UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

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

Date of report (Date of earliest event reported): October 9, 2003

Nabi Biopharmaceuticals

(Exact name of registrant as specified in its charter)

Delaware	**000-04829**	**59-1212264**
State or other jurisdiction of incorporation	Commission File Number	IRS Employer Identification No.

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

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

Item 5. Other Information and Regulation FD Disclosure

On October 9, 2003 we announced that we are accelerating licensing and commercialization plans for StaphVAX® (*S. aureus* polysaccharide conjugate vaccine) an investigational vaccine designed to prevent *S. aureus* blood stream infections. Based on the outcome of meetings in Europe with several regulatory authorities, we now plan to file our first license application for StaphVAX in Europe using the centralized approval process by the end of 2004. This advance in the timeline for launching StaphVAX will not delay our plan for commercializing the product in the United States. We continue to target filing our Biologics License Application for StaphVAX during the fourth quarter of 2005.

The license application for Europe is required to include laboratory testing data generated from the production of consistency lots of StaphVAX. In order to complete the submission of the license application in 2004, we must successfully manufacture consistency lots of StaphVAX in a facility that complies with European regulatory requirements. To achieve this, we also announced on October 9, 2003 that we have signed a ten-year manufacturing agreement with Cambrex Bio Science Inc., ("Cambrex Bio Science"), a subsidiary of Cambrex Corporation. Cambrex Bio Science, a contract manufacturer, has a facility licensed by EU, U.S. and Canadian regulators with immediately available capacity to manufacture StaphVAX for its launch in Europe and the United States. In conjunction with establishing our new manufacturing relationship with Cambrex Bio Science, we have ended the contract manufacturing agreement with Dow Biopharmaceutical Contract Manufacturing Services ("Dow") immediately. As a result of this action, we will write off costs we have capitalized in prior periods relating the right to manufacture StaphVAX in Dow's facility. We will record a non-cash charge of approximately $14 million in the fourth quarter of 2003 to write-off the manufacturing right intangible asset.

The following discussion provides further information regarding the acceleration of the European market as well as the agreement entered into with Cambrex Bio Science for contract manufacturing services:

1. What development led to the announcement that Nabi Biopharmaceuticals is accelerating its internal timeline for licensure and commercialization of StaphVAX into Europe?

During the second and third quarter of 2003 we submitted briefing documents and then met with several European regulatory authorities to present and discuss the clinical data from our StaphVAX development program. The responses from these regulatory authorities were consistent; they indicated that it is reasonable for Nabi Biopharmaceuticals to file for licensure in Europe based on the existing clinical data, including the results from our first Phase III trial in end stage renal (kidney) disease (ESRD) patients. After these meetings, we then defined the steps required to submit our first license application for StaphVAX in Europe, which includes commercial scale manufacturing.

2. Is this change in timing for European licensure significant for Nabi Biopharmaceuticals?

We now plan to file for licensure in Europe for the indication that StaphVAX prevents Staph aureus bacteremia (bloodstream infections) in ESRD patients for up to 40 weeks by year-end 2004, and a full year ahead of our planned submission for licensure in the U.S..

3. Can you describe your strategy for registration of StaphVAX in Europe in more detail?

The feedback from our meetings with European regulatory authorities indicated that it is reasonable to base our submission on current clinical data, including the results from our first Phase III clinical trial.

We plan to submit a second application in Europe in the fourth quarter of 2005. This submission will incorporate additional data, from the second phase III trial in ESRD patients in the U.S., which is currently underway, and from a number of immunogenicity studies in other patient populations including cardiothoracic and orthopedic surgery patients. We expect to conduct these immunogenicity studies in Europe and in the U.S. Based on the feedback from our discussions with European regulatory authorities, we believe the expanded clinical trial data from these immunogenicity trials, if they are positive, will be sufficient to apply for a broader indication for StaphVAX, namely the prevention of Staph aureus bacteremia and secondary infections that result from bacteremia in at risk adults.

For both submissions we will follow the Centralized Registration Procedure, meaning that approval will be for all countries in the European Union.

