectively, was included on our balance sheet in addition to accumulated deficit. 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 either license or partner our products in the markets the subsidiaries operate in, primarily Europe.

*Loss per share:* Basic loss per share is computed by dividing consolidated net loss by the weighted average number of common shares outstanding during the year. Diluted loss per share is computed by dividing consolidated net loss 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 2005, 2004 and 2003, we did not apply this method as there would have been an anti-dilutive effect on earnings per share. There were 1,844,087, 2,101,279 and 1,172,833 potential dilutive shares excluded in the calculation of diluted weighted average shares outstanding in 2005, 2004 and 2003, respectively.

*Financial instruments:* The carrying amounts of financial instruments including cash equivalents, marketable securities, trade accounts receivable and trade accounts payable approximated fair value as of December 31, 2005 and December 25, 2004, because of the relatively short-term maturity of these instruments. Total convertible senior notes, notes payable debt and capital leases obligations were \$122.7 million as of December 31, 2005 and \$23.9 million as of December 25, 2004. The carrying value of our convertible senior notes at December 31, 2005 is \$109.1 million compared to the fair value of \$90.1 million base on current market rates. The carrying amounts of our notes payable and capital lease obligations approximate their fair value and are calculated using an interest rate consistent with our current borrowing rate. Information regarding debt is included in Note 9.

*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, if we have any, are included in "Other comprehensive income" in the accompanying consolidated balance sheet and consolidated statement of changes in stockholders' equity and at December 31, 2005 and December 25, 2004 we did not have any.

*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 AmerisourceBergen, Telecris Biotherapeutics Corporation, Greencross Corporation and McKesson Drug Co., representing 39%, 13% 12% and 8% of our total accounts receivable, respectively at December 31, 2005. If the financial condition or operations of these customers and our other significant customers such as Cardinal Healthcare 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 once these products have attained a stage in the development process of having been subject to a Phase III clinical trial or its equivalent, or if a regulatory filing has been made for licensure for marketing the product and the product 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's 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.

*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 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.

Depreciable lives of property and equipment are as follows:

Asset	Initial Useful Life
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. 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:

Asset	Estimated Remaining Useful Life
PhosLo trademark/tradename	15.3 years
PhosLo tablet patent	1.3 years
PhosLo Gelcap patent	15.3 years
PhosLo customer relationships	2.6 years
PhosLo covenant not to compete	12.6 years
Other intangible assets	3.5 to 11.8 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 from the date of acquisition. We have established an initial 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.

*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. We incurred \$21.5 million in total costs to construct our vaccine manufacturing facility in Boca Raton, Florida in support of the anticipated global launch of StaphVAX. This facility was placed into service and began depreciating in February 2005. As a result of the Phase III clinical trial for StaphVAX not meeting its primary end point, we wrote down the carrying value to its estimated fair market value as determined by an outside valuation firm to \$0.5 million and recorded a \$19.8 million impairment charge during 2005.

*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 and director 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 31, 2005, December 25, 2004 and December 27, 2003 for stock-based employee awards granted at the market price. We did recognize expense related to modification of stock option terms related to the retirement of certain employees including \$0.1 million, \$0.2 million and \$0.4 million for the years ended December 31, 2005, December 25, 2004 and December 27, 2003, respectively. Refer to Note 19. We follow the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123, as amended by SFAS No. 148, Accounting for Stock-Based Compensation—Transition and Disclosure —an amendment of FASB Statement No. 123, or SFAS 148, for stock options issued to non-employees.

The following table summarizes our results as if we had recorded stock-based compensation expense for the years ended December 31, 2005, December 25, 2004 and December 27, 2003, based on the provisions of SFAS No. 123, as amended by SFAS No. 148:

(In thousands, except per share amounts)	December 31, 2005	December 25, 2004	December 27, 2003
Net loss:			
As reported	\$ (128,449)	\$ (50,390)	\$ (6,066)
Add: Stock-based employee compensation expense included in reported net loss, net of tax	62	150	350
Deduct: Total stock-based employee compensation expense determined under fair value based			
method, net of tax	(35,345)	(4,567)	(3,977)
Pro forma	\$ (163,732)	\$ (54,807)	\$ (9,693)
Basic and diluted loss per share:			
As reported	\$ (2.15)	\$ (0.86)	\$ (0.14)
Add: Stock-based employee compensation expense included in reported net loss, net of tax	—		_
Deduct: Total stock-based employee compensation expense determined under fair value based			
method, net of tax	(0.59)	(0.08)	(0.08)
Pro forma	\$ (2.74)	\$ (0.94)	\$ (0.22)

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 48 - 87%; and expected risk-free interest rates of 3.92 - 4.96%. The weighted-average estimated fair value of options granted during 2005, 2004 and 2003 was \$6.01, \$8.31 and \$4.45, respectively. Refer to Note 10.

On December 20, 2005, the Compensation Committee of our Board of Directors approved the acceleration of vesting of all unvested options to purchase our common stock having an exercise price of \$6.00 or higher, effective for all outstanding options as of December 20, 2005. The closing price or our common stock on December 20, 2005 was \$3.35 per share. As a result, the pro forma compensation expense presented in accordance with the provisions of FAS 148 reflected this acceleration. Refer to Note 10.

Included in the total above stock based employee compensation expense determined under the fair value based method, net of tax is \$2.1 million that would have been eligible for capitalization into inventory under FAS 123. Once adopted, FAS 123 requires that we include compensation expense related to stock options in the carrying value of the assets eligible for internal capitalization.

*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. 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. The gains and losses that result from this process are shown in "Other accumulated comprehensive income (loss)" in the accompanying consolidated balance sheets. Amounts in the statements of operations 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.

*New accounting pronouncements:* In April 2005, the SEC announced that Statement of Financial Accounting Standard, or SFAS, No. 123(R), *Share-Based Payment*, which requires all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value, had been deferred. SFAS No. 123(R) 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. 123(R) will be material to our reported results of operations. Using the Black-Scholes model for valuing stock options under SFAS No. 123(R) would result in pre-tax expense for options granted in prior years in the amount of \$1.7 million, \$1.7 million and \$2.0 million in 2006, 2007 and 2008, respectively. SFAS No. 123(R) became applicable to us beginning January 1, 2006.

On December 20, 2005, the Compensation Committee of our Board of Directors approved the acceleration of vesting of all unvested options to purchase our common stock having an exercise price of \$6.00 or higher, effective for all outstanding options as of December 20, 2005. The closing price of our common stock on December 20, 2005 was \$3.35 per share. All other terms and conditions applicable to such options, including the exercise prices, remain unchanged. The affected options were previously granted to our employees, including our executive officers, under the Company's 2000 Equity Incentive Plan and its 1998 Non-Qualified Employee Stock Option Plan. Options to purchase 3,962,159 shares of our common stock, or 96% of our outstanding unvested options, are subject to this acceleration and such options have exercise prices ranging from \$6.00 to \$17.15 per share and a weighted average exercise price of \$12.51 per share. Of the accelerated options, approximately 778,099 are held by our Named Executive Officers included in the Summary Compensation Table in the Company's 2005 Definitive Proxy Statement filed with the Securities and Exchange Commission on April 8, 2005.

Our decision to accelerate the vesting of the affected options was based primarily upon the issuance of SFAS No. 123(R), which will require us to treat all unvested stock options as compensation expense effective January 1, 2006. We believe that the acceleration of vesting of the affected options will enable us to avoid recognizing stock-based compensation expense associated with these options in future periods. We estimate this compensation expense, before tax, would total \$26.7 million (excluding the impact of forfeitures), which would have been recognized over approximately the next 3 years from the date of the acceleration. Compensation expense for options granted in prior years not subject to acceleration of vesting as described above at fair value is expected to be approximately \$1.7 million in 2006, \$1.7 million in 2007 and \$2.0 million in 2008.

Statement 123(R) permits public companies to adopt its requirements using one of two methods:

A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123(R) for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date.

A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate, based on the amounts previously recognized under Statement 123(R) for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

We plan to adopt Statement 123(R) using the modified prospective method.

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 overhead to the costs of conversion be based on the normal capacity of the production facilities. We do not expect the adoption of SFAS No. 151 to have a material impact on our financial condition, results of operations or cash flows.

In October 2005, the FASB announced that FSP No. 13-1, *Accounting for Rental Costs Incurred during a Construction Period*, is effective for reporting periods beginning after December 15, 2005. This Position concludes that rental costs incurred during and after a construction period are for the right to control the use of a leased asset during and after construction of a lessee asset, and that there is no distinction between the right to use a leased asset during the construction period are for the construction period and the right to use that asset after the construction period. This Position requires that rental costs associated with ground or building operating leases that are incurred during a construction period be recognized as rental expense, included in income from continuing operations. We do not expect the adoption of FSP No. 13-1 to have an impact on our financial condition, results of operations or cash flows.

#### NOTE 3 TRADE ACCOUNTS RECEIVABLE

Trade accounts receivable are composed of the following:

In thousands	De	December 31, 2005		cember 25, 2004
Trade accounts receivable	\$	22,328	\$	32,838
Allowance for doubtful accounts	_	(6)		(433)
Total	\$	22,322	\$	32,405

The allowance for doubtful accounts has decreased as a result of us writing off previously reserved bad debt.

#### **NOTE 4 INVENTORIES**

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

(In thousands)	December 31, 	December 25, 2004
Finished goods	\$ 13,594	\$ 11,475
Work in process	7,531	7,826
Raw materials	1,198	874
Total	\$ 22,323	\$ 20,175

The net inventory balances include provisions against inventory that have been recorded in accordance with our stated accounting policy.

Work in process inventory at December 31, 2005, 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. Work in process inventory at December 25, 2004 primarily consisted of Nabi-HB as well as pre-launch inventories of StaphVAX and Nabi-HB Intravenous. We have made and anticipate in future periods that we 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 European Medicines Agency, or EMEA, approval in the EU or FDA approval, in the U.S. (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, in future periods we may scale-up and build pre-launch inventories of certain products that have not yet received final governmental approval. At December 31, 2005 we had fully reserved pre-launch inventory and at December 25, 2004, we had approximately \$2.3 million of pre-launch inventories of StaphVAX and Nabi-HB Intravenous, pending final 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 if a regulatory filing has been made for licensure for marketing the product and the product 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's shelf life.

During 2005, we reserved \$4.9 million of StaphVAX pre-launch inventory based on the outcome of our Phase III clinical trial for StaphVAX that did not meet its primary end point and our withdrawal of our MAA for StaphVAX from consideration by the European Medicines Agency, or EMEA. Refer to Note 14. In addition, reserved \$0.8 million of Nabi-HB Intravenous during 2005 as a result of its shelf life being inadequate compared to the timing of our sales projections.

