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

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**FORM 10-K**

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- (Mark One)
- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 27, 2008
- OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

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**Nabi Biopharmaceuticals**

(Exact name of registrant as specified in its charter)

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

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

**12276 Wilkins Avenue, Rockville, MD 20852**  
(Address of principal executive offices, including zip code)

**(301) 770-3099**  
(Registrant's telephone number, including area code)

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

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

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Indicate by check mark 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, a non-accelerated filer, or a smaller reporting company (as defined in Exchange Act Rule 12b-2).

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller Reporting Company

Indicate by check mark whether the Registrant is a shell company  Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, as of the last business day of the Registrant's most recently completed second fiscal quarter was: \$212,393,851

As of February 16, 2009, 51,514,568 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 27, 2008, are incorporated by reference into Part III.

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**Nabi Biopharmaceuticals**

**PART I**

**ITEM 1. BUSINESS**

**OVERVIEW**

We are a biopharmaceutical company focused on the development of products that address unmet medical needs in the areas of nicotine addiction and infectious disease. We leverage our experience and knowledge in powering the human immune system to target serious medical conditions in these areas. Our products in development are NicVAX® [*Nicotine Conjugate Vaccine*], an innovative and proprietary investigational vaccine for treatment of nicotine addiction and prevention of smoking relapse, and PentaStaph™ [*Pentavalent S.aureus Vaccine*], a new pentavalent vaccine designed to prevent *S.aureus* infections including those infections caused by the most dangerous antibiotic-resistant strains of *S.aureus*. We were incorporated in Delaware in 1969 and our operations are located in Rockville, Maryland.

NicVAX is an investigational vaccine based on patented technology. Nicotine, a non-immunogenic small molecule, can cross the blood-brain barrier and reach specific receptors in the brain, thereby leading to the highly addictive pleasure sensation experienced by smokers and users of nicotine products. NicVAX is designed to stimulate the immune system to produce highly specific antibodies that bind to nicotine. A nicotine molecule attached to an antibody is too large to cross the blood-brain barrier, and thus is unable to reach the receptors in the brain and trigger pleasure sensations. In November 2007, we announced the successful completion of a Phase IIB “proof-of-concept” clinical trial for NicVAX that showed statistically significant rates of smoking cessation and continuous long-term smoking abstinence at 6 and 12 months for subjects injected with NicVAX as compared with subjects injected with placebo. In October 2008, we announced the results of a Phase II schedule optimization immunogenicity study assessing the antibody response and safety of a six-dose immunization schedule. This study showed that significantly higher antibody levels can be generated earlier in a higher percentage of subjects than in previous studies and that the revised dose regimen continued to be well-tolerated. These key results have confirmed the basis of our design for the NicVAX Phase III trials. In December 2008, we announced that we had reached agreement with the FDA on a Special Protocol Assessment, or SPA, for the pivotal Phase III clinical trial for NicVAX, which we are in a position to initiate in 2009. The SPA forms the foundation to support approval of a New Drug Application, or NDA. We are seeking a partner who will assist in further development of the vaccine including the Phase III trial and future commercialization.

PentaStaph is an investigational vaccine based on patented technology, including technology that we have licensed on an exclusive basis from the National Institutes of Health, or NIH. We are developing PentaStaph 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. PentaStaph requires additional development, including preclinical testing and human studies, as well as regulatory approvals before it can be marketed. We announced two significant events in 2008 that will help advance the development of PentaStaph. In September 2008, we entered into a collaboration agreement with the National Institute of Allergy and Infectious Diseases, or NIAID, to conduct pre-clinical toxicology evaluations of two new antigens designed to protect against two of the most virulent and debilitating toxins produced by the bacteria. This testing will enable the initiation of Phase I clinical trials for these new antigens in 2009. Additionally, in December 2008, we entered into a research and development agreement with the U.S. Department of Defense to conduct a series of collaborative clinical trials for PentaStaph. With these agreements in place, we will be able to advance the development of PentaStaph much further and faster than we could on our own. Further clinical development of PentaStaph and its components beyond that contemplated by our collaborations with NIAID and with the U.S. Department of Defense will require additional commercialization and development partners or additional commitments from existing partners.

Beginning in 2006 we initiated our strategic alternatives process to enhance shareholder value that resulted in the sale of all of our marketed products in a series of transactions, including the sale on December 4, 2007 of the assets constituting our Biologics strategic business unit and certain corporate shared assets to Biotest Pharmaceuticals Corporation, or Biotest, for \$185.0 million in cash (\$10.0 million of which has been escrowed

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for valid indemnification claims asserted on or before March 31, 2009). Consequently, as of December 29, 2007, we had sold all of our marketed products, moved our corporate headquarters to Rockville, Maryland and focused our efforts on developing and partnering our NicVAX and PentaStaph products.

Through our strategic alternatives process we are working with several advisors worldwide in our search for a partner or acquirer to advance the development of our products and further enhance shareholder value. These strategic alternatives may include, but are not limited to, licensing or development arrangements, joint ventures, strategic alliances, a recapitalization, and the sale or merger of all or part of the company.

### PRODUCTS IN DEVELOPMENT

The following table shows our current development products:

<u>Products</u>	<u>Indication/Intended Use</u>	<u>Status</u>
<b><i>Nicotine addiction</i></b>		
NicVAX®	Treatment of nicotine addiction	Phase IIb clinical trial completed in October 2007 and results presented at American Heart Association in November 2007 Primary claim of NicVAX patent in the European Union (EU) upheld under oppositions by Cytos by the European Patent Office (EPO) Phase II dose-schedule optimization study completed in October 2008 Special Protocol Assessment agreement reached with U.S. Food and Drug Administration in December 2008 for pivotal Phase III clinical trial Positioned to initiate Phase III clinical program in 2009
<b><i>Infectious disease</i></b>		
PentaStaph™	Protection against <i>S.aureus</i> infections	New pentavalent vaccine: <ul style="list-style-type: none"><li>• Types 5 and 8 capsular polysaccharides: Completed Phase III testing in 2005</li><li>• Type 336 cell-wall polysaccharide: Completed Phase I testing in 2005</li><li>• Panton-Valentine Leukocidin: Clinical manufacturing by a third party completed and pre-clinical toxicology evaluation in collaboration with NIH underway in preparation for Phase I clinical trial in 2009</li><li>• Alpha Toxin: Clinical manufacturing by a third party completed and pre-clinical toxicology evaluation in collaboration with NIH underway in preparation for Phase I clinical trial in 2009</li><li>• Further clinical efficacy testing through a Cooperative Research and Development Agreement with the U.S. Department of Defense beginning in 2009</li></ul>

## **NICOTINE ADDICTION**

### *Background*

Smoking is a global healthcare problem. The World Health Organization estimates that there are over 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 2030. According to the U.S. Centers for Disease Control and Prevention, or CDC, tobacco use is the single leading preventable cause of death in the U.S., responsible for approximately 440,000 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 46.2 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 after 12 months.

Nicotine addiction is difficult to treat. Most current therapies involve the use of “less harmful” forms of nicotine delivered via patches, lozenges or chewing gum. These therapies have shown only limited efficacy, particularly over the long term. Moreover, most smokers who stop smoking using current therapies resume their addiction after they stop therapy.

NicVAX is our investigational vaccine designed as an aid to smoking cessation, as well as an aid to prevent relapse. It represents an extension of our conjugate vaccine technology and allows us to address a significant medical need. We believe that, if approved, broad commercialization of NicVAX will require a marketing partner or partners that have demonstrated expertise in executing large scale primary care sales and marketing programs.

Nicotine is a small molecule that, upon inhalation into the body, quickly passes into the bloodstream and subsequently reaches the brain by crossing the blood-brain barrier. Once in the brain, the nicotine binds to specific nicotine receptors, resulting in the release of stimulants, such as dopamine, and providing the smoker with a positive sensation, leading to addiction. Because of its small size, nicotine on its own does not elicit the production of antibodies in humans. NicVAX is based on our proprietary conjugate technology whereby nicotine is bound to a carrier protein (technology licensed from the NIH) which renders the molecule immunogenic. Upon injection, NicVAX is capable of stimulating the immune system to produce nicotine-specific antibodies in the bloodstream that bind to nicotine upon cigarette smoking or the use of other nicotine products, thus preventing it from crossing the blood-brain barrier to enter the brain. As a result, the brain does not release the positive-sensation stimulants. We believe NicVAX has advantages over existing treatment therapies, in part, because it acts peripherally and is not expected to have significant central nervous system side effects, NicVAX’s benefit continues for approximately 6 to 12 months following vaccinations as antibodies to nicotine produced by the body’s immune system in response to the vaccine continue to be present in the bloodstream.

### *Clinical and Regulatory History*

In March 2006, we announced that NicVAX received Fast Track Designation from the U.S. Food and Drug Administration, or FDA. This designation is intended to facilitate the development of products that treat serious diseases where a significant unmet medical need exists. During 2006, we initiated and completed enrollment into a Phase IIb “proof-of-concept” study of 301 smokers who smoked an average of 24 cigarettes a day and thus were highly addicted to smoking and who were randomly allocated to receive one of four different doses or dosing schedules of NicVAX or a placebo. This study was funded in part by the National Institute for Drug Abuse, or NIDA.

The Phase IIb study was a double-blind, placebo-controlled and dose-ranging study was designed to establish proof-of-concept and the optimal dose for a Phase III program. This study, designed in collaboration with the FDA and other global regulatory agencies incorporated current clinical trial standards and protocol design for smoking cessation clinical research studies. The trial’s primary endpoint was the rate of carbon

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monoxide (CO)-confirmed continuous abstinence from smoking during weeks 19-26. In May 2007, we announced the trial's six-month data, which showed that a statistically significant number of patients in the high anti-nicotine antibody responder-group met the trial's primary endpoint of eight weeks of continuous abstinence between weeks 19-26.

In November 2007, we announced final results from this trial. The trial demonstrated that smoking cessation rates and long-term continuous abstinence rates correlated to higher levels of anti-nicotine antibodies, demonstrating proof-of-concept that antibodies to nicotine were useful as an aid to smoking cessation. The high-antibody responder group of vaccinated subjects showed continuous abstinence rates that were almost three times higher than placebo at 12 months. Those subjects in the NicVAX group with a high antibody response who continued to smoke showed a statistically significant reduction in cigarettes smoked over the full 12 months compared to placebo ( $p < 0.022$ ). The data also demonstrated that the group receiving 5 injections of 400 mcg of NicVAX had statistically significant increased rates of smoking cessation and continuous long-term smoking abstinence at one year compared with placebo. Furthermore, these data demonstrated that nearly three times the number of subjects treated with the optimal dose (400 micrograms) and schedule (five vaccinations), not stratified by antibody-response, were able to quit smoking and remained abstinent at 12 months compared with placebo ( $p < 0.038$ ). Importantly, there was no evidence of compensatory smoking or increase in withdrawal symptoms observed in NicVAX-treated patients at any stage of the trial. NicVAX was well-tolerated with a low prevalence of central nervous system side effects and an adverse event profile comparable to that seen with placebo.

Based on the results of the Phase IIb study, we believe that NicVAX could help more smokers to quit if they attempt to quit when higher levels of anti-nicotine antibodies are reached. Moreover, we reasoned that higher levels of antibodies could be achieved if an additional dose of NicVAX is administered. Therefore we initiated an additional study in January 2008 to further define this optimum dosing. The results of this study confirmed our hypothesis that significantly higher antibodies could be achieved earlier, and in a higher percentage of volunteers, with an additional dose of NicVAX. Those results were used to finalize the dosing schedule for the Phase III program for NicVAX. The FDA has agreed with our Phase III trial design, incorporating the additional dose of NicVAX, through a SPA which provides a clear, well-defined path for approval of NicVAX. The SPA is an agreement with the FDA which significantly reduces the regulatory risk of the program, in that if the Phase III trial achieves the SPA-specified end points, it typically leads to a license of the product, barring unforeseen safety outcomes.

Earlier clinical trials of NicVAX included four studies: one Phase I clinical trial (Nabi 4502) to evaluate safety in non-smoking adults, one Phase I/II clinical trial in 21 smokers and nine ex-smokers (Nabi 4503), one multi-site, NIDA-funded Phase II clinical trial in 68 smokers (Nabi 4504), and one Phase II dose-ranging clinical trial in 51 smokers (Nabi 4505). These studies demonstrated that the vaccine has a good safety profile and induces significant quantities of nicotine-specific antibodies in a dose-dependent manner. In Nabi 4504, the quit rate was increased and cigarette consumption, cotinine, CO and nicotine dependence were all reduced in the high-dose vaccine group compared with the placebo group. In addition, no compensatory smoking behavior or exacerbated withdrawal symptoms were observed.

The NicVAX development program has been guided by a panel of outside experts to provide input to the design of the Phase III clinical trials and the overall clinical development plans.

## **INFECTIOUS DISEASE**

### *Background*

*Staphylococcus aureus*, or *S.aureus*, is a major pathogen and is the leading cause of nosocomial, or hospital-acquired, infections. In a comprehensive survey of the U.S., Canada, and Europe, it was found that *S.aureus* accounted for 22% of all blood infections, 23% of all lower respiratory tract and 39% of all skin and soft tissue

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infections. The ability of *S.aureus* to acquire antibiotic resistance and to adapt to new antibiotics is well established. In some areas, more than 50% of *S.aureus* isolates are now resistant to methicillin. There are numerous examples demonstrating that vancomycin, presently the antibiotic of last resort against multi-drug resistant *S.aureus* infections, is not reliably able to clear *S.aureus* infections.

Methicillin-resistant *S.aureus*, or MRSA, infections are observed primarily in hospital settings, but there have been reports recently of significant increases in community-acquired MRSA infections. These community-acquired-methicillin resistant *S.aureus*, or CA-MRSA, infections typically cause skin and soft tissue infections, but they can cause sepsis and necrotizing pneumonia. These strains are resistant to  $\beta$ -lactams and a few other antibiotics, and produce Pantone Valentine Leukocidin, or PVL toxin.

*S.aureus* has developed a variety of methods to evade host defenses. The majority of clinically important *S.aureus* isolates possess capsular polysaccharides, or CPS, that cover the surface of *S.aureus* and contribute to the ability of the bacteria to evade immune clearance. Two types (5 and 8) were shown to comprise the majority of human clinical isolates. It has been demonstrated that antibodies specific for the CPS mediate opsonophagocytosis and bacterial killing by polymorphonuclear cells.

We have demonstrated that types 5 and 8 CPS can be targeted as a vaccine candidate. We also identified and patented the cell wall Type 336 antigen as a vaccine candidate. Type 336 is the third most common *S.aureus* clinical isolate, lacking or only partially covered by CPS types 5 or 8.

*S.aureus* also produces a variety of potent toxins. The toxin PVL can cause apoptosis (or cell death), tissue necrosis and leukocyte destruction, and is believed to play an important role in the virulence of CA-MRSA strains. Another important hemolytic toxin is alpha toxin, which is produced by almost all pathogenic strains of *S.aureus* and regarded as a major pathogenic factor of *S.aureus*. We have developed non-toxic versions of PVL and alpha toxin as components of a next generation pentavalent vaccine. This vaccine candidate may provide protection against a broad variety of hospital and community-acquired *S.aureus* infections.

### *Gram-positive vaccines*

Vaccines represent a new and innovative approach in broadening the available clinical tools against the global health problem of hospital-acquired bacterial infections. We have advanced the development of PentaStaph for use in patients who are at high risk of *S.aureus* infection. We believe that antibodies produced to the PentaStaph antigens help the immune system to eliminate the *S.aureus*.

In the original bivalent formulation (StaphVAX), only types 5 and 8 CPS were included. Data from our first Phase III trial announced in 2000 demonstrated that statistically significant prevention of *S.aureus* infections could be achieved in dialysis patients with our vaccine. In a second, confirmatory phase III trial in dialysis patients, the results of which were announced in November 2005, the vaccine failed to meet its endpoints. We believe that a next generation pentavalent PentaStaph vaccine, containing *S.aureus* Type 336 antigen combined with types 5 and 8 antigens, as well as PVL and detoxified alpha toxin will have the ability to provide protection against virtually all clinically significant *S.aureus* infections known today.

Both PVL and alpha toxin are major virulence factors of *S.aureus*. We have advanced programs for both of those toxins with the objective to include detoxified antigens of these toxins in our next generation pentavalent *S.aureus* vaccine. The programs are in the pre-clinical phase and are undergoing toxicology evaluations.

### *Clinical Trial History*

In 2005, we completed a Phase I study with our Type 336 vaccine. The trial was a double-blind, placebo-controlled study evaluating safety and antibody responses of the vaccine in 48 patients at four different dosage levels. The data supported the safety of the antigen and demonstrated a dose-related increase in levels of antibodies against *S.aureus* Type 336. In November 2005, we announced the results of our second Phase III

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clinical trial of StaphVAX, our bivalent version of the vaccine at the time. The study, a randomized, double-blind, placebo-controlled trial among 3,976 patients on hemodialysis did not meet its defined endpoint 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. These results were in contrast with the results of an earlier Phase III clinical trial among 1,804 end stage renal disease, or ESRD, patients previously reported in 2000, where it was shown that a single injection resulted in a 57% reduction in the incidence of *S.aureus* bacteremia. Consequently, we conducted an assessment in consultation with an outside panel of experts, including scientists and clinicians with expertise in immunology, vaccines, bacterial infections and nephrology. In an attempt to understand the results, the assessment focused on 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. Based on experimental data, the panel concluded that the quality of antibody produced in the recent trial was of lower quality than the antibody produced in the original trial. Moreover, evidence suggested that the vaccine lot used in the second Phase III trial had some subtle but significant structural differences from the lot used in the original trial as well as from lots manufactured more recently.

### *PentaStaph Development Status*

In collaboration with NIAID, we are conducting toxicology evaluations of two novel antigens that target two of the most virulent toxins produced by *S.aureus*; Pantone-Valentine Leukocidin, or PVL, and alpha toxin. Further clinical testing of PentaStaph will take place over the next three years under a Cooperative Research and Development Agreement, or CRADA, with the U.S. Department of Defense signed in November 2008. The CRADA proposes a series of collaborative clinical trials conducted and funded by the US Department of Defense, with Nabi providing the vaccines, regulatory support, site monitoring and data management. These trials include: Phase I evaluation of the safety and initial immunogenicity of the two toxoid compounds, PVL and alpha toxin; Phase II evaluation of the safety and immunogenicity of a trivalent vaccine containing the capsular polysaccharide types 5 and 8 and cell wall polysaccharide type 336; and Phase II evaluation of the safety and immunogenicity of the pentavalent vaccine containing all five components given in two separate, simultaneous doses. Further clinical development of PentaStaph and its components beyond that contemplated by our collaborations with NIAID and under the CRADA will require additional commercialization and development partners or additional commitments from existing partners.

## **STRATEGIC TRANSACTIONS**

On December 4, 2007, we sold certain assets constituting our Biologics SBU and certain corporate shared services assets to Biotest for \$185.0 million in cash, \$10.0 million of which was placed into an escrow account to support any valid indemnification claims made by Biotest on or before March 31, 2009. As of March 11, 2009, Biotest had not asserted any indemnification claims. Included in the assets sold were Nabi-HB® [*Hepatitis B Immune Globulin (Human)*], our plasma business assets including nine FDA-certified plasma collection centers across the U.S., our state-of-the-art plasma protein production plant, and the investigational products, IVIG, Civacir®, Anti-D and Altastaph® as well as most of our corporate shared services assets (other than cash, cash equivalents and marketable securities) and our Boca Raton, Florida headquarters and real property. We retained all accounts receivable and the vast majority of liabilities associated with the biologics business. We recorded a net gain on this sale of \$65.2 million during the fourth quarter of 2007 in discontinued operations, based on estimated asset and liability balances as of the date of sale. Adjustments to these estimates were charged to discontinued operations as necessary in 2008.

During the fourth quarter of 2007, we terminated an agreement with Fresenius Biotech GmbH, or Fresenius Biotech, for the development of the anti-thymocyte globulin product in the U.S. and Canada. Pursuant to this termination, we paid Fresenius Biotech the net sum of \$2.2 million in 2007. All activity related to this product, along with payments to Fresenius Biotech, is reported as discontinued operations.



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During the second quarter of 2007, we sold certain assets related to Aloprim to Bioniche Teoranta for aggregate sale proceeds of \$3.7 million. Of that amount, \$1.3 million was received at closing, \$1.4 million was received in the fourth quarter of 2007 and \$1.0 million was received in the fourth quarter of 2008. We recorded a net gain on this sale of \$2.6 million during the second quarter of 2007 in discontinued operations. In the first three quarters of 2007 as originally reported, we did not treat Aloprim as a discontinued operation given its relative immateriality. However, in the fourth quarter of 2007, we reclassified these results to discontinued operations along with the Biologics SBU business.

During the fourth quarter of 2006, we sold certain assets related to our PhosLo operations. Under the sale agreement, we received \$65.0 million in cash at closing and received an additional \$13.0 million of milestones as of March 11, 2009. We can also receive up to \$72.5 million in milestone payments and royalties. The royalties relate to sales of a new product formulation over a base amount for 10 years after the closing date.

Through our strategic alternatives process we are working with several advisors worldwide in our search for a partner or acquirer to advance the development of our products and further enhance shareholder value. These strategic alternatives may include, but are not limited to, licensing or development arrangements, joint ventures, strategic alliances, a recapitalization, and the sale or merger of all or part of the company.

### **CONTRACT MANUFACTURING AND OTHER SERVICES**

In connection with the sale of our Biologics SBU and certain corporate shared services assets, we entered into a Manufacturing Services Agreement with Biotest, which enables us to obtain clinical lots of our retained products as well as component products thereof from Biotest through December 31, 2009. The Manufacturing Services Agreement provides for payments to Biotest for manufacturing the products in an amount equal to Biotest's cost to manufacture the products, calculated in accordance with generally accepted accounting principles in substantially the same manner as calculated by us prior to the closing, but specifically excluding depreciation, amortization and other non-cash items. The Manufacturing Services Agreement obligates Biotest to allocate 50% of its vaccine manufacturing capacity in the Boca Raton facility, calculated on an average monthly basis, to the production of our products under the agreement. Also, Biotest is obligated to use commercially reasonable efforts to assist us in transitioning the manufacturing of products to us or our designee, including providing technical support, copies of relevant documentation, technical know-how and allowing third-party access to the Boca Raton facility, for which Biotest will be compensated on a time and materials basis at Biotest's cost to provide such services. Technology transfer relating to the manufacturing process has begun and we are in the process of identifying long-term manufacturing partners for our vaccine products in development.

