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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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

For the quarterly period ended September 24, 2011

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 000-04829

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**Nabi Biopharmaceuticals**

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) 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 whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer, large accelerated filer" and "small reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The number of shares outstanding of the registrant's common stock, par value \$.10 per share, at October 24, 2011, was 42,884,809 shares.

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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Nabi Biopharmaceuticals****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)****(In thousands)**

	<u>September 24, 2011</u>	<u>December 25, 2010</u>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 92,948	\$ 53,564
Marketable securities	9,065	54,603
Receivables	891	1,030
Prepaid expenses and other current assets	873	829
<b>Total current assets</b>	<u>103,777</u>	<u>110,026</u>
Marketable securities	—	2,500
Property and equipment, net	274	597
Other assets	—	748
<b>Total assets</b>	<u>\$ 104,051</u>	<u>\$ 113,871</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 983	\$ 552
Accrued expenses and other current liabilities	4,564	7,377
Deferred revenue	2,526	7,797
Liabilities of discontinued operations	1,817	2,207
<b>Total current liabilities</b>	<u>9,890</u>	<u>17,933</u>
Deferred revenue	33,474	35,368
<b>Total liabilities</b>	<u>43,364</u>	<u>53,301</u>
<b>Stockholders' equity:</b>		
Series A Junior participating preferred stock	—	—
Common stock	6,358	6,321
Capital in excess of par value	372,985	370,366
Treasury stock	(92,567)	(92,567)
Other comprehensive loss	(1)	(3)
Accumulated deficit	(226,088)	(223,547)
<b>Total stockholders' equity</b>	<u>60,687</u>	<u>60,570</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 104,051</u>	<u>\$ 113,871</u>

*See accompanying notes to condensed consolidated financial statements.*

## Nabi Biopharmaceuticals

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except share amounts)

	For the Three Months Ended		For the Nine Months Ended	
	September 24, 2011	September 25, 2010	September 24, 2011	September 25, 2010
<b>Revenue:</b>				
Revenue	\$ 1,086	\$ 12,335	\$ 14,003	\$ 30,925
<b>Operating expenses:</b>				
Costs of services	344	843	1,518	2,128
Research and development expenses	4,388	6,801	16,179	19,236
General and administrative expenses	1,291	1,415	4,059	4,380
<b>Total operating expenses</b>	<b>6,023</b>	<b>9,059</b>	<b>21,756</b>	<b>25,744</b>
<b>Operating income (loss)</b>	<b>(4,937)</b>	<b>3,276</b>	<b>(7,753)</b>	<b>5,181</b>
Interest income	32	75	154	166
Interest expense	—	(13)	—	(200)
Other income (expense), net	(17)	32	58	297
<b>Income (loss) from continuing operations before income taxes</b>	<b>(4,922)</b>	<b>3,370</b>	<b>(7,541)</b>	<b>5,444</b>
Benefit from income taxes	2,018	1,765	2,018	1,765
<b>Income (loss) from continuing operations</b>	<b>(2,904)</b>	<b>5,135</b>	<b>(5,523)</b>	<b>7,209</b>
<b>Income from discontinued operations, (net of tax provision of \$2.0 million)</b>	<b>2,982</b>	<b>—</b>	<b>2,982</b>	<b>—</b>
<b>Net income (loss)</b>	<b>\$ 78</b>	<b>\$ 5,135</b>	<b>\$ (2,541)</b>	<b>\$ 7,209</b>
<b>Basic income (loss) per share</b>				
Continuing operations	\$ (0.07)	\$ 0.12	\$ (0.13)	\$ 0.16
Discontinued operations	\$ 0.07	\$ —	\$ 0.07	\$ —
<b>Diluted income (loss) per share</b>				
Continuing operations	\$ (0.07)	\$ 0.12	\$ (0.13)	\$ 0.16
Discontinued operations	\$ 0.07	\$ —	\$ 0.07	\$ —
<b>Basic weighted average shares outstanding</b>	<b>42,397</b>	<b>42,356</b>	<b>42,269</b>	<b>45,084</b>
<b>Diluted weighted average shares outstanding</b>	<b>42,397</b>	<b>42,538</b>	<b>42,269</b>	<b>45,304</b>

*See accompanying notes to condensed consolidated financial statements.*

## Nabi Biopharmaceuticals

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	For the Nine Months Ended	
	September 24, 2011	September 25, 2010
<b>Cash flow from operating activities:</b>		
Net income (loss) from continuing operations	\$ (5,523)	\$ 7,209
Adjustments to reconcile net income (loss) from continuing operations to net cash provided by (used in) operating activities from continuing operations:		
Depreciation and amortization	130	302
Non-cash intra-period tax allocation	(2,018)	—
Accretion of discount on convertible senior notes	—	99
Share-based compensation	2,011	1,895
Loss (gain) on sale of property and equipment	29	(4)
Changes in assets and liabilities:		
Receivables	139	5,135
Prepaid expenses and other assets	704	(1,485)
Accounts payable, accrued expenses and other liabilities	(2,375)	952
Deferred revenue	(7,165)	27,985
<b>Net cash provided by (used in) operating activities from continuing operations</b>	<b>(14,068)</b>	<b>42,088</b>
Net cash used in operating activities from discontinued operations	(391)	(609)
<b>Net cash provided by (used in) operating activities</b>	<b>(14,459)</b>	<b>41,479</b>
<b>Cash flow from investing activities:</b>		
Proceeds from maturities of marketable securities	59,680	103,615
Purchases of marketable securities	(11,640)	(118,966)
Proceeds from sales of property and equipment	158	50
Capital expenditures	(1)	(3)
<b>Net cash provided by (used in) investing activities from continuing operations</b>	<b>48,197</b>	<b>(15,304)</b>
Net cash provided by investing activities from discontinued operations	5,000	—
<b>Net cash provided by (used in) investing activities</b>	<b>53,197</b>	<b>(15,304)</b>
<b>Cash flow from financing activities:</b>		
Proceeds from issuances of common stock for employee benefit plans	646	413
Purchase of common stock for treasury	—	(42,768)
Repurchase of convertible senior notes	—	(6,050)
<b>Net cash provided by (used in) financing activities</b>	<b>646</b>	<b>(48,405)</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>39,384</b>	<b>(22,230)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>53,564</b>	<b>59,510</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 92,948</b>	<b>\$ 37,280</b>