4. Why was the change in contract manufacturer announced on October 9, 2003 important for your European strategy?

The critical element for completing our submission in Europe is the analysis of data from commercial scale production of three consistency lots of StaphVAX. The vaccine needs to be manufactured in a European compliant facility.

The Cambrex Bio Science facility has been inspected by authorities from Europe, the United States and Canada. Cambrex Bio Science has already produced a licensed product for

Europe. Their facility is well suited for the manufacture of StaphVAX and operates at an appropriate scale for launch in Europe and the U.S. Cambrex Bio Science has capacity that is available immediately and our agreement provides that the capacity will be available for commercial manufacturing for at least a ten-year term.

With the agreement signed on October 9, 2003, we expect to begin manufacturing consistency lots at Cambrex Bio Science early in 2004. Manufacture of the consistency lots should be completed in the second half of 2004, allowing us to be in position to file our StaphVAX registration package in Europe by the end of 2004.

5. When do you expect that StaphVAX will be approved in Europe?

While we can clearly discuss when we plan to file our application in Europe, it is not possible to predict when or whether StaphVAX will be approved as it is outside of our control. We will be submitting our data package through the Centralized Registration Procedure for both indications and, given the serious healthcare challenges presented by *S. aureus* blood stream infections, we expect that StaphVAX will be granted a priority review in both instances, although we cannot be assured that this will happen. If the priority review is granted, approval within twelve months of filing is possible.

6. How does this affect the timeline for filing StaphVAX for licensure in the U.S.?

Our timeline for submission of our Biological License Application (BLA) for StaphVAX with the FDA in the U.S. is unchanged. We expect to file our BLA in the fourth quarter of 2005. This will follow the completion of our confirmatory Phase III trial in 3,000 end stage kidney (renal) disease patients, the completion of two immunogenicity studies in other at risk patient groups, and the manufacture of three lots of StaphVAX at commercial scale (consistency lots). We will also complete a bridging study to demonstrate safety and compare the antibody level response from the vaccines used in our Phase III clinical trials and the vaccine made for commercial sale. Finally, we will complete a consistency lot study to demonstrate comparability between the three lots of StaphVAX manufactured at commercial scale. We expect to complete all of this work in 2004 and 2005 prior to filing our BLA with the FDA.

7. What indication will you file for StaphVAX in the U.S.?

Our BLA submission will include the data from both Phase III clinical studies, the immunogenicity studies in other at risk patient groups and the bridging and consistency lot studies. Based on our discussions with the FDA and assuming the data are favorable, we believe it will be reasonable to file for the indication that StaphVAX prevents Staph aureus bacteremia and secondary infections caused by bacteremia in at risk adults. There will not be a two-step process in the U.S. because all of the clinical data will be available when the BLA is submitted.

8. When do you expect that StaphVAX will be approved in the US?

We can clearly discuss when we plan to file, but it is not possible to predict when or if approval will be granted, as that is outside of our control. When we complete the confirmatory Phase III clinical trial and compile all elements of the BLA, we plan to file for priority review with the FDA. We plan to submit our BLA to the FDA during the fourth quarter of 2005. Based on the serious healthcare challenges presented by *S. aureus* blood stream infections, we expect our request will be granted. This could result in approval within twelve months of submission of the BLA.

9. What led to this change in strategy for the launch of StaphVAX intoEurope?

Three factors have contributed to our developing this strategy. These factors are:

- The addition of key members to our StaphVAX development team,
- The verification that we could successfully transfer production of StaphVAX from our research and development pilot plant to a commercial manufacturing facility, and
- The meetings with European regulators.

10. Can you describe the key management changes that have contributed to the strategy to file for licensure of StaphVAX in Europe?

Henrik Rasmussen. MD, PhD joined Nabi Biopharmaceuticals as Senior Vice President, Clinical, Medical and Regulatory Affairs in February 2003 and Raafat Fahim, PhD joined us as Senior Vice President, Technical and Production Operations (manufacturing) in March 2003. They applied their European and regulatory experience towards our most important strategic objective, the licensure and commercial launch of StaphVAX. With the benefit of their new perspective and their established relationships with European regulators, we determined that this would be an appropriate time to review our program and objectives in several European countries.

