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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 25, 2010
- 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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  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. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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: \$237,830,848.

As of February 25, 2011, 42,569,399 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 25, 2010, 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 vaccines addressing the unmet medical need of nicotine addiction. We leverage our experience and knowledge in powering the human immune system to target this serious unmet medical need. We have been incorporated in Delaware since 1969 and our operations are located in Rockville, Maryland.

In 2006, we initiated a strategic alternatives process to enhance shareholder value which resulted in the sale, licensure or grant of an option to acquire all of our marketed products and major pipeline products.

Our sole remaining product currently in development is NicVAX® [*Nicotine Conjugate Vaccine*], an innovative and proprietary investigational vaccine for the treatment of nicotine addiction and prevention of smoking relapse based on patented technology. In the first quarter of 2010 we granted to GlaxoSmithKline Biologicals S.A. (GSK) (i) an option to exclusively license NicVAX on a worldwide basis and (ii) a license to develop follow-on next-generation nicotine vaccines using our intellectual property combined with GSK proprietary technology including GSK proprietary adjuvants.

The smoking cessation market is estimated to exceed \$4 billion annually and is currently considered to be a largely unmet medical need. Nicotine is a non-immunogenic small molecule that, upon inhalation into the lungs, 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, a chemical which triggers the highly addictive pleasurable effects experienced by smokers and users of other nicotine products. NicVAX is designed to stimulate the immune system to produce highly specific antibodies that bind to nicotine in the bloodstream. A nicotine molecule attached to specific antibodies is too large to cross the blood-brain barrier and thus is unable to reach the receptors in the brain thereby reducing the pleasure experienced by the smoker making it easier to quit.

In November 2007, we announced the successful completion of a Phase IIb “proof-of-concept” clinical trial for NicVAX that demonstrated 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 dose schedule optimization immunogenicity study assessing the antibody response and the 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 reached an agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for the pivotal Phase III clinical trials for NicVAX. The SPA forms the foundation to support approval of a Biologics License Application (BLA). In June 2009, we announced that we received Scientific Advice from the European Medicines Agency (EMA) which is well aligned with our SPA agreement with the FDA regarding the design of the trial. In September 2009, we announced that we received a \$10 million grant from the National Institute on Drug Abuse (NIDA) to partially offset the cost of the first of two Phase III studies that we are required to conduct by the FDA in support of NicVAX’s licensure. In October 2009, we also announced the initiation of an investigator initiated clinical trial in the Netherlands to test the efficacy of a combined therapy of NicVAX with varenicline, or Chantix/Champix. In November 2009, we announced the initiation of the first of two Phase III efficacy trials in the U.S., which is also the first such trial for an addiction vaccine, confirming NicVAX’s first in class nicotine vaccine in smoking cessation. We completed enrollment in this trial in July 2010. In March 2010, we initiated the second Phase III trial and announced the completion of enrollment in this Phase III trial in November 2010.

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In March 2010, we closed an exclusive worldwide option and licensing agreement with GSK for NicVAX as well as for the development of follow-on nicotine addiction vaccines. Upon closing, we received a \$40 million initial payment. Under the terms of the agreement, we granted to GSK (i) an option to obtain an exclusive worldwide license to develop, commercialize and manufacture NicVAX as it currently exists, as well as certain potential alternative forms of NicVAX together with an adjuvant other than a GSK proprietary adjuvant and/or with different presentation, dosage or administration (NicVAX Alternatives), and (ii) an exclusive worldwide license to develop, commercialize and manufacture certain future generation candidate vaccines for the prevention or treatment of nicotine addiction based on our NicVAX intellectual property (other than NicVAX and NicVAX Alternatives). In addition to the \$40 million upon closing, we may receive under the agreement more than \$460 million in potential option fees and regulatory, development, manufacturing and sales milestones for NicVAX and follow-on nicotine vaccines. We are also eligible to receive royalties on global sales of NicVAX should GSK exercise its option and commercialize the product, as well as royalties on global sales of next generation nicotine vaccines.

In August 2010, we received U.S. Patent No. 7,776,620 (Hapten-carrier conjugates for treating and preventing nicotine addiction) for the exclusive use of methods for treating and preventing nicotine addiction with NicVAX and related nicotine vaccines.

In addition to our NicVAX development effort, we are developing PentaStaph™ [*Pentavalent S.aureus Vaccine*] under contract for GSK. PentaStaph is a new pentavalent vaccine designed to prevent *S.aureus* infections including those infections caused by the most dangerous antibiotic-resistant strains of *S.aureus*. In August 2009, we entered into an Asset Purchase Agreement (APA) with GSK for the sale of PentaStaph for a total consideration of \$46 million including a \$20 million upfront payment upon closing and \$26 million payable upon achievement of certain milestones. The PentaStaph sale closed in November 2009, and we received payment from GSK of \$21.5 million representing the upfront payment of \$20 million, an additional \$1 million for the sale of our *Staphylococcus epidermidis* vaccine program and an additional \$0.5 million for transfer of certain specified materials. Under the APA, we agreed to a Transition Services Agreement (TSA) to help GSK advance the program while in parallel transferring the technology to GSK. Accordingly, we are continuing to develop PentaStaph under contract for GSK through a Phase I/II clinical trial of two of the antigens, in collaboration with the U.S. military. GSK is reimbursing us for the cost of our services under the TSA. We also have received \$21 million of the possible \$26 million in payments for milestones related to the TSA, \$16 million of which was paid in 2010. We expect to be able to complete our performance obligations under the TSA in 2011 and receive the final \$5 million milestone payment due under the APA.

In 2006, we sold certain assets related to our PhosLo operations. Under the sale agreement, we received \$65 million in cash at closing and are entitled to additional contingent 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. We have received \$13 million of milestones through March 8, 2011, and can also receive up to \$72.5 million in additional milestone payments and royalties.

## **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 an estimated 10 million deaths each year by 2030. According to the U.S. Centers for Disease Control and Prevention (CDC), tobacco use is the single leading preventable cause of death in the U.S., responsible for approximately 443,000 deaths each year. In addition, it is estimated that smoking results in an annual health-related economic cost in the U.S. of approximately \$193 billion. The CDC estimates that, among the 43.4 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.

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Nicotine addiction is difficult to treat. Most current therapies involve the use of nicotine replacement products 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. Chantix<sup>®</sup>, which is a prescription therapy introduced by Pfizer Inc. in 2006, acts by binding the nicotinic receptors in the brain and competing with inhaled nicotine for binding to these receptors, while simultaneously partially activating these receptors, thereby breaking the addiction cycle. Data from the efficacy trials have shown that the short-term cessation rates were superior to other therapies for smokers receiving Chantix, although most individuals relapsed to smoking over the longer term. In addition, significant neuropsychiatric adverse events have been reported including suicides and suicide ideation that led the FDA to require a warning (boxed warning) label on the drug in July 2009.

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 the conjugate vaccine technology we developed and allows us to address a significant unmet 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 or absorption 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, which provide the smoker with a positive sensation, leading to addiction. Because of its small size, nicotine on its own normally does not elicit the production of antibodies in humans. NicVAX is based on our proprietary conjugate technology whereby nicotine is attached to a carrier protein 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 from cigarette smoking or the use of other nicotine products and prevent it from crossing the blood-brain barrier and entering the brain. As a result, the brain does not release the positive-sensation stimulant dopamine. We believe NicVAX has safety advantages over existing treatment therapies, in part, because it does not act on the central nervous system. Additionally, NicVAX's benefit has been shown to continue for up 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 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 of 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 administrations of NicVAX (two different doses according to two different schedules) or a placebo. This study was funded in part by NIDA.

The Phase IIb study was a double blind, placebo-controlled and dose-ranging study 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 the current clinical trial standards and protocol design for smoking cessation clinical research studies. The trial's primary endpoint was the rate of carbon 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 subjects in the high anti-nicotine antibody responder-group met the trial's primary endpoint of eight weeks of continuous abstinence during weeks 19-26.

In November 2007, we announced final results from this trial. The trial demonstrated that higher levels of anti-nicotine antibodies correlated to higher smoking cessation rates and long-term continuous abstinence rates, demonstrating proof-of-concept that antibodies to nicotine generated through NicVAX immunization were useful as an aid to smoking cessation. The high-antibody responder group of vaccinated subjects showed continuous

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abstinence rates that were almost three times higher than the placebo group at 12 months. Moreover, 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 ( $p < 0.022$ ).

Importantly, for the first time, a statistically significant treatment effect was observed for a single intent-to-treat dose group (not stratified by antibody-response) of nicotine vaccine compared to placebo. The observed treatment effect was continuous long-term smoking abstinence to one year compared with placebo for the group receiving 5 injections of 400 mcg of NicVAX. This data demonstrated that nearly three times the number of subjects treated with the most effective dose and schedule tested, were able to quit smoking and remained abstinent to 12 months as compared with placebo ( $p < 0.038$ ).

NicVAX was well tolerated with a low prevalence of side effects and an adverse event profile comparable to that seen with placebo and other similar vaccines. Additionally, no statistically significant evidence of compensatory smoking or increase in withdrawal symptoms has been observed in NicVAX treated subjects as compared to placebo at any stage of the trial.

Based on the results of the Phase IIb study, we believe that NicVAX could help more smokers to stop smoking if they attempt to quit when higher levels of anti-nicotine antibodies are reached. Based on the profile of anti-nicotine antibodies achieved in the Phase IIb proof-of-concept trial, we reasoned that higher levels of antibodies could be achieved if an additional dose of NicVAX would be administered. Therefore, we initiated an immunogenicity study in January 2008, to further understand the potential of this improved dosing regimen. The results of this study confirmed our hypothesis that significantly higher antibodies could be achieved earlier, and in a higher percentage of volunteers, by including an additional dose of NicVAX. Those results were used to finalize the dosing schedule for the NicVAX Phase III program. The FDA agreed with our Phase III trial design and end points through an SPA, providing a clear, well-defined path for the approval of NicVAX. The SPA is an agreement with the FDA which is intended to reduce the regulatory risk of the program. In addition, we also sought and obtained Scientific Advice from the EMA which generally is well aligned with the SPA agreement with the FDA regarding the trial design.

In November 2009 and March 2010, respectively, we announced the initiation of the first and second Phase III clinical trials of NicVAX that we are required to conduct in support of the NicVAX license, based on our SPA agreement with the FDA. Each of the two Phase III clinical trials recruited 1,000 subjects randomized equally between NicVAX and placebo. Both Phase III clinical trials have completed enrollment. Results of the first trial are expected to be available in the second half of 2011 and results from the second Phase III trial are expected to be available in the first half of 2012.

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 providing input to the design and implementation of the Phase III clinical trials and the overall clinical development program.

## STRATEGIC TRANSACTIONS

In November 2009, we sold PentaStaph to GSK for a total consideration of up to \$46 million including a \$20 million upfront payment. In addition, GSK paid us \$1.5 million, \$1 million of which was for the purchase of the results of an early research program for a vaccine against *S.epidermidis* and \$0.5 million was for certain clinical materials. The remaining \$26 million was payable upon our achieving certain milestones. We have achieved three of the four milestones under this agreement and received payments totaling \$21 million. We expect to achieve the final remaining milestone and receive the \$5 million payment within the next few months.

As part of this transaction, we entered into a TSA with GSK that requires us to successfully transfer the PentaStaph technology and certain materials to GSK, as well as to manage, on their behalf, the relationship with the U.S. military and the conduct of a Phase I/II trial for two of the PentaStaph antigens. GSK is obligated to reimburse to us the full cost of such activities.

In November 2009, we signed an exclusive worldwide option and licensing agreement with GSK for NicVAX as well as for the development of a second-generation nicotine vaccine; this transaction closed in March 2010. Under the terms of the agreement:

- We have granted to GSK (i) an option to obtain an exclusive worldwide license to develop, commercialize and manufacture NicVAX and NicVAX Alternatives, and (ii) an exclusive worldwide license to develop, commercialize and manufacture certain future generation candidate vaccines for the prevention or treatment of nicotine addiction based on our NicVAX intellectual property (other than NicVAX and NicVAX Alternatives);
- In consideration for the option and license rights, GSK made a non-refundable \$40 million up-front payment and GSK agreed to make certain additional option, milestone and royalty payments if certain conditions are met, in each case;
- If GSK exercises the NicVAX option, it will pay us \$58 million following exercise;
- GSK will pay us a \$20 million milestone payment upon the successful completion of a Phase III clinical trial with respect to NicVAX regardless of whether GSK exercises the NicVAX option;
- If GSK does not exercise the NicVAX option, we retain the right to commercialize and partner NicVAX and NicVAX Alternatives (but not certain future generation candidate vaccines for the prevention or treatment of nicotine addiction based on our NicVAX intellectual property (other than NicVAX and NicVAX Alternatives));
- If GSK exercises the NicVAX option, it will pay us certain development milestone payments, including: (i) a payment of up to \$70 million based on the therapeutic effect of NicVAX as approved in its U.S. or EU labeling, with the specific payment depending on whether the NicVAX therapeutic effect meets or exceeds specified targets (although no payment is due if the NicVAX therapeutic effect is less than the therapeutic effect, as defined in the NicVAX Agreement, of the leading smoking cessation prescription product currently on the market); and (ii) payments of up to an aggregate of \$61 million based on obtaining regulatory approval for NicVAX in certain major market countries;
- For future generation candidates, if GSK exercises the NicVAX option, GSK will pay us (i) up to an aggregate of \$21 million based on Phase II and Phase III clinical trial-related milestones, and (ii) up to an aggregate of \$21 million based on obtaining regulatory approval in certain major market countries;
- Alternatively, for future generation candidates, if GSK does not exercise the NicVAX option, GSK will pay us (i) up to an aggregate of \$47 million based on Phase II and Phase III clinical trial-related milestones, and (ii) up to an aggregate of \$34 million based on obtaining regulatory approval in certain major market countries;
- GSK will pay us certain tiered, sales-milestone payments up to an aggregate of \$209 million based on aggregate annual sales of (i) NicVAX, licensed NicVAX Alternatives and future generation candidates,

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if GSK exercises the NicVAX option, or (ii) future generation candidates, if GSK does not exercise the NicVAX option;

- If GSK exercises the NicVAX option, it will make royalty payments to us on aggregate annual net sales of NicVAX, beginning at 10% and potentially increasing on incremental sales to as high as 15%, with the increase depending on whether aggregate annual net sales of NicVAX meet or exceed specified annual sales targets in any calendar year ranging from \$300 million to \$600 million;
- Whether or not GSK exercises the NicVAX option, it will pay us royalty payments on aggregate annual net sales of future generation candidates, beginning at 7% and potentially increasing on incremental sales to as high as 9%, with the increase depending on whether aggregate annual net sales of future generation candidates meet or exceed specified annual sales targets in any calendar year ranging from \$300 million to \$600 million;
- The royalties payable by GSK as described above (i) on future generation candidates are subject to certain reductions of up to 25% depending on improvements in the therapeutic effect and/or reduction in the dosing of future generation candidates relative to NicVAX, and (ii) on NicVAX and future generation candidates are subject to certain reductions if intellectual property license payments are owed to third parties. In either case, however, the minimum royalty rate on NicVAX will be 7.5% and the minimum royalty rate on future candidates will be 5%;
- The economic terms of GSK's license of NicVAX Alternatives (should GSK exercise the NicVAX option) are subject to mutual agreement between GSK and us. If the parties cannot mutually agree, then such economic terms will be determined through binding arbitration based on an agreed upon set of factors and principles relating to, among other things, the commercial potential of the NicVAX Alternatives subject to the option exercise and the relative contributions of us and GSK to the development of such NicVAX Alternatives.