*See accompanying notes to condensed consolidated financial statements.*

**Nabi Biopharmaceuticals**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**NOTE 1 COMPANY OVERVIEW**

We are a biopharmaceutical company mainly focused on the development of vaccines for nicotine addiction. We leverage our experience and knowledge in powering the human immune system to target serious unmet medical needs in this area.

In 2006, we initiated a strategic 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.

Pursuant to the terms of this agreement, we received a \$40 million initial payment and 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 initial payment, if GSK exercises the NicVAX option we could 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. If GSK does not exercise its option but develops the next-generation candidate, our maximum possible milestones under the agreement would be reduced to \$290 million. Under the agreement, 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 any next-generation nicotine vaccines regardless of whether GSK exercises its option. In the third quarter of 2011 we announced that the first of our two Phase III clinical trials failed to meet its primary endpoint (see further detail below), which reduces the likelihood that GSK will exercise its option.

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. Pre-clinical animal studies with NicVAX have shown that vaccination prevents the majority of nicotine from reaching the brain and blocks the pharmacological effects of nicotine, including effects that can lead to addiction or can reinforce and maintain addiction.

On July 18, 2011, we announced that NicVAX did not meet its primary endpoint in the first of our two confirmatory Phase III clinical trials. A preliminary assessment of the trial data showed that subjects treated with NicVAX quit smoking at a similar rate of approximately 11% compared to subjects who received placebo. As in previous trials, NicVAX was well-tolerated with a clinically acceptable safety and tolerability profile. The study was a double-blinded, placebo-controlled trial which enrolled approximately 1,000 subjects. The primary endpoint of the study was the abstinence rate for 16 weeks ending at 12 months. Abstinence was evaluated by self-reported cigarette consumption and biologically verified by exhaled carbon monoxide. Secondary endpoints included the abstinence rate at various time intervals, safety and immunogenicity, and the effect of NicVAX on withdrawal symptoms, cigarette consumption, smoking satisfaction and nicotine dependency. Further *post-hoc* analysis of the data indicated that subjects with higher anti-nicotine antibodies quit smoking for 36 weeks (from weeks 17 to 52) at a significantly greater rate than placebo, consistent with earlier finding from the Phase IIb proof-of-concept. These sub-population associations await confirmation in the second Phase III trial.

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In March 2010, we initiated the second Phase III trial and announced the completion of enrollment in this Phase III trial in November 2010. The results of this second Phase III clinical trial, which has a similar design and conduct to the first trial are expected before the end of this year. Data from this second trial may provide clues that could help explain the results from the first trial.

The results of the first Phase III trial were unexpected in view of the encouraging data from our Phase IIb proof-of-concept announced in November 2007. The Phase IIb study demonstrated statistically significant rates of smoking cessation and continuous long-term smoking abstinence at 6 and 12 months for subjects injected with NicVAX who had the highest immune response (top 30%) as compared with subjects injected with placebo. 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 and in June 2009, we announced that we received Scientific Advice from the European Medicines Agency (EMA). 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 the first such trial for an addiction vaccine. The results from this trial are discussed above.

In addition to our NicVAX development effort, during the second quarter of 2011 we completed our work to help develop PentaStaph™ [*Pentavalent S. aureus Vaccine*] under contract with 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 November 2009, we sold PentaStaph to GSK under an Asset Purchase Agreement for a total consideration of \$46 million including a \$20 million upfront payment and \$26 million payable upon achievement of certain milestones. At the same time, we received 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. The final milestone of \$5 million was earned in the first quarter of 2011 and we received payment in the second quarter.

### **NOTE 2 BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

In management's opinion, the accompanying condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The condensed consolidated balance sheet at December 25, 2010, has been derived from audited consolidated financial statements as of that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP) have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the U.S. Securities and Exchange Commission. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these condensed consolidated financial statements are read in conjunction with the Consolidated Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 25, 2010, filed with the Securities and Exchange Commission.

*Principles of consolidation and presentation:* The condensed 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 of our wholly-owned subsidiaries are dormant or are otherwise non-operative. Our fiscal year ends on the last Saturday of December; consequently, we will have a 53-week fiscal year in 2011.

*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.

*Financial instruments:* The carrying amounts of financial instruments including cash equivalents, marketable securities, receivables and accounts payable reflect approximate fair value as of September 24, 2011, and December 25, 2010, because of the relatively short-term nature of these instruments.

*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, and government agency and FDIC backed notes with maturities typically less than eighteen months. Marketable securities are classified as available-for-sale and recorded at fair value; unrealized gains and losses 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

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and identified no “permanent” or “other than temporary” impairment during the three and nine months ended September 24, 2011. Our investment policies and procedures are reviewed periodically including by management and our audit committee to minimize credit risk.

*Collaborative arrangements:* We are an active participant with exposure to significant risks and rewards of commercialization relating to the development of NicVAX and future generation nicotine vaccines based on NicVAX technology. 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.

*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.

For arrangements entered into prior to December 26, 2010, 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.