11. What was the manufacturing development that contributed to this change in 2003?

The rate-limiting factor in developing StaphVAX has been commercial manufacturing capacity. During 2003 we completed the transfer of manufacturing from our research and development pilot plant in Rockville, MD to a contract manufacturer and produced a clinical lot of vaccine that will be used in our Phase III confirmatory trial in the U.S. In August 2003, we announced the results of an immunogenicity study that demonstrated that the vaccine made at the contract manufacturer was safe and stimulated the immune system to produce antibodies to *S. aureus* at levels at least equal to the response to the vaccine made in our research and development pilot plant. The manufacturing transfer and the results of this study led us to conclude that the StaphVAX manufacturing process is scalable to commercial scale and reproducible. This allowed us to be confident that we had a viable manufacturing strategy that could support the commercialization of StaphVAX on an accelerated basis in Europe.

12. Can you describe your meetings with regulators in Europe in more detail?

During the second and third quarters of 2003 we have spoken with several regulatory authorities in European countries about the results from the first StaphVAX Phase III trial clinical trial that were published in the February 14, 2002 issue of *The New England Journal of Medicine.* The outcome of these discussions was consistent and we now believe it is reasonable to submit for licensure in Europe, based on data from this study for the indication of prevention of *S. aureus* bacteremia for up to 40 weeks in end stage kidney (renal) disease (ESRD) patients. We expect to submit our Marketing Application Authorization (MAA) package through the Centralized Registration Procedure by the end of 2004.

13. How will you commercialize StaphVAX in Europe?

Our commercialization strategy now becomes a very important initiative for Nabi Biopharmaceuticals. At this time, we are contrasting commercialization options for European markets. These analyses need to consider two market segments and two launch dates in target markets, StaphVAX for ESRD patients and StaphVAX for patients at risk for S. aureus infections. Our strategy will also consider the important synergies between the ESRD population for StaphVAX and the opportunity to introduce PhosLo into European markets.

Our business strategy in Europe could lead us to work in collaboration with another company (or companies) with an established presence in the European market. A European commercial alliance could support us as we build our own presence in key markets or could

independently commercialize the product for us while we focus on the U.S. market where we are already building a presence.

14. Does the decision to transfer manufacturing to Cambrex Bio Science set the manufacturing transfer process back? Will this duplicate cost already spent at Dow?

In transferring manufacturing from a small scale development facility into full commercial production for a product in the U.S., there are four major steps:

- Technology transfer – including documentation and process development
- Scale-up – increasing the size of the lots produced to the scale needed for commercial launch
- Consistency lot production – demonstrating that the process is reproducible by manufacturing three commercial scale lots in succession
- Licensure – preparing the manufacturing documentation for the license application and inspection of the facility and process by the FDA

The transfer from Dow Biopharmaceuticals Contract Manufacturing Services (Dow) to Cambrex Bio Science is happening at an optimal point. All of the documentation and process development completed at Dow can be transferred directly to Cambrex Bio Science. Before signing the contract with Cambrex Bio Science on October 9, 2003 we satisfied ourselves that this technology and process transfer had been successful, by completing the manufacture of proof of concept lots of StaphVAX.

Dow has also completed the initial scale-up for commercial production. Cambrex Bio Science will now attempt to complete the scale-up in their facility in the fourth quarter of 2003. The incremental or duplicate cost that Nabi Biopharmaceuticals will incur for scale-up activities is estimated to be $1.5 million.

The scale up process at Cambrex Bio Science should, in our opinion, advance to the point that we can initiate production of the commercial scale consistency lots in their facility in early 2004. Manufacture of the consistency lots is planned to be completed in the second half of 2004.

15. Does switching to Cambrex Bio Science make the approval process in the U.S. more complex because the data from your confirmatory Phase III trial will be with vaccine manufactured at Dow?

We do not believe so. The data from the bridging study should, in our opinion, confirm the comparability of the vaccines made in our R&D plant, at Dow and at Cambrex Bio Science. The results of the StaphVAX immunogenicity trial announced on September 8, 2003 provided proof of concept that Nabi Biopharmaceuticals can transfer production of StaphVAX from one manufacturing facility to another.