In 2007, we sold certain assets constituting our Biologics Strategic Business Unit (SBU) and certain corporate shared services assets to Biotest Pharmaceuticals Corporation (Biotest) for \$185 million in cash, \$10 million of which was placed into an escrow account to support any valid indemnification claims made by Biotest on or before March 31, 2009. The \$10 million restricted cash including interest was fully released to Nabi in 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 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 are charged to discontinued operations as necessary.

During the fourth quarter of 2006, we sold certain assets related to our PhosLo operations. Under the sale agreement, we received \$65 million in cash at closing and are entitled to additional contingent milestone payments and royalties. The royalties relate to sales of a new product formulation over a base amount through 2016. We have received \$13 million of milestones through March 8, 2011, and can also receive up to \$72.5 million in additional milestone payments and royalties.



## CONTRACT MANUFACTURING AND PRODUCT DEVELOPMENT RELATIONSHIPS

### *Contract Manufacturing*

In September 2010, we entered into a manufacturing agreement with Diosynth Biotechnology for the manufacture of NicVAX drug substance which is a step in the production of the vaccine. The drug substance will ultimately be combined with an adjuvant and filled in syringes at another contract manufacturing organization to produce NicVAX. We continue to negotiate long-term agreements with other contract manufacturing organizations for ancillary services related to the commercialization of NicVAX.

### *Product Development*

We have entered into relationships for certain products in development that should facilitate their development.

*National Institute for Drug Abuse* We have received grants from NIDA that in the past have supported clinical development of NicVAX. In addition, in September 2009, we were awarded a \$10 million grant from NIDA in support of the first of two Phase III efficacy trials of NicVAX.

*National Institutes of Health* Under a license agreement with NIH, we have a non-exclusive, worldwide right to use certain rEPA carrier protein technology to develop, manufacture and commercialize vaccines against nicotine addiction. Under the terms of this rEPA agreement, NicVAX is subject to a 0.5% royalty.

*Brookhaven National Labs* Under a license agreement with Brookhaven National Labs (Brookhaven), we have a non-exclusive right, with the right to sublicense, to patented T7 polymerase technology for research, development, and commercialization of vaccines for preventing and treating nicotine addiction, and for prevention and treatment of *Enterococcal* infections. Under the terms of this T7 agreement, NicVAX is subject to a 0.1% royalty upon commercialization, and EnteroVAX is subject to a 0.2% royalty upon its commercialization. The T7 license remains in effect until the expiration of the last-to-expire licensed patent, which is December 2, 2014, and no further payments or royalties will be due to Brookhaven for use of the subject technology after that date.

*University of Maryland, Baltimore County* Under a license agreement with the University of Maryland, Baltimore County (UMBC) we had an exclusive, worldwide right to use UMBC's patented ring-expanded nucleosides and nucleotides (RENS) for use in humans. Under the agreement with UMBC, we were responsible for prosecution and maintenance of the patent portfolio and since a suitable partner to advance development of this program was not identified, we terminated the agreement with UMBC in April 2010.

The contract manufacturing and 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 validate and allow us to manufacture 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.

## 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 25,</u> <u>2010</u>	<u>December 26,</u> <u>2009</u>	<u>December 27,</u> <u>2008</u>
NicVAX	\$ 25,447	\$ 14,583	\$ 5,186
PentaStaph	505	1,843	4,211
Other programs	126	64	80
	<u>26,078</u>	<u>16,490</u>	<u>9,477</u>
Unallocated overhead	—	—	3,079
Total R&D programs	<u>\$ 26,078</u>	<u>\$ 16,490</u>	<u>\$ 12,556</u>

Research and development expenses related to the NicVAX program are reflected net of grant reimbursements of \$8.5 million and \$1.5 million in 2010 and 2009, respectively (none in 2008). Research and development expenses related to the PentaStaph program are reflected net of grant reimbursements of \$0.4 million and \$0.1 million in 2010 and 2009, respectively (none 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 development. As of December 2010, we retain the rights to 96 patents and 51 patent applications pending worldwide.

### *Smoking Cessation*

Our patent portfolio comprehends both compositions and therapeutic methodology for treating or preventing addiction. Our patent claims related to the NicVAX product 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 related to our conjugates, antibodies against the conjugates, and methods for using the conjugates and antibodies against nicotine addiction. These patents expire in December 2018. Another granted U.S. patent related to a method of making nicotine haptens expires in 2027. We also have a pending U.S. patent application relating to our conjugates and their use. We hold granted patents in the U.S., Europe, Japan and various other countries and regions, relating to our conjugates and antibodies against our conjugates, for use in treating nicotine addiction. In addition, we also have pending foreign patent applications relating to our conjugate technology and to our method of making nicotine haptens in various countries and regions. We also have pending U.S., Patent Cooperation Treaty and foreign (Thailand, Argentina, Gulf Cooperation Council, Taiwan and Kosovo) applications relating to antibody-based diagnostic kits and methods for smoking cessation. Another granted U.S. patent filed in cooperation with NIH is directed towards a method to decrease the toxic effects of nicotine on fetuses.

In July 2005, Cytos Biotechnology Ltd. 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 (EPO) 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 EPO upheld the patent, preserving our primary claim that protects our exclusive use of NicVAX for treating and preventing nicotine addiction but cancelled some ancillary claims in the patent and we continue our appeal of these ancillary claim cancellations.

In September 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 Pharma (formerly Xenova), which covered hapten-carrier conjugates for use in drug abuse therapy including nicotine addiction. In a formal decision issued March 2010,

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the Opposition Division of the EPO revoked one of the patents in its entirety and Celtic Pharma subsequently filed an appeal that is under review by the EPO. The second patent was scheduled for oral proceedings in December 2010 but Celtic Pharma withdrew its request for oral proceedings in October 2010.

### *Gram-positive Program*

As of December 2010, we have 45 patents issued and 8 patent applications pending worldwide relating to our Gram-positive infections program.

With respect to *Enterococcus*, the 23 patents and 8 pending patent applications relate both to polysaccharide antigens *E.faecalis* and *E.faecium*, respectively.

Also in this portfolio are issued U.S., European, Canadian and Mexican patents 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. In November 2009, we granted GSK an exclusive (even as to Nabi), royalty-free, fully paid-up, worldwide, perpetual, irrevocable right and license, with the right to grant sublicenses to this family of patents and patent applications directed to glycoconjugate vaccines or a component thereof, for diagnosis, prevention or treatment of *Staphylococcus* infections in humans, in each case of the foregoing which utilizes or in part is comprised of peptidoglycan and a capsular polysaccharide expressed by *Staphylococcus*.

Our granted U.S. patent relating to a method of protecting a human being with a compromised immune system from *Staphylococcal* infection using Type 5 and Type 8 antigens is now owned by GSK under the APA with respect to PentaStaph. 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 other countries. GSK granted us an exclusive (even as to GSK), royalty-free, fully paid-up, worldwide, perpetual, irrevocable right and license, with the right to grant sublicenses for pending claims related to a method of protecting a human being with a compromised immune system from *Enterococcus* infection using the claimed CPS antigens of *E.faecalis* and *E.faecium*.

### *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 development products, including several international trademark registrations or common law rights.

## **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. 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.

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### *Biopharmaceutical Products*

In the United States, 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 (IND) application, to 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 potency, safety 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 Practices (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 sometimes 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 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 and/or efficacy. 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 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 (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 areas 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 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 accepted for filing, the FDA reviews the application to determine, among other things, whether a product is safe and efficacious for its intended use. The

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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 composed of a panel of physicians and other experts, for review, evaluation, and an approval recommendation. The FDA also may require post-marketing surveillance to monitor potential adverse effects of the product and/or efficacy. If required to conduct a post-approval study, periodic status reports must be submitted 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 (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.

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 an agreement with the FDA on an SPA for both pivotal Phase III trials 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 a 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.

### *European Regulatory Scientific Advice (SA)*

The Company announced in June 2009 that it has obtained SA from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for NicVAX. Although not binding on the EMA, the SA is intended to optimize Research and Development, reduce uncertainty in regulatory outcomes and accelerate time to approval of a MAA. In efforts to further mitigate regulatory risk, Nabi elected to seek clarifying follow-on Scientific Advice from EMA and in December of 2010, Nabi received follow-on Scientific Advice from EMA confirming the adequacy of the existing Phase III trial designs and CMC plans for NicVAX. EMA recommended increasing the duration of the primary endpoint for the Phase III studies and has agreed to

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the acceptability of a separate EU specific statistical analysis of a longer duration of assessment of abstinence. Nabi confirmed with EMA that no additional clinical studies are required prior to submission of an MAA for NicVAX.

### *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, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of 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 prescription 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 (NRTs) represent a first generation approach to assisting smokers to quit by substituting a less harmful form of nicotine than inhalation by smoking. NRTs are mildly effective and support smoking cessation in combination with behavioral modification counseling. NRTs come in a number of forms of administration: gums, patches, lozenges and inhalers. Many forms of NRTs are currently available over the counter. GSK's Zyban (bupropion) is the only anti-depressant which is FDA approved specifically as an aid to smoking cessation acting 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. More recently, it has been reported that Chantix causes some untoward neuropsychiatric side effects including suicides, suicide ideations and other psychotic behaviors. This has led the FDA to require Pfizer to add a "boxed warning" on Chantix's label.

Examples of other product candidates in development that pose competitive risk are additional selective glycine receptor antagonists (GlaxoSmithKline; Phase II) and additional nicotine-derived therapeutic vaccines. Nic-002 (Phase II), TA-Nic (Phase II) and Niccine (Phase II) are nicotine-derived therapeutic vaccines being developed by Cytos Biotechnology/Novartis Pharmaceuticals, Celtic Pharmaceuticals and Independent Pharmaceutica, respectively, which if successfully developed and registered, may directly compete with NicVAX. Recently, Cytos announced that an interim analysis showed that Nic-002 did not achieve its primary end point of smoking cessation in a Phase II study. Results from a Phase II proof of concept of TA-Nic were expected in 2008 but so far no announcements have been made regarding the vaccine's performance in the study. Finally, Independent Pharmaceutica's Niccine is also engaged in a relapse prevention Phase II proof-of-concept study which completed enrollment in November of 2008 and results of which were anticipated at the end of 2009 or early 2010, but so far no announcements have been made regarding the vaccine's performance in the study.

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 35 employees at December 25, 2010.

## 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 conduct and obtain successful results from our two Phase III clinical trials for NicVAX; GSK's failure to exercise its option for and successfully commercialize NicVAX; GSK's failure to successfully develop and commercialize any future generation candidate nicotine vaccine; our ability to commercialize NicVAX if GSK does not exercise its option for NicVAX; our ability to identify an alternative partner or to raise sufficient new capital resources to fully develop and commercialize NicVAX if GSK does not exercise the NicVAX option; our ability to successfully contract with and obtain manufactured NicVAX product from contract manufacturing organizations; our ability to attract, retain and motivate key employees; our ability to collect any further milestones and royalty payments under the PhosLo and PentaStaph agreements; the ability to obtain regulatory approval for NicVAX and any future generation candidate nicotine vaccine in the U.S. or other markets; our ability to comply with reporting and payment obligations under government rebate and pricing programs; and loss of full use of our net operating loss carry forwards. These factors and others are more fully discussed below.

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

***Our remaining product candidate is in clinical trials and unfavorable results from these trials would have a material adverse effect on us.***

NicVAX is undergoing Phase III clinical testing involving the conduct of two clinical trials. These trials may not meet their defined endpoints. 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. For example, if one or both of the two Phase III trials for NicVAX are unsuccessful, the FDA may not approve NicVAX for licensure or GSK may not exercise the NicVAX option, either or both of which would adversely affect our future business, market valuation, financial condition and results of operations.

***GSK may not exercise the NicVAX option which would have a material adverse effect on our business and prospects.***

In 2010, we entered into an exclusive license and option agreement with GSK for NicVAX. Under the agreement, we are responsible for developing the current generation of the vaccine at our cost until the end of the Phase III efficacy and consistency lot trials. At that stage, even if the trials are successful, GSK may not exercise the NicVAX option to acquire the worldwide rights to the vaccine. In this circumstance, we would need to commercialize NicVAX ourselves (which we currently do not have the resources to do) or find another commercialization partner, the likelihood of which will depend on numerous factors, including whether GSK is commercializing a future generation candidate nicotine vaccine. The failure of GSK to exercise the NicVAX option or to successfully commercialize NicVAX after exercising the option, or our inability in such a circumstance to commercialize NicVAX ourselves or find a commercialization partner, would have material adverse effect on our market valuation, our future business, financial condition and results of operations.



***GSK may not be successful in developing and commercializing the future generation candidate vaccine.***

Under the option and license agreement for NicVAX, we granted GSK an exclusive worldwide license to develop, commercialize and manufacture certain future generation candidate vaccines for the prevention or treatment of nicotine addiction based on our NicVAX intellectual property (other than NicVAX and NicVAX Alternatives) and using their own proprietary technologies. We may be eligible for milestones and royalties from such development, if successful. If such development and commercialization by GSK is not successful, we will not receive future milestones and royalties related to future generation candidate products which could have a material adverse effect on our future business, market valuation, financial condition and results of operations.