In connection with the sale of our Biologics SBU and certain corporate shared services assets, we also entered into a Transition Services Agreement with Biotest pursuant to which we and Biotest agreed to provide transition services (including services related to finance, human resources, information technologies, and clinical and regulatory) to each other for a period of up to six months after closing for a price equal to 150% of direct salary costs plus out of pocket costs, except that there was no charge for services provided by Biotest to us through February 4, 2008. The Transition Services Agreement expired in accordance with its terms on June 4, 2008. However, the parties have continued to provide certain transition services to each other under the fee structure set forth in the Transition Services Agreement.

## PRODUCT DEVELOPMENT RELATIONSHIPS

We have entered into important relationships for our products in development that validate these products and facilitate their development.

### *National Institute of Allergy and Infectious Diseases*

As discussed further under “Overview” and “Infectious Diseases – PentaStaph Development Status,” we have entered into a collaboration agreement with the NIAID to conduct pre-clinical toxicological evaluations of two new antigens related to PentaStaph.

### *National Institute for Drug Abuse*

We have received grants from the NIDA that in the past has supported clinical development of NicVAX. We do not anticipate significant additional funding from these grants.

### *Department of Defense*

As discussed further under “Overview” and “Infectious Diseases – PentaStaph Development Status,” we have entered into a CRADA with the Department of Defense to conduct a series of clinical trials for PentaStaph.

### *National Institutes of Health*

The development of our PentaStaph product was initially based upon an exclusive license from the NIH of the worldwide right to use their patented conjugation process to manufacture vaccines against *staphylococcal* infections. Since obtaining that license, we have developed our own extensive global portfolio of issued patents and pending patent applications relating to both our novel vaccine products and methods of using such products as described in further detail below under “Patents and Proprietary Rights.” The initial NIH license remains in effect until the expiration of the last-to-expire licensed patent, which is April 20, 2010, and no further royalties will be due to NIH for use of the subject technology after that date.

Under a later license agreement with NIH, we have a non-exclusive, worldwide right to use the rEPA carrier protein technology to develop, manufacture and commercialize vaccines for uses other than vaccines against *staphylococcal* infections. Under the terms of this agreement NicVAX is subject to a 0.5% royalty upon commercialization.

### *University of Maryland, Baltimore County*

Under a license agreement with the University of Maryland, Baltimore County, or UMBC, we have an exclusive, worldwide right to use UMBC’s patented ring-expanded nucleosides and nucleotides, or RENs, for use in humans. During the term of the license, we are obligated to pay UMBC a 2% royalty based on net sales of license products covered by patent rights which are sold by us. This agreement remains in effect until the expiration of the last-to-expire licensed patent, which is January 13, 2021, and no further royalties will be due to UMBC for use of the subject technology after that date. We are responsible for prosecution and maintenance of the patent portfolio as described in further detail below under “Patents and Proprietary Rights.” We currently do not plan to significantly advance development of RENs until we find a suitable partner.

The product development relationships described above were entered into in the ordinary course of our product development business. While these relationships are important to us because they have provided and continue to provide us with access to technology and funding for development, as well as validating our products under development, we do not believe that any of the agreements relating to these relationships are individually material to us at this time.

**ALTASTAPH (NEXT GENERATION)**

In connection with the sale of our Biologics SBU and certain corporate shared services assets, we entered into a Right of First Refusal and Right of First Negotiation Agreement with Biotest pursuant to which we granted Biotest a right of first negotiation and a right of first refusal to obtain rights to utilize PentaStaph and to license the PentaStaph intellectual property that is necessary to enable Biotest to use PentaStaph solely for the manufacture, production or use of Altastaph [*Staphylococcus aureus* Immune Globulin Intravenous (Human)], a development stage biologic product we sold to Biotest.

**RESEARCH AND DEVELOPMENT PROGRAMS**

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

<u>(in thousands)</u>	<u>December 27, 2008</u>	<u>December 29, 2007</u>	<u>December 30, 2006</u>
NicVAX	\$ 5,186	\$ 2,122	\$ 4,534
PentaStaph	4,211	2,311	3,966
Other programs	80	838	1,877
	9,477	5,271	10,377
Unallocated overhead	3,079	13,570	18,368
Total R&D programs—continuing operations	12,556	18,841	28,745
Total R&D programs—discontinued operations	—	20,201	14,498
Total operations	<u>\$ 12,556</u>	<u>\$ 39,042</u>	<u>\$ 43,243</u>

Research and development expenses related to the NicVAX program are reflected net of NIDA reimbursements of \$1.5 million and \$2.2 million in 2007 and 2006, respectively. We had no NIDA reimbursements in 2008.

**PATENTS AND PROPRIETARY RIGHTS**

Our success depends in part on our ability to maintain our rights to our existing patent portfolio and our ability to obtain patent protection for product candidates in clinical development. Currently, we have been granted 170 patents and have over 100 patent applications pending worldwide.

*Smoking Cessation*

Our patent portfolio for technology related to the NicVAX product comprehends both compositions and therapeutic methodology for treating or preventing nicotine addiction. Our patent claims are directed to compositions, or conjugates, that comprise a nicotine-like molecule linked to a carrier protein and to methods for the use of these conjugates to treat or prevent nicotine addiction. In particular, we hold four issued U.S. patents relating to our conjugates, antibodies against the conjugates, and methods for using the conjugates and antibodies against nicotine addiction. These patents expire in 2018. Another granted U.S. patent related to a method of making nicotine haptens expires in 2027. We also have pending U.S. patent applications relating to our conjugates and their use. We hold granted patents in the following countries and regions, relating to our conjugates and antibodies against our conjugates, for use in treating nicotine addiction: Europe (18 countries), Poland, Australia, China, Eurasia (Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russian Federation, Tajikistan, Turkmenistan), Hong Kong, Indonesia, Korea, New Zealand, Israel, South Africa, Mexico and Turkey. We also have pending foreign patent applications relating to our conjugate technology in Brazil, Canada, China, Europe, Hungary, India, Japan, Mexico, Norway, Serbia, Montenegro and Kosovo. A pending U.S. application filed in cooperation with NIH is directed towards a method to decrease the toxic effects of nicotine on fetuses in pregnant women.

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In July 2005 Cytos filed an opposition against our European patent that covers NicVAX and its use in the treatment and prevention of nicotine addiction. The European Patent Office originally issued this patent to Nabi in late 2004 with an expiration date of January 12, 2019. We filed our response to the opposition in December 2005 and in April 2008, the European Patent Office (EPO) upheld the patent, preserving our primary claim that protects our exclusive use of NicVAX for treating and preventing nicotine addiction. The EPO cancelled some ancillary claims in the patent and we plan to appeal these ancillary claim cancellations. In 2008, Nabi as well as four other entities filed oppositions to invalidate all or a portion of the claims of two patents issued in May 2007 to Celtic Pharmaceuticals (successor to Xenova), covering hapten-carrier conjugates for use in drug-abuse therapy including nicotine addiction.

### *Gram-positive Program*

We have 137 patents issued, including 12 U.S. patents, over 100 patents in European countries and 25 in other countries, and over 65 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—Type 5 and Type 8 as well as our 336 *S.aureus* antigen and PS-1 *S.epidermidis* antigen—and to a glycopeptide antigen common to *S.epidermidis*, *S.haemolyticus* and *S.hominis*. Additional issued patents relate to *Enterococcus* and describe polysaccharide antigens from *E.faecalis* and *E.faecium*, respectively.

In addition to the licensed NIH patent that relates to the manufacture of PentaStaph, our granted U.S. patents and foreign 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 NIH licensed rights expires on April 20, 2010. After this date, no further royalties will be due to the NIH for use of the technology.

Another granted U.S. patent relates to a method of protecting a human being with a compromised immune system from *Staphylococcal* infection using Type 5 and Type 8 antigens. This patent expires in 2022. Corresponding patents have been granted in Australia, China, Eurasia, India, New Zealand and South Africa and applications are pending in Europe, Canada, Japan, Mexico, Brazil, South Korea, Indonesia and Hong Kong.

Other patent applications still pending include claims directed to compositions and methods for treating and preventing *S.aureus* infections, including infections by CA-MRSA and bacteremia using our antigens and antibodies. In addition, we have filed U.S. and foreign patent applications covering methods directed to the use of PentaStaph, among other compositions. These applications, which address a method of protecting a human being with a compromised immune system from *Staphylococcal* bacterial infection, include claims that prescribe use of our proprietary antigens and or the Type 5 and Type 8 *S.aureus* antigens in combination with alpha toxin antigens, and also include parallel antibody claims for passive immunization. Patent applications also are pending for Pantone-Valentine Leukocidin antigens and antibodies that expand our gram-positive portfolio. Pending claims relate to LukF-PV and LukS-PV proteins and cognate antibodies, to mutated versions of those proteins, which are PVL subunits, and to fusion protein combinations of the subunits.

With regard to *S.epidermidis*, we have been issued 3 U.S. patents and foreign patents, including patents that have been issued in 18 European countries. The patents issued in the U.S. and Europe contain claims to vaccines and hyperimmune globulins against *S.epidermidis* surface antigen. Most of these patents expire in 2016. The granted U.S. patent to a glycopeptides antigen common to *S.epidermidis*, *S.haemolyticus* and *S.hominis* expires in 2019, and foreign counterparts expire in 2020.

Also in this portfolio are issued U.S., European and Canadian patents (and a pending patent application in Mexico) that contain claims directed to a pharmaceutical composition containing a glucan and antibodies 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 antibodies are used separately. Another related U.S. patent has been granted with claims to a pharmaceutical composition containing a glucan and intravenous hyperimmune globulin.

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Our patent portfolio for technology related to RENs program covers broad classes of RENs compounds targeting viral infections and cancer. We hold two U.S. patents and have patents in Europe (16 countries), Mexico and Canada. We have one U.S. pending patent application.

### *Trade Secrets and Trademarks*

We rely on unpatented proprietary technologies in the development 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 development products.

## **GOVERNMENT AND INDUSTRY REGULATION**

Our research, pre-clinical development and conduct of clinical trials are subject to regulation for safety and efficacy by numerous governmental authorities including the U.S., Canada, United Kingdom, 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. In addition, these statutes, regulations and policies may change and our products may be subject to new legislation or regulations.

### *Biopharmaceutical Products*

Vaccines are classified as biological products under FDA regulations and are subject to rigorous regulation by the FDA. All of our products will require regulatory approval by governmental agencies prior to commercialization. The process of obtaining these approvals and subsequent process of maintaining substantial compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. The steps required before a biological product may be marketed in the U.S. generally include pre-clinical laboratory tests, animal tests and formulation studies, and the submission 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, and adequate and well-controlled clinical trials to establish the purity, potency, and efficacy of the biological product for each indication for which FDA approval is sought.

The clinical phase of development involves the activities necessary to demonstrate safety, tolerability, efficacy and dosage of the substance in humans, as well as the ability to produce the substance and finished biological product in accordance with the FDA's current Good Manufacturing Practice, or cGMP, requirements. Clinical trials to support the approval of a biological product are typically conducted in three sequential phases, Phases I, II and III, with Phase IV clinical trials conducted after marketing approval. 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. Multiple Phase II clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some cases, a sponsor may decide to conduct what is referred to as a "Phase IIb" evaluation, which is a second, confirmatory Phase II clinical trial. 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

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post-licensure, such as additional large-scale, long-term studies of morbidity and mortality. The FDA may require sponsors to conduct Phase IV clinical trials to study certain safety issues. 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.

Success in early-stage clinical trials does not necessarily assure success in later-stage clinical trials. Data obtained from clinical activities is not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval. In addition, the FDA can request that additional clinical trials be conducted as a condition to product approval.

The results of all trials are submitted in the form of a Biologics License Application, or BLA. The BLA must be approved by the FDA prior to commencement of commercial sales. For BLA 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-blind, 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. If the FDA determines that a risk evaluation and mitigation strategy, or REMS, is necessary to ensure that the benefits of the biological product outweigh the risks, a sponsor may be required to include as part of the application a proposed REMS, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on distribution, or a medication guide to provide better information to consumers about the risks and benefits of the biological product. In addition, the prospective manufacturer's methods must conform to the agency's 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 submission of the BLA is no guarantee that the FDA will find it complete and accept it for filing. The FDA reviews all applications submitted before it accepts them for filing. It may refuse to file the BLA and request additional information rather than accept the application for filing, in which case, the application must be resubmitted with the supplemental information. After the BLA is deemed filed by the FDA, agency staff of the FDA reviews the application to determine, among other things, whether a product is safe and efficacious for its intended use. 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 has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its BLA. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of physicians, for review, evaluation, and an approval recommendation. The FDA also may require post-marketing surveillance to monitor potential adverse effects of the product. If required to conduct a post-approval study, we must submit periodic status reports to the FDA. Failure to conduct such post-approval studies in a timely manner may result in substantial civil fines.

The overall regulatory process is similar within the EU insofar as the sponsor needs to demonstrate a favorable risk-benefit ratio of the biological product, as well as reproducible manufacturing methods. The European equivalent of the BLA is called the Marketing Authorization Application, or MAA. There are two different procedures to file an MAA, the Centralized Registration Procedure and the Mutual Recognition Procedure. The Centralized Registration 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.

### *Fast Track Designation*

NicVAX was granted Fast Track review designation for the indication aid to smoking cessation in 2006. StaphVAX, the predecessor to PentaStaph was granted Fast Track review designation for protection from infection with *S.aureus* for the ESRD indications.

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Fast Track designation refers to a process of interacting with the FDA during drug development and is intended for a combination of a product and a claim that addresses an unmet medical need. The Fast Track mechanism is described in the Food and Drug Administration Modernization Act of 1997. The benefits of the Fast Track designation include scheduled meetings to seek FDA input into development plans, the option of submitting a BLA in sections rather than all components simultaneously, and the option of requesting evaluation of studies using surrogate endpoints. Award of the designation does not ensure product approval by the agency, and the agency can withdraw the designation if the product, during development, no longer meets the standards for meeting an unmet medical need. The Fast Track mechanism is independent of Priority Review and Accelerated Approval, which are other regulatory programs to expedite product development and review.

### *Special Protocol Assessment (SPA)*

The Company has reached agreement with the FDA on an SPA for a pivotal Phase III trial of NicVAX. The SPA is a process that provides for an official FDA evaluation of Phase III clinical study protocols. The SPA provides trial sponsors with binding written agreement that the design and analysis of the studies are adequate to support a license application submission if the study is performed according to the SPA parameters and the results are successful. The SPA agreement may only be changed by the sponsor company or the FDA by a written agreement, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety.

### *Post-Approval Regulation*

After approval, biological products are subject to ongoing review. The failure to comply with the applicable regulatory requirements may subject a company to a variety of administrative or judicially imposed sanctions. These sanctions could include FDA's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution.

### *Reimbursement*

Future commercial sales of our products depend significantly on appropriate payments from federal and state government healthcare authorities, which regularly consider and implement coverage and payment reforms. An example of payment reform is the addition of an expanded prescription drug benefit for all Medicare beneficiaries known as Medicare Part D. This is a voluntary benefit that is being implemented through private plans under contractual arrangements with the federal government. Similar to pharmaceutical coverage through private health insurance, Medicare Part D plans establish formularies that govern the drugs, biologicals and vaccines that will be offered and the out-of-pocket obligations for such products. Medicare Part D plans often negotiate discounts from manufacturers for drugs that will be included on their drug formularies. Effective January 1, 2008, private Medicare Part D plans will pay physicians one payment that includes both the administration cost and the cost of the vaccine.

## **COMPETITION**

Existing products in the smoking cessation marketplace consist of three general categories of therapeutic approach: (a) direct nicotine replacement; (b) anti-depressant therapy; and (c) nicotine receptor partial agonists. Nicotine replacement therapies, or NRT's, represent a first generation approach to assisting smokers to quit by substituting a less harmful form of nicotine than inhalation by smoking. NRT's are mildly effective and support smoking cessation in combination with behavioral modification. NRT's come in a number of forms of administration: gums, patches, lozenges and inhalers. Many forms of NRT's are currently available over the counter. Zyban is the only anti-depressant which is FDA approved specifically to aid smoking cessation that acts mainly through a reduction in craving and withdrawal symptoms. Pfizer Inc.'s Chantix® product, a nicotine receptor partial agonist, represents a new class of prescription therapeutic that blocks nicotine from interacting with the nicotine receptor in the brain and has defined a new standard of care.

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Examples of other product candidates in development that pose competitive risk are additional selective glycine receptor antagonists (GlaxoSmithKline; phase II) and nicotine-derived therapeutic vaccines. Nic-002 (phase II) and TA-Nic (phase II) are nicotine-derived therapeutic vaccines being developed by Cytos/Novartis Pharmaceuticals and Celtic Pharmaceuticals, respectively, which if successfully developed and registered, may directly compete with NicVAX.

Effective marketed products for the prevention of *S.aureus* infection do not exist. Currently, the treatment market is dominated by many small molecule antibiotics for which *S.aureus* has developed varying degrees of resistance. Several biologic products including monoclonal antibodies, polyclonal antibodies and vaccines are at various stages of development for the treatment and prevention of *S.aureus* infection. The more advanced competitive vaccine programs include: V710 from Merck/Intercell (phase II), SA75 from VRi (phase I) and Wyeth/Inhibitex *staphylococcal vaccine* (phase I). Given this landscape, we believe that the pentavalent PentaStaph program is currently one of the most advanced vaccine development programs for the prevention of *S.aureus* infection.

For a discussion of the risks associated with competition, see below under “Item 1A. Risk Factors.”

### **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 40 employees at December 27, 2008.

### **FINANCIAL INFORMATION ABOUT SEGMENTS AND GEOGRAPHIC AREAS**

We operate in one industry segment, and have no material operations in any country other than the U.S.

### **AVAILABLE INFORMATION**

Our Internet address is <http://www.nabi.com>. We make available, free of charge, through our Internet website, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.



## ITEM 1A. RISK FACTORS

*Statements in this document that are not strictly historical are forward-looking statements and include statements about products in development, results and analyses of clinical trials and studies, research and development expenses, cash expenditures, licensure applications and approvals, and alliances and partnerships, among other matters. You can identify these forward-looking statements because they involve our expectations, intentions, beliefs, plans, 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: successfully partner with third parties to fund, develop, manufacture and/or commercialize our products in development; initiate and conduct clinical trials and studies; raise sufficient new capital resources to fully develop and commercialize our products in development; attract, retain and motivate key employees; collect further milestone and royalty payments under the PhosLo Agreement; obtain regulatory approval for our products in the U.S. or other markets; successfully contract with third party manufacturers for the manufacture and supply of NicVAX and PentaStaph; and comply with reporting and payment obligations under government rebate and pricing programs; and raise additional capital on acceptable terms, or at all. These factors and others are more fully discussed below.*

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

***We do not have sufficient capital resources to fully develop, commercialize and market our products in development and will require partnerships or additional financing to do so.***

We have incurred and will continue to incur significant costs in connection with the development of our products, including the cost of clinical trials and manufacturing products for clinical trials as well as cost of the regulatory process. Our products under development may not generate sales for several years or at all. We do not have the financial resources to fund all of our products in development to completion. We expect that our existing capital resources will enable us to maintain our operations for at least the next 12 months based on current activities; however, to fully fund ongoing and planned activities we will need to collaborate with commercialization and development partners, or if we are unable to do so, raise additional funds. There can be no assurance that we will be successful in obtaining commercialization and development partners or that we otherwise will be able to raise sufficient funds. Our inability to do so will have a material adverse effect on our future prospects.

We may seek additional funding through public or private equity or debt financing, collaborative arrangements with strategic partners or from other sources. Our ability to raise additional equity may be negatively impacted from the trading price of our common stock and lack of currently marketable products. To the extent that we raise additional funds through collaboration or licensing arrangements, we will be required to relinquish some or all rights to our technologies or product candidates and may be required 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 will 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 or financial position.

***Our inability to enter into or successfully manage strategic relationships to develop, manufacture, commercialize and market our products in development will have a material adverse effect on our future business, financial condition and results of operations.***

Our strategy for developing, manufacturing, commercializing and marketing our products in development and to fund certain of these activities currently requires us to enter into and successfully maintain strategic relationships with other pharmaceutical companies or other industry participants to advance our programs. In

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particular, we will need to rely on strategic partners for the clinical testing and commercialization of PentaStaph and NicVAX. If we fail to enter into or maintain successful strategic relationships for our products in development, we will have to reduce or delay our product development, increase our expenditures or cease development with respect to certain of our pipeline products. No assurance can be given that we will be successful in our efforts to enter into or maintain successful strategic relationships. Even if we are successful in entering into a strategic alliance, there is no assurance that our collaborative partners will conduct their activities in a timely and effective manner. If we are not successful in our strategic alliance efforts, our ability to develop, manufacture, commercialize and market our products will be affected adversely. Even if we are successful in entering into strategic relationships, if any of our collaborative partners violates or terminates its agreements with us or otherwise fails to complete its collaborative activities in a timely manner, the development, manufacture, commercialization or marketing of our products could be delayed, including delays in our ability to conduct clinical trials or obtain licensure of our products. These and other possible problems with our collaborative partners, including litigation or arbitration, could be time consuming and expensive and could have a material adverse effect on our future business, financial condition and results of operations.

### ***Our strategic alternatives process may not be successful.***

We intend to continue our strategic alternatives process to further enhance shareholder value. These strategic alternatives may include, but are not limited to, licensing or development arrangements, joint ventures, strategic alliances, a recapitalization, and the sale or merger of all or part of the company. We are working with several advisors. There can be no assurance that the exploration of strategic alternatives will result in any future agreements or transactions. The failure of the Company to successfully conclude one or more strategic transactions could have a material adverse effect on the Company, including our ability to retain key personnel and advance our operational business objectives.