# NOTE 5 PROPERTY, PLANT AND EQUIPMENT

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

(in thousands)	December 31, 2005	December 25, 2004
Information systems	\$ 26,758	\$ 25,007
Leasehold improvements	7,004	8,064
Machinery and equipment	57,179	51,984
Land and buildings	44,929	50,099
Building systems	10,017	8,415
Furniture and fixtures	3,471	3,332
Capital leased property	539	674
Asset retirement obligation	193	
Construction in progress	2,098	19,170
Property, plant and equipment, gross	152,188	166,745
Less accumulated depreciation	(58,104)	(51,339)
Property, plant and equipment, net	\$ 94,084	\$ 115,406

We received FDA licensure to manufacture Nabi-HB at our biopharmaceutical manufacturing facility in 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 Florida 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 2005, 2004 and 2003 was \$10.1 million, \$9.5 million and \$10.3 million, respectively. Depreciation expense related to the initial operation of our biopharmaceutical manufacturing facility in 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 \$2.1 million, \$2.5 million and \$1.6 million in 2005, 2004 and 2003, 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 \$0.2 million for 2005, \$0.1 million for 2004 and zero for 2003.

We have capitalized costs related to the purchase and implementation of computer software totaling \$2.5 million, \$1.3 million and \$0.9 million during 2005, 2004 and 2003, respectively. In addition, we have recorded amortization expense related to capitalized software costs of \$0.9 million, \$1.1 million and \$0.8 million during 2005, 2004 and 2003, respectively, and have included these amounts in the total depreciation expenses above.

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 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.

Following completion of our vaccine manufacturing plant within our Florida facility in April 2005, we placed the asset into service. The primary commercial purpose of the vaccine facility was for the manufacture of our StaphVAX vaccine. In November 2005, we announced that the Phase III clinical trial of StaphVAX did not meets its defined clinical end point and our StaphVAX clinical development program was placed on clinical hold. Following the outcome of this clinical trial and in accordance with the provisions of Statement of Financial Accounting Standards, or SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, we reviewed the carrying value of the vaccine plant of \$20.4 million for impairment. As a result of not having financial projections in the near term that support the carrying value, we have written down the facility to its fair market value as determined by on outside valuation firm of \$0.5 million and reported a charge of \$19.8 million during 2005. Refer to Note 14.

Construction in progress primarily consisted of costs related to the development of an information technology system at December 31, 2005. At December 25, 2004, construction in progress primarily consisted of costs related to the construction of our vaccine manufacturing plant within our Florida facility. Interest capitalized in connection with construction in progress was \$0.1 million and \$0.3 million in 2005 and 2004, respectively.

# NOTE 6 INTANGIBLE ASSETS

Intangible assets consist of the following:

(in thousands)	Dee	December 31, 2005		ember 25, 2004
PhosLo related:				
Trademark/tradename	\$	1,423	\$	1,423
Tablet patent		11,381		11,381
Gelcap patent		80,670		80,670
Customer relationships		2,337		2,337
Covenant-not-to-compete		508		508
Manufacturing right – Cambrex				2,992
Other intangible assets		4,389		4,389
Total intangible assets		100,708		103,700
Less accumulated amortization		(22,376)		(13,972)
Total	\$	78,332	\$	89,728

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 September 27, 2005, we filed a lawsuit in the United States District Court for the Southern District of Ohio against Roxane Laboratories, Inc., or Roxane, for infringement of our U.S. PhosLo Gelcap patent. We filed this lawsuit under the Hatch-Waxman Act in response to a Paragraph IV Certification notice letter submitted by Roxane to us concerning Roxane's filing of an Abbreviated New Drug Application or, ANDA, with the FDA to market a generic version of PhosLo Gelcaps on the basis that Roxane's submission of its ANDA and its proposed generic product infringed patent held by the Company. The patent expires in 2021. Under the Hatch-Waxman Act, FDA approval of Roxane's proposed generic product will be stayed until the earlier of 30 months or resolution of the patent infringement lawsuit.

In October 2003, we entered into a contract manufacturing agreement with Cambrex Bio Science Baltimore, Inc., or Cambrex Bio Science. We commenced amortization of the manufacturing right in 2004. In December 2005, we determined that the manufacture of StaphVAX would not occur at Cambrex Bio Science's facility as a result of the Phase III clinical trial for StaphVAX not meeting its primary end point and our MAA for StaphVAX being withdrawn from consideration by EMEA. In accordance with our stated accounting policy, we wrote-off the unamortized intangible asset amount of \$2.7 million during 2005. Refer to Note 14.

Amortization of intangible assets during 2005, 2004 and 2003 was \$8.9 million, \$8.7 million and \$5.4 million, respectively. Amortization expense for intangible assets currently subject to amortization is expected to be \$8.5 million, \$6.2 million, \$5.2 million, \$4.8 million, and \$4.8 million in each of the five fiscal years subsequent to December 31, 2005, respectively.

# NOTE 7 ACCRUED EXPENSES

Accrued expenses consist of the following:

(in thousands)	Dec	December 31, 2005		cember 25, 2004
Sales deductions				
Accrued chargebacks	\$	2,080	\$	4,417
Accrued rebates		7,357		2,580
Accrued discounts		1,350		1,067
Other accrued sales deductions		632		488
Total accrued sales deductions		11,419		8,552
Employee compensation and benefits		4,876		8,411
Accrued royalties and product costs		483		5,236
Accrued clinical trial expenses		3,534		5,152
Accrued construction services fees		—		873
Accrued professional services		432		883
Accrued European expenses		1,462		222
Other		3,700		2,961
Total	\$	25,906	\$	32,290

# NOTE 8 CREDIT FACILITY

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 consolidated 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 DEBT

Debt consists of the following:

(in thousands)	December 31, 2005	December 25, 2004
Current maturities:		
Notes payable, PhosLo acquisition	\$ 2,389	\$ 9,949
Capital lease obligations	223	224
Total current maturities	2,612	10,173
Long term debt, net of current maturities:		
Notes payable, PhosLo acquisition long-term	10,707	13,340
Capital lease obligations	238	331
Long term notes payable and capital lease obligations, net	10,945	13,671
2.875% Convertible Senior Notes, net	109,145	
Total long-term debt	120,090	13,671
Total debt	\$ 122,702	\$ 23,844

On April 19, 2005, we issued \$100 million of our 2.875% Convertible Senior Notes, or the Notes, due 2025 through a private offering to qualified institutional buyers as defined in Rule 144A under the Securities Act. On May 13, 2005, the initial purchasers exercised \$12.4 million of their option to purchase additional Notes to cover over allotments.

The Notes were issued pursuant to an indenture between U.S. Bank National Association, as trustee, and us. The Notes are convertible, at the option of the holders, into shares of our common stock at a rate of 69.8348 shares per \$1,000 principal amount of notes, which is equivalent to a conversion price of approximately \$14.32 per share, subject to adjustment upon the occurrence of certain events. The initial implied conversion price represents a 30% premium over the closing sale price of our common stock on April 13, 2005, which was \$11.015 per share. The Notes, which represent our general, unsecured obligations, will be redeemable by us at 100% of their principal amount, or \$112.4 million, plus accrued and unpaid interest, any time on or after April 18, 2010. Holders of the Notes may require us to repurchase them for 100% of their principal amount, plus accrued and unpaid interest, on April 15, 2010, April 15, 2012, April 15, 2015 and April 15, 2020, or following the occurrence of a fundamental change as defined in the indenture governing the Notes.

The following table reconciles the net proceeds received from the sale of the Notes:

(in thousands)	
Cash received:	
Proceeds from issuance	\$ 112,400
Professional fees paid:	
Discount granted to initial purchasers	(3,372)
Legal and accounting fees	(256)
Other	(42)
	(3,670)
Net proceeds	\$108,730

Interest on the Notes is payable on each April 15 and October 15, beginning October 15, 2005. Accrued and unpaid interest related to the Notes was \$0.7 million at December 31, 2005. The \$3.4 million discount granted to the initial purchaser of the Notes and the \$0.3 million of deferred costs are being amortized to interest expense through April 15, 2020, the maturity date of the Notes.

On August 4, 2003, we acquired the worldwide rights to PhosLo from Braintree Laboratories, Inc., or Braintree. Under the terms of the agreement to acquire PhosLo, we agreed to pay \$30.0 million in cash over the period ending March 1, 2007. The discounted value of the future payment obligation on December 31, 2005 was \$13.1 million and has been reported as Notes payable, PhosLo acquisition. The future payment obligation was discounted at 4.5%, our estimated rate of interest under our credit facility in effect on August 4, 2003, the date of the closing of the agreement.

#### NOTE 10 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 proceeds of \$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%.

#### 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 2005 or 2004. 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 7,500 shares in 2005, a former officer of the Company exercised stock options for 6,250 shares in 2004, and two members of our Board of Directors exercised stock options for 639,311 shares and 4,500 shares, respectively, in 2003. These purchases were paid for by delivery of 1,958 shares of

common stock in 2005, 3,496 shares of common stock in 2004, and 411,956 and 2,371 shares of common stock in 2003, which were valued at \$24 thousand, \$57 thousand, \$3.1 million and \$16 thousand for the respective transactions. In each of the transactions, the shares delivered had been acquired more than six months earlier. 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.

On December 20, 2005, the Compensation Committee of our Board of Directors approved the acceleration of vesting of all unvested options to purchase our common stock having an exercise price of \$6.00 or higher, effective for all outstanding options as of December 20, 2005. The closing price of our common stock on December 20, 2005 was \$3.35 per share. All other terms and conditions applicable to such options, including the exercise prices, remain unchanged. The affected options were previously granted to our employees, including our executive officers, under the Company's 2000 Equity Incentive Plan and its 1998 Non-Qualified Employee Stock Option Plan. Options to purchase 3,962,159 shares of the our common stock, or 96% of our outstanding unvested options, are subject to this acceleration and such options have exercise prices ranging from \$6.00 to \$17.15 per share and a weighted average exercise price of \$12.51 per share. Of the accelerated options, approximately 778,099 are held by our Named Executive Officers included in the Summary Compensation Table in our 2005 Definitive Proxy Statement filed with the Securities and Exchange Commission on April 8, 2005.

Our decision to accelerate the vesting of the affected options was based primarily upon the issuance by the Financial Accounting Standards Board of SFAS No. 123(R), which will require us to treat all unvested stock options as compensation expense effective January 1, 2006. We believe that the acceleration of vesting of the affected options will enable us to avoid recognizing stock-based compensation expense associated with these options in future periods. We estimate this compensation expense, before tax, would total \$26.7 million (excluding the impact of forfeitures), which would have been recognized over approximately the next 3 years from the date of the acceleration.

During 2005 and 2004, we modified stock options for certain of our employees and, as a result, incurred charges of \$0.1 million and \$0.2 million, respectively. 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 19.