***We do not have sufficient resources to fully develop, commercialize and market NicVAX and will require a successful partnership with GSK, another partner or additional financing to do so.***

We have incurred and will continue to incur significant costs in connection with the development of NicVAX, including the cost of clinical trials and manufacturing products for clinical trials as well as cost of the regulatory process. NicVAX may not generate sales for several years, if at all. 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, there can be no assurance that we will be successful in realizing sufficient proceeds from our exclusive NicVAX license and option agreement with GSK or alternative financing sources to meet our future operating needs. Our inability to do so would have a material adverse effect on our market valuation, our future business, financial condition and results of operations.

***We depend upon third parties to manufacture NicVAX.***

We depend upon third parties to manufacture NicVAX. We entered into various development agreements with contract manufacturing organizations (CMOs) to both manufacture NicVax and transfer the manufacturing technologies and know-how of NicVAX. Under these agreements our CMOs are required to manufacture NicVAX and also demonstrate the ability to consistently manufacture NicVAX. If the CMOs fail to demonstrate their ability to consistently manufacture NicVAX or the manufactured product does not meet the stringent quality required by the various regulatory agencies for biologics, it may adversely impact GSK's decision to exercise the option, delay filing of the license submission of NicVAX and adversely affect our business plans, our market valuation, financial condition and results of operations. Although we have successfully negotiated long-term commercial agreements with two of these organizations, there can be no assurance that the various CMOs will be able to successfully manufacture sufficient quantities of quality products on a timely basis to permit continued development of our products and to commercialize our products in development. The failure of our contract manufacturers to supply us with sufficient amounts of quality 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.

***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. 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 million in cash at closing and received an additional \$13 million of milestones as of March 10, 2010. 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 any additional milestones are not completed or if there are no sales of the new product formulation, we will not collect the related future milestone or royalty payments under the PhosLo Agreement.

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

The patent positions of biopharmaceutical firms generally are highly uncertain and involve complex legal and factual questions. The ultimate degree of patent protection that will be afforded to biotechnology products and processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. There can be no assurance that existing patent applications will result in issued patents, that we will be able to obtain additional licenses to patents of others or that we will be able to develop additional patentable technology of our own. We cannot be certain that we were the first creator of inventions covered by our patents or pending patent applications or that we were the first to file patent applications for such inventions. There can be no assurance that any patents issued to us will provide us with competitive advantages or will not be challenged by others. Furthermore, there can be no assurance that others will not independently develop similar products, or, if patents are issued to us, 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 could 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.

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***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 staff and budgets than we have, as well as substantially greater experience in developing products, obtaining regulatory approvals, manufacturing and marketing biopharmaceutical products. We compete with our competitors to (i) develop and market products; (ii) acquire products and technologies; and (iii) 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 NicVAX or any future generation candidate nicotine vaccines upon their introduction.***

There can be no assurance that NicVAX or any future generation candidate nicotine vaccine will achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the clinical efficacy and safety of the 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 NicVAX or any future generation candidate nicotine vaccine to gain market acceptance could have a material adverse effect on our future business, financial condition and results of operations.

***The failure to comply with extensive regulations enforced by the FDA and foreign regulatory agencies could prevent or delay the sale of NicVAX or any future generation candidate nicotine vaccine.***

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 or condition;
- 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.

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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 are 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 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 a third party manufacturer. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business.

There can be no assurance that we or GSK will be able to obtain the necessary approvals to manufacture or market NicVAX or any future generation candidate nicotine vaccine. 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 NicVAX.***

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 NicVAX 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

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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.

***If we fail to obtain adequate levels of reimbursement from government health authorities, private healthcare insurers and other organizations our ability to generate sufficient revenues from future product sales will be adversely affected.***

Our ability or the ability of our partners 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 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 NicVAX or any future generation candidate nicotine vaccine, 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 NicVAX or any future generation candidate nicotine vaccine could have a material adverse effect on our future business, financial condition and results of operations.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), which includes a number of health care reform provisions, including an increase in the minimum Medicaid drug rebates for pharmaceutical companies, an expansion of the 340B drug discount program, and changes to affect the Medicare Part D coverage gap. The law also revises the definition of “average manufacturer price” for reporting purposes (effective October 1, 2011), which could increase the amount of Medicaid drug rebates from pharmaceutical companies to states. The new law also imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional change could be made to governmental healthcare programs that could significantly impact the success of our current and future products, and we could be adversely affected by current and future health care reforms.

***Our ability to use our federal and state net operating loss carry forwards to reduce taxable income generated in the future could be substantially limited.***

Our ability to use our net operating losses may be subject to an annual limitation due to ownership changes that may have occurred or that could occur in the future, as determined by Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state regulations. Depending on the actual amount of any limitation on our ability to use our net operating loss carry forwards, a significant portion of our future taxable income

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could be subject to federal and/or state income tax, creating federal and/or state income tax liabilities. Additionally, such limitation may result in our net operating losses expiring before we have the ability to use them. Moreover, the Internal Revenue Service may not agree with the amount or timing of prior losses, thereby further limiting our net operating loss carry forward.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 2. PROPERTIES

We lease office, laboratory, and warehouse space in Rockville, Maryland. The laboratory space is leased on a month-to-month basis. Our office and warehouse facilities leases expire December 31, 2011. We lease a facility in Bray, Ireland with a term through 2030. We have the right to terminate the lease under certain circumstances in the first quarter of 2014. 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 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.

### ITEM 3(a). EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers are listed below:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b>Raafat E.F. Fahim, Ph.D.</b>	57	Chief Executive Officer, President, Acting Chief Financial Officer and Director
<b>Paul Kessler, M.D.</b>	56	Senior Vice President, Clinical, Medical and Regulatory Affairs and Chief Medical Officer
<b>Matthew W. Kalnik, Ph.D.</b>	48	Senior Vice President, Strategic Planning and Business Operations

*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 product development, 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. He received his Ph.D. in Biochemistry from the University of Toronto.

*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,

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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.

*Dr. Kalnik* was appointed to the role of Senior Vice President, Strategic Planning and Business Operations in March 2009. He joined the Company as Vice President, Business Development and Project Management in July 2007. Prior to joining Nabi Biopharmaceuticals, Dr. Kalnik held senior management team positions at innovative biotechnology companies including Executive Vice President, Head of Business Development, at VistaGen Therapeutics and Senior Vice President, Business Development and Licensing, and corporate officer at Genaissance Pharmaceuticals. He has also served in an executive capacity in R&D and commercial development at global pharmaceutical companies Pfizer (Pharmacia) and Daiichi Medical Research including Executive Director, Commercial Development; Sr. Director, Development Technology, Medical Research; and Director, Technology Acquisitions, Discovery Research & Exploratory Development. Dr. Kalnik also founded Hedgerow Consulting and has authored more than a dozen primary research papers. He holds a Bachelor of Science in Chemistry from the University of North Carolina at Chapel Hill (1984) and an M.A, M.Sc. & Ph.D. in Molecular Biophysics from Columbia University (1989) and conducted his post-doctoral fellowship in Molecular Biology at The Scripps Research Institute in La Jolla, California.

#### **ITEM 4. RESERVED**



## 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>2010:</b>		
First Quarter ended March 27, 2010	\$6.42	\$4.70
Second Quarter ended June 26, 2010	5.98	4.40
Third Quarter ended September 25, 2010	5.85	4.68
Fourth Quarter ended December 25, 2010	5.75	4.75
<b>2009:</b>		
First Quarter ended March 28, 2009	\$4.75	\$3.10
Second Quarter ended June 27, 2009	4.20	2.29
Third Quarter ended September 26, 2009	3.76	2.15
Fourth Quarter ended December 26, 2009	5.30	3.16

The closing price of our common stock on February 25, 2011 was \$5.66 per share. The number of record holders of our common stock on February 25, 2011 was 817.

No cash dividends have been paid on our common stock and none are anticipated in 2011.

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

We had no unregistered sales of equity securities in 2010. Additionally, we repurchased the following shares of our common stock in the fourth quarter 2010 pursuant to our stock repurchase program:

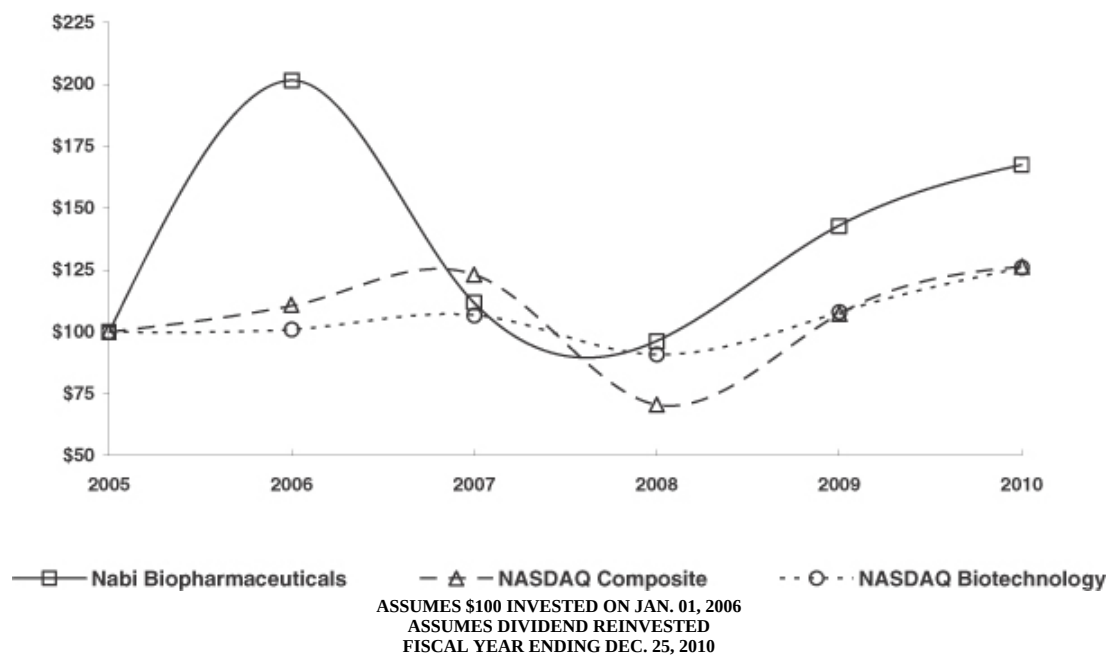
<u>Period</u>	<u>Total Number of Shares Purchased</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(1)</sup></u>	<u>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup></u>
09/26/2010-10/30/2010	800	\$ 4.77	800	\$27.8 million
10/31/2010-11/27/2010	—	—	—	\$27.8 million
11/28/2010-12/25/2010	—	—	—	\$27.8 million
Total	800	\$ 4.77	800	\$27.8 million

<sup>(1)</sup> Starting in December 2007, our Board of Directors approved the repurchase of up to \$115 million of our common stock in the open market or in privately negotiated transactions. There is no expiration date for this repurchase program. Since the inception of the program through February 25, 2011, we have repurchased a total of 19.9 million shares at a total cost of \$87.2 million, at an average price of \$4.39 per share, leaving a balance of \$27.8 million available for share repurchases under the current program.

COMPARATIVE STOCK PERFORMANCE

The following graph and chart compare, during the five-year period commencing December 31, 2005 and ending December 25, 2010, 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 31, 2005 (at the market close), and the reinvestment of any dividends.

COMPARISON OF CUMULATIVE TOTAL RETURN



Company/Market/Peer Group	2005	2006	2007	2008	2009	2010
<b>Nabi Biopharmaceuticals</b>	\$ 100.00	\$ 200.59	\$ 111.54	\$ 96.45	\$ 142.60	\$ 167.01
<b>NASDAQ Composite</b>	\$ 100.00	\$ 110.39	\$ 123.05	\$ 71.01	\$ 107.12	\$ 126.11
<b>NASDAQ Biotechnology</b>	\$ 100.00	\$ 101.07	\$ 106.81	\$ 90.97	\$ 107.88	\$ 125.80

**ITEM 6. SELECTED FINANCIAL DATA**

The following table sets forth selected consolidated financial data for the five years ended December 25, 2010 that was derived from our audited Consolidated Financial Statements. 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 25, 2010	December 26, 2009	December 27, 2008	December 29, 2007	December 30, 2006
<b>Statement of Operations Data:</b>					
Revenue:					
Revenue	\$ 35,005	\$ 10,489	\$ —	\$ —	\$ —
Operating expenses:					
Cost of services	3,951	1,988	—	—	—
General and administrative expense	6,174	9,987	12,415	26,090	32,576
Research and development expense	26,078	16,490	12,556	18,841	28,745
Operating loss	(1,198)	(17,976)	(24,971)	(44,931)	(61,321)
Interest income	230	368	4,579	6,026	4,148
Interest expense	(210)	(1,071)	(3,902)	(9,007)	(8,733)
Other income (expense), net	291	(48)	(1,454)	446	(66)
Loss from continuing operations before income taxes	(887)	(18,727)	(25,748)	(47,466)	(65,972)
Benefit for income taxes	1,765	—	2,765	14,265	753
Net income (loss) from continuing operations	878	(18,727)	(22,983)	(33,201)	(65,219)
Net income from discontinued operations	—	—	4,245	71,587	1,250
Net income (loss)	\$ 878	\$ (18,727)	\$ (18,738)	\$ 38,386	\$ (63,969)
Basic income (loss) per share:					
Continuing operations	\$ 0.02	\$ (0.37)	\$ (0.44)	\$ (0.55)	\$ (1.07)
Discontinued operations	\$ —	\$ —	\$ 0.08	\$ 1.19	\$ 0.02
Basic income (loss) per share	\$ 0.02	\$ (0.37)	\$ (0.36)	\$ 0.64	\$ (1.05)
Diluted income (loss) per share:					
Continuing operations	\$ 0.02	\$ (0.37)	\$ (0.44)	\$ (0.55)	\$ (1.07)
Discontinued operations	\$ —	\$ —	\$ 0.08	\$ 1.19	\$ 0.02
Diluted income (loss) per share	\$ 0.02	\$ (0.37)	\$ (0.36)	\$ 0.64	\$ (1.05)
<b>Balance Sheet Data (at year end):</b>					
Cash, cash equivalents and marketable securities	\$ 110,667	\$ 118,999	\$ 130,338	\$ 219,206	\$ 118,727
Working capital	92,093	95,783	134,540	205,893	217,715
Total assets	113,871	131,317	144,221	239,236	267,431
Convertible senior notes, non current	—	—	15,202	64,450	93,001
Total stockholders’ equity	\$ 60,570	\$ 97,407	\$ 121,382	\$ 154,486	\$ 129,254

## 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 vaccines addressing the unmet medical need of nicotine addiction. We leverage our experience and knowledge in powering the human immune system to target this serious unmet medical need. We have been incorporated in Delaware since 1969 and our operations are located in Rockville, Maryland.