For arrangements entered into or materially modified after December 25, 2010, 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 relative selling price, determined pursuant to a selling price hierarchy, and recognize revenue for that element according to its characteristics. We did not enter into or materially modify any revenue arrangements subsequent to December 25, 2010.

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. The joint steering committee related to the NicVAX agreement is currently expected to operate for 190 months from the date of the agreement (or through December 2025). Our efforts under the joint steering committee related to the PentaStaph agreement were completed in the second quarter of 2011; accordingly, we have fully recognized the upfront payment related to the PentaStaph agreement.

For milestones that are deemed substantive, we recognize the contingent revenue when: (i) the milestones have been achieved; (ii) no further performance obligations with respect to the milestones exist; and (iii) collection is reasonably assured. A milestone is 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 cost reimbursable grants and contracts to determine whether we should report such reimbursements as revenue or as an offset to research and development expenses incurred.

*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. 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. For the three months ended September 24, 2011, there were no cost reimbursements from government grants to offset research and development expenses. For the three months ended September 25, 2010, we recorded approximately \$2.7 million of cost reimbursements from government grants as a reduction to research and development expenses. For the nine months ended September 24, 2011 and September 25, 2010, we recorded approximately \$0.3 million and \$7.2 million respectively, of cost reimbursements from government grants as a reduction to research and development expenses.

*Share-based compensation:* We account for share-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 for stock options is determined at the grant date using an option pricing model; share-based compensation cost for restricted stock is determined at the grant date based on the closing price of our common stock on that date. 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.



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*Income taxes:* We account for income taxes using the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. For interim periods, we recognize an income tax provision (benefit) based on an estimated annual effective tax rate expected for the entire year. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. We also recognize a tax benefit from uncertain tax positions only if it is “more likely than not” that the position is sustainable based on its technical merits. Our policy is to recognize interest and penalties on uncertain tax positions as a component of income tax expense. We consider discontinued operations for purposes of determining the amount of tax benefits that result from a loss from continuing operations.

*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), including foreign currency translation adjustments and unrealized gains (losses) on our available-for-sale marketable securities.

*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. 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 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 in 2010 on our Convertible Senior Notes) 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, in 2010, the common shares underlying our Convertible Senior Notes. The dilutive impact of potential common shares resulting from stock options is determined by applying the treasury stock method. The dilutive impact in 2010 of potential common shares resulting from our Convertible Senior Notes is 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 for the nine month period ended September 24, 2011. For the three month period ended September 24, 2011 and for the three- and nine month periods ended September 25, 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 for shares related to stock options using the treasury stock method. A total of approximately 4.5 million, 4.0 million and 4.0 million potential dilutive shares related to “out of the money” stock options have been excluded in the calculation of diluted net income per share for the three month period ending September 24, 2011 and for the three- and nine month periods ended September 25, 2010, respectively, as their inclusion would be anti-dilutive.

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

*New accounting pronouncements:* In October 2009, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update 2009-13, “Revenue Recognition (Topic 605) Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force,” or ASU 2009-13. ASU 2009-13 amends existing accounting guidance for separating consideration in multiple-deliverable arrangements. ASU 2009-13 establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific evidence is not available, or the estimated selling price if neither vendor-specific evidence nor third-party evidence are available. ASU 2009-13 eliminates the residual method of allocation and requires that consideration be allocated at the inception of the arrangement to all deliverables using the “relative selling price method.” The relative selling price method allocates any discount in the arrangement proportionately to each deliverable on the basis of each deliverable’s selling price. ASU 2009-13 requires that a vendor determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a stand-alone basis.

The Company adopted the provisions of ASU 2009-13 effective December 26, 2010, for revenue arrangements entered into or materially modified in fiscal years beginning on or after that date. The adoption did not have any material effect on our condensed consolidated balance sheets, condensed consolidated statements of operations and condensed consolidated statements of cash flows for any historical periods or as of, or for, the three- and nine month periods ended September 24, 2011 because we did not enter into or materially modify any revenue arrangements subsequent to December 26, 2010. We are not able to reasonably estimate the effect of adopting these standards on future periods because the impact will vary based on the nature and volume of new or materially modified revenue arrangements in any given period.

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In April 2010, the FASB issued Accounting Standards Update 2010-17, "Revenue Recognition—Milestone Method (Topic 605) Milestone Method of Revenue Recognition, a consensus of the FASB Emerging Issues Task Force" or ASU 2010-17. ASU 2010-17 provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. A vendor can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. For the milestone to be considered substantive, the consideration earned by achieving the milestone should meet all of the following criteria: (i) be commensurate with either the vendor's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the vendor's performance to achieve the milestone, (ii) relate solely to past performance, and (iii) be reasonable relative to all deliverables and payment terms in the arrangement. An individual milestone may not be bifurcated and an arrangement may include more than one milestone. Accordingly, an arrangement may contain both substantive and non-substantive milestones.

The Company adopted the provisions of ASU 2010-17 effective December 26, 2010, for milestones achieved on or after that date. Since the Company's existing policies are consistent with those contained in ASU 2010-17, the adoption of ASU 2010-17 did not have any material effect on our condensed consolidated balance sheets, condensed consolidated statements of operations and condensed consolidated statements of cash flows for any historical periods or as of, or for the three- and nine month periods ended September 24, 2011. We believe that the effect of adopting these standards on future periods will not be material.