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 2005, one director elected to receive his annual retainer in common shares, receiving 1,201 shares of common stock. During 2003, two directors elected to receive their annual retainers in common shares, receiving 3,318 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 31, 2005, there were options outstanding under our various stock plans to acquire a total of 8.7 million shares of our common stock of which options for 8.5 million shares were then exercisable. Additionally, 3.1 million shares of common stock are reserved for future grants under the plans mentioned above.

Stock option activity is discussed below:

	Options (in thousands)	Exercise Price per Share	Weighted Average Exercise Price	
Balance at December 28, 2002	7,988	\$ 1.63 -13.75	\$	6.51
Granted	1,937	5.09 - 11.25		6.00
Exercised	(1,809)	1.63 - 11.13		4.46
Canceled	(1,002)	2.88 - 13.75		8.22
Balance at December 27, 2003	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
Balance at December 25, 2004	7,991	2.63 - 17.15		9.38
Granted	1,979	3.10 - 15.14		11.70
Exercised	(725)	2.69 - 14.85		6.41
Canceled	(546)	2.69 - 16.54		12.39
Balance at December 31, 2005	8,699	\$ 2.63 -17.15	\$	9.96

		Outstanding		Exercisable	
Exercise Price Range	Options (in thousands)	Average Years Remaining	Average Exercise Price	Options (in thousands)	Average Exercise Price
\$2.63 - \$4.25	488	3.1	\$ 3.08	460	\$ 3.06
\$4.35 - \$7.47	2,991	5.6	\$ 6.02	2,855	\$ 6.04
\$8.00 - \$11.25	1,008	5.4	\$ 9.65	1,008	\$ 9.65
\$11.69 - \$17.15	4,212	8.4	\$13.64	4,194	\$13.63
	8,699			8,518	

# 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 167,413, 90,382 and 112,494 shares of common stock during 2005, 2004 and 2003, respectively, pursuant to this plan at an average price per common share of \$4.85, \$10.60 and \$5.94, respectively.

#### 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 our 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 31, 2005, a total of 11.8 million shares of common stock in the aggregate were reserved for issuance under our stock options and employee benefit plans.

#### NOTE 11 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. If we choose to sell Securities under this shelf registration statement, we plan to use any such net proceeds 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 12 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 were obligated to purchase \$3.0 million of Aloprim product under this agreement and have a remaining commitment of \$2.7 million at December 31, 2005. Refer to Note 21.

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 31, 2005 was \$13.1 million of which \$2.4 million has been reported as a current liability under the caption, notes payable, and the balance of \$10.7 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:

(in thousands)	Decen	ıber 31, 2005
Notes payable, PhosLo acquisition	\$	13,095
Less current maturities		(2,388)
Notes payable, PhosLo acquisition, long-term	\$	10,707

The repayment terms for the notes payable, PhosLo Acquisition 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 \$3.1 million and \$10.8 million for the years ended 2006 and 2007, respectively.

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

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

#### NOTE 13 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. On March 24, 2005 our agreement to distribute WinRho SDF ended and we ceased distribution of that product. Net sales of WinRho SDF totaled \$6.2 million, \$47.9 million and \$50.0 million for the years ended December 31, 2005, December 25, 2004 and December 27, 2003, respectively.

# NOTE 14 STAPHVAX

On November 1, 2005, we announced the results of our Phase III clinical trial for StaphVAX. The results showed that the clinical trial did not meet its primary end point. In accordance with our accounting policy, we assess the carrying value of long term assets compared to the undiscounted future cash flows generated from the asset's intended use at least annually, or in circumstances where impairment may be indicated. In accordance with our accounting policy, we assessed the carrying value of the Cambrex Bio Science manufacturing right intangible asset and identified that we would not utilize their facility for the commercial manufacture of StaphVAX and wrote-off the carrying value of that intangible asset in the amount of \$2.7 million. Refer to Note 6. Further, we evaluated our vaccine manufacturing facility within our Florida manufacturing facility for impairment. As a result of not having financial projections in the near term that support the carrying value, we have written down the facility to its estimated fair market value as determined by an outside valuation firm. Based on this valuation, we have determined that the carrying value should be impaired to \$0.5 million and reported a charge of \$19.8 million. Refer to Note 5. We assessed the carrying value for pre-launch StaphVAX inventory. As a result of their not being an ongoing Phase III clinical trial, or pending marketing application for this product, we concluded that the entire carrying balance for StaphVAX pre-launch inventory, a total of \$4.9 million, should be impaired. Refer to Note 4.

# NOTE 15 INCOME TAXES

Income before income taxes was taxed domestically only.

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

		For the Years Ended			
	December 31,	December 25,	December 27,		
(in thousands)	2005	2004	2003		
Current:					
Federal	\$ —	\$ 5,413	\$ —		
State	(76)	271	(396)		
Subtotal	(76)	5,684	(396)		
Deferred:					
Federal	(75,420)	4,511	(5,465)		
State	(3,969)	203	(288)		
Subtotal	(79,389)	4,714	(5,753)		
Total	(79,465)	10,398	(6,149)		
Valuation allowance	78,556				
Total	\$ (908)	\$ 10,398	\$ (6,149)		

Deferred tax assets and liabilities are comprised of the following:

		Years Ended	
(in thousands)	December 31, 2005	December 25, 2004	
Deferred tax assets:			
Net operating loss carryforwards	\$ 29,940	\$ 3,076	
Research and development tax credit	16,340	12,464	
Inventory reserve and capitalization	4,956	2,639	
Amortization	2,477	2,555	
Bad debt reserve	2	162	
Inter-company bad debt reserve	29,670	—	
Depreciation	1,296	1,296	
Alternative minimum tax credit	1,187	1,117	
Accrued retirement	468	849	
PhosLo tax interest	277	—	
Sales deductions	3,212	—	
Accrued workers compensation	961	_	
Vaccine facility impairment	7,401	—	
Other	354	498	
Deferred tax assets	98,541	24,656	
Deferred tax liabilities:			
Depreciation	(19,985)	(19,733	
Other		(1,332	
Deferred tax liabilities	(19,985)	(21,065	
Net deferred tax assets	78,556	3,591	
Valuation allowance	(78,556)		
Net deferred tax assets	<u> </u>	\$ 3,591	

We have net operating loss carryforwards of approximately \$97.2 million that expire at various dates through 2024. Approximately \$17.0 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 \$6.3 million through capital in excess of par value when such losses are realized. A portion of our deferred tax assets relate to a tax planning transaction that took place during 2004. As a result of our change in strategy for distributing products in Europe, those assets could be limited in their use and, once liquidated, could be deemed capital losses that would expire with a 5 year limitation.

We have research and development tax credit carryforwards of \$16.3 million that expire in varying amounts through 2025. We have alternative minimum tax credit carryforwards of \$1.2 million that are available to offset future regular tax liabilities and do not expire.

We anticipated the tax planning strategy we had in place at the end of 2004 and throughout 2005 would be able to generate sufficient future taxable income to utilize our deferred tax assets at those dates, however after the November 1, 2005 announcement regarding the StaphVAX clinical trial, we determined that a full valuation allowance would be required against all of our deferred tax assets that we do not expect to be utilized by deferred tax liabilities. Refer to Note 14. As a result, we recorded a \$78.6 million valuation allowance is necessary as of December 31, 2005.

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

		For the Years Ended	
(in thousands) Pre-tax loss:	December 31, 	December 25, 2004	December 27, 2003
	¢ (100.027)	¢ (20,000)	¢ (10.01F)
U.S.	\$ (109,927)	\$ (29,908)	\$ (12,215)
Ex-U.S.	(19,430)	(10,084)	
Total	\$ (129,357)	\$ (39,992)	\$ (12,215)

Our ex-U.S. losses are primarily in zero-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 31, 2005	December 25, 2004	December 27, 2003		
Federal statutory rate	(34.0)%	(34.0)%	(34.0)%		
State income taxes, net of federal benefit	(3.3)	(3.3)	(3.3)		
Foreign tax rate differential	5.6	(12.1)	_		
Inder-company bad debt	(22.9)	—	—		
Foreign sales benefit and nondeductible items		0.1	(2.2)		
tax credits	(2.0)	(3.0)	(10.8)		
Gain on sale of intellectual property		75.8	_		
Valuation allowance	57.3	_	—		
Other	(1.4)	2.5	_		
Total	(0.7)%	26.0%	(50.3)%		

# NOTE 16 EARNINGS PER SHARE

The following table reconciles basic and diluted loss per share for the years ended December 31, 2005, December 25, 2004 and December 27, 2003:

			Effect of Dilut		
Amounts in thousands, Except Per Share Data		asic (Loss) rnings Per Share	Stock options and other dilutive Securities	F	Diluted (Loss) Earnings er Share
2005					
Net loss	\$ (	(128,449)	—	\$(	128,449)
Shares		59,862	—		59,862
Per share amount	\$	(2.15)		\$	(2.15)
2004					
Net loss	\$	(50,390)	—	\$	(50,390)
Shares		58,800	—		58,800
Per share amount	\$	(0.86)	—	\$	(0.86)
2003					
Net loss	\$	(6,066)	—	\$	(6,066)
Shares		42,888	—		42,888
Per share amount	\$	(0.14)		\$	(0.14)

#### NOTE 17 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. The discretionary company match for employee contributions to the Plan is 100% of up to the first 4% of the participant's earnings contributed to the Plan. Our matching contributions to the Plan were approximately \$1.4 million in 2005, \$1.4 million in 2004, and \$1.1 million in 2003, respectively.

#### NOTE 18 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, \$3.5 million and \$3.3 million for the years ended December 31, 2005, December 25, 2004 and December 27, 2003, respectively.



As of December 31, 2005, 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:

Year Ending	(in	thousands)
2006	\$	2,300
2007		1,746
2008		1,777
2009		493
2010		277
Thereafter		484
Total minimum lease commitments	\$	7,077

We currently lease a facility in Bray, Ireland for which we have lease obligations of \$0.1 million in 2006, \$0.1 million in 2007, \$0.1 million in 2008, \$0.1 million in 2009, \$0.1 million in 2010 and \$0.3 million thereafter. Due to our decision to close our operations in Ireland in December 2005 we are currently seeking to sub-lease this facility.

During 2005, we have recorded assets under capital leases that are included in property, plant and equipment totaling \$0.5 million. The following schedule summarizes future minimum lease payments under capital leases with terms greater than one year as of December 31, 2005:

(in th	ousands)
\$	437
	401
	838
	377
	461
	223
\$	238
	<u>(in th</u> \$

We entered into a lease agreement dated June 29, 2005 for a research and development facility in Gaithersburg, Maryland. Our obligation to pay rent under this agreement commenced January 1, 2006, however, we terminated this lease on October 31, 2005 by written notice accompanied by a \$0.8 million termination fee.