### ***Our product candidates are in or will undergo clinical trials and the results from these trials may not be favorable.***

Our product candidates are in or will undergo clinical trials. These trials may not meet their defined endpoints, and, even if they do achieve their endpoints, we cannot be certain that results from future clinical trials will be positive. For example, the results of our Phase III trial of StaphVAX, our original vaccine against *S.aureus* infection, announced in November 2005 were not positive. Unfavorable clinical trial results in any clinical trial will adversely affect our business plans and have an adverse effect on our market valuation and our future business, financial condition and results of operations.

### ***To be successful, we must attract, retain and motivate key employees, and the inability to do so could seriously harm our operations.***

Our ability to compete in the highly competitive biopharmaceutical industry depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. In order to induce valuable employees to remain at the Company, in 2006 we created a retention program offering to certain key employees cash and equity incentives that vest over time. At the end of 2007 and in 2008, we made equity and cash retention awards designed to motivate and retain key employees. The value to our employees of these incentives is significantly affected by our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, manufacturing, research and clinical teams may terminate their employment with us on short notice with a material impact on the Company. The loss of the services of any of our key employees could potentially harm our future business, financial condition and results of operations. Other biotechnology and pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. If we are unable to continue to attract and retain the right balance of high quality personnel with suitable expertise, our business and ability to continue our business and development programs will be adversely effected.

***We may not collect any further milestone or royalty payments under the PhosLo Agreement.***

We may not collect any further milestone or royalty payments under the PhosLo Agreement with Fresenius. We received \$65.0 million in cash at closing and received an additional \$13.0 million of milestones as of March 11, 2009. We can also receive up to \$72.5 million in milestone payments and royalties. The royalties relate to sales of a new product formulation over a base amount for 10 years after the closing date. There can be no assurance of the completion of additional milestones or sales of the new product formulation. If we are unable to complete any additional milestones and if there are no sales of the new product formulation, we will not collect any further milestone or royalty payments under the PhosLo Agreement.

***We depend upon third parties to manufacture our products in development.***

We depend upon third parties to manufacture our products in development. Pursuant to a Manufacturing Services Agreement between us and Biotest, we are relying on Biotest to manufacture and transfer manufacturing technology to another manufacturer during 2009. There can be no assurance that Biotest will meet its obligations to manufacture product and successfully transfer manufacturing ability to a new contract manufacturer. There also can be no assurance that we will be able to secure a new contract manufacturer for our products under development and that a new contract manufacturer will be able to successfully manufacture sufficient quantities of our products on a timely basis to permit continued development of our products and to commercialize our products in development. Creating and transferring a manufacturing process for biopharmaceutical products and manufacturing those products are complicated endeavors often fraught with technical difficulties that can significantly delay or prevent the successful manufacture of those products. At times, contract manufacturers have failed to meet our needs and we have experienced product losses at our contract fill and finisher. The failure of our contract manufacturers to supply us with sufficient amounts of product on a timely basis to meet our clinical or commercial needs, or to renew their contracts with us on commercially reasonable terms or at all, or to transfer manufacturing capability to a new contract manufacturer, would have a material adverse effect on our future business, financial condition and results of operations.

***Under the Biologics strategic business unit asset purchase agreement, we will have continuing obligations to indemnify Biotest, and may be subject to other liabilities.***

In connection with the sale of our Biologics SBU and certain corporate shared services assets to Biotest, we agreed to indemnify Biotest for a number of specified matters including the breach of our representations, warranties and covenants contained in the asset purchase agreement. Under the asset purchase agreement, \$10.0 million of the total cash consideration was deposited into an escrow account, which will be released to Nabi on April 15, 2009 unless Biotest presents a valid claim, to secure our indemnification obligations to Biotest following the closing. Our indemnification obligations under the asset purchase agreement could cause us to be liable to Biotest under certain circumstances, in excess of the amounts set forth in the escrow account and potentially could reach up to 25% of the purchase price. Also under the asset purchase agreement, we retained the liabilities related to our products sold prior to the consummation of the sale. As of March 11, 2009, Biotest had not asserted any indemnification claims; however, claims could arise and additional liabilities could be substantially higher than what we currently estimate. Either of these items could have a substantial negative impact on our continuing business.

***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

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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, others may design their patents around our 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. See “Business – Patents and Proprietary Rights – Smoking Cessation.”

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

Litigation may be necessary to enforce any patents issued to us or to determine the scope or validity of third-party proprietary rights or to defend against any claims that our business infringes on third-party proprietary rights. Patent litigation is expensive and could 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 do.***

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. 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 or marketing. In addition, one or more of our competitors may achieve product commercialization or patent protection for competitive products earlier than us, which would preclude or substantially limit sales of our products. 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.

***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;
- the potential advantages over existing treatment methods to the medical community;
- results and timing 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 products to gain market acceptance 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 and foreign regulatory agencies, the sale of our future products could 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, foreign regulatory agency or other required regulatory approvals is lengthy and expensive, and the time required for such approvals is uncertain. The approval process is affected by such factors as:

- the severity of the disease;
- the quality of submission;
- the clinical efficacy and safety 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 relative efficacy 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. Further, Congress can enact legislation that provides a formalized mechanism in the U.S. to allow for the approval of generic versions of biological products, which currently is not available.

Finished products and their components used for commercial sale or in clinical trials must be manufactured in accordance with cGMP requirements, a series of complex regulations and recommendations in guidance documents that govern manufacturing processes and procedures to assure the quality of our product candidates and products approved for commercial distribution. In addition, the FDA may, at any time, audit or inspect a manufacturing facility involved with the preparation of our products, its components, or our other product candidates for compliance with the regulations applicable to the activities being conducted. If any such inspection or audit identifies a failure to comply with applicable regulations, the FDA may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may result in an inability to receive approval, recall of products, delay in approval or restrictions on the product or on the manufacturing post-approval, including the temporary or permanent suspension of a clinical trial or commercial

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sales or the temporary or permanent closure of a facility. Material violations of cGMP requirements could result in regulatory sanctions and, in severe cases, could result in a mandated closure of our facility or the facility of our third party contractors. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business.

Some of our clinical trials are at a relatively early stage. 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 regulatory approvals 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 which could have a material adverse effect on our future business, financial condition and results of operations.

New regulations may be enacted and existing regulations, their interpretation and enforcement, are subject to change. There can be no assurance that we will be able to continue to comply with any regulations.

***We may be subject to costly and damaging product liability and other claims in connection with the development and commercialization of our product candidates.***

Pharmaceutical and biotechnology companies are subject to litigation, including class action lawsuits, and governmental and administrative investigations and proceedings, including with respect to product pricing and marketing practices. There can be no assurance that lawsuits will not be filed against us or that we will be successful in the defense of these lawsuits. Defense of suits can be expensive and time consuming, regardless of the outcome, and an adverse result in one or more suits could have a material adverse effect on our future business, financial condition and results of operations.

***We may not be able to maintain sufficient insurance, including products 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 any 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 officers.

***There are potential limitations on third-party reimbursement, complex regulations for reimbursement of products and other pricing-related matters that could adversely affect our ability to successfully commercialize our products in development and impair our ability to generate sufficient revenues from future product sales.***

Our ability to commercialize our products and related treatments depends in part upon the availability of, and our ability to obtain adequate levels of reimbursement from government health 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. There are high levels of regulatory complexity related to reimbursement from U.S. and other government payers that can significantly limit available reimbursement for marketed 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

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provide any coverage for specific disease indications for which the FDA has not granted marketing approval. The cost containment measures that healthcare providers are instituting or the impact of any healthcare reform laws could have an adverse effect on our ability to sell our products or 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. There can be no assurance that reimbursement in the U.S., the EU or other markets will be available for our products in development, 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 in development. The unavailability of government or third-party reimbursement or the inadequacy of the reimbursement for medical treatments using our products in development could have a material adverse effect on our future business, financial condition and results of operations.

### ***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 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

We lease office, laboratory, pilot manufacturing and warehouse space in Rockville, Maryland. The laboratory space is leased on a month to month basis. 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 have fully subleased the facility to a third party.

**ITEM 3. LEGAL PROCEEDINGS**

We are parties to legal proceedings that we believe to be ordinary, routine litigation, incidental to the business to present or former operations. It is management's opinion, based on the advice of counsel, that the ultimate resolution of such litigation will not have a material adverse affect on our financial condition, results of operations, or cash flows.

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

Not applicable.

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

The executive officers of Nabi Biopharmaceuticals are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b>Raafat E.F. Fahim, Ph.D.</b>	55	Chief Executive Officer, President, Acting Chief Financial Officer and Director
<b>Paul Kessler, M.D.</b>	54	Senior Vice President, Clinical, Medical and Regulatory and Chief Medical Officer

*Dr. Fahim* has served as Chief Executive Officer and President since January 22, 2008 and also as acting Chief Financial Officer since May 27, 2008. From July 2007 to January 2008, Dr. Fahim served as Senior Vice President, Research, Technical and Production Operations of the Company and Chief Operating Officer and General Manager of the Biologics SBU. From March 2003 to July 2007, Dr. Fahim served as Senior Vice President, Research, Technical and Production Operations of the Company. 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. Kessler* has been the Senior Vice President, Clinical, Medical and Regulatory and Chief Medical Officer since March 2007. He joined Nabi Biopharmaceuticals in March 2005 as Senior Director, Clinical Research, and in April 2006, he was promoted to Vice President, Clinical Research. From 1998 to 2005, he served in several positions at GenVec, Inc., a gene therapy company, including Program Director, Director Clinical Research, Senior Director Clinical Research, and Executive Director Clinical Research. From 1989 to 1998, he was an Assistant Professor and later Associate Professor of Medicine at the Johns Hopkins University School of Medicine, where he conducted gene and cell therapy research and where he was an attending cardiologist on the Heart Failure and Transplant Service. He earned a B.S. from the University of Pittsburgh, a M.Sc. from the University of London, and an M.D. from Columbia University College of Physicians and Surgeons. He trained in Medicine and Cardiology at The Mount Sinai Hospital, New York, and Johns Hopkins.



**PART II**

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

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

	<u>High</u>	<u>Low</u>
<b>2008:</b>		
First Quarter ended March 29, 2008	\$ 3.76	\$ 3.22
Second Quarter ended June 28, 2008	4.50	3.69
Third Quarter ended September 27, 2008	6.16	3.81
Fourth Quarter ended December 27, 2008	4.98	2.75
<b>2007:</b>		
First Quarter ended March 31, 2007	\$ 6.83	\$ 4.64
Second Quarter ended June 30, 2007	6.13	4.60
Third Quarter ended September 29, 2007	4.94	3.01
Fourth Quarter ended December 29, 2007	4.21	3.04

The closing price of our common stock on February 13, 2009 was \$4.28 per share. The number of record holders of our common stock on February 13, 2009 was 958.

No cash dividends have been previously paid on our common stock and none are anticipated in 2009.

Information regarding securities authorized for issuance under equity compensation plans is included in Item 12 of this Annual Report on Form 10-K.

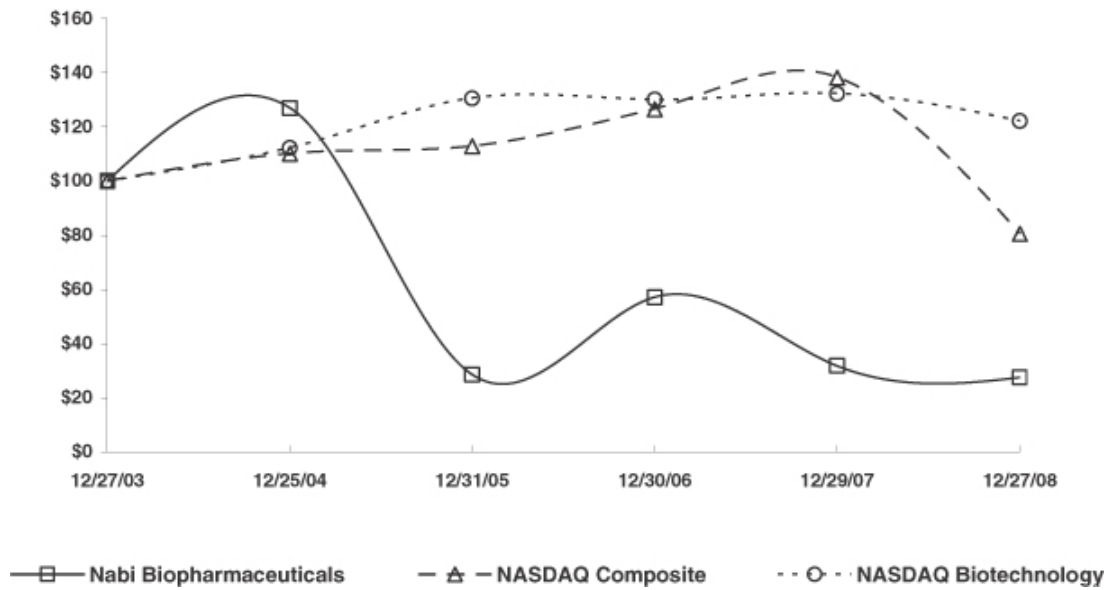
**ISSUER PURCHASES OF EQUITY SECURITIES IN THE FOURTH QUARTER OF 2008**

<u>Period</u>	<u>Total Number of Shares Purchased</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(1)</sup></u>	<u>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup></u>
9/28/08-11/1/08	112,649	\$ 3.11	112,649	\$ 29.4 million
11/2/08-11/29/08	308,111	\$ 3.17	308,111	\$ 28.5 million
11/30/08-12/27/08	111,123	\$ 3.21	111,123	\$ 28.1 million
Total	531,883	\$ 3.17	531,883	\$ 28.1 million

<sup>(1)</sup> On December 6, 2007, we announced that our Board of Directors approved the buyback of up to \$65 million of our common stock in the open market or in privately negotiated transactions. This share repurchase program includes the \$3.1 million outstanding balance from the \$5 million share repurchase program we announced in 2001. Repurchased shares have been accounted for as treasury stock. Subsequent to year end, through March 11, 2009, we have repurchased an additional 127,742 shares for \$411 thousand.

COMPARATIVE STOCK PERFORMANCE

The following graph and chart compare, during the five-year period commencing December 27, 2003 and ending December 27, 2008, the annual change in the cumulative total return of our common stock with the NASDAQ Stock Market (Composite) and the NASDAQ Biotech Stocks indices, assuming the investment of \$100 on December 27, 2003 (at the market close) and the reinvestment of any dividends.



	2003	2004	2005	2006	2007	2008
<b>Nabi Biopharmaceuticals</b>	\$ 100.00	\$ 126.89	\$ 28.40	\$ 56.97	\$ 31.68	\$ 27.39
<b>NASDAQ Composite</b>	\$ 100.00	\$ 110.08	\$ 112.88	\$ 126.51	\$ 138.13	\$ 80.47
<b>NASDAQ Biotechnology</b>	\$ 100.00	\$ 112.17	\$ 130.53	\$ 130.05	\$ 132.24	\$ 122.10

## ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth selected consolidated financial data for the five years ended December 27, 2008 that was derived from our audited consolidated financial statements. The consolidated financial data for 2007, 2006 and 2004 has been restated, as further described in Note 2 to our audited consolidated financial statements as of and for the year ended December 27, 2008. We determined in connection with the preparation of our 2008 consolidated financial statements that our consolidated financial statements required restatement to correct errors in the allocation of the income tax provision between continuing and discontinued operations. We previously did not consider income we reported from discontinued operations for purposes of determining the amount of income tax benefit that results from a loss from continuing operations and that should be allocated to continuing operations. The adjustments did not have any impact on our consolidated net income for any period. Additionally, for all periods shown, the results from our Biologics SBU, as well as our Aloprim and PhosLo product lines, have been reclassified as discontinued operations; these businesses represented all of our revenue-generating products.

The selected financial data should be read in conjunction with, and are qualified by reference to, our Consolidated Financial Statements and the Notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

(in thousands, except per share amounts)	For the Years Ended				
	December 27, 2008	December 29, 2007 (restated)	December 30, 2006 (restated)	December 31, 2005	December 25, 2004 (restated)
<b>Statement of Operations Data:</b>					
Operating expenses:					
Selling, general and administrative expense	\$ 12,415	\$ 26,090	\$ 32,576	\$ 37,042	\$ 27,512
Research and development expense	12,556	18,841	28,745	57,788	53,924
Amortization of intangible assets	—	—	—	414	111
Impairment of vaccine manufacturing facility	—	—	—	19,842	—
Write-off of inventory and manufacturing right	—	—	—	7,554	—
Operating loss	(24,971)	(44,931)	(61,321)	(122,640)	(81,547)
Interest income	4,579	6,026	4,148	4,094	1,628
Interest expense	(1,456)	(3,454)	(3,467)	(2,460)	(957)
Other income (expense), net	4,122	3,576	(66)	(478)	316
Loss from continuing operations before income taxes	(17,726)	(38,783)	(60,706)	(121,484)	(80,560)
(Provision) benefit for income taxes	2,765	14,265	753	2,916	17,444
Loss from continuing operations	(14,961)	(24,518)	(59,953)	(118,568)	(63,116)
Net income (loss) from discontinued operations	4,245	71,587	1,250	(9,881)	12,726
Net income (loss)	<u>\$ (10,716)</u>	<u>\$ 47,069</u>	<u>\$ (58,703)</u>	<u>\$ (128,449)</u>	<u>\$ (50,390)</u>
Basic and diluted income (loss) per share:					
Continuing operations	\$ (0.29)	\$ (0.41)	\$ (0.98)	\$ (1.98)	\$ (1.07)
Discontinued operations	0.09	1.19	0.02	(0.17)	0.21
Basic and diluted income (loss) per share	<u>\$ (0.20)</u>	<u>\$ 0.78</u>	<u>\$ (0.96)</u>	<u>\$ (2.15)</u>	<u>\$ (0.86)</u>
<b>Balance Sheet Data (at year end):</b>					
Cash, cash equivalents and marketable securities	\$ 130,338	\$ 219,206	\$ 118,727	\$ 106,934	\$ 103,109
Working capital	134,540	205,893	217,715	185,561	98,182
Total assets	144,149	238,570	265,877	329,336	368,171
Convertible senior notes	16,024	71,738	109,313	109,145	—
Total stockholders' equity	<u>\$ 120,488</u>	<u>\$ 146,532</u>	<u>\$ 111,388</u>	<u>\$ 161,827</u>	<u>\$ 284,321</u>

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

### Our Strategy

We are a biopharmaceutical company focused on the development of products that address unmet medical needs in the areas of nicotine addiction and infectious disease. We leverage our experience and knowledge in powering the human immune system to target serious medical conditions in these areas. Our products in development are NicVAX, an innovative and proprietary investigational vaccine for treatment of nicotine addiction and prevention of smoking relapse, and PentaStaph, a pentavalent vaccine designed to prevent *S.aureus* infections including those infections caused by the most dangerous antibiotic-resistant strains of *S.aureus*.

NicVAX is an investigational vaccine based on patented technology. Nicotine, a non-immunogenic small molecule, can cross the blood-brain barrier and reach specific receptors in the brain, thereby leading to the highly addictive pleasure sensation experienced by smokers and users of nicotine products. NicVAX is designed to stimulate the immune system to produce highly specific antibodies that bind to nicotine. A nicotine molecule attached to an antibody is too large to cross the blood-brain barrier, and thus is unable to reach the receptors in the brain and trigger pleasure sensations. In November 2007, we announced the successful completion of a Phase IIb "proof-of-concept" clinical trial for NicVAX that showed statistically significant rates of smoking cessation and continuous long-term smoking abstinence at 6 and 12 months for subjects injected with NicVAX as compared with subjects injected with placebo. In October 2008, we announced the results of a Phase II schedule optimization immunogenicity study assessing the antibody response and safety of a six-dose immunization schedule. This study showed that significantly higher antibody levels can be generated earlier in a higher percentage of subjects than in previous studies and that the revised dose regimen continued to be well-tolerated. These key results have confirmed the basis of our design for the NicVAX Phase III trials. In December 2008, we announced that we had reached agreement with the FDA on a SPA for the pivotal Phase III clinical trial for NicVAX, which we are in a position to initiate in 2009. The SPA forms the foundation to support approval of a NDA. We are seeking a partner who will assist in further development of the vaccine including the Phase III trial and future commercialization.

PentaStaph is an investigational vaccine based on patented technology, including technology that we have licensed on an exclusive basis from NIH. We are developing PentaStaph 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. PentaStaph requires additional development, including preclinical testing and human studies, as well as regulatory approvals before it can be marketed. We announced two significant events in 2008 that will help advance the development of PentaStaph. In September 2008, we entered into a collaboration agreement with the NIAID to conduct pre-clinical toxicology evaluations of two new antigens designed to protect against two of the most virulent and debilitating toxins produced by the bacteria. This testing will enable the initiation of Phase I clinical trials for these new antigens in 2009. Additionally, in December 2008, we entered into a research and development agreement with the U.S. Department of Defense to conduct a series of collaborative clinical trials for PentaStaph. With these agreements in place, we will be able to advance the development of PentaStaph much further and faster than we could on our own.

In 2006, we began strategic initiatives to enhance shareholder value. In November 2006, we sold our PhosLo (calcium acetate) product and the product's related assets to a U.S. subsidiary of Fresenius Medical Care, or Fresenius. Under the sale agreement, we received \$65.0 million in cash at closing and received an additional \$13.0 million of milestones as of March 11, 2009. We can also receive up to \$72.5 million in milestone payments and royalties. The royalties relate to sales of a new product formulation over a base amount for 10 years after the closing date. In June 2007, we sold certain assets related to our product Aloprim for proceeds of \$3.7 million. In December 2007, we sold certain assets constituting our Biologics SBU and certain corporate shared services assets to Biotest for \$185.0 million in cash (\$10.0 million of which has been escrowed for valid indemnification claims asserted on or before March 31, 2009). The results of operations from our PhosLo and Aloprim products

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and from our Biologics SBU are now included in discontinued operations. Consequently, as of December 29, 2007, we had sold all of our marketed products, moved our corporate headquarters to Rockville, Maryland and focused our efforts on developing and partnering our NicVAX and PentaStaph products.