### NOTE 3 AVAILABLE FOR SALE INVESTMENTS

The amortized cost, gross unrealized gains and losses and estimated fair value of available-for-sale short-term investments by security classification as of September 24, 2011 and December 25, 2010, were as follows:

<u>September 24, 2011</u> <u>(In thousands)</u>	<u>Amortized Costs</u>	<u>Gross</u> <u>Unrealized Gains</u>	<u>Gross</u> <u>Unrealized Losses</u>	<u>Estimated</u> <u>Fair Values</u>
Government-sponsored securities	\$ 5,186	\$ —	\$ (1)	\$ 5,185
Corporate debt securities	3,880	—	—	3,880
<b>Total securities</b>	<b>\$ 9,066</b>	<b>\$ —</b>	<b>\$ (1)</b>	<b>\$ 9,065</b>

  

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

During the nine months ended September 24, 2011 and September 25, 2010, we had no 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.

The contractual maturities of available-for-sale investments by security classification as of September 24, 2011 and December 25, 2010, are as follows:

<u>September 24, 2011</u> <u>(In thousands)</u>	<u>Total</u>	<u>Less than 12 Months</u>	<u>12 Months or More</u>
Government-sponsored securities	\$ 5,185	\$ 5,185	\$ —
Corporate debt securities	3,880	3,880	—
<b>Total securities</b>	<b>\$ 9,065</b>	<b>\$ 9,065</b>	<b>\$ —</b>

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December 25, 2010 (In thousands)	Total	Less than 12 Months	12 Months or More
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>

### NOTE 4 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. Our estimate of the remaining amounts due was approximately \$1.1 million at September 24, 2011 and \$1.5 million at December 25, 2010, which are included in the amounts recorded as current liabilities from discontinued operations. We intend to pay these obligations as they are re-billed to us.

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 termination of employment subsequent to a change in control of the Company.

#### *Litigation*

We are a party 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.

### NOTE 5 INCOME TAXES

We file income tax returns in the U.S., with various states and foreign jurisdictions, and 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. As of September 24, 2011, we have recorded a valuation allowance against all of our deferred tax assets. For interim periods, we recognize a provision (benefit) for income taxes based on an estimated annual effective tax rate expected for the entire year. Based on our current projection, we expect our annual effective tax rate for 2011 to be 0%.

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 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.

Under the tax statute of limitations applicable to the Internal Revenue Code, we are no longer subject to U.S. federal income tax examinations by the Internal Revenue Service for years before 2004. However, because we are carrying forward income tax attributes, such as net operating losses and tax credits from 2002 and earlier tax years, these attributes can still be audited when used on returns filed in the future. Under the statutes of limitation applicable to most state income tax laws, we are no longer subject to state income tax examinations by tax authorities for years before 2004 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 2004. We are subject to foreign tax examinations by tax authorities for all years of operation.

At December 25, 2010, we had net U.S. Federal operating loss carry-forwards of approximately \$138 million that we can use in certain circumstances to offset future U.S. taxable income. Pursuant to Section 382 of the Internal Revenue Code, the Company's use of the operating loss carry-forwards for U.S. federal income tax purposes may be limited in any given year as a result of certain changes in the Company's ownership, including significant increases in ownership by the Company's 5-percent shareholders. While the company believes that its operating loss carry-forwards as of September 24, 2011 are not limited under section 382, significant changes in ownership in the future may limit such usage. In August 2011, in an effort to protect the use of its operating loss carry-forwards, the Company adopted a "NOL" Rights Agreement that discourages significant changes in ownership of the Company's stock that might limit the use of our operating loss carry-forwards, as further discussed in Note 9.

**NOTE 6 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 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 value at September 24, 2011 and December 25, 2010. 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 inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy and the fair values are based on period-end statements supplied by the various banks and brokers. The majority of our funds were deposited in institutional money market mutual funds with the remainder held in regular interest bearing and non-interest bearing depository accounts with commercial banks.

The inputs used in measuring the fair value of our available-for-sale marketable securities are considered to be Level 2 in accordance with the three-tier fair value hierarchy. These securities are valued using a multi-dimensional pricing model that includes a variety of inputs, including quoted prices for similar assets and liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active. To assess the fair value of these securities, we obtain fair values from an independent third-party valuation service provider. As we are responsible for the determination of fair value, we review the values provided by the independent third-party valuation service provider for reasonableness, which could include reviewing other publicly available information.

September 24, 2011 (In thousands)	Total	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
		Level 1	Level 2	Level 3
Cash and cash equivalents	\$ 92,948	\$ 92,948	\$ —	\$ —
Government-sponsored enterprise securities	5,185	—	5,185	—
Corporate debt and other securities	3,880	2,733	1,147	—
Total	<u>102,013</u>	<u>95,681</u>	<u>6,332</u>	<u>—</u>

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December 25, 2010 (In thousands)	Total	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
		Level 1	Level 2	Level 3
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>

### NOTE 7 TREASURY STOCK

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. Since the inception of the program in December 2007, 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 the first nine months of 2010, we purchased 7.8 million shares for \$42.3 million at an average cost per share of \$5.45. No shares were repurchased during the nine months ended September 24, 2011.

### NOTE 8 SHARE BASED COMPENSATION

A summary of option activity under our stock compensation plans as of September 24, 2011, and the changes during the first nine months of 2011 is presented below:

<u>Options</u>	<u>Number of Options</u>
Outstanding at December 25, 2010	4,125,394
Granted	850,350
Exercised	(144,788)
Forfeited	(210,055)
Expired	(110,202)
Outstanding at September 24, 2011	<u>4,510,699</u>
Exercisable at September 24, 2011	<u>3,121,284</u>

We granted options to purchase 850,350 shares at exercise prices ranging from \$5.45 to \$5.81 during the first nine months of 2011, with an average fair value at the date of grant of \$2.90. These grants become exercisable between one and four years after the date of grant. We estimate the fair value of each stock option on the date of grant using a Black-Scholes option-pricing formula, applying the following assumptions and amortize expense over the option's vesting period using the straight-line attribution approach:

*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. We estimate our expected term to be between 4.5 and 7 years.