In 2006, we initiated a strategic alternatives process to enhance shareholder value which resulted in the sale, licensure or grant of an option to acquire all of our marketed products and major pipeline products.

Our sole remaining product currently in development is NicVAX, an innovative and proprietary investigational vaccine for the treatment of nicotine addiction and prevention of smoking relapse based on patented technology. In the first quarter of 2010 we granted to GSK (i) an option to exclusively license NicVAX on a worldwide basis and (ii) a license to develop follow-on next-generation nicotine vaccines using our intellectual property combined with GSK proprietary technology including GSK proprietary adjuvants.

The smoking cessation market is estimated to exceed \$4 billion annually and is currently considered to be a largely unmet medical need. Nicotine is a non-immunogenic small molecule that, upon inhalation into the lungs, 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, a chemical which triggers the highly addictive pleasurable effects experienced by smokers and users of other nicotine products. NicVAX is designed to stimulate the immune system to produce highly specific antibodies that bind to nicotine in the bloodstream. A nicotine molecule attached to specific antibodies is too large to cross the blood-brain barrier and thus is unable to reach the receptors in the brain thereby reducing the pleasure experienced by the smoker making it easier to quit.

In November 2007, we announced the successful completion of a Phase IIb "proof-of-concept" clinical trial for NicVAX that demonstrated 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 dose schedule optimization immunogenicity study assessing the antibody response and the 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 reached an agreement with the FDA on an SPA for the pivotal Phase III clinical trials for NicVAX. The SPA forms the foundation to support approval of a BLA. In June 2009, we announced that we received Scientific Advice from the EMA which is well aligned with our SPA agreement with the FDA regarding the design of the trial. In September 2009, we announced that we received a \$10 million grant from NIDA to partially offset the cost of the first of two Phase III studies that we are required to conduct by the FDA in support of NicVAX's licensure. In October 2009, we also announced the initiation of an investigator initiated clinical trial in the Netherlands to test the efficacy of a combined therapy of NicVAX with varenicline, or Chantix/Champix. In November 2009, we announced the initiation of the first of two Phase III efficacy trials in the U.S., which is the first such trial for an addiction vaccine, confirming NicVAX's first in class nicotine vaccine in smoking cessation. We completed enrollment in this trial in July 2010. In March 2010, we initiated the second Phase III trial and announced the completion of enrollment in this Phase III trial in November 2010.

In March 2010, we closed an exclusive worldwide option and licensing agreement with GSK for NicVAX as well as for the development of follow-on nicotine addiction vaccines. Upon closing, we received a \$40 million initial payment. Under the terms of the agreement, we granted to GSK (i) an option to obtain an exclusive worldwide license to develop, commercialize and manufacture NicVAX as it currently exists, as well as certain potential alternative forms of NicVAX together with an adjuvant other than a GSK proprietary adjuvant and/or

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with different presentation, dosage or administration (NicVAX Alternatives), and (ii) an exclusive worldwide license to develop, commercialize and manufacture certain future generation candidate vaccines for the prevention or treatment of nicotine addiction based on our NicVAX intellectual property (other than NicVAX and NicVAX Alternatives). In addition to the \$40 million upon closing, we may receive under the agreement more than \$460 million in potential option fees and regulatory, development, manufacturing and sales milestones for NicVAX and follow-on nicotine vaccines. We are also eligible to receive royalties on global sales of NicVAX should GSK exercise its option and commercialize the product, as well as royalties on global sales of next generation nicotine vaccines.

In August 2010, we received U.S. Patent No. 7,776,620 (Hapten-carrier conjugates for treating and preventing nicotine addiction) for the exclusive use of methods for treating and preventing nicotine addiction with NicVAX and related nicotine vaccines.

In addition to our NicVAX development effort, we are developing PentaStaph™ [*Pentavalent S.aureus Vaccine*] under contract for GSK. PentaStaph is a new pentavalent vaccine designed to prevent *S.aureus* infections including those infections caused by the most dangerous antibiotic-resistant strains of *S.aureus*. In August 2009, we entered into an APA with GSK for the sale of PentaStaph for a total consideration of \$46 million including a \$20 million upfront payment upon closing and \$26 million payable upon achievement of certain milestones. The PentaStaph sale closed in November 2009, and we received payment from GSK of \$21.5 million representing the upfront payment of \$20 million, an additional \$1 million for the sale of our *Staphylococcus epidermidis* vaccine program and an additional \$0.5 million for transfer of certain specified materials. Under the APA, we agreed to a Transition Services Agreement (TSA) to help GSK advance the program while in parallel transferring the technology to GSK. Accordingly, we are continuing to develop PentaStaph under contract for GSK through a Phase I/II clinical trial of two of the antigens, in collaboration with the U.S. military. GSK is reimbursing us for the cost of our services under the TSA. We also have received \$21 million of the possible \$26 million in payments for milestones related to the TSA, \$16 million of which was paid in 2010. We expect to be able to complete our performance obligations under the TSA in 2011 and receive the final \$5 million milestone payment due under the APA.

In 2006, we sold certain assets related to our PhosLo operations. Under the sale agreement, we received \$65 million in cash at closing and are entitled to additional contingent milestone payments and royalties. The royalties relate to sales of a new product formulation over a base amount through 2016. We have received \$13 million of milestones through March 8, 2011 and can also receive up to \$72.5 million in additional milestone payments and royalties.

## **Results of Operations**

The following discussion and analysis of our financial condition and results of operations for each of the three years ended December 25, 2010, December 26, 2009 and December 27, 2008, 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.

### **2010 as Compared to 2009**

*Revenue.* Revenue was \$35.0 million for 2010 compared to \$10.5 million for 2009. The increase of \$24.5 million reflects amounts recognized under the PentaStaph and NicVAX agreements with GSK. Revenue includes amortization of upfront fees received under our PentaStaph and NicVAX agreements; those fees are being recognized as revenue ratably over the period of our participation on joint steering committees created under these agreements. The joint steering committees are currently expected to be 20 months, or through June 2011 for PentaStaph and 190 months, or through December 2025 for NicVAX, from the date of the agreements. The amount recognized in 2010 includes \$13.2 million from the initial \$21.5 million payment received from GSK for PentaStaph and \$2.1 million from the initial \$40.0 million payment received from GSK for NicVAX compared to

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\$3.1 million recognized for PentaStaph in 2009. We also recognized \$16.0 million of revenue related to the successful achievement of two PentaStaph performance milestones in 2010 compared to \$5.0 million for the achievement of one performance milestone in 2009. We also recognized \$3.2 million and \$0.5 million related to services provided to GSK under the PentaStaph and NicVAX agreements, respectively, in 2010 compared to \$2.4 million for services under the PentaStaph agreement in 2009. Unless GSK exercises its NicVAX option, we expect our revenue to significantly decrease in 2011 as a result of the completion of the PentaStaph agreement with GSK.

*Cost of services.* Cost of services was \$4.0 million for 2010 compared to \$2.0 million for 2009. The increase of \$2.0 million represents the cost incurred by us to perform under the PentaStaph and NicVAX agreements with GSK with respect to the transitional services, including performance of the PentaStaph Phase I/II clinical trial and associated activities. These costs include internal labor, external contractors and allocated indirect costs. We expect these costs to decrease in 2011 as a result of completing the PentaStaph agreement with GSK.

*General and administrative expenses.* General and administrative expenses, net of an allocation of a portion of these expenses to cost of services, were \$6.2 million for 2010 compared to \$10.0 million for 2009. The decrease of \$3.8 million reflects our continued efforts to reduce overall expenses and lower legal and facility costs. General and administrative expenses in 2011 are expected to remain approximately at 2010 levels.

*Research and development expenses.* Research and development expenses were \$26.1 million for 2010 compared to \$16.5 million for 2009. The increase of \$9.6 million is primarily due to our two ongoing Phase III trials for NicVAX and NicVAX manufacturing-related activities. The costs related to the PentaStaph Phase I/II clinical trial were reimbursed to us by GSK as they are conducted by us under contract for GSK. GSK's payments for these costs are recognized as revenue. Approximately \$8.8 million of the 2010 costs for NicVAX and PentaStaph trials have been offset by grant funding compared to \$1.6 million of costs offset by grant funding in 2009. Research and development expenses in 2011 are expected to remain approximately at 2010 levels.

*Interest expense.* Interest expense was \$0.2 million and \$1.1 million for 2010 and 2009, respectively, and consisted largely of interest expense associated with our Convertible Senior Notes. The decrease of \$0.9 million reflects the impact of the repurchase of the remaining balance of our Convertible Senior Notes in the second quarter of 2010.

*Income tax expense (benefit).* During the third quarter 2010, as a result of recent tax law changes, we recognized an income tax benefit of \$1.8 million relating to a refund of prior year alternative minimum tax payments (none in 2009).

### **2009 as Compared to 2008**

*Revenue.* Revenue was \$10.5 million for 2009; we had no revenues in 2008. Revenue in 2009 reflects payments recognized under the PentaStaph agreement with GSK. This includes \$3.1 million from the initial \$21.5 million payment received from GSK which is being recognized as revenue ratably over the period we determine we have obligations related to the joint steering committee under the agreement. The joint steering committee is currently expected to be 20 months, or through June 2011 from the date of the agreement. We also recognized \$5.0 million of revenue in 2009 upon the successful achievement of a performance milestone and \$2.4 million related to our services provided under the agreement.

*Cost of services.* Cost of services of \$2.0 million represents the cost incurred by us to perform under the PentaStaph agreement with GSK with respect to the transitional services, including performance of the Phase I/II clinical trial and associated activities. These costs include internal labor, external contractors and allocated indirect costs.

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*General and administrative expenses.* General and administrative expense was \$10.0 million for 2009 compared to \$12.4 million for 2008. The decrease of \$2.4 million reflects our continued efforts to reduce overall infrastructure costs as well as a reduction in share-based compensation expense, offset in part by higher legal fees associated with the strategic alternatives process and in support of the indemnification claim by Biotest.

*Research and development expenses.* Research and development expense was \$16.5 million for 2009 compared to \$12.6 million for 2008. The increase of \$3.9 million is primarily due to the start of the NicVAX Phase III trial, NicVAX manufacturing-related activities, and the support of the PentaStaph Phase I/II trial prior to the GSK agreement. \$1.6 million of the 2009 costs for the NicVAX and PentaStaph trials were offset by grant funding (none in 2008).

*Interest income.* Interest income was \$0.4 million and \$4.6 million for 2009 and 2008, respectively. Interest earned on our cash and investments was lower in 2009 as compared to 2008 due to a lower average cash balance and lower prevailing interest rates on our investments.

*Interest expense.* Interest expense was \$1.1 million and \$3.9 million for 2009 and 2008, respectively and consisted largely of interest expense associated with our Convertible Senior Notes. The decrease of \$2.8 million was the result of the repurchase of \$10.4 million of our Convertible Senior Notes in 2009.

*Other income (expense).* Other income (expense) in 2008 consisted primarily of losses on the repurchase of our Convertible Senior Notes (none in 2009).

*Income taxes.* In 2009 and 2008, 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 in 2008, offset 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 result 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.

### **Liquidity and Capital Resources**

Our cash, cash equivalents and marketable securities at December 25, 2010 totaled \$110.7 million as compared to \$119.0 million at December 26, 2009. This decline is primarily the result of payments of approximately \$42.8 million for the repurchase of our shares of common stock and \$6.1 million for the repurchase of the remaining balance of our Convertible Senior Notes, offset in part by net cash provided by operating activities of \$39.9 million.

Cash provided by (used in) operating activities from continuing operations was \$40.5 million, (\$3.6) million and (\$22.8) million for 2010, 2009 and 2008, respectively. Cash provided by operating activities from continuing operations in 2010 was primarily related to the \$66.3 million received from GSK associated with the PentaStaph and NicVAX agreements offset in part by cash used for general and administrative and research and development expenses. In 2009, cash used in operating activities from continuing operations included cash expenditures for general and administrative expenses and research and development expenses, partially offset by \$21.5 million received in connection with the closing of the PentaStaph sale to GSK. Cash used in operating activities from continuing operations in 2008 included cash expenditures for general and administrative expenses and research and development expenses, partially offset by interest income. Cash provided by (used in) operating activities from discontinued operations was (\$0.6) million, \$9.8 million and \$3.9 million for 2010, 2009 and 2008, respectively.

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Cash provided by (used in) investing activities from continuing operations was \$2.3 million, (\$35.6) million and (\$22.2) million for 2010, 2009 and 2008, 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 includes net cash proceeds related to the sale of Biologics SBU and our Aloprim and PhosLo products.

Since December 2007, our Board of Directors has approved the repurchase of up to \$115 million of our common stock in the open market or in privately negotiated transactions. In 2010, we purchased 7.8 million shares for \$42.3 million at an average cost per share of \$5.45. Since the inception of the program in December 2007 through December 25, 2010, we have repurchased a total of 19.9 million shares for a total cost of \$87.2 million, at an average price of \$4.39 per share, leaving a balance of \$27.8 million available for share repurchases under the current program. Repurchased shares have been accounted for as treasury stock using the cost method.

In 2005, we issued \$112.4 million of our Convertible Senior Notes through a private offering to qualified institutional buyers. In 2010, we repurchased the remaining \$6.1 million balance of our Convertible Senior Notes for a total of \$6.1 million. In 2009, we repurchased \$10.4 million of our Convertible Senior Notes for a total of \$10.1 million. In 2008, we repurchased \$57.3 million of our Convertible Senior Notes for a total of \$51.6 million. As of December 25, 2010, we had repurchased all of the Convertible Senior Notes.