#### NOTE 19 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, as of December 31, 2005 and in accrued expenses as of, December 25, 2004 and December 27, 2003. Cash payments are being paid over three years commencing January 2004. There was no long-term portion in 2005 and in 2003 the long-term portion was included in other long-term liabilities.

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 12. 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 years ended December 31, 2005 and December 25, 2004 and during the year ended December 27, 2003 we paid \$0.5 million to Stonebridge, pursuant to the financial advisory services agreement.

There is no amounts receivable from corporate officers at December 31, 2005 or December 25, 2004.

#### NOTE 20 STRATEGIC ALLIANCES, LICENSES AND ROYALTY AGREEMENTS

Under a license and distribution agreement with Cangene, we had exclusive rights to distribute and market WinRho SDF in the U.S. through March 2005. On March 24, 2005, our agreement to distribute WinRho SDF ended and we ceased distribution of that product.

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 21 COMMITMENTS AND CONTINGENCIES

In 2005, we engaged an outside consultant to assess our pricing programs and in connection with that assessment it was determined that we may have inadvertently underpaid certain rebates due under Medicaid and likely other governmental pricing programs during the period from 2003 to 2005 due to the extension of best prices to ineligible entities. As a result we have established an accrual of approximately \$5.0 million in our financial statements for the future payment of those rebates. This amount represents our best estimate of the extent to which we underpaid amounts due under Medicaid and other governmental pricing programs during the period from 2003 to 2005, including amounts owing to the DVA and PHS. We expect to make the requisite payments during 2006. The amount also assumes that we will be successful in rebilling ineligible entities that improperly received best prices. We believe we have properly estimated the underpaid amounts due under Medicaid and other governmental pricing programs. However, if we are unable to effectively rebill and collect proper prices from ineligible entities we may be required to make additional payments to Medicaid and other similarly affected governmental pricing programs, all of which could have a material adverse effect on our future business, operating results and financial condition.

In connection with the determination that we have underpayments and overcharges under the Medicaid, PHS and FSS programs, we expect to engage in discussions with representatives of the Centers for Medicare and Medicaid Services, the DVA, the PHS and the Department of Defense. These discussions could include a detailed review by these agencies of our calculations of our underpayments and overcharges, and it is possible that this review could result in material changes to our calculations. Resolving the amounts owed to governmental agencies in connection with the underpayments has resulted, and is expected to continue to result, in a significant diversion of management's attention and resources and an increase in professional fees which could have a material adverse effect on our future business, results of operations and financial condition.

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. Refer to Note 12. Our purchase commitment requires us to purchase \$0.9 million in 2006, \$0.7 million in 2007, \$0.7 million in 2008 and \$0.4 million in 2009.

In accordance with the terms of our termination agreement with Cambrex we are obligated to pay Cambrex approximately \$0.1 million for reimbursement of certain expenses.

As of December 31, 2005, we had open purchase order commitments of \$5.5 million.

See lease commitments discussed at Note 18 for other commitments.

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 22 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:

(in thousands)	December 31, 2005	December 25, 2004	December 27, 2003
Sales:			
Biopharmaceutical products	\$ 62,137	\$ 131,813	\$ 109,459
Antibody products	45,918	47,950	67,111
	\$ 108,055	\$ 179,763	\$ 176,570
Gross margin:			
Biopharmaceutical products	\$ 30,924	\$ 82,086	\$ 72,104
Antibody products	6,291	3,763	4,725
	\$ 37,215	\$ 85,849	\$ 76,829
Operating loss:			
Biopharmaceutical products	\$ (126,343)	\$ (35,361)	\$ (6,712)
Antibody products	(3,529)	(4,273)	(4,971)
	\$ (129,872)	\$ (39,634)	\$ (11,683)
Depreciation and amortization expense:			
Biopharmaceutical products	\$ 16,928	\$ 15,771	\$ 12,893
Antibody products	1,735	2,090	2,655
	\$ 18,663	\$ 17,861	\$ 15,548
Capital expenditures:			
Biopharmaceutical products	\$ 4,779	\$ 20,274	\$ 3,594
Antibody products	372	450	1,555
	\$ 5,151	\$ 20,724	\$ 5,149
Assets:			
Biopharmaceutical products	\$ 249,579	\$ 309,467	
Antibody products	70,720	50,997	
	\$ 320,299	\$ 360,464	

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

	For the Years Ended		
(in thousands)	December 31, 2005	December 25, 2004	December 27, 2003
(Loss) income before income taxes:			
Reportable segment operating (loss) income	\$ (129,871)	\$ (39,634)	\$ (11,683)
Unallocated interest expense	(3,098)	(2,199)	(1,350)
Unallocated other income and expense, net	3,612	1,841	818
Consolidated loss before income taxes	\$ (129,357)	\$ (39,992)	\$ (12,215)
Depreciation and amortization expense:			
Reportable segment depreciation and amortization expense	\$ 18,663	\$ 18,101	\$ 15,548
Unallocated corporate depreciation and amortization expense	322	317	306
Consolidated depreciation and amortization expense	\$ 18,985	\$ 18,298	\$ 15,854
Capital expenditures:			
Reportable segment capital expenditures	\$ 5,151	\$ 20,724	\$ 5,149
Unallocated corporate capital expenditures	3,561	1,909	2,901
Consolidated capital expenditures	\$ 8,712	\$ 22,633	\$ 8,050
Assets:			
Reportable segment assets	\$ 320,299	\$ 360,464	
Unallocated corporate assets	8,098	7,707	
Consolidated assets	\$ 328,397	\$ 368,171	

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

	For the Years Ended					
	December 31, 2005		December 25, 2004		December 27, 2003	
(In thousands, except percentages)						
Segment						
Biopharmaceutical Products:						
- Nabi-HB	\$ 39,185	36.3%	\$ 40,176	22.3%	\$ 37,638	21.3%
- PhosLo	13,906	12.9	37,580	20.9	12,875	7.3
- WinRho SDF	6,172	5.7	47,882	26.7	49,957	28.3
- Other Biopharmaceuticals	2,874	2.6	6,175	3.4	8,989	5.1
	\$ 62,137	57.5	131,813	73.3	109,459	62.0
Antibody Products:						
- Specialty antibodies	22,936	21.2	23,270	13.0	21,425	12.1
- Non-specific antibodies	22,982	21.3	24,680	13.7	45,686	25.9
	45,918	42.5	47,950	26.7	67,111	38.0
Total	\$108,055	100.0%	\$179,763	100.0%	\$176,570	100.0%

Information regarding sales by geographic area for the years ended December 31, 2005, December 25, 2004 and December 27, 2003 and information regarding long-lived assets at December 31, 2005, December 25, 2004 and December 27, 2003 is as follows:

		For the Years Ended		
(in thousands)	December 31, 2005	December 25, December 27 2004 2003		
Sales:				
U.S.	\$ 92,382	\$ 167,363 \$ 161,595		
Ex-U.S.	15,673	12,400 14,975		
Total	\$ 108,055	\$ 179,763 \$ 176,570		
Operating loss:				
U.S.	\$ (111,077)	\$ (29,550) \$ (11,683		
Ex-U.S.	(18,795)	(10,084) —		
Total	<u>\$ (129,872)</u>	\$ (39,634) \$ (11,683		
Long-lived assets:				
U.S.	\$ 173,203	\$ 205,573 \$ 205,340		
Ex-U.S.	129	10 —		
Total	\$ 173,330	\$ 205,583 \$ 205,340		

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 2005. In the years ended December 31, 2005, December 25, 2004 and December 27, 2003, sales to ex-U.S. markets were derived wholly from antibody products.

Sales for the year ended December 31, 2005, included three customers of our biopharmaceutical product segment, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Drug Co. and one customer of our antibody products segment, Telecris Biotherapeutics Corporation, representing 25%, 21%, 15% and 17% of total sales, respectively. 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.

#### NOTE 23 SUPPLEMENTAL CASH FLOW INFORMATION

	For the Years Ended					
(in thousands)	Dec	ember 31, 2005	Dec	ember 25, 2004	Dec	ember 27, 2003
Interest paid	\$	1,588	\$	615	\$	331
Income taxes paid (refunded)	\$	182	\$	703	\$	(550)
Discount paid on non-interest bearing notes	\$	1,144	\$	654	\$	
Supplemental non-cash financing and investing activities:						
Stock options exercised in exchange for common						
stock	\$	93	\$	101	\$	3,100
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	\$	461	\$	555	\$	_

# NOTE 24 SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

(in thousands, except per share data)	Sales	Gross Margin	Net Loss	Basic Loss Earnings Per Share	Diluted Loss Earnings Per Share
2005					
1 <sup>st</sup> Quarter ended March 26, 2005	\$ 26,077	\$ 9,015	\$ (15,822)	\$ (0.27)	\$ (0.27)
2 <sup>nd</sup> Quarter ended June 25, 2005	25,879	10,031	(20,930)	(0.35)	(0.35)
3 <sup>rd</sup> Quarter ended September 24, 2005	30,768	15,980	(16,118)	(0.27)	(0.27)
4 <sup>th</sup> Quarter ended December 31, 2005	25,331	2,189	(75,579)	(1.25)	(1.25)
Year ended December 31, 2005	\$108,055	\$ 37,215	\$(128,449)	\$ (2.15)	\$ (2.15)
2004					
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)
Year ended December 25, 2004	\$179,763	\$ 85,849	\$ (50,390)	\$ (0.86)	\$ (0.86)

The fourth quarter of 2005 results include a \$4.4 million adjustment or \$0.07 per share, reflecting the cumulative effect of an adjustment for an error in calculating certain Federal rebate obligations we identified in that period. This amount was not material to any affected prior quarter or annual reporting period and as such, was recorded in the fourth quarter of 2005.

# NOTE 25 SUBSEQUENT EVENT

Effective February 24, 2006, the Compensation Committee of our Board of Directors adopted a retention program to help retain the services of key employees. Under the retention program, the Compensation Committee awarded to each employee designated as a participant in the retention program an award of restricted stock, an option to purchase shares of our common stock, and an opportunity to receive a cash bonus.

As part of the retention program, an aggregate of 304,610 restricted shares and 437,260 stock options were granted to employee participants on February 24, 2006 pursuant to the terms and conditions of the 2000 Equity Incentive Plan. The restricted shares and stock options will vest in full on March 1, 2009, provided that the participant is employed by us on that date. The exercise price of each stock option is \$3.83 per share, and each stock option will expire on February 24, 2016.

The Compensation Committee also approved as part of the retention program the payment of an aggregate of approximately \$1.5 million in cash bonuses to participants who are employed by us on March 1, 2007.

# 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 31, 2005. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2005. There has been no change in our internal control over financial reporting that occurred during our fiscal quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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

# ITEM 9b. OTHER INFORMATION

None.

### 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 31, 2005, 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 31, 2005, 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 31, 2005, 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 31, 2005, 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 31, 2005, and such information is incorporated herein by reference.