*Risk-Free Interest Rate:* The Company based the risk-free interest rate used in the assumptions 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. We used a risk-free interest rate of 1.27% - 2.47% per annum.

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*Expected Volatility:* The volatility factor used in the assumptions is based on the historical price of our stock over the most recent period commensurate with the expected term of the stock option award. We used expected volatility of 56.3% - 71.3%.

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

We recognized approximately \$0.3 million and \$1.1 million of expense related to stock options in the three- and nine month periods ended September 24, 2011, respectively.

A summary of our restricted stock awards as of September 24, 2011 and the changes during the first nine months of 2011 is presented below:

<u>Awards</u>	<u>Number of Awards</u>
Nonvested at December 25, 2010	437,051
Granted	226,268
Vested	(225,252)
Forfeited	(613)
Nonvested at September 24, 2011	437,454

We recognized approximately \$0.5 million and \$0.9 million of expense related to restricted stock awards in the three- and nine month periods ended September 24, 2011, respectively. During the three month period ended September 24, 2011, 72,012 awards were accelerated as result of a reduction in force in order to reduce costs. During the first nine months of 2011, we granted 226,268 restricted shares with a calculated average fair value of \$5.81, which vest over four years in equal installments after the date of the grant.

### **NOTE 9 NOL RIGHTS AGREEMENT**

On August 25, 2011, our Board of Directors adopted a stockholder Rights Agreement with American Stock Transfer & Trust Company, LLC, as rights agent, in an effort to prevent an "ownership change" under Section 382 from occurring and thereby protect the value of our net operating losses. The Rights Agreement serves the interests of all stockholders by seeking to protect the use of our deferred tax assets to offset future tax liabilities. Under the Rights Agreement, the Board of Directors declared a non-taxable dividend of one preferred share purchase right for each outstanding share of common stock to be distributed to stockholders of record on August 25, 2011. These rights will become active if triggered under the Rights Agreement. If any person or group acquires 4.99 percent or more of the outstanding shares of common stock, the rights under the Rights Agreement would be triggered resulting in significant dilution in the ownership interest of such person or group in Nabi stock. Stockholders who currently beneficially own 4.99 percent or more of the outstanding shares of common stock would not trigger the preferred share purchase rights unless they acquire additional shares. The Rights Agreement has a three-year term and will be reviewed periodically by a committee of the Board to assess whether the agreement should be maintained.

### **NOTE 10 LICENSES AND ROYALTY ARRANGEMENTS**

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

*PentaStaph:* In 2009, we sold our PentaStaph vaccine candidate and related assets to GSK for a total consideration of up to \$46 million, including a \$20 million upfront payment and \$26 million payable upon achievement of certain milestones related to PentaStaph. At the same time, we received an additional \$1 million for the sale of our *Staphylococcus epidermidis* vaccine program and an additional \$0.5 million for the transfer of certain specified materials. We have completed all of the milestones and we received the final \$5 million milestone payment in April 2011. We recognized the upfront payment from GSK ratably over the period of our participation on the PentaStaph joint steering committee, which ended in the second quarter of 2011.

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**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 if GSK exercises the NicVAX option. If GSK does not exercise its option but develops a next-generation candidate, our maximum possible milestones under the agreement would be reduced to \$290 million. Under the agreement, we are also eligible to receive 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 regardless of whether GSK exercises its option. In the third quarter we announced that the first of our two Phase III clinical trials failed to meet its primary endpoint (see further detail below), which reduces the likelihood that GSK will exercise its option.

We are recognizing the upfront payment from GSK ratably over the period of our participation on the NicVAX joint steering committee. The joint steering committee is currently expected to continue in effect for 190 months from the date of the NicVAX agreement, or through December 2025. 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.

**Other:** In November 2006, we sold certain assets related to our PhosLo operations. Under the sale agreement, we received \$65 million in cash at closing and \$18 million in milestones to date, of which \$5 million was related to the first commercial sale of a new liquid formulation and was received in the third quarter of 2011. We also are entitled to additional contingent milestone payments of \$2.5 million upon approval of a new indication for PhosLo and royalties of up to \$64.5 million on annual sales of the new formulation over a base amount of \$32 million for 10 years after the November 14, 2006 closing date.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

### **FORWARD LOOKING STATEMENTS**

*Statements in this quarterly report 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 the second of our two Phase III clinical trials for NicVAX (our first Phase III clinical trial failed to meet its primary endpoint) or our Dutch study of NicVAX in combination with varenicline; 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 royalty payments under the PhosLo agreement; 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. Some of these factors are more fully discussed, as are other factors, in our Annual Report on Form 10-K for the fiscal year ended December 25, 2010 filed with the Securities and Exchange Commission. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.*

The following is a discussion and analysis of the major factors contributing to our financial condition and results of operations for the three- and nine month periods ended September 24, 2011. The discussion and analysis should be read in conjunction with the condensed consolidated financial statements and notes thereto.

### **OVERVIEW**

We are a biopharmaceutical company focused on the development of vaccines for nicotine addiction. We leverage our experience and knowledge in powering the human immune system to target serious unmet medical needs in this area.

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In 2006, we initiated a strategic 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.

Pursuant to the terms of this agreement, we received a \$40 million initial payment and 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 initial payment, if GSK exercises its option we could 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. If GSK does not exercise its option but develops the next-generation candidate, our maximum possible milestones under the agreement would be reduced to \$290 million. Under the agreement, 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 any next-generation nicotine vaccines regardless of whether GSK exercises its option. In the third quarter we announced that the first of our two Phase III clinical trials failed to meet its primary endpoint (see further detail below), which reduces the likelihood that GSK will exercise its option.