We believe cash, cash equivalents and marketable securities on hand at December 25, 2010 will be sufficient to meet our anticipated cash requirements for operations for at least the next 12 months.

### Aggregate Contractual Obligations

The following table provides information as of December 25, 2010 with respect to the amounts and timing of our known material contractual obligations as specified below (*in thousands*). As of December 25, 2010, there were no significant contractual obligations related to our discontinued operations.

	<u>Total</u>	<u>Less than 1 Year</u>	<u>1 to 3 Years</u>	<u>3 to 5 Years</u>	<u>More than 5 Years</u>
Open purchase orders	\$ 288	\$ 288	\$—	\$—	\$ —
Operating leases	1,112	875	211	26	—
Manufacturing and clinical agreements	2,113	2,062	51	—	—
Total	<u>\$3,513</u>	<u>\$ 3,225</u>	<u>\$262</u>	<u>\$ 26</u>	<u>\$ —</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.

### 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.



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*Revenue recognition:* Our revenue-generating arrangements may include multiple elements, including one or more of up-front license fees, research payments, and milestone payments. In these situations, we allocate the total contract price to the multiple elements based on their relative fair values and recognize revenue for each element according to its characteristics. We analyze our cost reimbursable grants to determine whether we should report such reimbursements as revenue or as an offset to our research and development expenses incurred. In 2010 and 2009, we recorded approximately \$8.8 million and \$1.6 million, respectively of costs reimbursed by the government as an offset to research and development expenses (none in 2008).

Revenue consists of license fees, milestone payments, and payments for contractual services. License fees received are recorded as deferred revenue and recognized ratably over the underlying performance period. Milestone payments are recognized as revenue when; (i) the milestones are achieved; (ii) no further performance obligations with respect to the milestone exist; (iii) collection is reasonably assured; and (iv) substantive effort was necessary to achieve the milestone. Milestones are considered substantive if all of the following conditions are met: (i) the milestone is nonrefundable; (ii) achievement of the milestone was not reasonably assured at the inception of the arrangement; (iii) substantive effort is involved to achieve the milestone; and, (iv) the amount of the milestone appears reasonable in relation to the effort expended with the other milestones in the arrangement and the related risk associated with achievement of the milestone. If a milestone is deemed not to be substantive, the Company would recognize the portion of the milestone payment as revenue that correlates to work already performed; the remaining portion of the milestone payment will be deferred and recognized as revenue as the Company completes its performance obligations. Payments for contractual services are recognized as revenue when earned, typically when the services are rendered.

*Collaborative arrangements:* We are an active participant with exposure to significant risks and rewards of commercialization relating to the development of NicVAX. For costs incurred and revenues generated from third parties where we are deemed to be the principal participant, we recognize revenues and costs using the gross basis of accounting; otherwise we use the net basis of accounting.

*Research and development expenses:* Except for advance payments, which are recognized over the life of the contract, 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 (including an allocation of the costs of facilities and overhead). 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. Reimbursements from government grants are recorded as an offset to research and development expenses as incurred.

*Share-based compensation:* We currently account for equity-based compensation at fair value; accordingly we expense the estimated fair value of share-based awards made in exchange for employee services over the requisite employee service period. 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 2009 and 2008, we adopted several new accounting and disclosure requirements. These newly adopted requirements included: (i) new disclosure requirements about our non-financial assets and liabilities; (ii) new accounting and reporting standards for non-controlling interests in subsidiaries; (iii) new disclosures about derivative financial instruments; (iv) new accounting for deferred compensation and other post-retirement benefits; (v) new accounting for certain collaborative agreements; (vi) new accounting for instruments indexed to our own stock; and (vii) new accounting for advance payments for goods or services to be used in future research and development activities. The adoption of these new requirements did not have a material impact on our consolidated financial statements.

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In the first quarter of 2009, we adopted new accounting requirements for convertible debt instruments that may be settled in cash upon conversion. This new guidance clarifies that (1) convertible debt instruments that may be settled in cash upon conversion, including partial cash settlement, are not considered debt instruments 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). The adoption of this new guidance had the impact of decreasing our diluted earnings per share from continuing operations by approximately \$0.15 per share in 2008 as a result of non-cash interest expense recorded in connection with the adoption of the new guidance.

There are several new accounting and disclosure requirements that we will be required to adopt in the future, primarily with respect to revenue recognition practices. In 2011, we will be required to adopt new revenue recognition practices relating to revenue arrangements that include multiple elements and research and development milestones. Our license agreements with GSK related to our PentaStaph and NicVAX products may be affected by the new accounting and disclosure requirements. We are currently evaluating any potential impact these new requirements may have on our consolidated financial statements.

### **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 25, 2010, we had cash, cash equivalents and marketable securities in the amount of \$110.7 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. Interest income was \$0.2 million for 2010.

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 25, 2010, 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.

In our opinion, Nabi Biopharmaceuticals maintained, in all material respects, effective internal control over financial reporting as of December 25, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2010 consolidated financial statements of Nabi Biopharmaceuticals and our report dated March 8, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
March 8, 2011

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 25, 2010 and December 26, 2009, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 25, 2010. 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 25, 2010 and December 26, 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 25, 2010, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), internal control over financial reporting of Nabi Biopharmaceuticals as of December 25, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
March 8, 2011

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

## Nabi Biopharmaceuticals

CONSOLIDATED BALANCE SHEETS  
(In thousands, except share and per share data)

	December 25, 2010	December 26, 2009
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 53,564	\$ 59,510
Marketable securities	54,603	59,489
Receivables	1,030	9,122
Prepaid expenses and other current assets	829	1,572
<b>Total current assets</b>	<b>110,026</b>	<b>129,693</b>
Marketable securities	2,500	—
Property and equipment, net	597	855
Other assets	748	769
<b>Total assets</b>	<b>\$ 113,871</b>	<b>\$ 131,317</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 552	\$ 1,735
Accrued expenses and other current liabilities	7,377	4,961
Deferred revenue, current portion	7,797	18,447
2.875% convertible senior notes, net	—	5,951
Current liabilities of discontinued operations	2,207	2,816
<b>Total current liabilities</b>	<b>17,933</b>	<b>33,910</b>
Deferred revenue	35,368	—
<b>Total liabilities</b>	<b>53,301</b>	<b>33,910</b>
<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; 63,206,393 and 62,782,990 shares issued, respectively	6,321	6,278
Additional paid-in capital	370,366	365,841
Treasury stock, 20,696,277 and 12,930,460 shares, respectively, at cost	(92,567)	(50,267)
Other comprehensive loss	(3)	(20)
Accumulated deficit	(223,547)	(224,425)
<b>Total stockholders' equity</b>	<b>60,570</b>	<b>97,407</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 113,871</b>	<b>\$ 131,317</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 25, 2010	December 26, 2009	December 27, 2008
<b>Revenue:</b>			
Revenue	\$ 35,005	\$ 10,489	\$ —
<b>Operating expenses:</b>			
Cost of services	3,951	1,988	—
General and administrative expenses	6,174	9,987	12,415
Research and development expenses	26,078	16,490	12,556
<b>Operating loss</b>	<b>(1,198)</b>	<b>(17,976)</b>	<b>(24,971)</b>
Interest income	230	368	4,579
Interest expense	(210)	(1,071)	(3,902)
Other income (expense), net	291	(48)	(1,454)
<b>Loss from continuing operations before income taxes</b>	<b>(887)</b>	<b>(18,727)</b>	<b>(25,748)</b>
Benefit from income taxes	1,765	—	2,765
<b>Income (loss) from continuing operations</b>	<b>878</b>	<b>(18,727)</b>	<b>(22,983)</b>
<b>Income from discontinued operations, net of tax</b>	<b>—</b>	<b>—</b>	<b>4,245</b>
<b>Net income (loss)</b>	<b>\$ 878</b>	<b>\$ (18,727)</b>	<b>\$ (18,738)</b>
<b>Basic income (loss) per share:</b>			
Continuing operations	\$ 0.02	\$ (0.37)	\$ (0.44)
Discontinued operations	\$ —	\$ —	\$ 0.08
<b>Diluted income (loss) per share:</b>			
Continuing operations	\$ 0.02	\$ (0.37)	\$ (0.44)
Discontinued operations	\$ —	\$ —	\$ 0.08
<b>Basic weighted-average shares outstanding</b>	<b>44,312</b>	<b>50,633</b>	<b>51,866</b>
<b>Diluted weighted-average shares outstanding</b>	<b>44,440</b>	<b>50,633</b>	<b>51,866</b>

*See accompanying notes to consolidated financial statements.*

**Nabi Biopharmaceuticals**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
(In thousands)

	Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Other Accumulated Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
<b>Balance at December 29, 2007</b>	<b>62,117</b>	<b>\$6,212</b>	<b>\$358,877</b>	<b>(5,807)</b>	<b>\$(23,608)</b>	<b>\$ (186,995)</b>	<b>\$ —</b>	<b>\$ 154,486</b>
Net loss	—	—	—	—	—	(18,738)	—	(18,738)
Other comprehensive income	—	—	—	—	—	—	60	60
Comprehensive loss	—	—	—	—	—	—	—	(18,678)
Purchase of convertible senior notes	—	—	962	—	—	—	—	962
Stock options exercised	120	12	360	—	—	—	—	372
Share-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>\$363,003</b>	<b>(10,882)</b>	<b>\$(42,187)</b>	<b>\$ (205,733)</b>	<b>\$ 60</b>	<b>\$ 121,382</b>
Net loss	—	—	—	—	—	(18,727)	—	(18,727)
Other comprehensive income	—	—	—	—	—	—	(80)	(80)
Comprehensive loss	—	—	—	—	—	—	—	(18,807)
Stock options exercised	140	14	417	—	—	—	—	431
Share-based compensation expense	—	—	2,463	—	—	—	—	2,463
Purchase of treasury stock	—	—	—	(2,048)	(8,080)	—	—	(8,080)
Stock issued under Employee	—	—	—	—	—	—	—	—
Stock Purchase Plan	40	4	93	—	—	—	—	97
Restricted stock awards, net	206	21	(21)	—	—	—	—	—
Purchase of convertible senior notes	—	—	(114)	—	—	35	—	(79)
<b>Balance at December 26, 2009</b>	<b>62,783</b>	<b>\$6,278</b>	<b>\$365,841</b>	<b>(12,930)</b>	<b>\$(50,267)</b>	<b>\$ (224,425)</b>	<b>\$ (20)</b>	<b>\$ 97,407</b>
Net income	—	—	—	—	—	878	—	878
Other comprehensive income	—	—	—	—	—	—	17	17
Comprehensive income	—	—	—	—	—	—	—	895
Stock options exercised	138	14	509	—	—	—	—	523
Share-based compensation expense	—	—	3,923	—	—	—	—	3,923
Purchase of treasury stock	—	—	—	(7,766)	(42,300)	—	—	(42,300)
Stock issued under Employee Stock Purchase Plan	22	2	90	—	—	—	—	92
Restricted stock awards, net	257	26	(26)	—	—	—	—	—
Directors fee paid in stock	6	1	29	—	—	—	—	30
<b>Balance at December 25, 2010</b>	<b>63,206</b>	<b>\$6,321</b>	<b>\$370,366</b>	<b>(20,696)</b>	<b>\$(92,567)</b>	<b>\$ (223,547)</b>	<b>\$ (3)</b>	<b>\$ 60,570</b>

*See accompanying notes to consolidated financial statements.*

**Nabi Biopharmaceuticals**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	For the Years Ended		
	December 25, 2010	December 26, 2009	December 27, 2008
<b>Cash flow from operating activities:</b>			
Income (loss) from continuing operations	\$ 878	\$ (18,727)	\$ (22,983)
Adjustments to reconcile income (loss) from continuing operations to net cash provided by (used in) operating activities of continuing operations:			
Depreciation and amortization	376	502	574
Non-cash intra-period tax allocation	—	—	(2,765)
Accretion of discount on convertible senior notes	99	483	2,304
Share-based compensation	3,923	2,463	2,733
Loss (gain) on repurchase of convertible senior notes	—	302	1,553
Other	(4)	4	48
Changes in assets and liabilities:			
Receivables	8,093	(6,685)	—
Prepaid expenses and other assets	753	(2,713)	753
Accounts payable, accrued expenses and other	1,705	2,298	(4,982)
Deferred revenue	24,718	18,447	—
<b>Net cash provided by (used in) operating activities from continuing operations</b>	<b>40,541</b>	<b>(3,626)</b>	<b>(22,765)</b>
Net cash provided by (used in) operating activities from discontinued operations	(609)	9,843	3,864
<b>Net cash provided by (used in) operating activities</b>	<b>39,932</b>	<b>6,217</b>	<b>(18,901)</b>
<b>Cash flow from investing activities:</b>			
Proceeds from sales and maturities of marketable securities	142,693	55,833	1,600
Purchases of marketable securities	(140,289)	(91,471)	(23,871)
Proceeds from sales of property and equipment	50	—	—
Capital expenditures	(154)	(4)	(53)
Other investing activities, net	—	—	112
<b>Net cash provided by (used in) investing activities from continuing operations</b>	<b>2,300</b>	<b>(35,642)</b>	<b>(22,212)</b>
Net cash provided by investing activities from discontinued operations	—	—	1,567
<b>Net cash provided by (used in) investing activities</b>	<b>2,300</b>	<b>(35,642)</b>	<b>(20,645)</b>
<b>Cash flow from financing activities:</b>			
Proceeds from issuance of common stock for employee benefit plans and stock options	645	528	128
Purchase of common stock for treasury	(42,773)	(7,940)	(20,010)
Repurchase of convertible senior notes	(6,050)	(10,091)	(51,634)
Other financing activities, net	—	—	(83)
<b>Net cash used in financing activities from continuing operations</b>	<b>(48,178)</b>	<b>(17,503)</b>	<b>(71,599)</b>
Net cash used in financing activities from discontinued operations	—	—	(23)
<b>Net cash used in financing activities</b>	<b>(48,178)</b>	<b>(17,503)</b>	<b>(71,622)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(5,946)</b>	<b>(46,928)</b>	<b>(111,168)</b>
<b>Cash and cash equivalents at beginning of year</b>	<b>59,510</b>	<b>106,438</b>	<b>217,606</b>
<b>Cash and cash equivalents at end of year</b>	<b>\$ 53,564</b>	<b>\$ 59,510</b>	<b>\$ 106,438</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 vaccines addressing the unmet medical need of nicotine addiction. We leverage our experience and knowledge in powering the human immune system to target this serious unmet medical need. We have been incorporated in Delaware since 1969 and our operations are located in Rockville, Maryland.