### 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:

	Page No.
Reports of Independent Registered Public Accounting Firm	70
Consolidated Balance Sheets at December 31, 2005 and December 25, 2004	72
Consolidated Statements of Operations for the years ended December 31, 2005, December 25, 2004 and December 27, 2003	73
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2005, December 25, 2004 and December 27, 2003	74
Consolidated Statements of Cash Flows for the years ended December 31, 2005, December 25, 2004 and December 27, 2003	75
Notes to Consolidated Financial Statements	76
FINANCIAL STATEMENT SCHEDULES	
Schedule II - Valuation and Qualifying Accounts and Reserves	117

Schedule II - Valuation and Qualifying Accounts and Reserves

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

# (3) EXHIBITS

(2)

- 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 3.1 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)
- Certificate of Designations of Series One Preferred Stock contained in Nabi Biopharmaceutical's Certificate of Incorporation (incorporated by 4.1 reference to Exhibit 3.1 to our Quarterly Report on Form 10-Q for the period ended June 26, 2004)
- 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
- 4.3 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)

- 4.4 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)
- 4.5 Indenture between Nabi Biopharmaceuticals and U.S. Bank National Association, as trustee, dated April 19, 2005 (incorporated by reference to Exhibit 4.5 to our Registration Statement on Form S-3 (File No. 333-12541), filed with the Securities and Exchange Commission on March 25, 2005)
- 4.6 Registration Rights Agreement between Nabi Biopharmaceuticals and Lehman Brothers Inc., Bear, Stearns & Co. Inc., and Wachovia Capital Markets, LLC, dated April 19, 2005 (incorporated by reference to Exhibit 4.6 to our Registration Statement on Form S-3 (File No. 333-12541), filed with the Securities and Exchange Commission on March 25, 2005)
- 4.7 Global Note evidencing the unregistered portion of our 2.875% Convertible Senior Notes (incorporated by reference to Exhibit 4.7 to our Registration Statement on Form S-3 (File No. 333-12541), filed with the Securities and Exchange Commission on March 25, 2005)
- 4.8 Global Note evidencing the registered portion of our 2.875% Convertible Senior Notes\*
- 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 (incorporated by reference to Exhibit 10.5 to our Annual Report on Form 10-K for the year ended December 25, 2004)
- 10.6 1998 Non-Qualified Employee Stock Option Plan Award Letter (incorporated by reference to Exhibit 10.6 to our Annual Report on Form 10-K for the year ended December 25, 2004)
- 10.7 1998 Non-Qualified Employee Stock Option Plan Anniversary Award Letter (incorporated by reference to Exhibit 10.7 to our Annual Report on Form 10-K for the year ended December 25, 2004)
- 10.8 2000 Equity Incentive Plan Award Letter (incorporated by reference to Exhibit 10.8 to our Annual Report on Form 10-K for the year ended December 25, 2004)
- 10.9 2000 Equity Incentive Plan Special Award Letter (incorporated by reference to Exhibit 10.9 to our Annual Report on Form 10-K for the year ended December 25, 2004)

- 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 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)
- 10.13 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)
- 10.14 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)
- 10.15 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)
- 10.16 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)
- 10.17 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)
- 10.18 Employment Agreement dated September 1, 2005 between Joseph Johnson and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended September 24, 2005)
- 10.19 Change of Control Severance Agreement dated September 1, 2005 between Joseph Johnson and Nabi Biopharmaceuticals (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended September 24, 2005)
- 10.20 Severance Agreement dated January 13, 2006 between H. LeRoux Jooste and Nabi Biopharmaceuticals\*
- 10.21 Form of Director/Officer Indemnification Agreement (incorporated by reference to Exhibit 10.24 to our Annual Report on Form 10-K for the year ended December 25, 2004)
- 10.22 Summary of Director Compensation (incorporated by reference to Exhibit 10.25 to our Annual Report on Form 10-K for the year ended December 25, 2004)
- 10.23 2003 VIP Management Incentive Plan (incorporated by reference to Exhibit 10.26 to our Annual Report on Form 10-K for the year ended December 25, 2004)

- 10.24 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)
- 10.25 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)
- 10.26 Base Salary Levels of Executive Officers (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 26, 2005)
- 10.27 Termination Agreement dated February 17, 2006
- 12. Statement Re: Computation of Ratio of Earnings to Fixed Charges\*
- 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\*
- \* Filed herewith

# 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 3rd day of March, 2006.

# 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.

Signatures	Title	Date
/s/ Thomas H. McLain Thomas H. McLain	Chairman, Chief Executive Officer and President	March 3, 2006
/s/ Mark L. Smith Mark L. Smith	Senior Vice President, Finance, Chief Financial Officer, Chief Accounting Officer and Treasurer	March 3, 2006
/s/ David L. Castaldi David L. Castaldi	Director	March 3, 2006
/s/ Geoffrey F. Cox, Ph.D. Geoffrey F. Cox, Ph.D.	Director	March 3, 2006
/s/ George W. Ebright George W. Ebright	Director	March 3, 2006
/s/ Richard A. Harvey, Jr. Richard A. Harvey, Jr.	Director	March 3, 2006
/s/ Leslie Hudson, Ph.D. Leslie Hudson, Ph.D.	Director	March 3, 2006
/s/ Linda Jenckes Linda Jenckes	Director	March 3, 2006
/s/ Stephen G. Sudovar Stephen G. Sudovar	Director	March 3, 2006



# Nabi Biopharmaceuticals

# SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

				Ad	lditions			ductions		
Classification Year ended December 31, 2005:	Beg	alance at ginning of Period	Co	arged to osts and xpenses		arged to Other counts <sup>1</sup>	C A	rite-Offs harged Against Reserve		alance at d of Period
•	<i>•</i>	(22)	<b>.</b>	0	<b>^</b>		<i>•</i>	(10.0)	<b>^</b>	6
Allowance for doubtful accounts	\$	433	\$	9	\$	—	\$	(436)	\$	6
Inventory valuation allowance		6,421		8,580		(2,604)		(647)		11,750
Deferred tax assets valuation allowance		—		78,556				—		78,556
Year ended December 25, 2004:										
Allowance for doubtful accounts	\$	646	\$	428	\$	_	\$	(641)	\$	433
Inventory valuation allowance		5,219		3,950		(577)		(2,171)		6,421
Year ended December 27, 2003:										
Allowance for doubtful accounts	\$	647	\$	39	\$		\$	(40)	\$	646
Inventory valuation allowance		4,489		1,044		(7)		(307)		5,219

(1) Represents the reversal of reserves recorded in prior periods upon sale of reserved product.

# Exhibit Index

Exhibit No.	Description
4.8	Global Note evidencing the registered portion of our 2.875% Convertible Senior Notes
10.20	Severance Agreement dated January 13, 2006 between H. LeRoux Jooste and Nabi Biopharmaceuticals
10.27	Termination Agreement dated February 13, 2006
12.	Statement Re: Computation of Ratio of Earnings to Fixed Charges
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

UNLESS THIS CERTIFICATE IS PRESENTED BY AN AUTHORIZED REPRESENTATIVE OF THE DEPOSITORY TRUST COMPANY TO THE COMPANY OR ITS AGENT FOR REGISTRATION OF TRANSFER, EXCHANGE OR PAYMENT, AND ANY CERTIFICATE ISSUED IS REGISTERED IN THE NAME OF CEDE & CO. OR IN SUCH OTHER NAME AS IS REQUESTED BY AN AUTHORIZED REPRESENTATIVE OF THE DEPOSITORY TRUST COMPANY (AND ANY PAYMENT HEREON IS MADE TO CEDE & CO. OR TO SUCH OTHER ENTITY AS IS REQUESTED BY AN AUTHORIZED REPRESENTATIVE OF THE DEPOSITORY TRUST COMPANY), ANY TRANSFER, PLEDGE OR OTHER USE HEREOF FOR VALUE OR OTHERWISE BY OR TO ANY PERSON IS WRONGFUL SINCE THE REGISTERED OWNER HEREOF, CEDE & CO., HAS AN INTEREST HEREIN.

TRANSFERS OF THIS GLOBAL SECURITY SHALL BE LIMITED TO TRANSFERS TO NOMINEES OF THE DEPOSITORY TRUST COMPANY, OR TO A SUCCESSOR THEREOF OR SUCH SUCCESSOR'S NOMINEE AND TRANSFERS OF PORTIONS OF THIS GLOBAL SECURITY SHALL BE LIMITED TO TRANSFERS MADE IN ACCORDANCE WITH THE RESTRICTIONS SET FORTH IN ARTICLE TWO OF THE INDENTURE REFERRED TO ON THE REVERSE HEREOF.

The foregoing legend may be removed from this Security on satisfaction of the conditions specified in the Indenture.

# NABI BIOPHARMACEUTICALS

### 2.875% Convertible Senior Notes due 2025

No.: R-1 Issue Date: April 19, 2005 Issue Price: \$1,000 (for each \$1,000 Principal Amount) CUSIP: 629519 AB 5 Principal Amount: \$0.00

Nabi Biopharmaceuticals, a Delaware corporation, promises to pay to Cede & Co. or registered assigns, the principal amount of ZERO DOLLARS AND NO CENTS (\$0.00) on April 15, 2025 or such greater or lesser amount as is indicated on the Schedule of Increases and Decreases of Global Security attached to this Security.

Interest Payment Dates: April 15 and October 15, commencing October 15, 2005.

Record Dates: April 1 and October 1.

Reference is hereby made to the further provisions of this Security set forth on the reverse side of this Security, which further provisions shall for all purposes have the same effect as if set forth at this place.

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IN WITNESS WHEREOF, the Company has caused this instrument to be duly executed under its corporate seal.

Dated: August 10, 2005

# NABI BIOPHARMACEUTICALS

By: /s/ Mark L. Smith

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

# TRUSTEE'S CERTIFICATE OF AUTHENTICATION

U.S. BANK NATIONAL ASSOCIATION as Trustee, certifies that this is one of the Securities referred to in the within mentioned Indenture.

By: /s/ David Ganss

Authorized Signatory

Dated: August 10, 2005

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### **REVERSE OF NOTE**

#### 2.875% Convertible Senior Notes due 2025

This Security is one of a duly authorized issue of the 2.875% Convertible Senior Notes due 2025 (the "<u>Securities</u>") of Nabi Biopharmaceuticals, a Delaware corporation (including any successor corporation under the Indenture hereinafter referred to, the "<u>Company</u>"), issued under an Indenture, dated as of April 19, 2005 (the "<u>Indenture</u>"), between the Company and U.S. Bank National Association, as trustee (the "<u>Trustee</u>"). The terms of the Security include those stated in the Indenture, those made part of the Indenture by reference to the Trust Indenture Act of 1939, as amended ("<u>TIA</u>"), and those set forth in this Security. This Security is subject to all such terms, and Holders are referred to the Indenture and the TIA for a statement of all such terms. To the extent permitted by applicable law, in the event of any inconsistency between the terms of this Security and the terms of the Indenture, the terms of the Indenture shall control. Capitalized terms used but not defined herein have the meanings assigned to them in the Indenture referred to below unless otherwise indicated.