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. Pre-clinical animal studies with NicVAX have shown that vaccination prevents the majority of nicotine from reaching the brain and blocks the pharmacological effects of nicotine, including effects that can lead to addiction or can reinforce and maintain addiction.

On July 18, 2011, we announced that NicVAX did not meet its primary endpoint in the first of our two confirmatory Phase III clinical trials. A preliminary assessment of the trial data showed that subjects treated with NicVAX quit smoking at a similar rate of approximately 11% compared to subjects who received placebo. As in previous trials, NicVAX was well-tolerated with a clinically acceptable safety and tolerability profile. The study was a double-blinded, placebo-controlled trial which enrolled approximately 1,000 subjects. The primary endpoint of the study was the abstinence rate for 16 weeks ending at 12 months. Abstinence was evaluated by self-reported cigarette consumption and biologically verified by exhaled carbon monoxide. Secondary endpoints included the abstinence rate at various time intervals, safety and immunogenicity, and the effect of NicVAX on withdrawal symptoms, cigarette consumption, smoking satisfaction and nicotine dependency. Further *post-hoc* analysis of the data indicated that subjects with higher anti-nicotine antibodies quit smoking for 36 weeks (from weeks 17 to 52) at a significantly greater rate than placebo, consistent with earlier finding from the Phase IIb proof-of-concept. These sub-population associations await confirmation in the second Phase III trials.

In March 2010, we initiated the second Phase III trial and announced the completion of enrollment in this Phase III trial in November 2010. The results of this second Phase III clinical trial, which has a similar design and conduct to the first trial, are expected before the end of this year. Data from this second trial may provide clues that could help explain the results from the first trial.

The results of the first Phase III trial were unexpected in view of the encouraging data from our Phase IIb proof-of-concept announced in November 2007. The Phase IIb demonstrated statistically significant rates of smoking cessation and continuous long-term smoking abstinence at 6 and 12 months for subjects injected with NicVAX who had the highest immune response (top 30%) as compared with subjects injected with placebo. 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 and in June 2009, we announced that we received Scientific Advice from the EMA. 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. The results from this trial are discussed above.



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In addition to our NicVAX development effort, during the second quarter of 2011 we completed our work to help develop PentaStaph under contract with 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 November 2009, we sold PentaStaph to GSK under an Asset Purchase Agreement for a total consideration of \$46 million including a \$20 million upfront payment and \$26 million payable upon achievement of certain milestones. At the same time, we received 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. The final milestone of \$5 million was earned in the first quarter of 2011 and we received payment in the second quarter.

### **FOR THE THREE MONTHS ENDED SEPTEMBER 24, 2011 AND SEPTEMBER 25, 2010**

*Revenue:* Revenue reflects (i) the amortization of upfront fees received under our PentaStaph and NicVAX agreements, (ii) the completion of substantive milestones included in those agreements, and (iii) services provided to GSK. Total revenue in the third quarter of 2011 of \$1.1 million included \$0.6 million of deferred revenue amortization from the NicVAX agreement, and \$0.5 million for services under the PentaStaph and NicVAX agreements. Total revenue in the third quarter of 2010 of \$12.3 million included \$8 million in milestones from PentaStaph, \$3.2 million of deferred revenue amortization from the PentaStaph and NicVAX agreements and \$1.1 million for services under the PentaStaph and NicVAX agreements. We expect our revenue for the remainder of 2011 to be significantly less than our revenue in 2010 as a result of the completion of our obligations under the PentaStaph agreement.

*Cost of services:* Cost of services was \$0.3 million for the third quarter of 2011 compared to \$0.8 million for the third quarter of 2010. These costs include internal labor, external contractors and allocated indirect costs. We expect these costs to decrease in the fourth quarter of 2011 relative to the third quarter as a result of completing the PentaStaph agreement with GSK.

*Research and development expenses:* Research and development expenses were \$4.4 million for the third quarter of 2011 compared to \$6.8 million for the third quarter of 2010. Research and development expenses for the fourth quarter of 2011 are expected to continue to decline relative to the third quarter costs, as we have completed the first of two Phase III trials and are nearing completion of the second trial.

*General and administrative expenses:* General and administrative expenses, after an allocation of a portion of these expenses to cost of services and research and development expenses, were \$1.3 million for the third quarter of 2011 compared to \$1.4 million for the third quarter of 2010. In light of the recent results of the first NicVAX Phase III trial, we expect general and administrative expenses in the fourth quarter of 2011 to decline compared to the third quarter, as management intensifies its effort to reduce such costs, including a reduction in force as appropriate.

*Income tax benefit:* Because of the intra-period income tax allocation requirements, we recorded a benefit for income taxes from continuing operations of \$2.0 million during the third quarter of 2011, 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. During the third quarter 2010, we recognized an income tax benefit of \$1.8 million relating to an expected refund of prior year alternative minimum tax payments.

*Discontinued operations:* During the third quarter of 2011, we recognized \$3.0 million of income, net of tax of \$2.0 million, from discontinued operations relating to the milestone of the first commercial sale of a new liquid formulation from the PhosLo agreement. For the third quarter of 2010, we recorded no activity.

### **FOR THE NINE MONTHS ENDED SEPTEMBER 24, 2011 AND SEPTEMBER 25, 2010**

*Revenue:* Revenue reflects (i) the amortization of upfront fees received under our PentaStaph and NicVAX agreements, (ii) the completion of substantive milestones included in those agreements, and (iii) services provided to GSK. Total revenue in the first nine months of 2011 of \$14.0 million included \$7.2 million of deferred revenue amortization from the PentaStaph and NicVAX agreements, \$5.0 million for a completed PentaStaph milestone, and \$1.8 million for services under the PentaStaph and NicVAX agreements. Total revenue in the first nine months of 2010 of \$30.9 million included \$12.0 million of deferred revenue amortization, \$16.0 million of completed milestones, and \$2.9 million for services under the PentaStaph agreement. The decrease in revenue from amortization of upfront fees resulted from a change made in the second quarter of 2010 in the estimated completion date of the

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PentaStaph joint steering committee as well as the complete amortization of the upfront fees from the PentaStaph agreement. We expect our revenue for the remainder of 2011 to be significantly less than our revenue in 2010 as a result of the completion of our obligations under the PentaStaph agreement.