In 2006, we initiated a strategic alternatives process to enhance shareholder value which resulted in the sale, licensure or grant of an option to acquire all of our marketed products and major pipeline products.

Our sole remaining product currently in development is NicVAX, an innovative and proprietary investigational vaccine for the treatment of nicotine addiction and prevention of smoking relapse based on patented technology. In the first quarter of 2010 we granted to GSK (i) an option to exclusively license NicVAX on a worldwide basis and (ii) a license to develop follow-on next-generation nicotine vaccines using our intellectual property combined with GSK proprietary technology including GSK proprietary adjuvants.

In March 2010, we closed an exclusive worldwide option and licensing agreement with GSK for NicVAX as well as for the development of follow-on nicotine addiction vaccines. Upon closing, we received a \$40 million initial payment. Under the terms of the agreement, we granted to GSK (i) an option to obtain an exclusive worldwide license to develop, commercialize and manufacture NicVAX as it currently exists, as well as certain potential alternative forms of NicVAX together with an adjuvant other than a GSK proprietary adjuvant and/or with different presentation, dosage or administration (NicVAX Alternatives), and (ii) an exclusive worldwide license to develop, commercialize and manufacture certain future generation candidate vaccines for the prevention or treatment of nicotine addiction based on our NicVAX intellectual property (other than NicVAX and NicVAX Alternatives). In addition to the \$40 million received upon closing, we may receive under the agreement more than \$460 million in potential option fees and regulatory, development, manufacturing and sales milestones for NicVAX and follow-on nicotine vaccines. We are also eligible to receive royalties on global sales of NicVAX should GSK exercise its option and commercialize the product, as well as royalties on global sales of next generation nicotine vaccines.

In addition to our NicVAX development effort, we are developing PentaStaph™ [*Pentavalent S.aureus Vaccine*] under contract for GSK. PentaStaph is a new pentavalent vaccine designed to prevent *S.aureus* infections including those infections caused by the most dangerous antibiotic-resistant strains of *S.aureus*. In August 2009, we entered into an Asset Purchase Agreement (APA) with GSK for the sale of PentaStaph for a total consideration of \$46 million including a \$20 million upfront payment upon closing and \$26 million payable upon achievement of certain milestones. The PentaStaph sale closed in November 2009, and we received payment from GSK of \$21.5 million representing the upfront payment of \$20 million, an additional \$1 million for the sale of our *Staphylococcus epidermidis* vaccine program and an additional \$0.5 million for transfer of certain specified materials. Under the APA, we agreed to a Transition Services Agreement (TSA) to help GSK advance the program while in parallel transferring the technology to GSK. Accordingly, we are continuing to develop PentaStaph under contract for GSK through a Phase I/II clinical trial of two of the antigens, in collaboration with the U.S. military. GSK is reimbursing us for the cost of our services under the TSA. We also have received \$21 million of the possible \$26 million in payments for milestones related to the TSA, \$16 million in 2010. We expect to be able to complete our performance obligations under the TSA in 2011 and receive the final \$5 million milestone payment due under the APA.

NicVAX is an innovative and proprietary investigational vaccine for treatment of nicotine addiction and prevention of smoking relapse based on patented technology. The smoking cessation market is estimated to exceed \$4 billion annually and is currently considered to be a largely unmet medical need. Nicotine is a non-immunogenic small molecule that, upon inhalation into the lungs, quickly passes into the bloodstream and

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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, a chemical which triggers the highly addictive pleasurable effects experienced by smokers and users of other nicotine products. NicVAX is designed to stimulate the immune system to produce highly specific antibodies that bind to nicotine in the bloodstream. A nicotine molecule attached to specific antibodies is too large to cross the blood-brain barrier and thus is unable to reach the receptors in the brain thereby reducing the pleasure experienced by the smoker making it easier to quit. Pre-clinical animal studies with NicVAX have shown that vaccination prevents nicotine from reaching the brain and blocks the effects of nicotine, including effects that can lead to addiction or can reinforce and maintain addiction.

In November 2007, we announced the successful completion of a Phase IIb “proof-of-concept” clinical trial for NicVAX that demonstrated 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 dose schedule optimization immunogenicity study assessing the antibody response and the 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 reached an agreement with the FDA on an SPA for the pivotal Phase III clinical trials for NicVAX. The SPA forms the foundation to support approval of a NDA. In June 2009, we announced that we received Scientific Advice from the EMA which is well aligned with our SPA agreement with the FDA regarding the design of the trial. In September 2009, we announced that we received a \$10 million grant from NIDA to partially offset the cost of the first of two Phase III studies that we are required to conduct by the FDA in support of NicVAX’s licensure. In October 2009, we also announced the initiation of an investigator initiated clinical trial in the Netherlands to test the efficacy of a combined therapy of NicVAX with varenicline, or Chantix/Champix. In November 2009, we announced the initiation of the first of two Phase III efficacy trials in the U.S., which is the first such trial for an addiction vaccine, confirming NicVAX’s first in class nicotine vaccine in smoking cessation. We completed enrollment in this trial in July 2010. In March 2010, we initiated the second Phase III trial and announced the completion of enrollment in this Phase III trial in November 2010.

### *Previous Strategic Transactions*

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 million in cash at closing and are entitled to additional contingent 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. We have received \$13 million of milestones through March 8, 2011 and can also receive up to \$72.5 million in additional milestone payments and royalties. In June 2007, we sold certain assets related to our product Aloprim (allopurinol sodium for Injection) for \$3.7 million. In December 2007, we sold our Biologics Strategic Business Unit (SBU) and certain corporate shared services assets to Biotest Pharmaceuticals Corporation, or Biotest, for \$185 million.

## **NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Principles of Consolidation:* The consolidated financial statements include the accounts of Nabi Biopharmaceuticals and our wholly-owned subsidiaries (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.

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*Basis of Presentation and Reclassifications:* As further discussed in Note 3, 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. 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.

*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 25, 2010, December 26, 2009 and December 27, 2008; all three years were 52-week years.

*Financial Instruments:* The carrying amounts of financial instruments including cash equivalents, marketable securities, accounts receivable and accounts payable approximated fair value as of December 25, 2010 and December 26, 2009, because of the relatively short-term maturity of these instruments. The carrying value of our Convertible Senior Notes, at December 26, 2009 was \$6.0 million, compared to the approximate fair value of \$5.2 million, based on quoted market prices. We repurchased the entire remaining balance of our Convertible Senior Notes on April 15, 2010.

*Cash, Cash Equivalents and Marketable Securities:* Cash equivalents consist of investments in low risk, highly liquid securities with original maturities of 90 days or less. Marketable securities consist of low risk fixed income investment instruments such as government obligations, government agencies and FDIC backed notes with maturities typically less than eighteen months. Marketable securities are classified as available-for-sale and recorded at market value; unrealized gains and losses on those securities are reflected in other comprehensive income (loss). We assess the risk of impairment related to securities held in our investment portfolio on a regular basis and noted no "permanent" or "other than temporary" impairment during the twelve months ended December 25, 2010. Our investment policies and procedures are reviewed periodically including by management and our audit committee to minimize credit risk.

*Concentration of Credit Risk:* Financial instruments that potentially subject us to credit and liquidity risk consist primarily of cash, marketable securities and receivables.

*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 whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When an evaluation indicates that an impairment has occurred, a loss is recognized and the asset is adjusted to its estimated fair value.

*Revenue Recognition:* Our revenue generating-arrangements may include multiple elements and deliverables, including licenses, options, research and development activities, participation on joint steering committees, and contract manufacturing, among other elements. When we determine that an element has stand-alone value to our customer, we allocate a portion of the total contract price to that element based on its objectively determined and relative fair value, and recognize revenue for that element according to its characteristics. When we cannot reliably and objectively determine fair value of any delivered element, we combine that element with undelivered elements as a single unit of accounting.

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Revenue consists of license fees, milestone payments, and payments for contractual services. License fees received are initially recorded as deferred revenue, and are subsequently recognized as revenue ratably over the period of our participation on joint steering committees. In May 2010, the Company revised its estimated completion date related to its obligations under the transition services agreement with GSK for PentaStaph from December 2010 to June 2011. Accordingly, the remaining deferred revenue related to this agreement will be recognized ratably through June 2011. The joint steering committees are currently expected to be 20 months, or through June 2011 for PentaStaph and 190 months, or through December 2025 for NicVAX, from the date of the agreements. Milestone payments are recognized as revenue when: (i) the milestones are achieved; (ii) no further performance obligations with respect to the milestone exist; (iii) collection is reasonably assured; and (iv) substantive effort was necessary to achieve the milestone. Milestones are considered substantive if all of the following conditions are met: (i) the milestone is nonrefundable; (ii) achievement of the milestone was not reasonably assured at the inception of the arrangement; (iii) substantive effort is involved to achieve the milestone; and, (iv) the amount of the milestone appears reasonable in relation to the effort expended with the other milestones in the arrangement and the related risk associated with achievement of the milestone. If a milestone is deemed not to be substantive, the Company would recognize the portion of the milestone payment as revenue that correlates to work already performed; the remaining portion of the milestone payment will be deferred and recognized as revenue as the Company completes its performance obligations. Payments for contractual services are recognized as revenue when earned, typically when the services are rendered.

We analyze our cost reimbursable grants to determine whether we should report such reimbursements as revenue or as a reduction to our research and development expenses incurred.

*Collaborative Arrangements:* We are an active participant with exposure to significant risks and rewards of commercialization relating to the development of NicVAX. For costs incurred and revenues generated from third parties where we are deemed to be the principal participant, we recognize revenues and costs using the gross basis of accounting; otherwise we use the net basis of accounting.

*Research and Development Expenses:* Research and development costs are expensed as incurred; advanced payments are deferred and subsequently expensed over the period of performance. Research and development expenses include direct labor costs as well as the costs of contractors and other direct and indirect expenses (including an allocation of the costs of facilities). 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. We recorded approximately \$8.8 million and \$1.6 million for 2010 and 2009, respectively, of cost reimbursements from government grants as an offset to research and development expenses (none in 2008).

*Comprehensive Income (Loss):* We calculate comprehensive income (loss) as the total of our net income (loss) and all other changes in equity other than transactions with owners. For 2010, 2009 and 2008, comprehensive income consisted of our net income (loss), our net unrealized loss on our available for sale portfolio of marketable securities, and our cumulative foreign currency translation adjustments.

*Income (Loss) Per Share:* Basic income (loss) per share is computed by dividing consolidated net income (loss) available to common shareholders by the weighted-average number of common shares outstanding during the period. For periods of net income when the effects are dilutive, diluted earnings per share is computed by dividing net income available to common shareholders (as adjusted for interest expense on our Convertible Senior Notes net of taxes when they were outstanding) by the weighted-average number of shares outstanding and the dilutive impact of all dilutive potential common shares. Dilutive potential common shares consist primarily of stock options and the common shares underlying our Convertible Senior Notes when they were outstanding. The dilutive impact of potential common shares resulting from stock options is determined by applying the treasury stock method. The dilutive impact of potential common shares resulting from our Convertible Senior Notes was determined by applying the "if converted" method. For all periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses; accordingly, diluted loss per share is the same as basic loss per share.

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The Company's unvested restricted shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; the calculation of basic and diluted income per share excludes net income attributable to the unvested restricted shares from the numerator and excludes the impact of the shares from the denominator.

For 2010, the computation of diluted income per share differed from the computation of basic income per share as a result of a (i) numerator adjustment for net income allocated to participating securities and (ii) denominator adjustment related to stock options using the treasury stock method. A total of approximately 4.0 million potentially dilutive shares related to stock options have been excluded from the calculation of diluted net income per share as their inclusion would be anti-dilutive. A total of 1.8 million and 0.2 million potential diluted shares have been excluded in the calculation of diluted net loss per share in 2009 and 2008 respectively.

The following table provides the computation of our basic and diluted earnings per share for 2010. Because of our net losses in 2009 and 2008, we did not present diluted earnings per share.

<u>(in thousands, except per share data)</u>	<b>December 25, 2010</b>
<b>Numerator:</b>	
Net income (loss)	\$ 878
Net income allocated to participating securities	(6)
Numerator for basic income (loss) per share	\$ 872
Incremental allocation of net income to participating securities	—
Numerator for diluted income (loss) per share	<u>\$ 872</u>
<b>Denominator:</b>	
Denominator for basic income (loss) per share—Weighted average outstanding common shares	44,312
Dilutive effect of stock options	128
Denominator for diluted income (loss) per share	<u>44,440</u>
Income (loss) per share—basic	\$ 0.02
Income (loss) per share—diluted	\$ 0.02

*Share-based Compensation:* We currently account for equity-based compensation at fair value; accordingly we expense the estimated fair value of share-based awards made in exchange for employee services over the requisite employee service period. 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 the asset and liability approach for financial accounting and reporting of income taxes, which requires, among other things, recognition of future tax benefits and liabilities measured at enacted rates attributable to temporary differences between financial statement and income tax bases of assets and liabilities and to tax net operating loss carryforwards to the extent that realization of these benefits is more likely than not. We periodically evaluate the realizability of our net deferred tax assets. 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 result from a loss from continuing operations.

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

*New Accounting Pronouncements:* There are several new accounting and disclosure requirements that we will be required to adopt in the future, primarily with respect to revenue recognition practices. In 2011, we will be required to adopt new revenue recognition practices relating to revenue arrangements that include multiple elements and research and development milestones. Our license agreements with GSK related to our PentaStaph and NicVAX products may be affected by the new accounting and disclosure requirements. We are currently evaluating any potential impact these new requirements may have on our consolidated financial statements.

### NOTE 3 DISCONTINUED OPERATIONS

Prior to 2008, we sold several of our existing products and businesses. In 2006, we sold our PhosLo (calcium acetate) product and the product's related assets. Under the sale agreement, we received \$65 million in cash at closing and have subsequently received an additional \$13 million in milestone payments. We can also receive up to \$72.5 million in additional milestone payments and royalties for 10 years after the closing date. In 2007, we sold certain assets related to our product Aloprim (allopurinol sodium for Injection) for \$3.7 million. Also in 2007, we sold our Biologics SBU and certain corporate shared services assets for \$185 million. The assets and liabilities related to these businesses have identifiable cash flows that are largely independent of the cash flows of other groups of assets and liabilities, and we do not have a significant continuing involvement with the related products. Accordingly, the remaining assets and liabilities, and the results of operations, related to these businesses are presented as discontinued operations in all periods.