16. Does this change in manufacturing location place the results of the confirmatory trial at risk?

We do not believe so. The results of the StaphVAX immunogenicity trial announced on September 8, 2003 provided proof of concept that Nabi Biopharmaceuticals can transfer production of StaphVAX from one manufacturing facility to another. Since we have already demonstrated this with the transfer of manufacturing from our research and development pilot plant to a contract manufacturer, we are confident that StaphVAX manufactured at Cambrex Bio Science will be consistent with that produced in other facilities.

17. What are the advantages of working with Cambrex Bio Science?

The primary advantages of working with an experienced contract manufacturer of biological products such as Cambrex Bio Science can be summarized as follows:

- It will allow us to submit our license application in Europe 2004.
- The Cambrex Bio Science facility has already demonstrated EU and FDA compliance, reducing the regulatory risk .
- The cost to Nabi Biopharmaceuticals to develop manufacturing capacity at Cambrex Bio Science is significantly below total projected costs for the remaining cost to complete commercial manufacturing capacity at alternative locations

18. Why are you making this manufacturing change at such a late stage in the development of StaphVAX?

The change in manufacturing strategy allows us to file an MAA in Europe based on existing data by the end of 2004. Cambrex Bio Science, which is already EU compliant, was a key element in our plan to accelerate our internal plans for European registration.

19. Why do you have confidence in Cambrex Bio Science?

Cambrex Bio Science provides biopharmaceutical development and cGMP manufacturing services from pre-clinical development through Phase III clinical and commercial production. They are experienced in all aspects of biological manufacturing including technology transfer and project management, process development and scale-up, cGMP manufacturing, quality control and regulatory assurance. Furthermore, their manufacturing facility has been fully validated and inspected by the FDA, EMEA, Health Canada and Team Biologics. Finally, Cambrex Bio Science is already producing biologics for commercialization in Europe.

Our confidence has only increased through the transfer of technology and process to Cambrex Bio Science, and the manufacture of proof of concept lots of StaphVAX between Nabi Biopharmaceuticals and Cambrex Bio Science that has already occurred.

20. Why did you report that you would incur a $14 million write-off for the manufacturing right asset related to Dow during the fourth quarter of 2003?

The benefits we derived from our previous contract manufacturing relationship were seed banks that will grow the carrier protein and Staph bacteria, manufacturing equipment that will be used by Cambrex Bio Science and Nabi Biopharmaceuticals, manufacturing protocols, standard operating procedures, the development of critical assays and manufacturing operations at commercial scale. Under this relationship we were able to begin the confirmatory Phase III clinical trial that is required for U.S. licensure in September 2003. In addition, we were able to conclude that we can transfer our manufacturing process to a commercial manufacturing facility.

By reason of our agreement for the commercial manufacture of StaphVAX at Dow, we established a manufacturing right asset on our balance sheet related to the utilization of the Dow facility for commercial manufacture of StaphVAX in future periods. As we have disclosed previously, if the contract with Dow ended, we would have to write off this intangible asset. The agreement with Dow had been extended through October 10, 2003 upon reaching agreement with Cambrex Bio Science on October 9, 2003, we ended the agreement with Dow. As a result, the manufacturing right asset must be written off on this date. This write-off will be reported in our fiscal fourth quarter of 2003.

21. What is happening with your U.S. regulatory plans? Are there any new developments?

Our strategy for potential StaphVAX licensure in the US remains unchanged, that is we will complete the second confirmatory Phase III study that started on September 29, 2003 and file our BLA in Q4 2004.

22. Is the need for StaphVAX in Europe similar to that in the US?

The issues of *S. aureus* resistance and the effective treatment of staph infections are essentially the same between the United States and the European Union. As reported by the SENTRY Antimicrobial Surveillance Program, 1997-1999, the rate of Methicillin Resistant *Staph Aureus* was 34.2% for the US and 26.3% for Europe.

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 hereunto duly authorized.

Nabi Biopharmaceuticals

Date: October 9, 2003

By: /s/ Mark L. Smith

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