Through our strategic alternatives process we are working with several advisors worldwide in our search for a partner or acquirer to advance the development of our products and further enhance shareholder value. These strategic alternatives may include, but are not limited to, licensing or development arrangements, joint ventures, strategic alliances, a recapitalization, and the sale or merger of all or part of the company.

### **Restatement Related to Intra-Period Income Tax Allocations**

We determined in connection with the preparation of our 2008 consolidated financial statements that our 2007 and 2006 consolidated financial statements required restatement to correct errors in the allocation of the income tax provision between continuing and discontinued operations. We previously did not consider income we reported from discontinued operations for purposes of determining the amount of income tax benefit that results from a loss from continuing operations and that should be allocated to continuing operations. As a result of these errors, we restated our income statement for the years ended December 29, 2007 and December 30, 2006. The adjustments did not have any impact on our consolidated net income for any period. The adjustment did not have any impact on our net cash flows for any period.

Additionally, for all periods presented herein, the results from our Biologics SBU, as well as our Aloprim and PhosLo product lines, have been reclassified as discontinued operations; these businesses represented all of our revenue-generating products.

### **Results of Operations**

The following discussion and analysis of our financial condition and results of operations for each of the three years ended December 27, 2008, December 29, 2007 and December 30, 2006, should be read in conjunction with our Consolidated Financial Statements and Notes thereto and with the information contained under "Risk Factors" in Item 1A. All amounts are expressed in thousands, except for per share and percentage data. For all periods shown, the results from our Biologics SBU, as well as the Aloprim and PhosLo product lines, have been reclassified as discontinued operations. Refer to Note 4 of our Consolidated Financial Statements.

#### **2008 as Compared to 2007**

*Selling, general and administrative expense.* Selling, general and administrative expense was \$12.4 million for 2008 compared to \$26.1 million for 2007. The decrease of \$13.7 million reflects the reduced scale of our operations following the sale of our Biologics SBU in December 2007, and our continued efforts to reduce overall infrastructure costs. We had no selling expenses in 2008. During 2007, we recorded \$1.6 million of expense associated with the resignation of our former Chairman, President and Chief Executive Officer. General and administrative expenses in 2009 are expected to remain approximately at 2008 levels.

*Research and development expense.* Research and development expense was \$12.6 million for 2008 compared to \$18.8 million for 2007. Research and development expenses for our NicVAX and PentaStaph vaccine candidates increased by approximately \$5.0 million in 2008 as we continued to pursue clinical development. Research and development expenses for pre-clinical and other development products decreased by approximately \$11.2 million, as a result of our reduced scale of operations following the sale of our Biologics SBU and as we focused our efforts on the clinical development of NicVAX and PentaStaph.

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*Interest income.* Interest income was \$4.6 million and \$6.0 million for 2008 and 2007, respectively. The decrease of \$1.4 million in interest income is largely the result of generally prevailing lower interest rates for our investments, offset in part by an increase in our average cash balance primarily due to the sale of our Biologics SBU in the fourth quarter of 2007.

*Interest expense.* Interest expense was \$1.5 million and \$3.5 million for 2008 and 2007, respectively, and consisted largely of interest expense associated with our Convertible Senior Notes. The decrease of \$2.0 million was the result of the repurchase of \$57.3 million of our Convertible Senior Notes in 2008. As a result of these repurchases, we expect interest expense in 2009 to be significantly less than 2008.

*Other income.* Other income in 2008 and 2007 consisted primarily of gains on repurchases of our Convertible Senior Notes.

*Income taxes.* In 2008 and 2007 we recorded a full valuation allowance against all net deferred tax assets. As a result of the valuation allowance, our consolidated effective tax rate for both years is approximately 0%. Because of the intra-period income tax allocation requirements, we recorded a benefit for income taxes from continuing operations of \$2.8 million and \$14.3 million in 2008 and 2007, respectively, offset each year in total by an identical income tax provision from discontinued operations. The intra-period income tax allocation considers discontinued operations for purposes of determining the amount of tax benefits that results from our loss from continuing operations.

*Discontinued operations.* In 2008, income from discontinued operations (net of intra-period tax allocation) of \$4.2 million reflects \$2.5 million of contingent proceeds from the sale of PhosLo, \$2.2 million from the settlement of our arbitration with Inhibitex, and various adjustments to assets and liabilities relating to our discontinued operations. In 2007, we recorded a net gain on disposal of discontinued operations of \$67.6 million. This primarily reflects net gains on the disposals of our Biologics SBU and Aloprim product line of \$65.2 million and \$2.6 million, respectively. In 2007, we also recorded \$4.0 million of income from discontinued operations related to our Biologics SBU and Aloprim product lines prior to their disposals.

### **2007 as Compared to 2006**

*Selling, general and administrative expense.* Selling, general and administrative expense was \$26.1 million for 2007 compared to \$32.6 million for 2006. The decrease of \$6.5 million reflects our continued efforts to reduce overall infrastructure costs. During 2007, we recorded \$1.6 million of expense associated with the resignation of our former Chairman, President and Chief Executive Officer. In 2006, we incurred \$1.7 million of expense related to activist shareholders matters. As a result of a review of historical equity grants in 2006, we recorded additional equity-based compensation expense of \$1.2 million in selling, general and administrative expense in 2006 which related to prior periods.

*Research and development expense.* Research and development expense was \$18.8 million for 2007 compared to \$28.7 million for 2006. This decrease includes \$4.8 million in reduced overhead costs as we have re-aligned our business to focus on our remaining product candidates as well as \$2.4 million in reduced spending on NicVAX due to the timing of development activities.

We incurred lower expenses related to our NicVAX program in 2007 in comparison with the prior year, as 2006 included the initiation and completion of enrollment into a 301-patient Phase IIb “proof-of-concept” study, the manufacture of material which was used in a Phase IIb clinical trial, as well as completion of an open-labeled Phase II dose ranging clinical trial. We completed the Phase IIb “proof-of-concept” study in 2007.

2007 reflected a further reduction of activities supporting our Gram-positive programs following the conclusion of the StaphVAX Phase III clinical trial in 2005. Research and development expense in 2006 included a reversal of \$1.1 million of previously recorded depreciation expense, which was largely offset by \$0.8 million of equity-based compensation expense recorded in 2006 related to prior years, resulting from the review of our historical equity grants.

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*Interest income.* Interest income was \$6.0 million and \$4.1 million for 2007 and 2006, respectively. The increase in interest income is largely the result of an increase in our average cash balance primarily due to the sale of the PhosLo product line in the fourth quarter of 2006 and the sale of the biologics business and certain corporate shared services assets in the fourth quarter of 2007.

*Interest expense.* Interest expense for both 2007 and 2006 was \$3.5 million and consisted largely of cash interest of \$3.2 million associated with our Convertible Senior Notes.

*Other income.* Other income in 2007 primarily consisted of a \$3.6 million gain related to the repurchase of \$38.8 million in principal of our Convertible Senior Notes at a discount of \$4.7 million. The gain represents the discounted price paid, reduced by the write-off of the related portion of the unamortized deferred financing costs and original discount associated with the original offering.

*Income taxes.* During 2007 and consistent with 2006, we recorded a full valuation allowance against all net deferred tax assets. As a result of this valuation allowance, our consolidated effective tax rate for both years is approximately 0%. Because of the intra-period income tax allocation requirements, we recorded a benefit for income taxes from continuing operations of \$14.3 million and \$0.8 million in 2007 and 2006, respectively, offset each year in total by an identical income tax provision from discontinued operations. The intra-period income tax allocation considers discontinued operations for purposes of determining the amount of tax benefits that results from our loss from continuing operations. In connection with our adoption of Financial Accounting Standards Board, or FASB, Interpretation Number 48, *Accounting for Uncertainty in Income Taxes* or FIN 48, we identified certain potential liabilities for years prior to 2007 that would have met the pre-FIN 48 accrual criteria and therefore, we recorded a \$0.2 million adjustment in our first quarter period income tax provision, as it was not material to any period impacted.

*Discontinued operations.* In 2007, we recorded a net gain on disposal of discontinued operations of \$67.6 million. This primarily reflects net gains on the disposals of our Biologics SBU and Aloprim product line of \$65.2 million and \$2.6 million, respectively. In 2006, we recorded a net gain of \$2.0 million on the disposal of our PhosLo product line. For additional details on our disposal transactions, refer to Note 4 of our Consolidated Financial Statements.

We also recorded \$4.0 million of income from discontinued operations related to our Biologics SBU and Aloprim product lines prior to their disposals. In 2006, the \$3 thousand net loss from operations of discontinued operations consisted of a \$6.3 million operating loss related to our PhosLo business and \$0.9 million of non-operating expenses, largely offset by \$7.1 million of operating income related to the Biologics SBU and Aloprim product line. Included in the results of the Biologics SBU in 2007 is a \$3.3 million reduction of the revenues that we had previously recorded in 2006 related to our dispute with Inhibitex.

### **Liquidity and Capital Resources**

Our cash, cash equivalents and marketable securities at December 27, 2008 totaled \$130.3 million as compared to \$219.2 million at December 29, 2007. This decline is primarily the result of payments of \$51.6 million for the repurchases of \$57.3 million par value Convertible Senior Notes in 2008, the payment of \$18.2 million for treasury stock purchased and settled in 2008, the payment of \$1.8 million for treasury stock purchased in 2007 and settled in 2008, and net cash used in operating activities of \$18.9 million. At December 27, 2008, we also had restricted cash of \$10.2 million related to discontinued operations that is held in escrow subject to any valid claims by Biotest related to the sale of our Biologics SBU asserted before March 31, 2009. Any balance net of valid claims will be released to us on April 15, 2009; as of March 11, 2009, Biotest had not asserted any indemnification claims.

Cash used in operating activities from continuing operations was \$22.8 million, \$42.6 million and \$61.7 million for 2008, 2007 and 2006, respectively, and primarily included cash expenditures for selling, general and

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administrative expenses and research and development expenses partially offset by net interest income. Cash provided by operating activities from discontinued operations was \$3.9 million, \$15.9 million and \$17.8 million for 2008, 2007 and 2006, respectively.

Cash provided by (used in) investing activities from continuing operations was (\$22.2) million, \$30.9 million and (\$27.5) million for 2008, 2007 and 2006, respectively, which consists largely of net proceeds from the sale (purchases) of marketable securities.

Cash provided by investing activities from discontinued operations of \$1.6 million in 2008, \$176.4 million in 2007 and \$56.8 million in 2006 includes net cash proceeds related to the sale of Biologics SBU and our Aloprim and PhosLo products.

In 2007, our Board of Directors approved the repurchase of up to \$65 million of our common stock in the open market or in privately negotiated transactions. In 2008 the Company purchased 5.1 million shares at a cost of \$18.6 million with an average cost per share of \$3.66, \$18.2 million of which was paid in 2008 and the balance was settled and paid in 2009. In addition, \$1.8 million was paid in 2008 to settle shares repurchased in 2007. We have acquired a total of 10.1 million shares for a total cost of \$36.9 million under the program. At December 27, 2008, \$28.1 million remains available for share repurchase under the current authorization. Repurchased shares have been accounted for as treasury stock using the cost method. Subsequent to year end, through March 11, 2009, we have repurchased an additional 127,742 shares for \$411 thousand.

In 2005, we issued \$112.4 million of Convertible Senior Notes through a private offering to qualified institutional buyers as defined under Rule 144A of the Securities Act of 1933, as amended, or the Securities Act. 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. In 2007 we repurchased \$38.8 million of our Convertible Senior Notes for a total of \$34.1 million resulting in a net gain of \$3.6 million. In 2008, we repurchased an additional \$57.3 million of our Convertible Senior Notes for a total of \$51.6 million, resulting in a net gain of \$4.0 million recorded in other income. Interest on our Convertible Senior Notes is payable on each April 15 and October 15, beginning October 15, 2005. We can redeem our Convertible Senior Notes at 100% of their principal amount, plus accrued and unpaid interest, any time on or after April 18, 2010. Holders of our Convertible Senior Notes may require us to repurchase our Convertible Senior 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 change in control as defined in the indenture agreement governing the Notes. We may continue to repurchase our Convertible Senior Notes in the open market or in privately negotiated transactions.

Through our strategic alternatives process we are working with several advisors worldwide in our search for a partner or acquirer to advance the development of our products and further enhance shareholder value. These strategic alternatives may include, but are not limited to, licensing or development arrangements, joint ventures, strategic alliances, a recapitalization, and the sale or merger of all or part of the company.

We believe cash, cash equivalents and marketable securities on hand at December 27, 2008 will be sufficient to meet our anticipated cash requirements for operations and debt service for at least the next 12 months.



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The following table provides information as of December 27, 2008 with respect to the amounts and timing of our known material contractual obligations as specified below. As of December 27, 2008, there were no significant contractual obligations related to our discontinued operations.

<u>Contractual Obligations</u> (in thousands)	<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>After</u> <u>2013</u>	<u>Total</u>
Operating leases	\$ 910	\$ 791	\$ 870	\$ 113	\$ 113	\$ 226	\$ 3,023
Convertible Senior Notes	—	16,400	—	—	—	—	16,400
Interest payments	472	236	—	—	—	—	708
Total	<u>\$ 1,382</u>	<u>\$ 17,427</u>	<u>\$ 870</u>	<u>\$ 113</u>	<u>\$ 113</u>	<u>\$ 226</u>	<u>\$ 20,131</u>

The preceding table does not include information where the amounts of the obligations are currently not determinable, including contractual obligations in connection with clinical trials, which are payable on a per-patient basis. While the Convertible Senior Notes are not due until 2025, in 2010 the holders of our Convertible Senior Notes can require us to repurchase them. Our interest payments are related to our Convertible Senior Notes and will remain an obligation for as long as our Convertible Senior Notes are outstanding.

### Critical Accounting Policies and Estimates

We believe that the following policies and estimates are critical because they involve significant judgments, assumptions and estimates. We have discussed the development and selection of our critical accounting estimates with the Audit Committee of our Board of Directors and the Audit Committee has reviewed the disclosures presented below relating to those policies and estimates.

*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 income and expenses during the reporting period, including such amounts related to discontinued operations. Actual results could differ from those estimates.

*Research and development expenses:* Except for advance payments, research and development costs are expensed as incurred. We use our research and development resources, including employees, equipment and facilities, across multiple drug development programs. Research and development expenses include direct labor costs as well as the costs of contractors and other direct and indirect expenses, but exclude an allocation of selling, general and administrative expenses. We expense amounts payable to third parties under collaborative product development agreements at the earlier of the milestone achievement or as payments become contractually due. In circumstances where we receive grant income (which is a reimbursement to research and development costs incurred), we record the income as an offset to the related expense. In 2007 and 2006, \$1.5 million and \$2.2 million, respectively, of income related to our NIDA grant was recorded as an offset to clinical trials expenses for NicVAX. We had no NIDA reimbursements in 2008.

*Equity-based compensation:* We currently account for equity-based compensation under the fair value recognition provisions of SFAS No. 123R, "Share-Based Payment," which establish accounting for share-based awards in exchange for employee services and require companies to expense the estimated fair value of these awards over the requisite employee service period. Under SFAS No. 123R, share-based compensation cost is determined at the grant date using an option pricing model. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the employee's requisite service period.

### New Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141R, "Business Combinations," ("SFAS 141R"). SFAS 141R requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their fair values,

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changes the recognition of assets acquired and liabilities assumed arising from contingencies, changes the recognition and measurement of contingent consideration, and requires the expensing of acquisition-related costs as incurred. SFAS 141R also requires additional disclosure of information surrounding a business combination, so that users of the financial statements can fully understand the nature and financial impact of the business combination. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS 141R will only impact the company if it is a party to a business combination after the pronouncement has been adopted.

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements,” (“SFAS 157”). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies to other accounting pronouncements that require or permit fair value measurements and does not require any new fair value measurements. In February 2008, the FASB issued FSP No. 157-1, “Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13,” (“FSP 157-1”) and FSP No. 157-2, “Effective Date of FASB Statement No. 157,” (“FSP 157-2”), as amendments to SFAS No. 157. FSP 157-1 and FSP 157-2 exclude lease transactions from the scope of SFAS No. 157 and also defer the effective date of the adoption of SFAS 157 for certain non-financial assets and non-financial liabilities. In October of 2008, the FASB issued FSP No. 157-3, “Determining the Fair Value of Financial Assets When the Market for That Asset is Not Active,” (“FSP 15-3”) as an amendment to SFAS No. 157, clarifying the application of SFAS No. 157 in a non-active market. SFAS 157 (along with FSP 157-1 and FSP 157-3) is effective for fiscal years beginning after November 15, 2007, and we adopted SFAS 157 beginning in the first quarter of 2008; the adoption of SFAS 157 did not have a material impact to our financial position or results of operations. We will adopt FSP 157-2 in our first quarter of 2009; we have not yet determined the impact, if any, that the adoption of FSP 157-2 will have on our financial statements.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities,” (“SFAS 159”) which gives companies the option to measure eligible financial assets, financial liabilities and firm commitments at fair value (i.e., the fair value option), on an instrument-by-instrument basis, that are otherwise not permitted to be accounted for at fair value under other accounting standards. The election to use the fair value option is available when an entity first recognizes a financial asset or financial liability or upon entering into a firm commitment. Subsequent changes in fair value must be recorded in earnings. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We adopted SFAS 159 beginning in the first quarter of our 2008 fiscal year and currently have elected not to use the fair value option for any eligible financial assets or liabilities.

In December 2007, the FASB issued SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements—An Amendment of ARB No. 51,” (“SFAS 160”). SFAS No. 160 amends APB’s Accounting Research Bulletin No. 51 and establishes accounting and reporting standards for non-controlling interests (i.e., minority interests) in a subsidiary and for the deconsolidation of a subsidiary. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. We do not expect that adoption of this standard will have a material impact on its financial statements.

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities—an Amendment of FASB Statement No. 133,” (“SFAS 161”). SFAS 161 states that entities are required to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 “Accounting for Derivative Instruments and Hedging Activities,” (“SFAS 133”) and its related interpretations, and how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. The provisions of SFAS 161 are effective for fiscal years beginning on or after November 15, 2008. We anticipate that the adoption of this statement will not have a material impact on its financial statements.

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In May 2008, the FASB issued SFAS No. 162, “The Hierarchy of Generally Accepted Accounting Principles,” (“SFAS 162”). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the U.S. SFAS 162 is effective 60 days following the Securities and Exchange Commission approval of the Public Company Accounting Oversight Board amendments to AU Section 411, “The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.” We anticipate that the adoption of this statement will not have a material impact on its financial statements.

In March 2007, the Emerging Issues Task Force (“EITF”) issued EITF Issue No. 06-10, “Accounting for Deferred Compensation and Postretirement Benefit Aspects of Collateral Assignment Split-Dollar Life Insurance Arrangements,” (“EITF 06-10”). EITF 06-10 provides guidance to help companies determine whether a liability for the postretirement benefit associated with a collateral assignment split-dollar life insurance arrangement should be recorded in accordance with either SFAS No. 106, “Employers’ Accounting for Postretirement Benefits Other Than Pensions” or the Accounting Principles Board (“APB”) Opinion No. 12 “Omnibus Opinion -1967,” (“APB 12”). EITF 06-10 also provides guidance on how a company should recognize and measure the asset in a collateral assignment split-dollar life insurance contract. EITF 06-10 is effective for fiscal years beginning after December 15, 2007. We adopted EITF 06-10 beginning in the first quarter of our 2008 fiscal year and it did not have a material impact to our financial position or results of operations.

In November 2007, the EITF issued EITF Issue No. 07-1, “Accounting for Collaborative Arrangements,” (“EITF 07-1”). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 is effective for fiscal years beginning on or after December 15, 2008, and is to be applied to all periods presented for all collaborative arrangements existing as of its adoption. We are currently evaluating the impact of the adoption of this statement on its financial statements.

In June 2008, the EITF issued EITF Issue No. 07-2, “Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity’s Own Stock,” (“EITF 07-2”). EITF 07-2 applies to any freestanding financial instrument or embedded feature that has all the characteristics of a derivative pursuant to SFAS 133, for purposes of determining whether that instrument or embedded feature qualifies for the first part of the scope exception in SFAS 133. EITF 07-2 also applies to any freestanding financial instrument that is potentially settled in an entity’s own stock, regardless of whether the instrument has all the characteristics of a derivative, for purposes of determining whether the instrument is within the scope of EITF Issue No. 00-19. EITF 07-2 is effective for financial statements issued for fiscal years beginning after December 15, 2008; we are currently evaluating the impact of the adoption of this statement on its financial statements.

In June 2007, the EITF issued EITF Issue No. 07-03, “Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development,” (“EITF 07-03”). EITF 07-03 addresses the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Pursuant to EITF 07-03, an entity is required to defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. We adopted EITF 07-03 beginning in the first quarter of our 2008 fiscal year and it did not have a material impact to our financial position or results of operations.

In May 2008, the FASB issued FASB Staff Position No. APB 14-1, “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement),” (“FSP 14-1”). FSP 14-1 clarifies that (1) convertible debt instruments that may be settled in cash upon conversion, including partial cash settlement, are not considered debt instruments within the scope of APB Opinion No. 14, “Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants,” (“APB 14”) and (2) issuers of such instruments should separately account for the liability and equity components of those instruments by allocating the proceeds from issuance of the instrument between the liability component and the embedded

conversion option (i.e., the equity component). APB 14-1 is effective for fiscal years beginning after December 15, 2008 and is required to be applied retrospectively to convertible debt instruments that are within the scope of this guidance and were outstanding during any period presented in the financial statements. Our Convertible Senior Notes fall within the scope of this guidance. While APB 14-1 does not change the cash flow requirements under our Convertible Senior Notes, non-cash interest expense will increase as a result of amortizing the discounted carrying value of our Convertible Senior Notes. We are in the process of further evaluating the financial impact that the adoption of APB 14-1 will have on its financial statements; however, on a preliminary basis the company believes that diluted earnings per share from continuing operations would be reduced by approximately \$0.15 per share, \$0.14 per share and \$0.09 per share in 2008, 2007 and 2006, respectively, as a result of non-cash interest expense recorded in connection with the adoption of APB 14-1.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We do not have “trading” or “other than trading” portfolios of market risk sensitive instruments, and we do not purchase hedging instruments that are likely to expose us to significant market risk, whether interest rate, foreign currency exchange, commodity price or equity price risk.