### NOTE 4 AVAILABLE FOR SALE INVESTMENTS

The amortized cost, gross unrealized gains, gross unrealized losses and estimated fair value of available-for-sale investments by security classification as of December 25, 2010 and December 26, 2009 are as follows:

<u>December 25, 2010 (in thousands)</u>	<u>Amortized Costs</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Values</u>
Government-sponsored securities	\$ 50,943	\$ 15	\$ (19)	\$ 50,939
Corporate debt securities	6,163	1	—	6,164
Total securities	<u>\$ 57,106</u>	<u>\$ 16</u>	<u>\$ (19)</u>	<u>\$ 57,103</u>

<u>December 26, 2009 (in thousands)</u>	<u>Amortized Costs</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Values</u>
US Treasury bills	\$ 14,996	\$ —	\$ (1)	\$ 14,995
Government-sponsored securities	43,450	5	(1)	43,454
Corporate debt securities	1,041	—	(1)	1,040
Total securities	<u>\$ 59,487</u>	<u>\$ 5</u>	<u>\$ (3)</u>	<u>\$ 59,489</u>

During 2010 and 2009, we had no significant realized gains (losses) on sales of available-for-sale securities. Gains and losses on available-for-sale securities are based on the specific identification method.

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The contractual maturities of available-for-sale investments by security classification as of December 25, 2010 and December 26, 2009 were as follows:

<u>December 25, 2010 (in thousands)</u>	<u>Total</u>	<u>Less than 12 Months</u>	<u>12 Months or More</u>
Government-sponsored securities	\$50,939	\$ 48,439	\$ 2,500
Corporate debt securities	6,164	6,164	—
Total securities	<u>\$57,103</u>	<u>\$ 54,603</u>	<u>\$ 2,500</u>

<u>December 26, 2009 (in thousands)</u>	<u>Total</u>	<u>Less than 12 Months</u>	<u>12 Months or More</u>
US Treasury bills	\$14,995	\$ 14,995	\$ —
Government-sponsored securities	43,454	43,454	—
Corporate debt securities	1,040	1,040	—
Total securities	<u>\$59,489</u>	<u>\$ 59,489</u>	<u>\$ —</u>

### NOTE 5 PROPERTY AND EQUIPMENT

Property and equipment and related accumulated depreciation are summarized below:

<u>(in thousands)</u>	<u>December 25, 2010</u>	<u>December 26, 2009</u>
Information systems	\$ 2,160	\$ 2,156
Leasehold improvements	3,204	3,204
Machinery and equipment	4,420	4,547
Furniture and fixtures	239	238
Property and equipment	<u>10,023</u>	<u>10,145</u>
Less accumulated depreciation	<u>(9,426)</u>	<u>(9,290)</u>
Property and equipment, net	<u>\$ 597</u>	<u>\$ 855</u>

We recorded depreciation expense in continuing operations related to property and equipment of \$0.4 million, \$0.5 million and \$0.6 million, in 2010, 2009 and 2008, 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 25, 2010</u>	<u>December 26, 2009</u>
Employee compensation and benefits	\$ 2,504	\$ 1,830
Unsettled treasury stock transactions	—	472
Accrued clinical trial expenses	4,411	1,853
Accrued interest payable	—	37
Other	462	769
Total	<u>\$ 7,377</u>	<u>\$ 4,961</u>

### NOTE 7 SUPPLEMENTAL FAIR VALUE DISCLOSURES

We follow a three-tier fair value hierarchy which prioritizes the inputs used in measuring the fair value of our assets and liabilities. These tiers include (i) Level 1, defined as observable inputs such as quoted prices in active markets for identical assets, (ii) 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

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can be corroborated by observable market data for substantially the full term of the assets or liabilities; and (iii) 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 25, 2010 and December 26, 2009. The inputs used in measuring the fair value of these instruments are considered to be Level 1 and Level 2 in accordance with the three-tier 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.

<u>December 25, 2010 (in thousands)</u>	<u>Total</u>	<u>Quoted Prices in Active</u>	<u>Significant Other</u>	<u>Significant</u>
		<u>Markets for Identical</u>	<u>Observable Inputs</u>	<u>Unobservable Inputs</u>
		<u>Assets</u>	<u>Level 2</u>	<u>Level 3</u>
		<u>Level 1</u>		
Cash and cash equivalents	\$ 53,564	\$ 50,564	\$ 3,000	\$ —
Government-sponsored enterprise securities	50,939	6,021	44,918	—
Corporate debt and other securities	6,164	4,324	1,840	—
Total	<u>\$110,667</u>	<u>\$ 60,909</u>	<u>\$ 49,758</u>	<u>\$ —</u>

<u>December 26, 2009 (in thousands)</u>	<u>Total</u>	<u>Quoted Prices in Active</u>	<u>Significant Other</u>	<u>Significant</u>
		<u>Markets for Identical</u>	<u>Observable Inputs</u>	<u>Unobservable Inputs</u>
		<u>Assets</u>	<u>Level 2</u>	<u>Level 3</u>
		<u>Level 1</u>		
Cash and cash equivalents	\$ 43,013	\$ 43,013	\$ —	\$ —
US Treasury bills	19,995	19,995	—	—
Government-sponsored enterprise securities	54,547	—	54,547	—
Corporate debt and other securities	1,444	—	1,444	—
Total	<u>\$118,999</u>	<u>\$ 63,008</u>	<u>\$ 55,991</u>	<u>\$ —</u>

### 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 2010, we repurchased the remaining \$6.1 million balance of our Convertible Senior Notes for a total of \$6.1 million. In 2009, we repurchased \$10.4 million of our Convertible Senior Notes for a total of \$10.1 million resulting in a net loss of \$0.3 million. In 2008, we repurchased \$57.3 million of our Convertible Senior Notes for a total of \$51.6 million resulting in a net loss of \$1.6 million. Interest payments for 2010, 2009 and 2008 were \$0.1 million, \$0.2 million, and \$1.7 million, which largely consisted of the interest payments for our Convertible Senior Notes. As of December 25, 2010, we had repurchased all of the 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 of which 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. Currently, there are no outstanding shares of preferred stock.



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### *Treasury Stock*

Since December 2007, our Board of Directors has approved the buyback of up to \$115 million of our common stock in the open market or in privately negotiated transactions. In 2010, we purchased 7.8 million shares for \$42.3 million at an average cost per share of \$5.45. Since the inception of the program in December 2007 through December 25, 2010, we have repurchased a total of 19.9 million shares for a total cost of \$87.2 million, at an average price of \$4.39 per share, leaving a balance of \$27.8 million available for share repurchases under the current program. Repurchased shares have been accounted for as treasury stock using the cost method.

### **NOTE 10 EMPLOYEE BENEFIT PLANS AND EQUITY-BASED COMPENSATION**

We maintain several employee benefit plans for our employees. As of December 25, 2010, a total of 10.3 million shares of common stock were authorized for issuance under our stock option and employee benefit plans.

#### ***Retirement Savings Plan***

We maintain a retirement savings plan which permits employees to contribute 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 in 2010, 2009 and 2008. 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.

#### ***Employee Stock Purchase Plan***

Under the Nabi Employee Stock Purchase Plan (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 21,576 shares, 40,284 shares, and 27,796 shares of common stock during 2010, 2009 and 2008, respectively, pursuant to this plan at an average price per common share of \$4.25, \$2.41 and \$3.35, respectively. As of December 25, 2010, we had 0.4 million shares available for future issuance under the ESPP.

#### ***Incentive Stock Plan***

In 2007, our shareholders approved the 2007 Omnibus Equity and Incentive Plan (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 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 25, 2010, we had 2.7 million shares of common stock available for issuance 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.

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We also issue restricted stock awards; such awards generally vest over periods from two to four years.

### **Accounting for Share-Based Compensation**

Share-based compensation expense for the three years ended December 25, 2010, was comprised of:

<u>(in thousands)</u>	<b>For the Years Ended</b>		
	<b>December 25, 2010</b>	<b>December 26, 2009</b>	<b>December 27, 2008</b>
Stock option expense	\$ 2,854	\$ 1,722	\$ 1,569
Employee stock purchase plan expense	37	49	39
Restricted stock expense	1,032	692	1,125
Total share-based compensation	<u>\$ 3,923</u>	<u>\$ 2,463</u>	<u>\$ 2,733</u>

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

<u>(in thousands)</u>	<b>For the Years Ended</b>		
	<b>December 25, 2010</b>	<b>December 26, 2009</b>	<b>December 27, 2008</b>
Cost of services	\$ 827	\$ 294	\$ —
General and administrative expense	719	712	1,824
Research and development expense	2,377	1,457	909
Total share-based compensation expense	<u>\$ 3,923</u>	<u>\$ 2,463</u>	<u>\$ 2,733</u>

Share-based compensation costs in 2010 reflect \$1.3 million of share-based compensation expense relating to the modification of the terms of certain outstanding stock option awards. The modifications included accelerated vesting and extended exercise periods relating to certain employee terminations.

### *Stock Options*

We determine the fair value of each stock option on the date of grant using the Black-Scholes option-pricing formula and recognize the resulting expense over the option's vesting period using the straight-line attribution approach. Below are the calculated weighted-average fair values for 2010, 2009 and 2008 as well as the assumptions used in calculating those values:

	<b>For the Years Ended</b>		
	<b>December 25, 2010</b>	<b>December 26, 2009</b>	<b>December 27, 2008</b>
Weighted-average fair value (per share)	\$ 3.51	\$ 1.98	\$ 2.49
Assumptions:			
Expected term (in years)	4.5 - 6.3	4.5 - 6.3	4.5 - 6.3
Risk-free interest rate	1.39% - 2.75%	1.45% - 2.96%	2.48% - 3.45%
Expected volatility	58.51% - 83.72%	74.94% - 83.6%	73.34% - 76.4%
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.

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- *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 expected volatility 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.

A summary of option activity under our stock plans as of December 25, 2010 and the changes during 2010 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 26, 2009	3,688,003	\$ 6.13	4.68	\$ 3,797
Granted	849,805	5.43		
Exercised	(137,669)	3.79		
Forfeited	(19,670)	4.49		
Expired	(255,075)	7.53		
Outstanding at December 25, 2010	<u>4,125,394</u>	<u>\$ 5.99</u>	<u>4.13</u>	<u>\$ 3,704</u>
Vested and expected to vest at December 25, 2010	<u>3,996,509</u>	<u>\$ 6.03</u>	<u>4.09</u>	<u>\$ 3,587</u>
Exercisable at December 25, 2010	<u>2,836,542</u>	<u>\$ 6.55</u>	<u>3.48</u>	<u>\$ 2,538</u>

As of December 25, 2010, there was \$2.9 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 four years. The total intrinsic value of stock options exercised was \$0.2 million, \$0.2 million, and \$0.1 million in 2010, 2009 and 2008, respectively.

### *Restricted Stock*

A summary of the status of our restricted stock awards as of December 25, 2010 and changes during 2010 is presented below:

<u>Restricted Stock</u>	<u>Number of Shares</u>	<u>Weighted-Average Fair Value at Grant Date</u>
Nonvested at December 26, 2009	356,715	\$ 2.20
Granted	267,238	5.10
Vested	(183,822)	2.64
Forfeited	(3,080)	3.20
Nonvested at December 25, 2010	<u>437,051</u>	<u>\$ 3.78</u>

As of December 25, 2010, there was \$0.9 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 four years. The total fair value of shares vested during 2010, 2009 and 2008 was \$0.5 million, \$0.9 million and \$1.3 million, respectively.

**NOTE 11 INCOME TAXES**

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

(in thousands)	For the Years Ended		
	December 25, 2010	December 26, 2009	December 27, 2008
<b>Current:</b>			
Federal	\$ (1,765)	\$ —	\$ —
State	—	—	—
	(1,765)	—	—
<b>Deferred:</b>			
Federal	(1,692)	(17,980)	(5,712)
State	(8,587)	(1,366)	(635)
	(10,279)	(19,346)	(6,347)
<b>Total</b>	(10,279)	(19,346)	(6,347)
Change in Valuation Allowance	10,279	19,346	6,347
<b>Total, net before intra period allocation</b>	(1,765)	—	—
Intra-period tax allocation	—	—	(2,765)
<b>Total, net</b>	\$ (1,765)	\$ —	\$ (2,765)

The following table includes deferred tax assets and liabilities from both continuing and discontinued operations as of December 25, 2010 and December 26, 2009:

(in thousands)	December 25, 2010	December 26, 2009
<b>Deferred tax assets:</b>		
Federal net operating loss carryforwards	\$ 62,325	\$ 67,019
State net operating loss carryforwards	11,455	3,713
Research and experimental tax credit	12,708	12,670
Income from sale of assets	7,295	—
Deferred research and experimental costs	5,402	6,393
Depreciation	1,237	1,191
Alternative minimum tax credit	854	896
Equity-based and accrued compensation related costs	6,399	4,925
Other	1,302	1,763
Deferred tax assets	108,977	98,570
<b>Deferred tax liabilities:</b>		
Other	(329)	(76)
Deferred tax liabilities	(329)	(76)
Net deferred tax assets	108,649	98,494
Valuation allowance	(108,649)	(98,494)
Net deferred tax assets	\$ —	\$ —

As of December 25, 2010, we have gross federal net operating loss carryforwards of approximately \$178.1 million that expire at various dates through 2030. We have federal research and experimental tax credit carryforwards of approximately \$15.0 million (\$12.7 million, net of unrecognized tax benefit) that expire in varying amounts through 2026. We have federal alternative minimum tax credit carryforwards of \$0.9 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 (IRC), certain significant changes in ownership may restrict the future

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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 calculations performed for the period through December 25, 2010, the Company's tax attributes are not currently limited under Section 382.

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 \$108.6 million and \$98.5 million valuation allowance as of December 25, 2010 and December 26, 2009, respectively.