*Cost of services:* Cost of services was \$1.5 million for the first nine months of 2011 compared to \$2.1 million for the first nine months of 2010. These costs include internal labor, external contractors and allocated indirect costs. We expect these costs to decrease in the fourth quarter of 2011 as a result of completing the PentaStaph agreement with GSK.

*Research and development expenses:* Research and development expenses were \$16.2 million for the first nine months of 2011 compared to \$19.2 million for the first nine months of 2010. The decrease is due to a reduction in NicVAX manufacturing related activities in 2011. Research and development expenses for the fourth quarter of 2011 are expected to continue to decline relative to the third quarter costs, as we have completed the first of two Phase III trials and are nearing completion of the second trial.

*General and administrative expenses:* General and administrative expenses, after an allocation of a portion of these expenses to cost of services and research and development expenses, were \$4.1 million for the first nine months of 2011 compared to \$4.4 million for the first nine months of 2010. In light of the recent results of the first NicVAX Phase III trial, we expect general and administrative expenses in the fourth quarter of 2011 to decline compared to the third quarter, as management intensifies its effort to reduce such costs, including reduction in force as appropriate.

*Interest expense:* We recorded no interest expense for the third quarter of 2011. Interest expense in 2010 consisted largely of interest expense associated with our Convertible Senior Notes. We repurchased the remaining balance of these notes in April 2010.

*Income tax benefit:* Because of the intra-period income tax allocation requirements, we recorded a benefit for income taxes from continuing operations of \$2.0 million for the first nine months of 2011, 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. During the first nine months of 2010, we recognized an income tax benefit of \$1.8 million relating to an expected refund of prior year alternative minimum tax payments.

*Discontinued operations:* During the first nine months of 2011, we recognized \$3.0 million of income, net of tax of \$2.0 million, from discontinued operations relating to the milestone of the first commercial sale of a new liquid formulation from the PhosLo agreement. For the first nine months of 2010, we recorded no activity.

## **LIQUIDITY AND CAPITAL RESOURCES**

Our cash, cash equivalents and marketable securities at September 24, 2011 totaled \$102.0 million compared to \$110.7 million on December 25, 2010. The decline is primarily the result of our net cash used in operations of \$14.5 million offset in part by net cash provided by investing activities and the \$5 million milestone payment received through discontinued operations related to the first commercial sale of the new liquid formulation under the PhosLo agreement.

Cash (used in) provided by operating activities was (\$14.5) million and \$41.5 million for the nine months ended September 24, 2011, and September 25, 2010, respectively. The decrease is primarily the result of a reduction in the amount of the payments received from GSK during the first nine months of 2011 compared to the first nine months of 2010.

We believe cash, cash equivalents and marketable securities on hand at September 24, 2011 will be sufficient to meet our anticipated cash requirements for operations for at least the next 12 months.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

*New accounting pronouncements:* In October 2009, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update 2009-13, "Revenue Recognition (Topic 605) Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force," or ASU 2009-13. ASU 2009-13 amends existing accounting guidance for separating consideration in multiple-deliverable arrangements. ASU 2009-13 establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific evidence is not available, or the estimated selling price if neither vendor-specific evidence nor third-party evidence is available. ASU 2009-13 eliminates the residual method of allocation and requires that consideration be allocated at the inception of the arrangement to all deliverables using the "relative selling price method." The relative selling price method allocates

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any discount in the arrangement proportionately to each deliverable on the basis of each deliverable's selling price. ASU 2009-13 requires that a vendor determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a stand-alone basis.

The Company adopted the provisions of ASU 2009-13 effective December 26, 2010 for revenue arrangements entered into or materially modified in fiscal years beginning on or after that date. The adoption did not have any material effect on our condensed consolidated balance sheets, condensed consolidated statements of operations and condensed consolidated statements of cash flows for any historical periods or as of, or for, the nine months ended September 24, 2011 because we did not enter into or materially modify any revenue arrangement subsequent to December 26, 2010. We are not able to reasonably estimate the effect of adopting these standards on future periods because the impact will vary based on the nature and volume of new or materially modified revenue arrangements in any given period.

In April 2010, the FASB issued Accounting Standards Update 2010-17, "*Revenue Recognition—Milestone Method (Topic 605) Milestone Method of Revenue Recognition, a consensus of the FASB Emerging Issues Task Force*" or ASU 2010-17. ASU 2010-17 provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. A vendor can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. For the milestone to be considered substantive, the consideration earned by achieving the milestone should meet all of the following criteria: (i) be commensurate with either the vendor's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the vendor's performance to achieve the milestone, (ii) relate solely to past performance, and (iii) be reasonable relative to all deliverables and payment terms in the arrangement. An individual milestone may not be bifurcated and an arrangement may include more than one milestone. Accordingly, an arrangement may contain both substantive and non-substantive milestones.

The Company adopted the provisions of ASU 2010-17 effective December 26, 2010 for milestones achieved on or after that date. Since the Company's existing policies are consistent with those contained in ASU 2010-17, the adoption of ASU 2010-17 did not have any material effect on our condensed consolidated balance sheets, condensed consolidated statements of operations and condensed consolidated statements of cash flows for any historical periods or as of, or for, the nine months ended September 24, 2011. We believe that the effect of adopting these standards on future periods will not be material.