At December 27, 2008, we had cash, cash equivalents and marketable securities in the amount of \$130.3 million. Our exposure to market interest rate risk relates solely to our cash, cash equivalents and marketable securities. Cash equivalents and marketable securities consist principally of money market funds placed with major financial institutions. Because of the nature of these funds and the short-term maturities of their investment securities, we do not believe that a change in market rates would have a material negative impact on the value of our investment portfolio. Declines of interest rates over time will, however, reduce our interest income from our investments. Interest income was \$4.6 million for 2008.

The carrying value of our Convertible Senior Notes was \$16.0 million at December 27, 2008. Based on quoted market prices for our Convertible Senior Notes, their fair value was approximately \$14.2 million at December 27, 2008.

Report of Independent Registered Public Accounting Firm

The Board of Directors  
and Stockholders of Nabi Biopharmaceuticals

We have audited Nabi Biopharmaceuticals' (the "Company") internal control over financial reporting as of December 27, 2008, 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 included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Management has identified a material weakness in internal controls over the accounting for income taxes. Specifically, the process and procedures for intraperiod allocation of the provision for income taxes between loss from continuing operations and income from discontinued operations were not effective. This material weakness in internal controls over income taxes resulted in the restatement of the 2007 and 2006 financial statements. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2008 consolidated financial statements, and this report does not affect our report dated March 11, 2009, on those consolidated financial statements.

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Nabi Biopharmaceuticals has not maintained effective internal control over financial reporting as of December 27, 2008, based on the COSO criteria.

/s/ Ernst & Young LLP

McLean, Virginia  
March 11, 2009

Report of Independent Registered Public Accounting Firm

The Board of Directors  
and Stockholders of Nabi Biopharmaceuticals

We have audited the accompanying consolidated balance sheets of Nabi Biopharmaceuticals as of December 27, 2008 and December 29, 2007, 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 27, 2008. 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 at December 27, 2008 and December 29, 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 27, 2008, 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.

As discussed in Note 2 to the Consolidated Financial Statements, the 2007 and 2006 consolidated financial statements have been restated to correct an error in the allocation of the provision for income taxes between continuing operations and discontinued operations.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), internal control over financial reporting of Nabi Biopharmaceuticals as of December 27, 2008, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
March 11, 2009

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Nabi Biopharmaceuticals  
CONSOLIDATED BALANCE SHEETS

<u>In thousands, except share and per share data</u>	<u>December 27,</u> <u>2008</u>	<u>December 29,</u> <u>2007</u>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 106,438	\$ 217,606
Marketable securities	23,900	1,600
Prepaid expenses and other current assets	1,430	2,371
Assets of discontinued operations (including restricted cash in 2008)	10,409	4,616
<b>Total current assets</b>	<b>142,177</b>	<b>226,193</b>
Property and equipment, net	1,315	1,971
Other assets (including discontinued operations restricted cash in 2007)	657	10,406
<b>Total assets</b>	<b>\$ 144,149</b>	<b>\$ 238,570</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,226	\$ 3,647
Accrued expenses and other current liabilities	3,030	7,105
Current liabilities of discontinued operations	3,381	9,548
<b>Total current liabilities</b>	<b>7,637</b>	<b>20,300</b>
2.875% convertible senior notes, net	16,024	71,738
<b>Total liabilities</b>	<b>23,661</b>	<b>92,038</b>
Commitments and contingencies		
<b>Stockholders' equity:</b>		
Convertible preferred stock, par value \$0.10 per share; 5,000,000 shares authorized; no shares outstanding	—	—
Common stock, par value \$0.10 per share; 125,000,000 shares authorized; 62,396,414 and 62,116,963 shares issued, respectively	6,239	6,212
Capital in excess of par value	336,691	333,527
Treasury stock, 10,881,846 and 5,807,055 shares, respectively, at cost	(42,187)	(23,608)
Other comprehensive income	60	—
Accumulated deficit	(180,315)	(169,599)
<b>Total stockholders' equity</b>	<b>120,488</b>	<b>146,532</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 144,149</b>	<b>\$ 238,570</b>

See accompanying notes to consolidated financial statements.

**Nabi Biopharmaceuticals**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

In thousands, except per share data	For the Years Ended		
	December 27, 2008	December 29, 2007 (restated)	December 30, 2006 (restated)
<b>Operating expenses:</b>			
Selling, general and administrative expense	\$ 12,415	\$ 26,090	\$ 32,576
Research and development expense	12,556	18,841	28,745
<b>Operating loss</b>	<u>(24,971)</u>	<u>(44,931)</u>	<u>(61,321)</u>
Interest income	4,579	6,026	4,148
Interest expense	(1,456)	(3,454)	(3,467)
Other income (expense), net	4,122	3,576	(66)
<b>Loss from continuing operations before income taxes</b>	<u>(17,726)</u>	<u>(38,783)</u>	<u>(60,706)</u>
Benefit from income taxes	2,765	14,265	753
<b>Loss from continuing operations</b>	<u>(14,961)</u>	<u>(24,518)</u>	<u>(59,953)</u>
<b>Discontinued operations:</b>			
Income (loss) before gain on disposals, net of tax benefit (provision) of \$2.8 million, \$0.7 million and (\$0.2) million in 2008, 2007 and 2006	4,245	4,036	(3)
Gain on disposals, net of tax provision of \$15.0 million and \$0.7 million in 2007 and 2006	—	67,551	1,253
<b>Income from discontinued operations</b>	<u>4,245</u>	<u>71,587</u>	<u>1,250</u>
<b>Net income (loss)</b>	<u>\$ (10,716)</u>	<u>\$ 47,069</u>	<u>\$ (58,703)</u>
<b>Basic and diluted income (loss) per share:</b>			
Continuing operations	\$ (0.29)	\$ (0.41)	\$ (0.98)
Discontinued operations	0.09	1.19	0.02
<b>Basic and diluted income (loss) per share</b>	<u>\$ (0.20)</u>	<u>\$ 0.78</u>	<u>\$ (0.96)</u>
<b>Basic and diluted weighted average shares outstanding</b>	<u>51,866</u>	<u>60,295</u>	<u>60,936</u>

*See accompanying notes to consolidated financial statements.*



**Nabi Biopharmaceuticals**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**

<u>In thousands</u>	<u>Common Stock</u>		<u>Capital in Excess of Par Value</u>	<u>Treasury Stock</u>		<u>Accumulated Deficit</u>	<u>Other Accumulated Comprehensive (Loss) Income</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>		<u>Shares</u>	<u>Amount</u>			
<b>Balance at December 31, 2005</b>	<b>60,323</b>	<b>\$6,032</b>	<b>\$318,910</b>	<b>(806)</b>	<b>\$ (5,321)</b>	<b>\$ (157,965)</b>	<b>\$ 171</b>	<b>\$ 161,827</b>
Net loss	—	—	—	—	—	(58,703)	—	(58,703)
Currency translation adjustment	—	—	—	—	—	—	(171)	(171)
Comprehensive loss								(58,874)
Stock options exercised	477	48	2,293	—	—	—	—	2,341
Recognition of option-related expense, net of tax benefit	—	—	2,434	—	—	—	—	2,434
Stock-based compensation expense	—	—	2,831	—	—	—	—	2,831
Stock issued under Employee Stock Purchase Plan	224	23	734	—	—	—	—	757
Restricted stock awards, net	450	45	(45)	—	—	—	—	—
Directors fees paid in stock	12	1	71	—	—	—	—	72
<b>Balance at December 30, 2006</b>	<b>61,486</b>	<b>\$6,149</b>	<b>\$327,228</b>	<b>(806)</b>	<b>\$ (5,321)</b>	<b>\$ (216,668)</b>	<b>\$ —</b>	<b>\$ 111,388</b>
Net income	—	—	—	—	—	47,069	—	47,069
Comprehensive income								47,069
Stock options exercised	229	23	966	—	—	—	—	989
Stock-based compensation expense	—	—	4,981	—	—	—	—	4,981
Purchase of treasury stock	—	—	—	(5,001)	(18,287)	—	—	(18,287)
Stock issued under Employee Stock Purchase Plan	97	9	343	—	—	—	—	352
Restricted stock awards, net	297	30	(30)	—	—	—	—	—
Directors fees paid in stock	8	1	39	—	—	—	—	40
<b>Balance at December 29, 2007</b>	<b>62,117</b>	<b>\$6,212</b>	<b>\$333,527</b>	<b>(5,807)</b>	<b>\$ (23,608)</b>	<b>\$ (169,599)</b>	<b>\$ —</b>	<b>\$ 146,532</b>
Net loss	—	—	—	—	—	(10,716)	—	(10,716)
Other comprehensive income							60	60
Comprehensive loss								(10,656)
Stock options exercised	120	12	360	—	—	—	—	372
Stock-based compensation expense	—	—	2,733	—	—	—	—	2,733
Purchase of treasury stock	—	—	—	(5,075)	(18,579)	—	—	(18,579)
Stock issued under Employee Stock Purchase Plan	28	3	83	—	—	—	—	86
Restricted stock awards, net	132	12	(12)	—	—	—	—	—
<b>Balance at December 27, 2008</b>	<b>62,397</b>	<b>\$6,239</b>	<b>\$336,691</b>	<b>(10,882)</b>	<b>\$ (42,187)</b>	<b>\$ (180,315)</b>	<b>\$ 60</b>	<b>\$ 120,488</b>

*See accompanying notes to consolidated financial statements.*

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

In thousands	For the Years Ended		
	December 27, 2008	December 29, 2007 (restated)	December 30, 2006 (restated)
<b>Cash flow from operating activities:</b>			
Loss from continuing operations	\$ (14,961)	\$ (24,518)	\$ (59,953)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities of continuing operations:			
Depreciation and amortization	574	1,725	954
Non-cash intra-period tax allocation	(2,765)	(14,265)	(753)
Accretion of discount on convertible senior notes	70	168	168
Non-cash compensation	2,733	2,770	4,348
Gain on repurchase of convertible senior notes	(4,023)	(3,583)	—
Other	48	(5)	102
Changes in assets and liabilities:			
Prepaid expenses and other assets	541	(401)	(172)
Accounts payable, accrued expenses and other	(4,982)	(4,488)	(6,382)
Total adjustments	(7,804)	(18,079)	(1,735)
<b>Net cash used in operating activities from continuing operations</b>	<b>(22,765)</b>	<b>(42,597)</b>	<b>(61,688)</b>
Net cash provided by operating activities from discontinued operations	3,864	15,853	17,776
<b>Net cash used in operating activities</b>	<b>(18,901)</b>	<b>(26,744)</b>	<b>(43,912)</b>
<b>Cash flow from investing activities:</b>			
Purchases of marketable securities	(23,871)	(29,475)	(82,325)
Proceeds from sales of marketable securities	1,600	60,375	54,997
Capital expenditures	(53)	(110)	(223)
Other investing activities, net	112	80	8
<b>Net cash (used in) provided by investing activities from continuing operations</b>	<b>(22,212)</b>	<b>30,870</b>	<b>(27,543)</b>
Net cash provided by investing activities from discontinued operations	1,567	176,362	56,807
<b>Net cash (used in) provided by investing activities</b>	<b>(20,645)</b>	<b>207,232</b>	<b>29,264</b>
<b>Cash flow from financing activities:</b>			
Proceeds from issuance of common stock for employee benefit plans	128	728	1,564
Purchase of common stock for treasury	(20,010)	(16,523)	—
Repurchase of convertible senior notes	(51,634)	(34,071)	—
Other financing activities, net	(83)	82	—
<b>Net cash (used in) provided by financing activities from continuing operations</b>	<b>(71,599)</b>	<b>(49,784)</b>	<b>1,564</b>
Net cash (used in) provided by financing activities from discontinued operations	(23)	675	(2,451)
<b>Net cash used in financing activities</b>	<b>(71,622)</b>	<b>(49,109)</b>	<b>(887)</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(111,168)</b>	<b>131,379</b>	<b>(15,535)</b>
<b>Cash and cash equivalents at beginning of year</b>	<b>217,606</b>	<b>86,227</b>	<b>101,762</b>
<b>Cash and cash equivalents at end of year</b>	<b>\$ 106,438</b>	<b>\$ 217,606</b>	<b>\$ 86,227</b>

*See accompanying notes to consolidated financial statements.*

**Nabi Biopharmaceuticals**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1 BUSINESS AND ORGANIZATION**

We are a biopharmaceutical company focused on the development of products that address unmet medical needs in the areas of nicotine addiction and infectious disease. We leverage our experience and knowledge in powering the human immune system to target serious medical conditions in these areas. Our products in development are NicVAX [*Nicotine Conjugate Vaccine*], an innovative and proprietary investigational vaccine for treatment of nicotine addiction and prevention of smoking relapse, and PentaStaph [*Pentavalent S.aureus Vaccine*], a new pentavalent vaccine designed to prevent *S.aureus* infections including those infections caused by the most dangerous antibiotic-resistant strains of *S.aureus*. We were incorporated in Delaware in 1969 and our operations are located in Rockville, Maryland.

*Products in Development*

NicVAX is an investigational vaccine based on patented technology. Nicotine, a non-immunogenic small molecule, can cross the blood-brain barrier and reach specific receptors in the brain, thereby leading to the highly addictive pleasure sensation experienced by smokers and users of nicotine products. NicVAX is designed to stimulate the immune system to produce highly specific antibodies that bind to nicotine. A nicotine molecule attached to an antibody is too large to cross the blood-brain barrier, and thus is unable to reach the receptors in the brain and trigger pleasure sensations. In November 2007, we announced the successful completion of a Phase IIB “proof-of-concept” clinical trial for NicVAX that showed statistically significant rates of smoking cessation and continuous long-term smoking abstinence at 6 and 12 months for subjects injected with NicVAX as compared with subjects injected with placebo. In October 2008, we announced the results of a Phase II schedule optimization immunogenicity study assessing the antibody response and safety of a six-dose immunization schedule. This study showed that significantly higher antibody levels can be generated earlier in a higher percentage of subjects than in previous studies and that the revised dose regimen continued to be well-tolerated. These key results have confirmed the basis of our design for the NicVAX Phase III trials. In December 2008, we announced that we had reached agreement with the FDA on a SPA for the pivotal Phase III clinical trial for NicVAX, which we are in a position to initiate in 2009. The SPA forms the foundation to support approval of a NDA. We are seeking a partner who will assist in further development of the vaccine including the Phase III trial and future commercialization.

PentaStaph is an investigational vaccine based on patented technology, including technology that we have licensed on an exclusive basis from NIH. We are developing PentaStaph 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. PentaStaph requires additional development, including preclinical testing and human studies, as well as regulatory approvals before it can be marketed. We announced two significant events in 2008 that will help advance the development of PentaStaph. In September 2008, we entered into a collaboration agreement with the NIAID to conduct pre-clinical toxicology evaluations of two new antigens designed to protect against two of the most virulent and debilitating toxins produced by the bacteria. This testing will enable the initiation of Phase I clinical trials for these new antigens in 2009. Additionally, in December 2008, we entered into a research and development agreement with the U.S. Department of Defense to conduct a series of collaborative clinical trials for PentaStaph. With these agreements in place, we will be able to advance the development of PentaStaph much further and faster than we could on our own.

*Strategic Initiatives*

In 2006, we began strategic initiatives to enhance shareholder value. In November 2006, we sold our PhosLo (calcium acetate) product and the product’s related assets to a U.S. subsidiary of Fresenius Medical Care, or Fresenius. Under the sale agreement, we received \$65.0 million in cash at closing and received an additional \$13.0 million of milestones as of March 11, 2009. We can also receive up to \$72.5 million in milestone payments

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and royalties. The royalties relate to sales of a new product formulation over a base amount for 10 years after the closing date. In June 2007, we sold certain assets related to our product Aloprim (allopurinol sodium for Injection) of \$3.7 million. On December 4, 2007, we sold our Biologics SBU and certain corporate shared services assets to Biotest Pharmaceuticals Corporation, or Biotest, for \$185.0 million (\$10.0 million of which has been escrowed for indemnification claims asserted on or before March 31, 2009).

As a result of these strategic actions, as of December 29, 2007 we had sold all of our marketed products, moved our corporate headquarters to Rockville, Maryland and focused our efforts on developing and partnering our NicVAX and PentaStaph products.

In 2008, we announced that we had retained a prominent investment bank to assist with our continued exploration of the full range of strategic alternatives available to us to further enhance shareholder value. These alternatives may include, but are not limited to, licensing or development arrangements, joint ventures, strategic alliances, a recapitalization, and the sale or merger of all or part of the company. In addition, we have engaged several other life science strategic advisors to assist with the process.

### NOTE 2 RESTATEMENT OF OUR 2007 AND 2006 CONSOLIDATED FINANCIAL STATEMENTS

We determined in connection with the preparation of our 2008 consolidated financial statements that our 2007 and 2006 consolidated financial statements required restatement to correct errors in the allocation of the income tax provision between continuing and discontinued operations. We previously did not consider income we reported from discontinued operations for purposes of determining the amount of income tax benefit that results from a loss from continuing operations and that should be allocated to continuing operations. As a result of these errors, we restated our consolidated financial statements for the years ended December 29, 2007 and December 30, 2006.

The following table summarizes adjustments to our financial statements for the years ended December 29, 2007 and December 30, 2006:

	<u>As Previously Reported</u>	<u>As Restated</u>	<u>Increase (Decrease)</u>
<b>Year ended December 29, 2007:</b>			
(Provision) benefit for income taxes	\$ (201)	\$ 14,265	\$(14,466)
Loss from continuing operations	(38,984)	(24,518)	(14,466)
Discontinued operations:			
Income before gain on disposals	4,818	4,036	(782)
Gain on disposals	81,235	67,551	(13,684)
Income from discontinued operations	86,053	71,587	(14,466)
Net income	47,069	47,069	—
Basic and diluted income (loss) per share:			
Continuing operations	\$ (0.65)	\$ (0.41)	\$ 0.24
Discontinued operations	\$ 1.43	\$ 1.19	\$ (0.24)
Basic and diluted income (loss) per share	\$ 0.78	\$ 0.78	\$ —
<b>Year ended December 30, 2006:</b>			
(Provision) benefit for income taxes	\$ 69	\$ 753	\$ 684
Loss from continuing operations	(60,637)	(59,953)	(684)
Discontinued operations:			
Income before gain on disposals	(64)	(3)	61
Gain on disposals	1,998	1,253	(745)
Income from discontinued operations	1,934	1,250	(684)
Net income (loss)	(58,703)	(58,703)	—
Basic and diluted income (loss) per share:			
Continuing operations	\$ (1.00)	\$ (0.98)	\$ 0.02
Discontinued operations	\$ 0.04	\$ 0.02	\$ (0.02)
Basic and diluted income (loss) per share	\$ (0.96)	\$ (0.96)	\$ —

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The adjustments did not have any effect on the reported amount of our consolidated net income (loss) for any period. As a result of the decrease in the loss from operations from the intra-period tax allocation, a non-cash line item for a corresponding amount was included as an adjustment in our consolidated statements of cash flows to reconcile our loss from continuing operations to net cash used in operating activities from continuing operations of \$14.3 million and \$0.8 million for the years ended December 29, 2007 and December 30, 2006, respectively.

### **NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Principles of consolidation:* The consolidated financial statements include the accounts of Nabi Biopharmaceuticals and our wholly-owned subsidiaries (referred to as “Nabi,” the “Company,” “us,” or “we” throughout this report). All significant inter-company accounts and transactions are eliminated in consolidation. All our wholly-owned subsidiaries are dormant or are otherwise non-operative.

*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 income and expenses during the reporting period, including such amounts related to discontinued operations. Actual results could differ from those estimates.

*Basis of presentation and reclassifications:* As further discussed in Note 4, the results of operations and the assets and the liabilities related to the Biologics SBU as well as those amounts related to the Aloprim product line have been accounted for as discontinued operations in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets,” or SFAS 144. Accordingly, the results of the operations related to the Biologics SBU business and to Aloprim from prior periods have been reclassified to discontinued operations. Although we have sold substantially all assets of our corporate shared services and our vaccine manufacturing facility, we continue to reflect these expenses in continuing operations because we continue to require similar functions on an ongoing basis. Certain prior period amounts have been reclassified to conform to the current year’s presentation.

*Fiscal year periods:* Our fiscal year ends on the last Saturday of December. Consequently, we will periodically have a 53-week fiscal year. The fiscal years ended for the periods presented in the accompanying consolidated financial statements are December 27, 2008, December 29, 2007 and December 30, 2006; all three years were 52-week years.

*Research and development expenses:* Except for advance payments, research and development costs are expensed as incurred. We use our research and development resources, including employees, equipment and facilities, across multiple drug development programs. Research and development expenses include direct labor costs as well as the costs of contractors and other direct and indirect expenses, but exclude an allocation of selling, general and administrative expenses. We expense amounts payable to third parties under collaborative product development agreements at the earlier of the milestone achievement or as payments become contractually due. In circumstances where we receive grant income (which is a reimbursement to research and development costs incurred), we record the income as an offset to the related expense. In 2007 and 2006, \$1.5 million and \$2.2 million, respectively, of income related to our NIDA grant was recorded as an offset to clinical trials expenses for NicVAX. We had no NIDA reimbursements in 2008.

*Comprehensive income (loss):* We follow SFAS No. 130, “Reporting Comprehensive Income,” which calculates comprehensive income (loss) as the total of our net income (loss) and all other changes in equity other than transactions with owners. For the year ended December 27, 2008, comprehensive income consisted of net

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loss, net unrealized gains on our available for sale portfolio of marketable securities of approximately \$29, and \$31 of cumulative foreign currency translation adjustments; for the year ended December 29, 2007, comprehensive income consisted solely of net income. For the year ended December 30, 2006, comprehensive loss consisted of our net loss as well as foreign currency adjustments.