#### 1. Interest.

The Company promises to pay interest on the principal amount of the Securities at the interest rate of 2.875% per annum (the "<u>Interest Rate</u>") from the date of issuance until repayment in full at April 15, 2025, or until an earlier conversion, redemption or repurchase. The Company will pay interest on this Security semi-annually in arrears on April 15 and October 15 of each year (each, an "<u>interest payment date</u>"), commencing October 15, 2005.

The Securities shall bear interest from April 19, 2005 until the principal amount thereof is paid or made available for payment, or until such date on which the Securities are converted, redeemed or purchased as provided herein at the Interest Rate.

Interest on the Securities shall be computed (i) for any full semi-annual period for which the Interest Rate is applicable, on the basis of a 360-day year of twelve 30-day months and (ii) for any period for which the Interest Rate is applicable for less than a full semi-annual period for which interest is calculated, on the basis of a 30-day month and, for such periods of less than a month, the actual number of days elapsed over a 30-day month.

If this Security is redeemed or repurchased by the Company on a date that is after the record date and on or prior to the corresponding interest payment date, interest and Liquidated Damages, if any, accrued and unpaid hereon to but not including the applicable Redemption Date, Repurchase Date or Fundamental Change Purchase Date, as the case may be, will be paid to the same Holder to whom the Company pays the principal of this Security.

Interest on Securities converted after a record date but prior to the corresponding interest payment date will be paid to the Holder of the Securities on the record date but, upon conversion, the Holder must pay the Company the interest and Liquidated Damages, if any, which have accrued and will be paid on such interest payment date; *provided*, that no such payment need be made with respect to Securities which will be redeemed or repurchased by the Company after a record date and on or prior to the third Business Day after the corresponding interest payment date.

If the principal amount hereof or any portion of such principal amount or any interest, including Liquidated Damages, if any, on any Security is not paid when due (whether upon acceleration pursuant to Section 6.2 of the Indenture, upon the date set for payment of the Redemption Price pursuant to Section 3.1 of the Indenture or the Repurchase Price or the Fundamental Change Purchase Price pursuant to Section 3.7 or Section 3.11 of the Indenture, as the case may be, or upon the Stated Maturity of this Security), then in each such case the overdue amount shall, to the extent permitted by law, bear interest at the Interest Rate, compounded semi-annually, which interest shall accrue from the date on which such overdue amount was originally due until the date on which payment of such amount, including interest thereon, has been made or duly provided for. All such interest shall be payable on demand.

### 2. Method of Payment.

Except as provided below, interest will be paid (i) on the Global Securities to The Depository Trust Company ("<u>DTC</u>") or its nominee in immediately available funds, (ii) on any definitive Securities having an aggregate principal amount of \$2,000,000 or less, by check mailed to the Holders of such Securities, and (iii) on any definitive Securities having an aggregate principal amount of more than \$2,000,000, by wire transfer in immediately available funds at the election of the Holders of such Securities.

At Stated Maturity, the Company will pay interest on definitive Securities at the Company's office or agency in New York City, which initially will be the corporate trust office of U.S. Bank National Association, in New York City.

Principal on Global Securities will be paid to DTC or its nominee in immediately available funds. Principal on definitive Securities will be payable, upon Stated Maturity or when due, at the office or agency of the Company in New York City, maintained for such purpose, initially the corporate trust office of U.S. Bank National Association, in New York City.

Subject to the terms and conditions of the Indenture, the Company will make payments in cash in respect of Redemption Prices, Repurchase Prices, Fundamental Change Purchase Prices and at Stated Maturity to Holders who surrender Securities to a Paying Agent to collect such payments in respect of the Securities. The Company will pay cash amounts in money of the United States that at the time of payment is legal tender for payment of public and private debts. However, the Company may make such cash payments by check payable in such money, subject to the terms of the Indenture.

#### 3. Paying Agent, Conversion Agent and Registrar.

Initially, U.S. Bank National Association will act as Paying Agent, Conversion Agent and Registrar. The Company may appoint and change any Paying Agent, Conversion Agent or Registrar without notice, other than notice to the Trustee; *provided* that the Company will maintain at least one Paying Agent in the State of New York, City of New York, Borough of Manhattan, which shall initially be an office or agency of the Trustee. The Company or any of its Subsidiaries or any of their Affiliates may act as Paying Agent, Conversion Agent or Registrar.

#### 4. Indenture.

The Securities are senior unsecured obligations of the Company initially limited to \$100,000,000 aggregate principal amount (or such greater amount necessary to reflect the exercise by the Initial Purchasers of their option to purchase additional Securities in compliance with the Purchase Agreement, but not in excess of \$120,000,000).

The Company may, without the consent of the Holders of the Securities, increase the Principal Amount of the Securities by issuing additional securities in the future on the same terms and conditions, except for any differences in the issue price and interest accrued prior to the issue date of the additional securities, provided, that such difference does not cause the additional securities to constitute a different class of securities than the Securities for U.S. federal income tax purposes, and provided further, that the additional securities have the same CUSIP number as the Securities. The Securities and any additional securities would rank equally and ratably and would be treated as a single class for all purposes under the Indenture. No additional securities may be issued if any Event of Default has occurred with respect to the Securities. The Indenture does not limit other indebtedness of the Company, secured or unsecured.

#### 5. Redemption at the Option of the Company.

No sinking fund is provided for the Securities. The Securities are not redeemable by the Company prior to April 18, 2010. On or after April 18, 2010, the Securities will be redeemable for cash at the option of the Company, in whole or in part, at any time or from time to time, upon not less than 30 nor more than 60 days' notice by mail for a redemption price equal to the principal amount of those Securities plus accrued and unpaid interest, including Liquidated Damages, if any, on those Securities to, but not including, the Redemption Date (the "<u>Redemption Price</u>") as set forth in the Indenture.

#### 6. Purchase By the Company at the Option of the Holder.

Subject to the terms and conditions of the Indenture, the Company shall become obligated to purchase, at the option of the Holder, the Securities held by such Holder on April 15, 2010, April 15, 2012, April 15, 2015 and April 15, 2020 at a Repurchase Price equal to the principal amount of such Securities on the applicable Repurchase Date plus accrued and unpaid interest, including Liquidated Damages, if any, to, but not including, the Repurchase Date, upon delivery of a Repurchase Notice containing the information set forth in the Indenture, at any time from the opening of business on the date that is 20 Business Days prior to such Repurchase Date until the close of business on the Business Day preceding such Repurchase Date and upon delivery of the Securities or the required transfer to the Paying Agent by the Holder as set forth in the Indenture.

At the option of the Holder and subject to the terms and conditions of the Indenture, the Company shall become obligated to offer to purchase the Securities held by such Holder for a Fundamental Change Purchase Price equal to the principal amount of such Securities plus accrued and unpaid interest, including Liquidated Damages, if any, to, but not including, the Fundamental Change Purchase Date. The Fundamental Change Purchase Date, which shall be determined by the Company, shall be between 30 and 60 days of the Company's delivery of the notice describing such Fundamental Change and the resulting repurchase right. The Fundamental Change Purchase Price shall be paid in accordance with the Indenture.

Holders have the right to withdraw any Repurchase Notice or Fundamental Change Purchase Notice, as the case may be, by delivering to the Paying Agent a written notice of withdrawal in accordance with the provisions of the Indenture.

If cash sufficient to pay the Repurchase Price or the Fundamental Change Purchase Price, as the case may be, of all Securities, or portions thereof to be purchased as of the Repurchase Date or the Fundamental Change Purchase Date, as the case may be, is deposited with the Paying Agent on the Business Day following the Repurchase Date or the Fundamental Change Purchase Date, as the case may be, interest will cease to accrue on such Securities (or portions thereof) immediately after such Repurchase Date or Fundamental Change Purchase Date, as the case may be, and the Holder thereof shall have no other rights as such other than the right to receive the Repurchase Price or the Fundamental Change Purchase Price upon surrender of such Security.

### 7. Notice of Redemption.

Notice of redemption pursuant to Section 3.1 of the Indenture of this Security will be mailed at least 30 days but not more than 60 days before the Redemption Date to each Holder of Securities to be redeemed at the Holder's registered address. If money sufficient to pay the Redemption Price of all Securities (or portions thereof) to be redeemed on the Redemption Date is deposited with the Paying Agent prior to or on the Redemption Date, immediately after such Redemption Date interest ceases to accrue on such Securities or portions thereof. Securities in denominations larger than \$1,000 of principal amount may be redeemed in part but only in integral multiples of \$1,000 of principal amount.

#### 8. Conversion.

Subject to and in compliance with the provisions of the Indenture, a Holder is entitled, at such Holder's option, to convert the Holder's Security (or any portion of the principal amount thereof that is \$1,000 or an integral multiple of \$1,000), into fully paid and nonassessable shares of Common Stock at the Conversion Rate in effect at the time of conversion, subject to the Company's right to deliver cash in lieu of Common Stock.

A Security in respect of which a Holder has delivered a Fundamental Change Purchase Notice, exercising the option of such Holder to require the Company to purchase such Security, may be converted only if such Fundamental Change Purchase Notice is withdrawn in accordance with the terms of the Indenture.

The initial Conversion Rate is 69.8348 shares per \$1,000 principal amount of securities, subject to adjustment in certain events described in the Indenture. No fractional shares of Common Stock shall be issued upon conversion of any Security. A Holder that surrenders Securities for conversion will receive cash in lieu of any fractional share of Common Stock.

To surrender a Security for conversion, a Holder must (i) complete and manually sign the conversion notice below (or complete and manually sign a facsimile of such notice), (ii) deliver such completed notice and surrender the Security to the Conversion Agent and, (iii) pay all funds required and furnish appropriate endorsements and transfer documents and (iv) pay any transfer or similar tax, if required by the Indenture.

If the Company (i) is a party to a consolidation, merger or binding share exchange, (ii) reclassifies the Common Stock or (iii) conveys, transfers or leases its properties and assets substantially as an entirety to any Person, the right to convert a Security into shares of Common Stock shall be changed into a right to convert it into securities, cash or other assets of the Company or such other Person, in each case in accordance with the Indenture.