Note 2 to our condensed consolidated financial statements includes a discussion of our significant accounting policies. A summary of the more significant policies follows:

*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.

*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.

For arrangements entered into prior to December 26, 2010, 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.

For arrangements entered into or materially modified after December 25, 2010, 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 relative selling price, determined pursuant to a selling price hierarchy, and recognize revenue for that element according to its characteristics. We did not enter into or materially modify any revenue arrangements subsequent to December 25, 2010.

Accordingly, 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. The joint steering committee related to the NicVAX agreement is currently expected to operate for 190 months from the date of the agreement (or through December 2025). The joint steering committee related to the PentaStaph agreement ended in the second quarter of 2011.

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For milestones that are deemed substantive, we recognize the contingent revenue when: (i) the milestones have been achieved; (ii) no further performance obligations with respect to the milestones exist; and (iii) collection is reasonably assured. A milestone is 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.

*Research and development expenses:* Research and development costs are expensed as incurred; advanced payments are deferred and amortized 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. In circumstances where we receive grant income (which is a reimbursement to research and development costs incurred), we record the income as an offset to the related expense.

*Share-based compensation:* We currently account for share-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. 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.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

There have been no material changes to our market risk as described in Item 7A of our Annual Report on Form 10-K for the year ended December 25, 2010.

### **Item 4. Controls and Procedures**

Our Chief Executive Officer currently serves as acting Chief Financial Officer.

#### ***Evaluation of Disclosure Controls and Procedures***

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Accounting Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Accounting Officer concluded that these disclosure controls and procedures were effective.

#### ***Changes in Internal Controls Over Financial Reporting***

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met, and therefore, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. We do not expect that our disclosure controls and procedures or our internal control over financial reporting are able to prevent with certainty all errors and all fraud.

## **PART II OTHER INFORMATION**

### **Item 1. Legal Proceedings**

We are a party 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.

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### **Item 1A. Risk Factors**

In addition to the changes to our Risk Factors disclosed in our Periodic Report on Form 10-Q for the quarter ended June 25, 2011, the last risk factor disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 25, 2010 has materially changed and is restated as follows:

#### ***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 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. On August 25, 2011, we entered into a Rights Agreement with American Stock Transfer & Trust Company, LLC, as rights agent, in an effort to prevent an “ownership change” under Section 382 from occurring and thereby protect the value of our net operating losses. There can be no assurance, however, that the Rights Agreement will prevent an ownership change from occurring or protect the value of the net operating losses.

### **Item 6. Exhibits**

- 3.1 Certificate of Designations for the Nabi Biopharmaceuticals Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.1 to our Form 8-K filed on August 25, 2011).
- 4.1 Rights Agreement, dated as of August 25, 2011, between Nabi Biopharmaceuticals and American Stock Transfer & Trust Company, LLC, which includes the form of Certificate of Designations of Series A Junior Participating Preferred Stock as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C (incorporated by reference to Exhibit 4.1 to our Form 8-K filed on August 25, 2011).
- 31 Rule 13a-14(a)/15d-14(a) Certification.
- 32 Section 1350 Certification.
- 101\* The following materials from the Nabi Biopharmaceuticals Quarterly Report on Form 10-Q for the quarterly period ended June 25, 2011 formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of June 25, 2011 (unaudited), and December 25, 2010 (audited), (ii) the Unaudited Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 25, 2011, and June 26, 2010, (iii) the Unaudited Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 25, 2011, and June 26, 2010 and (iv) related notes.

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\* Furnished herewith.

**SIGNATURES**

Pursuant to the requirements 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.

Date: November 2, 2011

**Nabi Biopharmaceuticals**

By: /s/ Raafat E.F. Fahim, Ph.D.  
Raafat E.F. Fahim, Ph.D.  
President, Chief Executive Officer and acting Chief Financial Officer

By: /s/ Ronald B. Kocak  
Ronald B. Kocak  
Corporate Controller and Chief Accounting Officer

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**EXHIBIT INDEX**

<b>Exhibit</b>	<b><u>Description</u></b>
3.1	Certificate of Designations for the Nabi Biopharmaceuticals Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.1 to our Form 8-K filed on August 25, 2011).
4.1	Rights Agreement, dated as of August 25, 2011, between Nabi Biopharmaceuticals and American Stock Transfer & Trust Company, LLC, which includes the form of Certificate of Designations of Series A Junior Participating Preferred Stock as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C (incorporated by reference to Exhibit 4.1 to our Form 8-K filed on August 25, 2011).
31	Rule 13a-14(a)/15d-14(a) Certification.
32	Section 1350 Certification.

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## CERTIFICATIONS

## Rule 13a-14(a)/15d-14(a) CERTIFICATION

I, Raafat E.F. Fahim, Ph.D., certify that:

1. I have reviewed this report on Form 10-Q of Nabi Biopharmaceuticals;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which could adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2011

By: /s/ Raafat E.F. Fahim, Ph.D.

Raafat E.F. Fahim, Ph.D.

President, Chief Executive Officer and acting Chief Financial Officer

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**SECTION 1350 CERTIFICATION**

The undersigned officer of Nabi Biopharmaceuticals, or the Company, hereby certifies that, as of the date of this statement, the Company's report on Form 10-Q for the quarter ended September 24, 2011, or 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, the information contained in the Report fairly presents, in all material respects, the financial condition of the Company as of September 24, 2011 and the results of operations of the Company for the three and nine months ended September 24, 2011.

The purpose of this certification 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: November 2, 2011

By: /s/ Raafat E.F. Fahim, Ph.D.

Raafat E.F. Fahim, Ph.D.

President, Chief Executive Officer and acting Chief Financial Officer

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