*Income (loss) per share:* Basic income (loss) per share is computed by dividing consolidated net income (loss) by the weighted average number of common shares outstanding during the year, excluding unvested restricted stock. For the periods presented in the accompanying Consolidated Statements of Operations, diluted income (loss) per share is calculated similarly because the impact of all potentially dilutive securities is anti-dilutive due to our net loss from continuing operations each year.

When the effects are not anti-dilutive, diluted earnings per share is computed by dividing our net income (loss) by the weighted average number of shares outstanding and the impact of all potentially dilutive securities, consisting primarily of stock options, restricted stock grants and the common shares underlying our Convertible Senior Notes. The dilutive impact of our potentially dilutive securities is determined by applying the treasury stock method. A total of 0.2 million, 0.3 million, and 1.7 million potential dilutive shares have been excluded in the calculation of diluted net income (loss) per share in 2008, 2007 and 2006, respectively, because their inclusion would be anti-dilutive.

*Financial instruments:* The carrying amounts of financial instruments including cash equivalents, marketable securities, accounts receivable and accounts payable approximated fair value as of December 27, 2008 and December 29, 2007, because of the relatively short-term maturity of these instruments. The carrying value of our Convertible Senior Notes, at December 27, 2008 and December 29, 2007 was \$16.0 million and \$71.7 million, respectively, compared to the approximate fair value of \$14.2 million and \$64.1 million, respectively, based on quoted market prices.

*Cash, cash equivalents and marketable securities:* Cash equivalents consist of investments in highly liquid securities with original maturities of three months or less. Marketable securities consist of short-term available-for-sale securities. Our cash equivalents and marketable securities are carried at market values using quoted market prices. We have investment policies and procedures that are reviewed periodically to minimize credit risk.

*Restricted cash:* Restricted cash includes (i) \$10.2 million of restricted cash from discontinued operations held in escrow to support valid indemnification claims that may be made by Biotest related to the sale of our Biologics SBU, and (ii) restricted cash related to various insurance policies. Any remaining restricted cash held in escrow will be released to us on April 15, 2009; as of March 11, 2009, Biotest had not asserted any indemnification claims against us, and we are not aware of any such claims.

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

<u>Asset</u>	<u>Estimated Useful Life</u>
Furniture and fixtures	8 years
Information systems	3 - 7 years
Machinery and equipment	4 - 8 years
Leasehold improvements	Lesser of lease term or economic life

*Recoverability of Long-Lived Assets:* Our policy is to evaluate our long-lived assets for impairment, pursuant to the provisions of SFAS No. 144, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When an evaluation indicates that an asset impairment has occurred, a loss is recognized and the asset is adjusted to its estimated fair value. Given the inherent technical and commercial risks within the biopharmaceuticals industry and the special purpose use of certain of our assets,

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future impairment charges could be required if we were to change our current expectation that we will recover the carrying amount of our long-lived assets from future operations.

*Equity-based compensation:* We currently account for equity-based compensation under the fair value recognition provisions of SFAS No. 123R, “Share-Based Payment,” which establish accounting for share-based awards in exchange for employee services and require companies to expense the estimated fair value of these awards over the requisite employee service period. Under SFAS No. 123R, share-based compensation cost is determined at the grant date using an option pricing model. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the employee’s requisite service period.

*Income taxes:* We follow SFAS No. 109, “Accounting for Income Taxes,” or SFAS 109, 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. A valuation allowance is established when the Company believes that it is more likely than not that its deferred tax assets will not be realized. Changes in valuation allowances from period to period are included in the Company’s tax provision in the period of change. We consider discontinued operations for purposes of determining the amount of tax benefits that results from a loss from continuing operations.

*Segment information:* We currently operate in a single business segment.

*New accounting pronouncements:* In December 2007, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 141R, “Business Combinations,” (“SFAS 141R”). SFAS 141R requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their fair values, changes the recognition of assets acquired and liabilities assumed arising from contingencies, changes the recognition and measurement of contingent consideration, and requires the expensing of acquisition-related costs as incurred. SFAS 141R also requires additional disclosure of information surrounding a business combination, so that users of the financial statements can fully understand the nature and financial impact of the business combination. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS 141R will only impact us if we are a party to a business combination after the pronouncement has been adopted.

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements,” (“SFAS 157”). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies to other accounting pronouncements that require or permit fair value measurements and does not require any new fair value measurements. In February 2008, the FASB issued FSP No. 157-1, “Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13,” (“FSP 157-1”) and FSP No. 157-2, “Effective Date of FASB Statement No. 157,” (“FSP 157-2”), as amendments to SFAS No. 157. FSP 157-1 and FSP 157-2 exclude lease transactions from the scope of SFAS No. 157 and also defer the effective date of the adoption of SFAS 157 for certain non-financial assets and non-financial liabilities. In October of 2008, the FASB issued FSP No. 157-3, “Determining the Fair Value of Financial Assets When the Market for That Asset is Not Active,” (“FSP 15-3”) as an amendment to SFAS No. 157, clarifying the application of SFAS No. 157 in a non-active market. SFAS 157 (along with FSP 157-1 and FSP 157-3) is effective for fiscal years beginning after November 15, 2007, and we adopted SFAS 157 beginning in the first quarter of 2008; the adoption of SFAS 157 did not have any impact on our financial position or results of operations. We will adopt FSP 157-2 in our first quarter of 2009; we have not yet determined the impact, if any, that the adoption of FSP 157-2 will have on our financial statements.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities,” (“SFAS 159”) which gives companies the option to measure eligible financial assets,

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financial liabilities and firm commitments at fair value (i.e., the fair value option), on an instrument-by-instrument basis, that are otherwise not permitted to be accounted for at fair value under other accounting standards. The election to use the fair value option is available when an entity first recognizes a financial asset or financial liability or upon entering into a firm commitment. Subsequent changes in fair value must be recorded in earnings. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We adopted SFAS 159 beginning in the first quarter of our 2008 fiscal year and currently have elected not to use the fair value option for any eligible financial assets or liabilities.

In December 2007, the FASB issued SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements—An Amendment of ARB No. 51,” (“SFAS 160”). SFAS No. 160 amends APB’s Accounting Research Bulletin No. 51 and establishes accounting and reporting standards for non-controlling interests (i.e., minority interests) in a subsidiary and for the deconsolidation of a subsidiary. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. We do not expect that adoption of this standard will have a material impact on our financial statements.

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities—an Amendment of FASB Statement No. 133,” (“SFAS 161”). SFAS 161 states that entities are required to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 “Accounting for Derivative Instruments and Hedging Activities,” (“SFAS 133”) and its related interpretations, and how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. The provisions of SFAS 161 are effective for fiscal years beginning on or after November 15, 2008. We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In May 2008, the FASB issued SFAS No. 162, “The Hierarchy of Generally Accepted Accounting Principles,” (“SFAS 162”). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the U.S. SFAS 162 is effective 60 days following the Securities and Exchange Commission approval of the Public Company Accounting Oversight Board amendments to AU Section 411, “The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.” We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In March 2007, the Emerging Issues Task Force (“EITF”) issued EITF Issue No. 06-10, “Accounting for Deferred Compensation and Postretirement Benefit Aspects of Collateral Assignment Split-Dollar Life Insurance Arrangements,” (“EITF 06-10”). EITF 06-10 provides guidance to help companies determine whether a liability for the postretirement benefit associated with a collateral assignment split-dollar life insurance arrangement should be recorded in accordance with either SFAS No. 106, “Employers’ Accounting for Postretirement Benefits Other Than Pensions” or the Accounting Principles Board (“APB”) Opinion No. 12 “Omnibus Opinion -1967,” (“APB 12”). EITF 06-10 also provides guidance on how a company should recognize and measure the asset in a collateral assignment split-dollar life insurance contract. EITF 06-10 is effective for fiscal years beginning after December 15, 2007. We adopted EITF 06-10 beginning in the first quarter of our 2008 fiscal year and it did not have a material impact to our financial position or results of operations.

In November 2007, the EITF issued EITF Issue No. 07-1, “Accounting for Collaborative Arrangements,” (“EITF 07-1”). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 is effective for fiscal years beginning on or after December 15, 2008, and is to be applied to all periods presented for all collaborative arrangements existing as of its adoption. We are currently evaluating the impact of the adoption of this statement on our financial statements.

In June 2008, the EITF issued EITF Issue No. 07-2, “Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity’s Own Stock,” (“EITF 07-2”). EITF 07-2 applies to any freestanding financial instrument or embedded feature that has all the characteristics of a derivative pursuant to SFAS 133, for purposes



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of determining whether that instrument or embedded feature qualifies for the first part of the scope exception in SFAS 133. EITF 07-2 also applies to any freestanding financial instrument that is potentially settled in an entity's own stock, regardless of whether the instrument has all the characteristics of a derivative, for purposes of determining whether the instrument is within the scope of EITF Issue No. 00-19. EITF 07-2 is effective for financial statements issued for fiscal years beginning after December 15, 2008; we are currently evaluating the impact of the adoption of this statement on our financial statements.

In June 2007, the EITF issued EITF Issue No. 07-03, "Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development," ("EITF 07-03"). EITF 07-03 addresses the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Pursuant to EITF 07-03, an entity is required to defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. We adopted EITF 07-03 beginning in the first quarter of our 2008 fiscal year and it did not have a material impact to our financial position or results of operations.

In May 2008, the FASB issued FASB Staff Position No. APB 14-1, "Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)," ("FSP 14-1"). FSP 14-1 clarifies that (1) convertible debt instruments that may be settled in cash upon conversion, including partial cash settlement, are not considered debt instruments within the scope of APB Opinion No. 14, "Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants," ("APB 14") and (2) issuers of such instruments should separately account for the liability and equity components of those instruments by allocating the proceeds from issuance of the instrument between the liability component and the embedded conversion option (i.e., the equity component). APB 14-1 is effective for fiscal years beginning after December 15, 2008 and is required to be applied retrospectively to convertible debt instruments that are within the scope of this guidance and were outstanding during any period presented in the financial statements. Our Convertible Senior Notes fall within the scope of this guidance. While APB 14-1 does not change the cash flow requirements under our Convertible Senior Notes, non-cash interest expense will increase as a result of amortizing the discounted carrying value of our Convertible Senior Notes. We are in the process of further evaluating the financial impact that the adoption of APB 14-1 will have on our financial statements; however, on a preliminary basis we believe that diluted earnings per share from continuing operations would be reduced by approximately \$0.15 per share, \$0.14 per share and \$0.09 per share in 2008, 2007 and 2006, respectively, as a result of non-cash interest expense recorded in connection with the adoption of APB 14-1.

### **NOTE 4 DISCONTINUED OPERATIONS**

In December 2007, we sold certain assets constituting our Biologics SBU and certain corporate shared services assets to Biotest for \$185.0 million (\$10.0 million of which was placed into an escrow account to support any valid indemnification claims made by Biotest on or before March 31, 2009). Included in the assets sold were Nabi-HB [*Hepatitis B Immune Globulin (Human)*], our plasma business assets including nine FDA-certified plasma collection centers across the U.S., our state-of-the-art plasma protein production facility, and the investigational products, IVIG, Civacir, Anti-D and Altastaph as well as most of our corporate shared services assets (other than cash, cash equivalents and marketable securities) and our Boca Raton, Florida headquarters. We retained all accounts receivable and the vast majority of liabilities associated with the Biologics SBU. We recorded a net gain on this sale of \$65.2 million in the fourth quarter of 2007 in discontinued operations, based on estimated asset and liability balances as of the date of sale. Adjustments to these estimates were charged to discontinued operations as necessary in 2008.

We also entered into the following agreements with Biotest: (i) a Transition Services Agreement pursuant to which the parties agreed to provide transition services (including services related to finance, human resources, information technologies, and clinical and regulatory) to each other for a period of up to six months after closing for a price equal to 150% of direct salary costs plus out-of-pocket costs, except that there was no charge for services provided by Biotest to us through February 4, 2008; (ii) a Contract Manufacturing Agreement pursuant

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to which Biotest will provide manufacturing and technology transfer services related to NicVAX and PentaStaph to us at cost until December 31, 2009; (iii) a Right of First Negotiation/Refusal Agreement pursuant to which we granted Biotest a right of first negotiation and a right of first refusal to obtain rights to utilize PentaStaph and to license the PentaStaph intellectual property that is necessary to enable Biotest to use PentaStaph solely for purposes relating to the production of Altastaph; and (iv) a Trademark License Agreement pursuant to which, we will license to Biotest the “Nabi-HB” trademarks on a worldwide, perpetual, royalty-free basis solely for Biotest’s use in the promotion, distribution and sale of Nabi-HB. The Transition Services Agreement expired in accordance with its terms in 2008; however, the parties have continued to provide certain transition services to each other under the fee structure set forth in the Transition Services Agreement.

During the second quarter of 2007, we sold certain assets related to Aloprim to Bioniche Teoranta for \$3.7 million. Of that amount, \$1.3 million was received at closing, \$1.4 million was received in the fourth quarter of 2007 and \$1.0 million was received in the fourth quarter of 2008. Bioniche Teoranta also assumed the remaining commitments under our agreement with DSM Pharmaceuticals, Inc. In connection with the closing of this transaction, we recorded a gain of \$2.6 million during the second quarter of 2007. In the first three quarters of 2007 as originally reported, we did not treat Aloprim as a discontinued operation given its relative immateriality; in the fourth quarter of 2007, we reclassified these results to discontinued operations along with the results of Biologics SBU.

During the fourth quarter of 2006, we sold certain assets related to our PhosLo operations. Under the sale agreement, we received \$65.0 million in cash at closing and received an additional \$13.0 million of milestones as of March 11, 2009. We can also receive up to \$72.5 million in milestone payments and royalties. The royalties relate to sales of a new product formulation over a base amount for 10 years after the closing date.

The assets and liabilities related to our Biologics SBU, Aloprim and PhosLo businesses have identifiable cash flows that are largely independent of the cash flows of other groups of assets and liabilities, and we will not have a significant continuing involvement with the related products beyond one year after the closing of the transactions. Therefore in accordance with SFAS 144, the accompanying Consolidated Balance Sheets report the assets and liabilities related to our Biologics SBU, Aloprim and PhosLo businesses as discontinued operations in all periods presented, and the results of operations of these businesses have been classified as discontinued operations in the accompanying Consolidated Statements of Operations for all periods presented.

The following table presents the major classes of assets and liabilities that have been presented as assets and liabilities of discontinued operations in the accompanying Consolidated Balance Sheets:

<u>(In thousands)</u>	<u>December 27, 2008</u>	<u>December 29, 2007</u>
Accounts receivable, net	\$ —	\$ 2,690
Other assets (including restricted cash in 2008)	10,409	1,926
<b>Total current assets of discontinued operations</b>	<b>\$ 10,409</b>	<b>\$ 4,616</b>
Other assets (including restricted cash in 2007)	—	10,027
<b>Total assets of discontinued operations</b>	<b>\$ 10,409</b>	<b>\$ 14,643</b>
Accounts payable	—	1,016
Accrued expenses and other liabilities	3,381	8,180
Notes payable	—	352
<b>Total liabilities of discontinued operations</b>	<b>\$ 3,381</b>	<b>\$ 9,548</b>

The restricted cash balances relate to funds held in escrow associated with the sale of our Biologics SBU, pending the settlement of any claims presented by Biotest. Accrued expenses and other liabilities at December 27, 2008 and December 29, 2007 include \$2.8 million and \$4.3 million, respectively, of accrued rebates and other sales discounts and credits.

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The following table presents summarized financial information for the discontinued operations:

<u>(In thousands)</u>	<u>For the Years Ended</u>		
	<u>December 27, 2008</u>	<u>December 29, 2007</u>	<u>December 30, 2006</u>
Total revenues	\$ —	\$ 80,855	\$ 117,852
Operating income	7,010	4,718	(64)
Income (loss) before (provision) benefit for income taxes	7,010	4,718	(64)
Net income (loss) from discontinued operations	4,245	4,036	(3)

### **NOTE 5 PROPERTY AND EQUIPMENT**

Property and equipment and related accumulated depreciation are summarized below:

<u>(In thousands)</u>	<u>December 27, 2008</u>	<u>December 29, 2007</u>
Information systems	\$ 2,113	\$ 2,069
Leasehold improvements	3,204	3,204
Machinery and equipment	4,608	5,003
Furniture and fixtures	239	242
Property and equipment	10,164	10,518
Less accumulated depreciation	(8,849)	(8,547)
<b>Property and equipment, net</b>	<b>\$ 1,315</b>	<b>\$ 1,971</b>

We recorded depreciation expense in continuing operations related to property and equipment of \$0.6 million, \$1.7 million and \$1.0 million, in 2008, 2007 and 2006, respectively.

### **NOTE 6 ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES**

Accrued expenses and other current liabilities consist of the following:

<u>(In thousands)</u>	<u>December 27, 2008</u>	<u>December 29, 2007</u>
Employee compensation and benefits	\$ 1,772	\$ 3,223
Unsettled treasury stock transactions	332	1,763
Accrued clinical trial expenses	98	295
Accrued interest payable	100	450
Other	728	1,374
<b>Total</b>	<b>\$ 3,030</b>	<b>\$ 7,105</b>

### **NOTE 7 SUPPLEMENTAL FAIR VALUE DISCLOSURES**

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements," or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. We adopted the provisions of SFAS 157 as of the beginning of the first quarter of 2008 for financial assets and liabilities. Pursuant to SFAS 157-2, we will adopt similar requirements related to non-recurring nonfinancial assets and liabilities in 2009.

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SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1, defined as observable inputs such as quoted prices in active markets for identical assets;
- Level 2, defined as observable inputs other than level 1 prices such as quoted prices for similar assets; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

All cash and cash equivalents, as well as available for sale marketable securities, are recorded at fair market value at December 27, 2008 and December 29, 2007. The inputs used in measuring the fair value of these instruments are considered to be Level 1 in accordance with the SFAS 157 fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds deposited in institutional money market mutual funds with the remainder held in regular interest bearing and non-interest bearing depository accounts with commercial banks.

### **NOTE 8 CONVERTIBLE SENIOR NOTES**

In 2005, we issued \$112.4 million of our Convertible Senior Notes through a private offering to qualified institutional buyers. In 2007, we repurchased \$38.8 million of our Convertible Senior Notes in two transactions for a total of \$34.1 million resulting in a net gain of \$3.6 million. In 2008 we repurchased an additional \$57.3 million of our Convertible Senior Notes for a total of \$51.6 million resulting in a net gain of \$4.0 million recorded in other income (expense) in our Consolidated Statement of Operations.

Our Convertible Senior Notes were issued pursuant to an indenture between our trustee and us. Our Convertible Senior Notes are convertible, at the option of the holders, into shares of our common stock at a rate of approximately 69.8 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 represented a 30% premium over the closing sale price of our common stock on the date of issuance. Our Convertible Senior Notes, which represent our general, unsecured obligations, will be redeemable by us at 100% of their principal amount, plus accrued and unpaid interest, any time on or after April 18, 2010. Holders of our Convertible Senior 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 change in control as defined in the indenture agreement.

Interest on our Convertible Senior Notes is payable on each April 15 and October 15, beginning October 15, 2005. Accrued and unpaid interest related to our Convertible Senior Notes was \$0.1 million and \$0.4 million at December 27, 2008 and December 29, 2007, respectively. Interest payments for 2008, 2007 and 2006 were \$1.7 million, \$3.5 million and \$3.3 million, respectively, which largely consisted of the semi-annual payments for our Convertible Senior Notes.

### **NOTE 9 STOCKHOLDERS' EQUITY**

#### *Preferred Stock*

We have 5,000,000 shares of preferred stock authorized, approximately 1,500,000 of which have been designated as "Series A Convertible Preferred Stock," approximately 750,000 of which have been designated "Series One Preferred Stock" and approximately 2,700,000 remain available for future designation. Holders of preferred stock would normally be entitled to receive a preference payment in the event of any liquidation, dissolution or winding-up of us before any payment is made to the holders of common stock.

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Currently, there are no outstanding shares of preferred stock. We have issued rights that are in some cases exercisable for shares of our Series One Preferred Stock.

### *Shareholders Rights Plan*

In 1997, we 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 plan is designed to deter coercive or unfair takeover tactics. The Rights 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 of Directors' 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. The Rights expire in August 2009.

### *Treasury Stock*

In the fourth quarter of 2007, our Board of Directors approved the repurchase of up to \$65 million of our common stock in the open market or in privately negotiated transactions. In 2008 we purchased 5.1 million shares at a cost of \$18.6 million with an average cost per share of \$3.66, \$18.2 million of which was paid in 2008 and the balance was settled and paid in 2009. In 2007, we purchased 5.0 million shares at a cost of \$18.3 million with an average cost per share of \$3.66, \$16.5 million of which was paid in 2007 and the balance was settled and paid in 2008. We have acquired a total of 10.1 million shares for a total cost of \$36.9 million. At December 27, 2008, \$28.1 million remains available for share repurchase under the current authorization. Under a previous repurchase plan, 0.8 million shares of common stock had been repurchased. Repurchased shares have been accounted for as treasury stock using the cost method. Subsequent to year end, through March 11, 2009, we have repurchased an additional 127,742 shares for \$411 thousand.

## **NOTE 10 EMPLOYEE BENEFIT PLANS**

We maintain several employee benefit plans for our employees. As of December 27, 2008, a total of 13.3 million shares of common stock were reserved for issuance under our stock option and employee benefit plans.

### *Retirement Savings Plan*

We maintain a retirement savings plan which 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 \$0.2 million, \$1.0 million and \$1.4 million in 2008, 2007 and 2006, respectively.

In 2000, the stockholders approved the issuance of up to 425,000 shares of our common stock to our employees participating in our retirement saving plan. To date, no shares have been issued under this plan.

### *Incentive Stock Plan*

In 2007, our shareholders approved the 2007 Omnibus Equity and Incentive Plan, or 2007 Stock Plan, which supersedes and replaces our previous incentive stock plans. All other incentive stock plans will remain in effect with respect to outstanding awards issued under those plans. Accordingly, we have one plan for both employees

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and directors related to both stock option and restricted stock awards. In connection with the approval of the 2007 Stock Plan, shareholders approved an additional 2.5 million shares of common stock and the transfer of all shares which were available for issuance under the prior incentive stock plans to be available for issuance under the new plan. As of December 27, 2008, we had 12.5 million shares of common stock reserved for the issuance of common stock upon the exercise of outstanding options, future grants of options or restricted stock under our incentive stock plans.