The Company may elect to deliver either shares of its Common Stock, cash or a combination of cash and shares of Common Stock in satisfaction of the Company's Conversion Obligation. The Company shall notify the Holder or Holders, as the case may be, through the Trustee of the method the Company chooses to satisfy its Conversion Obligation, (i) in the Company's Notice of Redemption, if the Company has called the Securities for redemption, (ii) 26 Trading Days immediately preceding Stated Maturity in respect of Securities to be converted during the period beginning 25 Trading Days immediately preceding the Stated Maturity and ending one Trading Day immediately preceding Stated Maturity, and (iii) no later than three Trading Days immediately following the date of conversion in all other cases. If the Company elects to satisfy any portion of its Conversion Obligation by delivering cash, the Company shall specify in such notice the portion to be paid in cash either as a percentage of the Conversion Obligation or as the lesser of (a) a fixed dollar amount and (b) the Conversion Value. The Company shall treat all Holders converting on the same Trading Day in the same manner. The Company shall not have any obligation to satisfy Conversion Obligations arising on different Trading Days in the same manner.

At any time prior to the 26th Trading Day preceding the Stated Maturity, the Company may irrevocably elect, in its sole discretion without the consent of the Holders of the Notes, by written notice to the Trustee and the Holders of the Notes, to satisfy in cash the Conversion Obligation with respect to the principal amount of Notes to be converted after the date of such election, with any remaining amount of the Conversion Obligation to be satisfied in shares of Common Stock. The settlement amount will be computed as described under Section 9.13(a)(iii) of the Indenture, using the \$1,000 as the fixed dollar amount per \$1,000 principal amount of Notes of the Conversion Obligation to be satisfied in cash.

#### 9. Denominations; Transfer; Exchange.

The Securities are in fully registered form, without coupons, in denominations of \$1,000 of principal amount and integral multiples of \$1,000. A Holder may transfer or exchange Securities in accordance with the Indenture. The Registrar may require a Holder, among other things, to furnish appropriate endorsements and transfer documents and to pay any taxes and fees required by law or permitted by the Indenture. The Registrar need not transfer or exchange any Securities selected for redemption (except, in the case of a Security to be redeemed in part, the portion of the Security not to be redeemed) or any Securities in respect of which a Fundamental Change Purchase Notice has been given and not withdrawn (except, in the case of a Security to be purchased in part, the portion of the Security not to be purchased) or to issue, register the transfer of, or exchange any Securities for a period of 15 days before the redemption date.

### 10. Persons Deemed Owners.

The registered Holder of this Security may be treated as the owner of this Security for all purposes.

#### 11. Unclaimed Money or Securities.

The Trustee and the Paying Agent shall return to the Company upon written request any money held by them for the payment of any amount with respect to the Securities that remains unclaimed for two years, subject to applicable unclaimed property law. After return to the Company, Holders entitled to the money or securities must look to the Company for payment as general creditors unless an applicable abandoned property law designates another Person.

#### 12. Amendment; Waiver.

Subject to certain exceptions set forth in the Indenture, (i) the Indenture or the Securities may be amended with the written consent of the Holders of at least a majority in aggregate principal amount of the outstanding Securities and (ii) certain Defaults may be waived with the written consent of the Holders of a majority in aggregate principal amount of the outstanding Securities. The Indenture and the Securities may also be amended by the Company and the Trustee, without the consent of any Holder, in certain circumstances set forth in the Indenture; *provided*, that certain provisions of the Indenture and the Securities may not be amended without the consent of each affected Holder.

#### 13. Defaults and Remedies.

If any Event of Default with respect to Securities shall occur and be continuing, the principal of all the Securities may be declared due and payable in the manner and with the effect provided in the Indenture.

#### 14. Trustee Dealings with the Company.

Subject to certain limitations imposed by the TIA, the Trustee under the Indenture, in its individual or any other capacity, may become the owner or pledgee of Securities and may otherwise deal with and collect obligations owed to it by the Company or its Affiliates and may otherwise deal with the Company or its Affiliates with the same rights it would have if it were not Trustee.

#### 15. No Recourse Against Others.

A director, officer, employee or shareholder, as such, of the Company shall not have any liability for any obligations of the Company under the Securities or the Indenture or for any claim based on, in respect of or by reason of such obligations or their creation. By accepting a Security, each Securityholder waives and releases all such liability. The waiver and release are part of the consideration for the issue of the Securities.

# 16. Treatment of Securities.

Each holder, by acceptance of a Security, and beneficial owner, by acceptance of a beneficial ownership interest in a Security, agrees to treat the Securities as indebtedness of the Company for U.S. federal income tax purposes and to not take any action inconsistent with such treatment.

#### 17. Authentication.

This Security shall not be valid until an authorized signatory of the Trustee manually signs the Trustee's Certificate of Authentication on the other side of this Security.

#### 18. Abbreviations.

Customary abbreviations may be used in the name of a Securityholder or an assignee, such as TEN COM (=tenants in common), TEN ENT (=tenants by the entireties), JT TEN (=joint tenants with right of survivorship and not as tenants in common), CUST (=custodian), and U/G/M/A (=Uniform Gift to Minors Act).

### 19. GOVERNING LAW.

THIS SECURITY AND THE INDENTURE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK.

The Company will furnish to any Securityholder upon written request and without charge a copy of the Indenture which has in it the text of this Security. Requests may be made to:

Nabi Biopharmaceuticals 5800 Park of Commerce Boulevard N.W. Boca Raton, FL 33487 Attention: Chief Financial Officer Facsimile No.: (561) 989-5801

### 20. Registration Rights.

The Holders of any Restricted Security are entitled to the benefits of the Registration Rights Agreement, dated as of April 19, 2005, among the Company and the Initial Purchasers, including the receipt of Liquidated Damages upon a registration default (as defined in such agreement).

# ASSIGNMENT FORM

To assign this Security, fill in the form below:

I or we assign and transfer this Security to

(Insert assignee's soc. sec. or tax ID no.)

(Print or type assignee's name, address and zip code)

and irrevocably appoint \_\_\_\_\_\_ agent to transfer this Security on the books of the Company. The agent may substitute another to act for him.

Date: \_\_\_\_\_ Your Signature:

(Sign exactly as your name appears on the other side of this Security)

Signature Guaranteed

Participant in a Recognized Signature Guarantee Medallion Program

By:

Authorized Signatory

### **CONVERSION NOTICE**

To convert this Security into Common Stock of the Company, check the box

To convert only part of this Security, state the principal amount to be converted (which must be \$1,000 or an integral multiple of \$1,000):

\$

If you want the stock certificate made out in another person's name fill in the form below:

(Insert the other person's soc. sec. or tax ID no.)

(Print or type other person's name, address and zip code)

# SCHEDULE OF INCREASES AND DECREASES OF GLOBAL SECURITY

# Initial Principal Amount of Global Security: (\$0.00).

		Amount of	Principal	
	Amount of	Decrease	Amount of	
	Increase in	in Principal	Global Security	Notation by
	Principal	Amount	After	Registrar
	Amount of	of Global	Increase or	or Security
Date	Global Security	Security	Decrease	Custodian
	DО			

#### Re: <u>Separation of Employment</u>

### Dear LeRoux:

As you know, Nabi Biopharmaceuticals ("Nabi") has terminated your employment with Nabi effective February 28, 2006 (the "Effective Date"). This letter agreement (the "Agreement") will confirm the details of your separation from Nabi.

- 1. Services. From the date hereof through the Effective Date, you shall provide such services to Nabi as Nabi shall request.
- 2. **Resignation**. You have resigned as an officer of Nabi, and as an officer or director of any of Nabi's subsidiaries in which you may serve in that capacity, effective January 13, 2006.
- 3. **Severance**. Provided that you do not revoke this Agreement as provided in Section 10 below and you comply with the other terms and provisions of this Agreement and with Sections 9 and 10 of your Employment Agreement, you shall receive Severance benefits of ten (10).

You hereby confirm that notwithstanding Section 8(D) of the Employment Agreement, your Option to purchase 160,000 shares of Nabi Common Stock granted pursuant to the option agreement dated December 20, 2004 shall expire and terminate on the Effective Date.

You should be aware of the potential characterization of Severance Pay as non-qualified deferred compensation under the American Jobs Creation Act. Notwithstanding that, Nabi has agreed with you to make a ten (10) month lump sum payment minus appropriate deductions to include health benefit premiums on March 10, 2006. The gross payment will be \$253,666.67 and represents ten (10) months pay plus ten (10) months of auto allowance.

You should consult with your tax advisor to consider how the American Jobs Creation Act and the related regulations and other applicable tax laws affect your severance benefits.

During the period of your severance your health benefits will continue in the same manner as existed during your employment. You will be sent information to coordinate the appropriate COBRA requirements with this health benefits continuation.

- 4. **Non-Disparagement**. You agree that you will not make any communication, oral or written, that disparages, criticizes or otherwise reflects adversely upon Nabi or any of its shareholders, employees, representatives and agents, past or present, except if testifying truthfully under oath pursuant to subpoena or other legal process. Nabi agrees to instruct its executive officers not to make any communication, oral or written, that disparages you.
- 5. Release. For and in consideration of the representations of Nabi set forth herein, and intending to be legally bound, you hereby release Nabi and its subsidiaries and their respective shareholders, directors, officers, employees, representatives, and agents, past or present, and its and their respective successors and assigns, heirs, executors, and administrators, from any and all actions, suits, and claims which you ever had, now have, or which your heirs, executors or administrators may have, up to and including the date on which you execute this Agreement. Particularly, but without limitation, you release any claims arising from or relating in any way to your employment relationship or the termination of your employment relationship with Nabi, including any claims under any federal, state or local laws, including Title VII of the Civil Rights Act of 1964, as amended, the Age Discrimination in Employment Act, the Americans with Disabilities Act, the Employee Retirement Income Security Act, and the Family and Medical Leave Act, any common law contract or tort claims now or hereafter recognized, and all claims for legal fees and costs.

For the purposes of implementing a full and complete release of claims, you expressly acknowledge that this Agreement is intended to include, without limitation, all claims described in this Section 5 herein, whether known or unknown, and that this Agreement contemplates the extinction of all such claims. You expressly waive any right to assert after signing this Agreement that any such claim has, through ignorance or oversight, been omitted from the scope of the Agreement.

Nothing contained in this Section 5 shall affect your right to indemnification for any period while you were serving as an officer of Nabi.

- 6. **Governing Law**. This Agreement shall be subject to and governed by and in accordance with the laws of the State of Florida, without regard to conflict of laws principles.
- 7. **Interpretation**. Neither the fact that this offer for severance has been made or that this Agreement has been entered into, nor any provisions of this Agreement, shall be construed as an admission by Nabi or any of its shareholders, agents, employees, or representatives, past or present, or by you that it or they or you violated any law or regulation or any other legal or equitable obligation it or they or you have or ever had to each other.
- 8. No Obligation to Re-employ. You agree that Nabi is under no obligation to rehire or re-employ you in the future.
- 9. **Return of Property**. You agree to return to Nabi on or before the Effective Date all property of Nabi used or obtained by you in connection with your employment that is in your possession or control.