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

<u>(in thousands)</u>	<u>For the Years Ended</u>		
	<u>December 25, 2010</u>	<u>December 26, 2009</u>	<u>December 27, 2008</u>
<b>Pre-tax (loss) income:</b>			
U.S.	\$ (821)	\$ (18,720)	\$ (25,714)
Foreign	(66)	(7)	(34)
<b>Total</b>	<u>\$ (887)</u>	<u>\$ (18,727)</u>	<u>\$ (25,748)</u>

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

	<u>For the Years Ended</u>		
	<u>December 25, 2010</u>	<u>December 26, 2009</u>	<u>December 27, 2008</u>
Federal statutory rate	(35.0)%	(35.0)%	(34.0)%
State income taxes, net of federal benefit	(5.0)	(5.4)	(5.4)
Foreign tax rate differential	2.6	—	(0.1)
Tax credits	194.7	—	(0.5)
Valuation allowance	1,144.7	105.0	35.8
Federal refund claim	(199.0)	—	—
Return to provision and other prior period adjustments	(1,305.0)	(50.1)	—
Other	3.0	(14.5)	4.2
<b>Total before intra-period allocation</b>	<u>(199.0)%</u>	<u>— %</u>	<u>— %</u>
Intra-period tax allocation	—	—	15.6
<b>Total</b>	<u>(199.0)%</u>	<u>— %</u>	<u>15.6%</u>

During the third quarter of 2010, as a result of new legislation allowing for the carryback of Net Operating Losses generated in 2008 or 2009 for up to five years, we filed a refund claim with the IRS to recover taxes paid in 2007 and 2004 totaling approximately \$1.8 million. We paid no income taxes in calendar years 2009 or 2007. 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. Additionally, in 2010 the Company adjusted its deferred tax asset related to state net operating loss carryforwards (and corresponding valuation allowance) so that the state net operating loss carryforwards reflect the amounts on the Company's various state income tax returns.

### **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 IRC, we are no longer subject to U.S. federal income tax examinations by the IRS for years before 2006. 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. Tax attributes carried forward from 2002 and earlier tax years recently utilized in tax years for which the statute of limitations have not yet expired are also subject to audit. 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 2006 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 2006. 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:

(in thousands)	For the Years Ended		
	December 25, 2010	December 26, 2009	December 27, 2008
Unrecognized tax benefit - opening balance	\$ 5,750	\$ 8,150	\$ 7,718
Gross increases	—	3,634	432
Gross decreases	(1,833)	(6,034)	—
Unrecognized tax benefit - ending balance	<u>\$ 3,917</u>	<u>\$ 5,750</u>	<u>\$ 8,150</u>

As of December 25, 2010, any potential interest and penalties on unrecognized tax benefits were not significant. Unrecognized tax benefits are shown as a reduction in net deferred tax assets in the accompanying balance sheets.

### NOTE 12 LEASES

Aggregate minimum commitments under non-cancelable operating leases, primarily for office and laboratory space and equipment rentals, at December 25, 2010 were as follows (in thousands):

2011	\$875
2012	106
2013	106
2014	26

Aggregate minimum receipts under non-cancelable operating leases, related to our facility in Bray, Ireland are approximately \$131 thousand for 2011 through 2013 and \$33 thousand for 2014.

Rent expense for continuing operations was approximately \$1.1 million, \$1.0 million, and \$1.5 million in 2010, 2009 and 2008, respectively.

### NOTE 13 LICENSES AND ROYALTY AGREEMENTS

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

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*PentaStaph.* In 2009, we sold our PentaStaph vaccine candidate and related assets to GSK for a total consideration of up to \$47.5 million. Under the terms of the sale agreement with GSK, we received an initial cash payment of \$21.5 million and became eligible to receive an additional \$26 million contingent upon four milestone accomplishments. Three of the milestones were accomplished in the fourth quarter of 2009, the first quarter of 2010 and the third quarter of 2010 resulting in revenue of \$21.0 million. We believe we will achieve the final remaining milestone in the next few months.

We are recognizing the upfront payment from GSK ratably over the period of our participation on the joint steering committee. The joint steering committee is currently expected to be 20 months, or through June 2011, from the date of the agreement. We will recognize revenues related to the substantive milestones in the periods we accomplish them.

*NicVAX.* In 2010, we entered into an exclusive worldwide option and licensing agreement with GSK for our NicVAX vaccine candidate, and the development of follow-on next-generation nicotine vaccine candidates. Under the terms of the agreement, GSK paid us an upfront non-refundable fee of \$40 million for (i) an option to exclusively in-license NicVAX on a worldwide basis and (ii) a license to develop follow-on next-generation nicotine vaccines using our intellectual property. In addition to the upfront payment, we are eligible to receive option fees as well as regulatory, development, and sales milestone payments and other payments for NicVAX and follow-on nicotine vaccines. In total, these additional payments may exceed \$460 million. We will also receive potentially double-digit royalties on global sales of NicVAX should GSK exercise its option, as well as royalties on global sales of next-generation nicotine vaccines utilizing intellectual property acquired from us. Under the terms of the agreement, we will be responsible for the cost and performance of the Phase III development of NicVAX. Upon completion of the ongoing Phase III studies, if GSK exercises its option, GSK will take responsibility (including cost responsibilities) for further development and commercialization of NicVAX. In parallel and independent of whether it exercises its option to in-license NicVAX, GSK will be developing a next-generation nicotine vaccine based on our intellectual property together with GSK's own technology.

We are recognizing the upfront payment from GSK ratably over the period of our participation on the joint steering committee. The joint steering committee is currently expected to be 190 months, or through December 2025 from the date of the agreement. If GSK exercises its option, we will recognize any such option payment over the remaining period of the joint steering committee. We recognize revenues related to the substantive milestones in the periods we complete them.

### **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 estimates of the remaining amounts due was approximately \$1.5 million at December 25, 2010 and \$2.1 million at December 26, 2009, which are included in the amounts recorded as accrued rebates.

We have agreements with our employees 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.

[Table of Contents](#)**NOTE 15 SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

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

<u>(in thousands, except per share data)</u>	<u>For the Fiscal 2010 Quarters Ended</u>			
	<u>March 27, 2010</u>	<u>June 26, 2010</u>	<u>September 25, 2010</u>	<u>December 25, 2010</u>
(Loss) income from continuing operations	\$ 5,480	\$ (3,406)	\$ 5,135	\$ (6,331)
Income from discontinued operations	—	—	—	—
Net (loss) income	5,480	(3,406)	5,135	(6,331)
Basic income (loss) per share				
Continuing operations	\$ 0.11	\$ (0.08)	\$ 0.12	\$ (0.15)
Net (loss) income	\$ 0.11	\$ (0.08)	\$ 0.12	\$ (0.15)
Diluted income (loss) per share				
Continuing operations	\$ 0.11	\$ (0.08)	\$ 0.12	\$ (0.15)
Net (loss) income	\$ 0.11	\$ (0.08)	\$ 0.12	\$ (0.15)

<u>(in thousands, except per share data)</u>	<u>For the Fiscal 2009 Quarters Ended</u>			
	<u>March 28, 2009</u>	<u>June 27, 2009</u>	<u>September 26, 2009</u>	<u>December 26, 2009</u>
(Loss) income from continuing operations	\$ (7,046)	\$ (5,808)	\$ (6,983)	\$ 1,110
Income from discontinued operations	—	—	—	—
Net (loss) income	(7,046)	(5,808)	(6,983)	1,110
Basic and diluted (loss) income per share:				
Continuing operations	\$ (0.14)	\$ (0.11)	\$ (0.14)	\$ 0.02
Net (loss) income	\$ (0.14)	\$ (0.11)	\$ (0.14)	\$ 0.02

For the first quarter of 2010, dilutive potential common shares related to our Convertible Senior Note have been excluded from diluted income per share because their inclusion would be anti-dilutive. For the fourth quarter of 2009, dilutive potential common shares related to our stock options and Convertible Senior Note have been excluded from diluted income per share because their inclusion would be anti-dilutive.



**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 25, 2010. Based upon this evaluation, our management has concluded that our disclosure controls and procedures were effective as of December 25, 2010.

**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).

Our 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 accounting principles generally accepted in the United States of America. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 25, 2010, and this assessment identified no material weaknesses in our internal control over financial reporting as of that date. Based on our evaluation under the framework in Internal Control – Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 25, 2010. The effectiveness of our internal control over financial reporting as of December 25, 2010 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 was no change in the Company's internal control over financial reporting during the most recently completed quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None

**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 3(a) will be contained in our Proxy Statement, which we intend to file within 120 days following our fiscal year end, December 25, 2010, and such information is incorporated herein by reference.

**ITEM 11. EXECUTIVE COMPENSATION**

The information called for by this Item will be contained in our Proxy Statement, which we intend to file within 120 days following our fiscal year end, December 25, 2010, and such information is incorporated herein by reference.

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

The information called for by this Item will be contained in our Proxy Statement, which we intend to file within 120 days following our fiscal year end, December 25, 2010, 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 25, 2010, 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 25, 2010, 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:

	<u>Page</u>
<a href="#">Reports of Independent Registered Public Accounting Firm</a>	33
<a href="#">Consolidated Balance Sheets at December 25, 2010 and December 26, 2009</a>	35
<a href="#">Consolidated Statements of Operations for the years ended December 25, 2010, December 26, 2009 and December 27, 2008</a>	36
<a href="#">Consolidated Statements of Stockholders' Equity for the years ended December 25, 2010, December 26, 2009 and December 27, 2008</a>	37
<a href="#">Consolidated Statements of Cash Flows for the years ended December 25, 2010, December 26, 2009 and December 27, 2008</a>	38
<a href="#">Notes to Consolidated Financial Statements</a>	39

**(2) FINANCIAL STATEMENT SCHEDULES**

<a href="#">Schedule II - Valuation and Qualifying Accounts and Reserves</a>	61
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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)
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)+

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- 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 Nabi Biopharmaceuticals has 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: Raafat E.F. Fahim, Ph.D., Matthew Kalnik, Ph.D. and Paul Kessler, M.D.+
- 10.8 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)+
- 10.9 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)++
- 10.10 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)
- 10.11 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)++
- 10.12 Non-Competition and Non-solicitation 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)
- 10.13 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)
- 10.14 Employment Agreement between Nabi Biopharmaceuticals and Raafat E.F. 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)+
- 10.15 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)+
- 10.16 Change of Control Severance Agreement between Nabi Biopharmaceuticals and Paul Kessler, M.D. dated August 21, 2007 (incorporated by reference to Exhibit 10.28 to our Annual Report on Form 10-K for the year ended December 27, 2008)+
- 10.17 Asset Purchase Agreement between Nabi Biopharmaceuticals and GlaxoSmithKline Biologicals S.A., dated August 5, 2009 (incorporated by reference to Exhibit 2.1 to our Quarterly Report on Form 10-Q for the quarter ended September 26, 2009)++
- 10.18 Consulting Agreement between Nabi Biopharmaceuticals and Linda Jenckes dated August 1, 2009 (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended September 26, 2009)+
- 10.19 Employment Agreement between Nabi Biopharmaceuticals and Matthew W. Kalnik, Ph.D., dated March 17, 2009 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 28, 2009)+

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10.20	Change of Control Severance Agreement between Nabi Biopharmaceuticals and Matthew W. Kalnik, Ph.D., dated March 17, 2009 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 28, 2009)+
10.21	Exclusive Option and License Agreement between Nabi Biopharmaceuticals and GlaxoSmithKline Biologicals S.A., dated November 13, 2009 (incorporated by reference to Annex A to our Definitive Proxy Statement dated February 4, 2010)++
23.	Consent of Independent Registered Public Accounting Firm*
31.1	Rule 13a-14(a)/15d-14(a) Certification*
32.	Section 1350 Certification
+	<i>Management contract or compensatory plan or arrangement filed pursuant to Item 15(b) of Form 10-K.</i>
++	<i>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.</i>
*	<i>Filed herewith</i>

**Nabi Biopharmaceuticals**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 8th day of March 2011.

**Nabi Biopharmaceuticals**

By:           /s/ RAAFAT E.F. FAHIM, PH.D.            
          Raafat E.F. Fahim, Ph.D.  
          Chief Executive Officer, President, Acting Chief Financial Officer and  
          Director

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

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
<u>          /s/ RAAFAT E.F. FAHIM, PH.D.          </u> Raafat E.F. Fahim, Ph.D.	Chief Executive Officer, President, Acting Chief Financial Officer and Director	March 8, 2011
<u>          /s/ RONALD B. KOCAK          </u> Ronald B. Kocak	Controller and Chief Accounting Officer	March 8, 2011
<u>          /s/ JASON ARYEH          </u> Jason Aryeh	Director	March 8, 2011
<u>          /s/ DAVID L. CASTALDI          </u> David L. Castaldi	Director	March 8, 2011
<u>          /s/ GEOFFREY F. COX, PH.D.          </u> Geoffrey F. Cox, Ph.D.	Non-executive Chairman of the Board of Directors	March 8, 2011
<u>          /s/ PETER B. DAVIS          </u> Peter B. Davis	Director	March 8, 2011
<u>          /s/ RICHARD A. HARVEY, JR.          </u> Richard A. Harvey, Jr.	Director	March 8, 2011
<u>          /s/ TIMOTHY LYNCH          </u> Timothy Lynch	Director	March 8, 2011

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

<u>Classification</u>	<u>Balance at Beginning of Period</u>	<u>Additions</u>		<u>Deductions</u>		<u>Balance at End of Period</u>
		<u>Charged to Costs and Expenses</u>	<u>Charged to Other Accounts</u>	<u>Write-Offs Charged Against Reserve</u>	<u>Other</u>	
<b>Year ended December 25, 2010:</b>						
Net deferred tax asset valuation allowance	\$ 98,494	10,155	—	—	—	\$ 108,649
<b>Year ended December 26, 2009:</b>						
Net deferred tax asset valuation allowance	\$ 86,634	11,860	—	—	—	\$ 98,494
<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

**Nabi Biopharmaceuticals****EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
23.	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a)/15d-14(a) Certification
32.	Section 1350 Certification

**Consent of Independent Registered Public Accounting Firm**

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

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 8, 2011, 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 25, 2010.

/s/ Ernst & Young LLP

McLean, Virginia

March 8, 2011





**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 Annual Report on Form 10-K for the year ended December 25, 2010 (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 25, 2010 and the results of operations of the Company for the year ended December 25, 2010.

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 8, 2011

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

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