Under our incentive stock plans, we have granted options to employees and directors entitling them to purchase shares of common stock within seven to ten years of the date of grant. The options have generally been granted at exercise prices equal to the fair market value of the underlying common stock on the date of grant. Options granted to employees under our stock incentive plan typically become exercisable over four years in equal annual installments after the date of grant, and to non-employee directors become fully exercisable after six months or in equal quarterly installments over one year, subject to, in all cases, continuous service with the Company. Certain option awards are subject to accelerated vesting. Non-employee directors may 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 director's annual cash retainer divided by the closing price of our common stock on the date the annual retainer is awarded.

We began issuing restricted stock awards in 2006. Awards issued generally vest over periods from two to four years, or are contingent on the achievement of certain performance goals.

### **Employee Stock Purchase Plan**

Under the Nabi Employee Stock Purchase Plan, or the ESPP, qualified employees may purchase 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 27,796 shares, 97,305 shares and 224,353 shares of common stock during 2008, 2007 and 2006, respectively, pursuant to this plan at an average price per common share of \$3.35, \$3.62 and \$3.37, respectively. As of December 27, 2008, we had 0.5 million shares reserved for future issuance under the ESPP.

### **Accounting for Equity-Based Compensation**

Equity-based compensation expense for the three years ended December 27, 2008, including amounts reclassified to discontinued operations, was comprised of:

<u>(In thousands)</u>	<u>For the Years Ended</u>		
	<u>December 27,</u> <u>2008</u>	<u>December 29,</u> <u>2007</u>	<u>December 30,</u> <u>2006</u>
Stock option expense	\$ 1,569	\$ 3,717	\$ 4,406
Employee stock purchase plan expense	39	135	500
Restricted stock expense	1,125	1,129	521
Stock compensation to directors	—	40	72
Total equity-based compensation	<u>\$ 2,733</u>	<u>\$ 5,021</u>	<u>\$ 5,499</u>

In September 2007, we approved certain compensation-related actions in connection with the sale of our Biologics SBU to Biotest. The actions included additional benefits provided to employees whose employment would terminate as a result of the asset sale, related to the acceleration of vesting of all their unvested stock options, acceleration of vesting of all their restricted stock that would have vested in 2008 or 2009 and the modification of all their outstanding options to extend the post-termination of employment exercise period from 90 days to six months. There were approximately 174 employees affected by these actions, resulting in the immediate vesting of 783,094 options and 77,448 restricted stock awards that originally had vesting terms of over three or four years. The 2007 stock option expense and restricted stock expense in the table above includes

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expense of \$1.6 million and \$0.2 million, respectively, related to these benefits, of which \$0.1 million was associated with the modification of the options to add three months to the post termination exercise term, while the remainder related to the vesting acceleration. This total charge of \$1.8 million was recorded as a reduction of the gain on the sale of Biologics SBU in discontinued operations.

As required by SFAS 123R, we estimate forfeitures of stock options and restricted stock awards and recognize compensation cost for only those awards expected to vest. Forfeiture rates are determined for three groups of non-employee directors, senior management and all other employees based on historical experience. Estimated forfeiture rates are adjusted from time to time based on actual forfeiture experience and expected future trends.

Our equity-based compensation expense is reflected in our Consolidated Statements of Operations as follows:

<u>(in thousands)</u>	For the Years Ended		
	December 27, 2008	December 29, 2007	December 30, 2006
Selling, general and administrative expense	\$ 1,824	\$ 1,819	\$ 2,645
Research and development expense	909	951	1,703
Total continuing operations	2,733	2,770	4,348
Discontinued operations	—	2,251	1,151
Total employee stock compensation expense	\$ 2,733	\$ 5,021	\$ 5,499

### Stock Options

In applying SFAS 123R, we determine the fair value of each stock option on the date of grant using the Black-Scholes option-pricing formula and record the resulting expense over the option's vesting period using the straight-line attribution approach. Below are the calculated weighted average fair values for the years ended December 27, 2008, December 29, 2007 and December 30, 2006 as well as the assumptions used in calculating those values:

	For the Years Ended		
	December 27, 2008	December 29, 2007	December 30, 2006
Weighted average fair value (per share)	\$2.49	\$3.23	\$3.48
Assumptions:			
Expected term (in years)	4.5 - 6.3	4.9 - 6.3	2.2 - 8.1
Risk-free interest rate	2.48% - 3.45%	3.41% - 4.91%	4.47% - 5.70%
Expected volatility	73.34% - 76.4%	73.4% - 76.9%	81.4% - 98.4%
Expected dividend yield	0%	0%	0%

*Expected Term:* The expected term represents the period over which the share-based awards are expected to be outstanding based on the historical experience of our employees.

*Risk-Free Interest Rate:* The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equivalent to the stock option award's expected term.

*Expected Volatility:* The volatility factor is based on the historical price of our stock over the most recent period commensurate with the expected term of the stock option award.

*Expected Dividend Yield:* We do not intend to pay dividends on common stock for the foreseeable future. Accordingly, we used a dividend yield of 0% in the assumptions.

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A summary of option activity under our stock plans as of December 27, 2008 and the changes during fiscal 2008 is presented below:

<u>Stock Options</u>	<u>Number of Options</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value (\$000's)</u>
Outstanding at December 29, 2007	6,207,678	\$ 7.60	3.19	\$ 79
Granted	612,250	3.91		
Exercised	(119,750)	3.10		
Forfeited	(198,130)	4.24		
Expired	(2,361,844)	8.12		
Outstanding at December 27, 2008	<u>4,140,204</u>	<u>\$ 7.04</u>	<u>3.71</u>	<u>\$ 44</u>
Vested and expected to vest at December 27, 2008	<u>3,654,102</u>	<u>\$ 7.47</u>	<u>3.43</u>	<u>\$ 44</u>
Exercisable at December 27, 2008	<u>3,041,503</u>	<u>\$ 8.05</u>	<u>3.04</u>	<u>\$ 44</u>

As of December 27, 2008, there was \$1.3 million of unrecognized compensation cost related to the stock options granted under our stock plans which is expected to be recognized over a weighted-average period of 1.8 years. The total intrinsic value of stock options exercised was \$0.1 million, \$0.3 million and \$0.8 million in 2008, 2007 and 2006, respectively. Cash received from the exercise of stock options for 2008, 2007 and 2006 was \$0.4 million, \$1.0 million and \$2.3 million, respectively (including \$0.4 million and \$0.5 million from discontinued operations in 2007 and 2006, respectively).

### *Restricted Stock*

A summary of the status of our restricted stock awards as of December 27, 2008 and changes during fiscal 2008 is presented below:

<u>Restricted Stock</u>	<u>Number of Shares</u>	<u>Weighted-Average Fair Value at Grant Date</u>
Nonvested at December 29, 2007	582,793	\$ 4.55
Granted	195,700	3.90
Vested	(347,242)	4.27
Forfeited	(63,803)	3.91
Nonvested at December 27, 2008	<u>367,448</u>	<u>\$ 4.22</u>

As of December 27, 2008, there was \$0.7 million of total unrecognized compensation cost related to restricted stock awards granted under our stock plans. That cost is expected to be recognized over a weighted-average period of 1.6 years. The total fair value of shares vested during 2008 and 2007 was \$1.3 million and \$0.8 million, respectively. No shares vested during 2006.



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**NOTE 11 INCOME TAXES**

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

<u>(in thousands)</u>	<b>For the Years Ended</b>		
	<b>December 27, 2008</b>	<b>December 29, 2007</b>	<b>December 30, 2006</b>
<b>Current:</b>			
Federal	\$ —	\$ —	\$ (69)
State	—	201	—
	—	201	(69)
<b>Deferred:</b>			
Federal	(5,712)	(420)	(23,511)
State	(635)	(22)	(1,238)
	(6,347)	(442)	(24,749)
<b>Total</b>	(6,347)	(241)	(24,818)
Change in valuation allowance	6,347	442	24,749
<b>Total, net before intra-period allocation</b>	\$ —	\$ 201	\$ (69)
Intra-period tax allocation	(2,765)	(14,466)	(684)
<b>Total, net</b>	<b>\$ (2,765)</b>	<b>\$ (14,265)</b>	<b>\$ (753)</b>

The following table includes deferred tax assets and liabilities from both continuing and discontinued operations as of December 27, 2008 and December 29, 2007, respectively:

<u>(in thousands)</u>	<b>December 27, 2008</b>	<b>December 29, 2007</b>
<b>Deferred tax assets:</b>		
Federal net operating loss carryforwards	\$ 37,129	\$ 30,893
State net operating loss carryforwards	1,437	518
Research and experimental tax credit	15,963	15,870
Inventory reserve and capitalization	1,921	1,921
Sale of Phoslo assets	8,020	9,006
Deferred research and experimental costs	7,928	9,250
Depreciation	1,302	1,201
Alternative minimum tax credit	2,438	2,438
Accrued compensated-related costs	5,352	6,087
Other	5,218	6,071
Deferred tax assets	86,708	83,255
<b>Deferred tax liabilities:</b>		
Other	(74)	(192)
Deferred tax liabilities	(74)	(192)
Net deferred tax assets	86,634	83,063
Valuation allowance	(86,634)	(83,063)
Net deferred tax assets	\$ —	\$ —

As of December 27, 2008, we have Federal net operating loss carryforwards of approximately \$124.2 million that expire at various dates through 2028. Approximately \$18.3 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 \$7.2 million through capital in excess of par value to the extent such losses can be used to reduce

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current taxes payable. We have Federal research and experimental tax credit carryforwards of approximately \$18.8 million that expire in varying amounts through 2028. We have Federal alternative minimum tax credit carryforwards of \$2.4 million that are available to offset future regular tax liabilities and do not expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, or IRC, certain significant changes in ownership may restrict the future utilization of our tax loss carryforwards and tax credit carryforwards. The annual limitation is equal to the value of our stock immediately before the ownership change, multiplied by the long-term tax-exempt rate (i.e., the highest of the adjusted Federal long-term rates in effect for any month in the three-calendar-month period ending with the calendar month in which the change date occurs). Based upon preliminary calculations, we estimate that the utilization of \$15 million of remaining tax losses for federal income tax purposes would be limited to approximately \$14.2 million per year. This limitation may be increased under the IRC Section 338 Approach (IRS approved methodology for determining recognized Built-In Gain). As a result, federal net operating losses and tax credits may expire before we are able to fully utilize them.

We have determined that a full valuation allowance is required against all our deferred tax assets that we do not expect to be offset by deferred tax liabilities. As a result, we recorded \$86.6 million and \$83.1 million valuation allowance as of December 27, 2008 and December 29, 2007, respectively.

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

<u>(in thousands)</u>	For the Years Ended		
	December 27, 2008	December 29, 2007	December 30, 2006
<b>Pre-tax (loss) income:</b>			
U.S.	\$ (17,692)	\$ (38,839)	\$ (59,302)
Foreign	(34)	56	(1,404)
<b>Total</b>	<u>\$ (17,726)</u>	<u>\$ (38,783)</u>	<u>\$ (60,706)</u>

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 27, 2008	December 29, 2007	December 30, 2006
Federal statutory rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(5.4)	(3.3)	(3.3)
Foreign tax rate differential	(0.1)	(0.1)	0.9
Tax credits	(0.5)	(0.3)	(0.4)
Valuation allowance	35.8	37.4	36.9
Other	4.2	0.8	(0.2)
<b>Total before intra-period allocation</b>	— %	0.5%	(0.1)%
Intra-period tax allocation	15.6	37.2	1.1
<b>Total</b>	<u>15.6%</u>	<u>37.7%</u>	<u>1.0%</u>

We paid no income taxes in 2007 or 2006. In 2008 we paid approximately \$1.3 million of income taxes to federal and state jurisdictions relating to taxable income generated in 2007 from the sale of our Biologics SBU.

### **Uncertain Income Tax Positions**

We are subject to income taxes in the U.S., various states and numerous foreign jurisdictions. Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. We establish reserves for tax-related uncertainties based on estimates of whether, and the extent to which, additional

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taxes will be due. These reserves are established when we believe that certain positions might be challenged despite our belief that our tax return positions are fully supportable. We adjust these reserves in light of changing facts and circumstances, such as the outcome of a tax audit. The provision for income taxes includes the impact of reserve provisions and changes to reserves that are considered appropriate.

We are subject to tax audits in all jurisdictions for which we file tax returns. Tax audits by their very nature are often complex and can require several years to complete. Under the tax statute of limitations applicable to the Internal Revenue Code, we are no longer subject to U.S. federal income tax examinations by the Internal Revenue Service for years before 2003. However, because we are carrying forward income tax attributes, such as net operating losses and tax credits from 2002 and earlier tax years, these attributes can still be audited when used on returns filed in the future. Under the statutes of limitation applicable to most state income tax laws, we are no longer subject to state income tax examinations by tax authorities for years before 2003 in states in which we have filed income tax returns. Certain states may take the position that we are subject to income tax in such states even though we have not filed income tax returns in such states and, depending on the varying state income tax statutes and administrative practices, the statute of limitations in such states may extend to years before 2003. We began foreign operations in 2004. We are subject to foreign tax examinations by tax authorities for all years of operation.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits for the 2008 year (in thousands):

Unrecognized tax benefit - opening balance	\$7,718
Gross increases	432
Gross decreases	—
Unrecognized tax benefit—ending balance	<u>\$8,150</u>

As of December 27, 2008 accrued interest and penalties on unrecognized tax benefits were \$0.1 million.

### **NOTE 12 LEASES**

Aggregate minimum commitments under non-cancelable operating leases, primarily for office and laboratory space and equipment rentals, at December 27, 2008 were as follows:

2009	\$910
2010	791
2011	870
2012	113
2013 and thereafter	339

Rent expense for continuing operations was approximately \$1.5 million, \$1.5 million and \$0.9 million for the years ended December 27, 2008, December 29, 2007 and December 30, 2006, respectively.

### **NOTE 13 LICENSES AND ROYALTY AGREEMENTS**

We have entered into licenses and royalty agreements for our products in development.

#### *National Institute of Allergy and Infectious Diseases*

We have entered into a collaboration agreement with the NIAID to conduct pre-clinical toxicological evaluations of two new antigens related to PentaStaph.

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### *National Institute for Drug Abuse*

We have received grants from the NIDA that in the past has supported clinical development of NicVAX. We do not anticipate significant additional funding from these grants.

### *Department of Defense*

We have entered into a CRADA with the Department of Defense to conduct a series of clinical trials for PentaStaph.

### *National Institutes of Health*

The development of our PentaStaph product was initially based upon an exclusive license from the NIH of the worldwide right to use their patented conjugation process to manufacture vaccines against *staphylococcal* infections. Since obtaining that license, we have developed our own extensive global portfolio of issued patents and pending patent applications relating to both our novel vaccine products and methods of using such products. The initial NIH license remains in effect until the expiration of the last-to-expire licensed patent, which is April 20, 2010, and no further royalties will be due to NIH for use of the subject technology after that date.

Under a later license agreement with NIH, we have a non-exclusive, worldwide right to use the rEPA carrier protein technology to develop, manufacture and commercialize vaccines for uses other than vaccines against *staphylococcal* infections. Under the terms of this agreement NicVAX is subject to a 0.5% royalty upon commercialization.

### *University of Maryland, Baltimore County*

Under a license agreement with the University of Maryland, Baltimore County, or UMBC, we have an exclusive, worldwide right to use UMBC's patented ring-expanded nucleosides and nucleotides, or RENs for use in humans. During the term of the license, we are obligated to pay UMBC a 2% royalty based on net sales of license products covered by patent rights which are sold by us. This agreement remains in effect until the expiration of the last-to-expire licensed patent, which is January 13, 2021, and no further royalties will be due to UMBC for use of the subject technology after that date. We are responsible for prosecution and maintenance of the patent portfolio. We currently do not plan to significantly advance development of RENs until we find a suitable partner.

## **NOTE 14 COMMITMENTS AND CONTINGENCIES**

During 2006, we engaged an outside consultant to assess our pricing programs under Medicare/Medicaid and other governmental pricing programs during the period from 2002 through the second quarter of 2006. In connection with this review, we identified additional liabilities related to discontinued operations for possible overbilling under Medicare/Medicaid and other governmental pricing programs, of which our estimate of the remaining amounts due were approximately \$2.1 million and \$2.5 million respectively at December 27, 2008 and December 29, 2007, which are included in the amounts recorded as accrued rebates. We are paying these obligations as they are rebilled to us. The calculated amount due assumes that we will be successful in rebilling ineligible entities that improperly received best prices.

In January 2008, we announced that we had retained a prominent investment bank to assist with our continued exploration of the full range of strategic alternatives available to us to further enhance shareholder value. These alternatives may include, but are not limited to, licensing or development arrangements, joint ventures, strategic alliances, a recapitalization, and the sale or merger of all or part of the company. We have agreed to pay the bank 1.1% of the value of a qualifying transaction with a minimum of \$1.8 million upon the

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successful completion of a strategic transaction as defined in our agreement with them. In October 2008, we engaged the services of a life sciences strategic advisory firm to assist with the strategic alternatives process. We have agreed to pay this firm a fee of up to \$3.5 million upon the successful completion of a strategic transaction. In January 2009, we engaged an industry consultant to further assist in these initiatives. We have granted this consultant options to acquire up to 100,000 shares of our common stock, subject to performance-based vesting requirements.

We have agreements with certain members of our senior management that include certain cash payments and equity-based award modifications in the event of a termination of employment or a change in control of the Company.

### *Litigation*

We are parties to legal proceedings that we believe to be ordinary, routine litigation incidental to the business of present or former operations. It is management's opinion, based on the advice of counsel, that the ultimate resolution of such litigation will not have a material adverse effect on our financial condition, results of operations or cash flows.

In July 2006, we commenced an arbitration proceeding against Inhibitex, Inc., or Inhibitex, arising in connection with a specific Production Agreement. In August 2006, Inhibitex asserted certain counterclaims in the arbitration proceeding, which was subsequently dismissed by the arbitrator. In February 2007, the arbitrator entered an award in our favor in the amount of \$4.5 million. We subsequently moved to confirm the award in the Supreme Court of New York and Inhibitex moved to vacate the award. In October 2007, the court issued a decision denying our petition with respect to \$3.3 million in cancellation fees, but affirmed the arbitrator's award in the amount of \$1.2 million, which amount was received by us in January 2008. We appealed the decision of the court with respect to the cancellation fees. In August 2008 we settled the arbitration with Inhibitex. Under the terms of the settlement, Inhibitex agreed to pay us \$2.2 million, which we received in 2008.

### **NOTE 15 SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

We determined in connection with the preparation of our 2008 consolidated financial statements that our 2007 and 2006 consolidated financial statements required restatement to correct errors in the allocation of the income tax provision between continuing and discontinued operations. We previously did not consider income we reported from discontinued operations for purposes of determining the amount of income tax benefit that results from a loss from continuing operations and that should be allocated to continuing operations. As a result of these errors, we restated our consolidated financial statements for the years ended December 29, 2007 and December 30, 2006.

The adjustments did not have any impact on our consolidated net income (loss) for any period. Accordingly, there was no cumulative effect of the adjustment on our consolidated balance sheet as of December 29, 2007.

As Originally Reported:

<u>(in thousands, except per share data)</u>	<u>March 29, 2008</u>	<u>June 28, 2008</u>	<u>Sept. 27, 2008</u>	<u>Dec. 27, 2008</u>
Loss from continuing operations	\$ (6,735)	\$ (3,672)	\$ (4,307)	\$ (3,012)
Income from discontinued operations	494	3,296	2,593	627
Net loss	(6,241)	(376)	(1,714)	(2,385)
Basic and diluted loss per share:				
Continuing operations	\$ (0.13)	\$ (0.07)	\$ (0.08)	\$ (0.06)
Net income (loss)	(0.12)	(0.01)	(0.03)	(0.05)

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<u>(in thousands, except per share data)</u>	For the Fiscal 2007 Quarters Ended			
	March 31, 2007	June 30, 2007	Sept. 29, 2007	Dec. 29, 2007
Loss from continuing operations	\$ (13,873)	\$ (10,498)	\$ (10,382)	\$ (4,231)
Income (loss) from discontinued operations	2,844	5,720	(5,492)	82,981
Net (loss) income	(11,029)	(4,778)	(15,874)	78,750
Basic and diluted (loss) income per share:				
Continuing operations	\$ (0.23)	\$ (0.17)	\$ (0.17)	\$ (0.07)
Net (loss) income	(0.18)	(0.08)	(0.26)	1.32

Due to rounding the quarterly per share amounts may not add to the annual amount.

As Restated:

<u>(in thousands, except per share data)</u>	For the Fiscal 2008 Quarters Ended			
	March 29, 2008	June 28, 2008	Sept. 27, 2008	Dec. 27, 2008
Loss from continuing operations	\$ (6,539)	\$ (2,372)	\$ (3,285)	\$ (2,765)
Income from discontinued operations	299	1,996	1,570	380
Net loss	(6,240)	(376)	(1,715)	(2,385)
Basic and diluted loss per share:				
Continuing operations	\$ (0.13)	\$ (0.05)	\$ (0.06)	\$ (0.05)
Net income (loss)	(0.12)	(0.01)	(0.03)	(0.05)

<u>(in thousands, except per share data)</u>	For the Fiscal 2007 Quarters Ended			
	March 31, 2007	June 30, 2007	Sept. 29, 2007	Dec. 29, 2007
Loss from continuing operations	\$ (13,401)	\$ (9,549)	\$ (11,293)	\$ 9,725
Income (loss) from discontinued operations	2,372	4,771	(4,581)	69,025
Net (loss) income	(11,029)	(4,778)	(15,874)	78,750
Basic and diluted (loss) income per share:				
Continuing operations	\$ (0.22)	\$ (0.16)	\$ (0.18)	\$ 0.16
Net (loss) income	(0.18)	(0.08)	(0.26)	1.32

Due to rounding the quarterly per share amounts may not add to the annual amount.