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- 10. **Revocation**. You have the right to revoke this Agreement within seven (7) days of its execution by giving written notice of such revocation by handdelivery or fax to William E. Vandervalk, Vice President, Human Resources, Nabi Biopharmaceuticals, 5800 Park of Commerce Blvd., N.W., Boca Raton, FL 33487 (Fax No. 561.989.5874). In the event of such revocation, you shall not be entitled to receive the severance benefits set forth above.
- 11. **Amendment.** This Agreement cannot be amended orally or by any course of conduct or dealing and may only be amended or any of its provisions waived by a written agreement signed by you and Nabi.
- 12. Entire Agreement. When accepted by you, this Agreement and Sections 9, 10, 11 and 12 of the Employment Agreement set forth the entire agreement between you and Nabi and fully supersede any and all prior agreements or understandings between you and Nabi pertaining to the subject matter thereof.
- 13. **Nabi Representation**. Nabi represents that as of the date hereof, none of its executive officers knows of any claims or causes of action of whatever kind or nature that Nabi has against you that arise on or before the date hereof.

If this Agreement is acceptable to you, please indicate your agreement by signing and dating the enclosed copy of this Agreement and returning it to be received by me, on or before February 6, 2006, during which time you are advised to consult with an attorney. In the event that you fail to execute and return this Agreement to me, on or before the close of business February 6, 2006, this Agreement will be of no further force and effect, and neither you nor Nabi will have any rights or obligations hereunder.

Sincerely,

/s/ Joseph S. Johnson Senior Vice-President People, Process & Technology

# cc: Payroll/Human Resources

I expressly agree to accept the Severance Agreement set forth above and verify that I am entering this Agreement knowingly and voluntarily, without any coercion or duress. I acknowledge that I was given adequate time to review this letter and that I was advised to obtain legal advice from an attorney regarding its terms. I understand the contents of this Agreement, and agree to all its terms and conditions including the release of all claims contained in Section 5.

Date: January 17, 2006

Signed: /s/ LeRoux Jooste

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### **TERMINATION AGREEMENT**

This Termination Agreement is dated effective February 17, 2006 (the "**Termination Date**") by and between Nabi Biopharmaceuticals, a Delaware corporation with an address at 5800 Park of Commerce Blvd., N.W., Boca Raton, FL 33487 ("**Nabi**"), and Cambrex Bio Science Baltimore, Inc., a Delaware corporation with an address at 5901 E. Lombard St., Baltimore, MD 21224 ("**Cambrex**"). Nabi and Cambrex are referred to herein collectively as the "**Parties**."

WHEREAS, pursuant to that certain Manufacturing Agreement dated as of October 9, 2003, as amended by that certain Amendment to Manufacturing Agreement, dated as of December 2, 2003 (the "**Manufacturing Agreement**") by and between the Parties, Nabi retained Cambrex as a manufacturer of clinical and commercial quantities of Drug Substance and purchased from Cambrex manufacturing services to supply clinical and commercial quantities of such Drug Substance; and

WHEREAS, although the Parties to date have each performed their respective obligations pursuant to the Manufacturing Agreement, the Parties now mutually desire to terminate the Manufacturing Agreement on the terms and conditions set forth below;

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows.

1. Capitalized Terms. Capitalized terms used herein and not otherwise defined shall have the meanings set forth in the Manufacturing Agreement.

2. *Termination of Manufacturing Agreement*. Effective immediately upon the Termination Date, the Parties agree that the Manufacturing Agreement will be and hereby is canceled and terminated, and shall be of no further force and effect and the rights and obligations of each Party thereunder shall terminate; *provided, however*, that the specific provisions of the Manufacturing Agreement set forth in Section 21.4 thereof and the rights and obligations contained therein shall survive such termination and remain binding upon each Party, as applicable.

3. *Open Delivery/Payment.* Cambrex confirms and agrees that, except as set forth in this Section 3, Nabi has satisfied all of its obligations with respect to any amounts due and payable to Cambrex pursuant to the Manufacturing Agreement, including, but not limited to, all payments required to be made pursuant to Section 8 thereof. The Parties further agree that, notwithstanding any provision in the Manufacturing Agreement to the contrary, Nabi's sole remaining payment obligation to Cambrex under the Manufacturing Agreement (other than a payment obligation that may arise in the future under Section 18 of the Manufacturing Agreement) thereunder consists of (a) payment of invoices relating to Purchase Orders 2500000529, 2500000532, and 2500000534, such payments to equal \$250,000, \$402,000 and

\$66,666, respectively and (b) a final payment for all costs incurred by Cambrex in connection with activities related to termination of the Manufacturing Agreement, such sum not to exceed \$50,000 in the aggregate. The parties agree that Cambrex owes no credits in favor of Nabi.

4. *Return of Materials*. The Parties confirm and agree that they will comply with the requirements set forth in Section 21.3 of the Manufacturing Agreement, including, but not limited to, (a) the return to Nabi or destruction, at Nabi's election, of any and all Cell Line, Master Cell Bank and Working Cell Bank quantities, (b) the return to Nabi, at Nabi's sole cost and expense of any and all Nabi Equipment and Materials for which Nabi has reimbursed Cambrex for the Acquisition Cost, and (c) the return by each Party of the other's Confidential Information, except that neither Party will be required to delete any electronic mail exchanged between the Parties, provided that any Confidential Information contained in such electronic mail shall remain subject to the confidentiality and non-use obligations set forth in Article 19 of the Manufacturing Agreement.

5. *Release*. The Parties, on behalf of themselves and on behalf of their successors, assignees, and current and former representatives, attorneys, assigns and partners, and any other person or entity claiming by, through or under it or any of them do hereby unconditionally release and forever discharge each other, and each and all of their successors, assigns, and current and former representatives, attorneys, assigns and partners from any and all claims, counterclaims, demands, judgments, liabilities, damages, losses, accounts, bonds, bills, covenants, contracts, agreements, promises, claims, complaints, and causes of action of whatever kind or character, whether known or unknown, at law or in equity, contingent or liquidated (collectively, "Liabilities"), which each may now have or ever had against the other from the effective date of the Manufacturing Agreement to the Termination Date, arising out of or relating to the Manufacturing Agreement, except for Liabilities for which a Party may seek indemnification under Article 18 of the Manufacturing Agreement or any other provision of the Manufacturing Agreement that is intended to survive termination thereof.

6. *Authority*. Each Party represents and warrants that the undersigned has the authority to act on its behalf and to bind it, and any and all others who may claim through it, to this Termination Agreement. Each person signing this Termination Agreement represents and warrants that he or she has the authority to bind the entity on whose behalf he or she has executed this Termination Agreement to all terms and conditions of this Termination Agreement.

7. *Entire Agreement; Amendment.* This Termination Agreement contains the entire agreement between the Parties pertaining to the termination of the Manufacturing Agreement and supercedes any and all prior and/or concurrent oral or written negotiations, discussions, agreements, representations and understandings with respect thereto. No modification of this Termination Agreement is valid unless in writing signed by both Parties.

8. *Severability*. If any provision of this Termination Agreement shall be held to be invalid, illegal or unenforceable, such invalidity, illegality or unenforceability shall not affect

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any other provision hereof, and this Agreement shall be construed as if such provision had never been contained herein; *provided*, *however*, that if the deletion of any provision hereof frustrates an essential purpose of this Termination Agreement or the material rights of a Party hereunder, the Parties shall seek in good faith alternative provisions to achieve the same purposes as the invalid, illegal or unenforceable provision.

9. *Governing Law*. This Termination Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to its internal conflicts of law rules.

IN WITNESS WHEREOF, the Parties have caused this Termination Agreement to be executed under seal as of the Termination Date.

### NABI BIOPHARMACEUTICALS

By:	/s/ Raafat Fahim
Name:	Raafat Fahim
Its:	Sr. Vice President, Research, Technical and Production
	Operations

# CAMBREX BIO SCIENCE BALTIMORE, INC.

By:	/s/ Steve Klosk
Name:	Steve Klosk
Its:	Executive Vice President and COO

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	For the Year Ended						
	December 31, 2005	December 25, 2004	December 27, 2003	December 28, 2002	December 20, 2001		
Fixed charges							
Interest expense	3,098	2,199	1,350	2,130	2,128		
Interest capitalized	106	326	83	—	5,202		
Capitalized expenses related to indebtedness				—			
Estimate of interest within rental expense	183	156	149	218	422		
Preference security dividend				—			
Total fixed charges	3,387	2,681	1,582	2,348	7,752		
Earnings							
Pretax income from continuing operations	(129,872)	(39,992)	(12,215)	1,738	115,769		
Fixed charges	3,387	2,681	1,582	2,348	7,752		
Amortization of capitalized interest	1,277	1,266	1,273	1,274	148		
Interest capitalized	(106)	(326)	(83)	—	(5,202)		
Total earnings	(125,314)	(36,371)	(9,443)	5,360	118,467		
Ratio							
Adjusted Earnings	(125,314)	(36,371)	(9,443)	5,360	118,467		
Total Fixed charges	3,387	2,681	1,582	2,348	7,752		
Ratio of Earnings to fixed charges	N/A	N/A	N/A	2.3	15.3		

For the years ended December 27, 2003, December 25, 2004 and December 31, 2005, Nabi Biopharmaceuticals did not generate sufficient earnings to cover its fixed charges by the following amounts:

		For the Year Ended						
	Dec. 31, Dec. 25, Dec. 27, Dec. 28, D							
Dollar amounts in thousands	2005	2004	2003	2002	2001			
Coverage deficiency	\$128,701	\$39,052	\$11,025	N/A	N/A			

### Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statements (Forms S-3 No. 333-42188, No. 333-107134, No. 333-108086, No. 333-112006, No. 333-121050 and No. 333-125241) and the related prospectuses of Nabi Biopharmaceuticals; and
- (2) Registration Statements (Forms S-8 No. 333-115691, No. 333-115688, No. 333-109017, No. 333-38866, No. 333-38864, No. 333-38868, No. 333-95269, No. 333-81009, No. 333-56037, No. 333-56071, No. 033-65069 and No. 033-60795) pertaining to various employee-related plans of Nabi Biopharmaceuticals;

of our reports dated February 28, 2006, 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 31, 2005.

Certified Public Accountants

/s/ Ernst & Young, LLP

West Palm Beach, Florida February 28, 2006

### 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 3, 2006

By: /s/ Thomas H. McLain

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 3, 2006

By: /s/ Mark L. Smith

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 31, 2005 (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 31, 2005 and the results of operations of the Company for the year ended December 31, 2005.

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 3, 2006

/s/ Thomas H. McLain

Name: Thomas H. McLain Title: Chairman, Chief Executive Officer and President

/s/ Mark L. Smith

Name: Mark L. Smith

Title: Chief Financial Officer, Chief Accounting Officer and Treasurer

Date: March 3, 2006