We disposed of our Biologics SBU, Aloprim product line and PhosLo product line in the fourth quarter of 2007, second quarter of 2007 and fourth quarter of 2006, respectively. The results from these operations have been reclassified to discontinued operations for all the periods above. Included in income from discontinued operations in the fourth quarter of 2007 is a net gain of \$65.2 million associated with the sale of our Biologics SBU. Included in income from discontinued operations in the second quarter of 2007 is a gain of \$2.6 million associated with the disposal of Aloprim.

**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 (who is also our acting Chief Financial Officer), the effectiveness of our disclosure controls and procedures as of December 27, 2008. Because we identified our material weakness related to intra-period allocation of the provision for income taxes between the loss from continuing operations and income from discontinued operations, our management has concluded that our disclosure controls and procedures were not effective as of December 27, 2008 as it relates to intra-period allocation of its provision for income taxes between the loss from continuing operations and income from discontinued operations.

**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 Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Under the supervision and with the participation of our management, including our Chief Executive Officer (who is also our acting 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 (COSO criteria).

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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 27, 2008, and this assessment identified a material weakness in the accounting for income taxes. Specifically our process and procedures related to the intra-period allocation of the provision for income taxes between loss from continuing operations and income from discontinued operations were not effective. This material weakness in internal controls over income taxes resulted in the restatement of the 2007 and 2006 financial statements. Accordingly we did not maintain effective internal controls over financial reporting as of December 27, 2008, based on COSO criteria.

The effectiveness of our internal control over financial reporting as of December 27, 2008 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 27, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

On March 11, 2009, our Board of Directors appointed Ronald B. Kocak, age 51, as our Chief Accounting Officer. Since August 2008, Mr. Kocak has served as our Corporate Controller, a position he will continue to hold. From June 2008 to August 2008, Mr. Kocak served as our Director of Financial Accounting and Reporting. From February 2008 to August 2008, Mr. Kocak served as our Senior Manager for Financial Accounting. From 2007 to 2008, Mr. Kocak held the position of Manager of Financial Assurance at Ryan, Sharkey & Crutchfield, LLP, certified public accountants, where he performed various audit engagements and advised clients on SEC reviews. From 2005 to 2007, Mr. Kocak held the position of Manager of Accounting and Corporate Consolidations at WGL Holdings, Inc., a gas utility company based in Washington, D.C., where he managed the monthly accounting and consolidation process for SEC reporting purposes. From 2004 to 2005, Mr. Kocak held the position of Controller of Metregenix US, Inc., a biotechnology company, overseeing all accounting and financial operations for the U.S. and Canada operations.



**Nabi Biopharmaceuticals**

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information called for by this Item and not already provided in Item 4(a) will be contained in our Proxy Statement, which we intend to file within 120 days following our fiscal year end, December 27, 2008, 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 27, 2008, 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 27, 2008, and such information is incorporated herein by reference.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

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 27, 2008, and such information is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTING 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 27, 2008, and such information is incorporated herein by reference.

**Nabi Biopharmaceuticals**

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

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

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

	<b>Page</b>
<a href="#">Reports of Independent Registered Public Accounting Firm</a>	35
<a href="#">Consolidated Balance Sheets at December 27, 2008 and December 29, 2007</a>	37
<a href="#">Consolidated Statements of Operations for the years ended December 27, 2008, December 29, 2007 and December 30, 2006</a>	38
<a href="#">Consolidated Statements of Stockholders' Equity for the years ended December 27, 2008, December 29, 2007 and December 30, 2006</a>	39
<a href="#">Consolidated Statements of Cash Flows for the years ended December 27, 2008, December 29, 2007 and December 30, 2006</a>	40
<a href="#">Notes to Consolidated Financial Statements</a>	41

**(2) FINANCIAL STATEMENT SCHEDULES**

<a href="#">Schedule II - Valuation and Qualifying Accounts and Reserves</a>	69
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All other schedules omitted are not required, inapplicable or the information required is furnished in the financial statements or notes thereto.

**(3) EXHIBITS**

- 2.1 Asset Purchase Agreement by and among Nabi Biopharmaceuticals, Biotest Pharmaceuticals Corporation and Biotest AG, dated as of September 11, 2007 (incorporated by reference to Exhibit 2.1 to our Form 8-K filed on September 11, 2007)
- 3.1 Restated Certificate of Incorporation of Nabi Biopharmaceuticals, as amended (incorporated by reference to Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 26, 2004)
- 3.2 By-Laws of Nabi Biopharmaceuticals (incorporated by reference to Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 28, 2003)
- 4.1 Certificate of Designations of Series One Preferred Stock contained in the Restated Certificate of Incorporation of Nabi Biopharmaceuticals (incorporated by reference to Exhibit 3.1 to our Quarterly Report on Form 10-Q for the period ended June 26, 2004)
- 4.2 Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to our Annual Report on Form 10-K for the year ended December 30, 2006)
- 4.3 Rights Agreement dated August 1, 1997, as amended, between Nabi Biopharmaceuticals 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)

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- 4.5 Second Amendment to Rights Agreement dated July 26, 2007 between Nabi Biopharmaceuticals and American Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2007)
- 4.6 Third Amendment to Rights Agreement dated July 27, 2007 between Nabi Biopharmaceuticals and American Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.2 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2007)
- 4.7 Fourth Amendment to Rights Agreement dated July 31, 2008 between Nabi Biopharmaceuticals and American Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.1 to our Quarterly Report on Form 10-Q for the quarter ended June 28, 2008)
- 4.8 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 May 25, 2005)
- 4.9 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 May 25, 2005)
- 4.10 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 May 25, 2005)
- 4.11 Global Note evidencing the registered portion of our 2.875% Convertible Senior Notes (incorporated by reference to Exhibit 4.8 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2005)
- 10.1 2004 Stock Plan for Non-Employee Directors (incorporated by reference to Appendix C to our Definitive Proxy Statement dated April 9, 2004)+
- 10.2 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)+
- 10.3 2000 Equity Incentive Plan, as amended (incorporated by reference to Appendix B to our Definitive Proxy Statement dated April 9, 2004)+
- 10.4 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)+
- 10.5 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)+
- 10.6 2007 Omnibus Equity and Incentive Plan (incorporated by reference to Appendix A of our Definitive Proxy Statement dated April 12, 2007)+
- 10.7 Employment Agreement between Leslie Hudson, Ph.D. and Nabi Biopharmaceuticals effective as of February 15, 2007 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007)+
- 10.8 Employment Agreement between Leslie Hudson, Ph.D. and Nabi Biopharmaceuticals effective as of August 16, 2007 (incorporated by reference to Exhibit 10.11 to our Annual Report on Form 10-K for the year ended December 29, 2007)+
- 10.9 Nabi Biopharmaceuticals had entered into an Indemnification Agreement in the form filed as Exhibit 10.24 to our Annual Report on Form 10-K for the year ended December 25, 2004, with the following named executive officers: Leslie Hudson, Ph.D., Jordan I. Siegel, Raafat E.F. Fahim, Ph.D. and Paul Kessler, M.D.+

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- 10.10 Form of Retention Plan Restricted Stock Agreements entered into by Nabi Biopharmaceuticals and Raafat E.F. Fahim, Ph.D. and Jordan I. Siegel (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended April 1, 2006)+
- 10.11 Form of Letter Agreement for Stock Option Grant and Acceptance between Nabi Biopharmaceuticals and Raafat E.F. Fahim, Ph.D. (incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the quarter ended April 1, 2006)+
- 10.12 Form of Letter Agreement for Retention Program Cash Bonus and Other Awards between Nabi Biopharmaceuticals and Raafat E.F. Fahim, Ph.D. (incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q for the quarter ended April 1, 2006)+
- 10.13 Restricted Stock Agreement between Nabi Biopharmaceuticals and Raafat E.F. Fahim, Ph.D., dated May 12, 2006 (incorporated by reference to Exhibit 10.23 to our Annual Report on Form 10-K for the year ended December 30, 2006)+
- 10.14 Nabi Biopharmaceuticals has entered into an Indemnification Agreement with each of its directors in the form filed as Exhibit 10.24 to our Annual Report on Form 10-K for the year ended December 25, 2004)+
- 10.15 Transition/Termination Agreement between Nabi Biopharmaceuticals and Fresenius Biotech GmbH dated October 19, 2007 (incorporated by reference to Exhibit 10.26 to our Annual Report on Form 10-K for the year ended December 29, 2007)
- 10.16 Asset Purchase Agreement between Nabi Biopharmaceuticals and Fresenius USA Manufacturing, Inc. dated October 11, 2006 (incorporated by reference to Exhibit 10.35 to our Annual Report on Form 10-K for the year ended December 30, 2006)++
- 10.17 Amendment No. 1 to Asset Purchase Agreement between Nabi Biopharmaceuticals and Fresenius USA Manufacturing, Inc. dated October 31, 2006 (incorporated by reference to Exhibit 10.36 to our Annual Report on Form 10-K for the year ended December 30, 2006)
- 10.18 Amendment No. 2 to Asset Purchase Agreement between Nabi Biopharmaceuticals and Fresenius USA Manufacturing, Inc. dated November 14, 2006 (incorporated by reference to Exhibit 10.37 to our Annual Report on Form 10-K for the year ended December 30, 2006)++
- 10.19 Non-Competition and Nonsolicitation Agreement between Nabi Biopharmaceuticals and Fresenius USA Manufacturing, Inc. dated November 14, 2006 (incorporated by reference to Exhibit 10.38 to our Annual Report on Form 10-K for the year ended December 30, 2006)
- 10.20 Asset Purchase Agreement, dated as of September 11, 2007, by and among Nabi Biopharmaceuticals, Biotest Pharmaceuticals Corporation and Biotest AG (incorporated by reference to Annex A to our Definitive Proxy Statement dated October 16, 2007)
- 10.21 Manufacturing Services Agreement, dated as of December 4, 2007, by and among Nabi Biopharmaceuticals, Biotest Pharmaceuticals Corporation and Biotest AG (incorporated by reference to Exhibit 10.33 to our Annual Report on Form 10-K for the year ended December 29, 2007)
- 10.22 Side Letter, dated December 4, 2007, by and among Nabi Biopharmaceuticals, Biotest Pharmaceuticals Corporation and Biotest AG (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on December 10, 2007)
- 10.23 Transition Services Agreement, dated as of December 4, 2007, by and among Nabi Biopharmaceuticals and Biotest Pharmaceuticals Corporation (incorporated by reference to Exhibit 10.2 to our Form 8-K filed on December 10, 2007)
- 10.24 Right of First Refusal and Right of First Negotiation Agreement, dated as of December 4, 2007, by and among Nabi Biopharmaceuticals and Biotest Pharmaceuticals Corporation (incorporated by reference to Exhibit 10.3 to our Form 8-K filed on December 10, 2007)

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10.25	Employment Agreement between Nabi Biopharmaceuticals and Raafat Fahim dated January 22, 2008 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 29, 2008)+
10.26	Letter Agreement between Nabi Biopharmaceuticals and Jordan Siegel dated February 27, 2008 (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 29, 2008)+
10.27	Employment Agreement between Nabi Biopharmaceuticals and Paul Kessler, M.D. dated May 1, 2008 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 28, 2008)+
10.28	Change of Control Severance Agreement between Nabi Biopharmaceuticals and Paul Kessler, M.D. dated August 21, 2007*+
23.	Consent of Independent Registered Public Accounting Firm*
31.1	Rule 13a-14(a)/15d-14(a) Certification*
32.	Section 1350 Certification

\* *Filed herewith*

+ *Management contract or compensatory plan or arrangement filed pursuant to Item 15(b) of Form 10-K.*

++ *The Company has requested confidential treatment of the redacted portions of this exhibit pursuant to Rule 24b-2, under the Securities Exchange Act of 1934, as amended, and has separately filed a complete copy of this exhibit with the Securities and Exchange Commission.*



**Nabi Biopharmaceuticals**  
**SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS AND RESERVES**  
**FROM TOTAL OPERATIONS**  
**(in thousands)**

Classification	Balance at Beginning of Period	Additions		Deductions		Balance at End of Period
		Charged to Costs and Expenses	Charged to Other Accounts	Write-Offs Charged Against Reserve	Other <sup>(1)</sup>	
<b>Year ended December 27, 2008:</b>						
Allowance for doubtful accounts	\$ 11	\$ —	\$ —	\$ (11)	\$ —	\$ —
Inventory valuation allowance	\$ 4,870	—	—	(4,870)	—	—
Net deferred tax asset valuation allowance	\$ 83,063	3,571	—	—	—	86,634
<b>Year ended December 29, 2007:</b>						
Allowance for doubtful accounts	\$ 20	\$ 33	\$ —	\$ (42)	\$ —	\$ 11
Inventory valuation allowance	13,622	244	—	(3,949)	(5,047)	4,870
Net deferred tax asset valuation allowance	103,295	—	—	—	(20,232)	83,063
<b>Year ended December 30, 2006:</b>						
Allowance for doubtful accounts	\$ 6	\$ 7	\$ —	\$ 7	\$ —	\$ 20
Inventory valuation allowance	11,750	2,143	—	(271)	—	13,622
Net deferred tax asset valuation allowance	78,556	24,739	—	—	—	103,295

<sup>(1)</sup> Other consists of the reversal of reserves no longer required, primarily due to the sale of businesses.

**Nabi Biopharmaceuticals**

**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
10.28	Change of Control Severance Agreement between Nabi Biopharmaceuticals and Paul Kessler, M.D. dated August 21, 2007
23.	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a)/15d-14(a) Certification
32.	Section 1350 Certification



Nabi Biopharmaceuticals

5800 Park of Commerce Boulevard, N.W.  
Boca Raton, FL 33487**Change of Control Severance Agreement****Effective as of August 21, 2007**Paul Kessler, M.D.  
10604 Avonlea Hills Court  
Hagerstown, MD 21742

Dear Paul:

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

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

1. In view of the foregoing and in further consideration of your continued employment with the Corporation, the Corporation will pay you as termination compensation an amount, determined as provided below, in the event that within twelve months following a Change of Control (as defined below) (a) you terminate your employment with the Corporation for Good Reason (as defined below) or (b) your employment with the Corporation is terminated by the Corporation for any reason other than Cause (as defined below), death or disability. The compensation so payable (hereinafter referred to as the "Severance Amount") shall be an amount equal to two times the sum of (a) the higher of (i) your current annual base salary or (ii) your base salary immediately prior to the Change of Control plus (b) the target bonus you could have earned for the fiscal year in which the Change of Control occurred. The Severance

Amount shall be paid to you ratably over the twenty-four month period commencing on the date of the termination of your employment with the Corporation (the "Termination Date") in accordance with the normal payroll practices of the Corporation, but in any event no less frequently than semimonthly. Notwithstanding the foregoing, if it is necessary in order to satisfy the requirements of the American Jobs Creation Act, the parties agree that the payments to which you would otherwise be entitled under this Agreement on account of your separation from service (within the meaning of Section 409A(2)(A)(i) of the Internal Revenue Code of 1986, as amended) from the Corporation during the six-month period commencing on the Termination Date shall be accumulated and paid on the first regular payroll date for employees following such six-month period.

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

(a) Any compensation and other amounts previously deferred by you, to which you are entitled, and any accrued vacation pay and accrued paid leave bank amounts not yet paid by the Corporation, shall be paid to you within five business days of the Termination Date.

(b) All other amounts accrued or earned by you through the date of such termination and amounts otherwise owing under the Corporation's plans and policies shall be paid to you in accordance with the terms of those plans and policies.

(c) The Corporation shall maintain in full force and effect, for the continued benefit of you and/or your family for twelve months after the Termination Date, all employee welfare benefit plans and any other employee benefit programs or arrangements (including, without limitation, medical and dental insurance plans and disability and life insurance plans) in which you were entitled to participate immediately prior to the Change of Control, provided that your continued participation is possible under the general terms and provisions of such plans and programs.

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

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

(f) You shall not be required to mitigate the amount of any payment provided for in this Agreement by seeking other employment or otherwise, nor shall the amount of any payment provided for in this Agreement be reduced by any compensation earned by you as the result of employment by another employer after the Termination Date, or otherwise.

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

4. Anything in this Agreement notwithstanding, you and the Corporation agree that you will not terminate your employment with the Corporation for Good Reason within six months following a Change of Control, or for any reason within the period beginning on the sixth monthly anniversary of a Change of Control and ending on the twelfth monthly anniversary thereof, and seek, obtain or retain any compensation pursuant to Sections 1 and 2 of this Agreement if you become employed by or otherwise provide services to the company that was involved in the Change of Control by acquiring assets or securities of the Corporation or merging or consolidating with the Corporation or any Affiliate of that company during the twelve months following the Change of Control.

5. For purposes of this Agreement:

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

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

(c) "Cause" means (i) any act of fraud or embezzlement or other felonious act by you, (ii) your refusal to comply with reasonable directions in connection with the performance of your duties after notice of such failure is delivered to you, (iii) your failure to comply with the material provisions of any employment-related agreement between you and the Corporation or any of the Corporation's policies applicable to you or (iv) your gross negligence or intentional misconduct in connection with the performance of your duties.

(d) A "Change of Control" shall be deemed to have taken place if (i) any "person" (as such term is used in Sections 13(d) and 14(d)(2) of the Exchange Act) is or becomes the beneficial owner (within the meaning of Rule 13d-3 promulgated under the Exchange Act), directly or indirectly, of securities of the Corporation representing 50% or more of the combined voting power of the Corporation's then outstanding securities; (ii) (A) a reorganization, merger or consolidation, in each case, with respect to

which persons who were shareholders of the Corporation immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities or (B) a liquidation or dissolution of the Corporation approved by the shareholders of the Corporation in accordance with Delaware law; or (iii) as the result of a tender offer, exchange offer, merger, consolidation, sale of assets or contested solicitation of proxies or stockholder consents or any combination of the foregoing transactions (a "Transaction"), the persons who were directors of the Corporation immediately before the Transaction shall cease to constitute a majority of the Board of Directors of the Corporation or of any parent of or successor to the Corporation immediately after the Transaction occurs.

(e) "Good Reason" means:

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

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

(iii) The Corporation's requiring you to be based at any office or location more than fifty (50) miles from that location at which you are employed on the date of the Change of Control, except for travel reasonably required in the performance of your responsibilities.

6. Anything in this Agreement to the contrary notwithstanding, if your employment with the Corporation is terminated by the Corporation prior to the date on which a Change of Control occurs, and such termination (a)(i) was at the request of a third party who has taken steps reasonably calculated to effect a Change of Control or (ii) otherwise arose in anticipation of a Change of Control and not for reasons unrelated to the Change of Control and (b) such termination occurs within six (6) months of the occurrence of a Change of Control, then for purposes of Section 1 of this Agreement your termination of employment will be deemed to have occurred immediately following the Change of Control.

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

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

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

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

11. Nothing in this Agreement shall prevent or limit your continuing or future participation in any benefit plan or program provided by the Corporation in which you may continue to participate under the terms of such plan or program notwithstanding the termination of your employment, nor shall anything herein limit or otherwise prejudice such rights as you may have under any other agreements with the Corporation, provided, however, that if the Severance Amount is payable under the terms of this Agreement, the only severance pay and benefits that you shall be entitled to receive from the Corporation are those provided under this Agreement and no other severance pay or benefits will be provided to you under any other agreement, plan or program of the Corporation. To the extent the terms of any other agreements you may have with the Corporation are inconsistent with this Agreement, the terms of this Agreement shall control.

12. If you assert any claim in any contest (whether initiated by you or by the Corporation) as to the validity, enforceability or interpretation of any provision of this Agreement and you prevail on at least one material claim, the Corporation shall reimburse your legal expenses (or cause such expenses to be paid), including, without limitation, your reasonable attorneys' fees, upon presentation of proof of such expenses in a form reasonably acceptable to the Corporation, plus simple interest thereon at the 90-day United States Treasury Bill rate as in effect from time to time, compounded annually.

13. All payments and benefits to you under this Agreement (other than payments and benefits already due to you other than pursuant to the terms of this Agreement) will not be given unless you execute (and do not rescind) a written employment termination agreement in a form prescribed by the Corporation, containing terms consistent with this Agreement as well as a general release of all claims against the Corporation and related parties with respect to all matters occurring prior to or on the date of the release, including (but not limited to) employment matters or matters in connection with your termination.

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

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

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

Very truly yours,

Nabi Biopharmaceuticals

By: /s/ Leslie Hudson, Ph.D.  
Leslie Hudson, Ph.D.  
President and Chief Executive Officer

Agreed:

/s/ Paul Kessler, M.D.  
Paul Kessler, M.D.

Dated: August 24, 2007

**Consent of Independent Registered Public Accounting Firm**

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

- (1) Registration Statement (Form S-3 No. 333-125241) and the related prospectus of Nabi Biopharmaceuticals; and
- (2) Registration Statements (Forms S-8 No. 333-115691, No. 333-115688, No. 333-109017, No. 333-38864, No. 333-38868, No. 333-95269, No. 333-56037, No. 333-56071, No. 033-65069, No. 033-60795, No. 333-134954, No. 333-143238 and No. 333-143239) pertaining to various employee-related plans of Nabi Biopharmaceuticals;

of our reports dated March 11, 2009, with respect to the consolidated financial statements and schedule of Nabi Biopharmaceuticals 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 27, 2008.

/s/ Ernst & Young LLP

McLean, Virginia

March 11, 2009





**Nabi Biopharmaceuticals****SECTION 1350 CERTIFICATION**

The undersigned officer of Nabi Biopharmaceuticals (the "Company") hereby certifies that, as of the date of this statement, the Company's report on Form 10-K for the year ended December 27, 2008 (the "Report") fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 and that, to the best of his knowledge, information contained in the Report fairly presents, in all material respects, the financial condition of the Company as of December 27, 2008 and the results of operations of the Company for the year ended December 27, 2008.

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 11, 2009

/s/ RAAFAT E.F. FAHIM, PH.D.

**Name:** Raafat E.F. Fahim, Ph.D.  
**Title:** Chief Executive Officer, President and Acting Chief Financial Officer