NANOBAC PHARMACEUTICALS INC
Form 10KSB
May 04, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB
Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended
December 31, 2006

Nanobac Pharmaceuticals, Incorporated
(Exact name of registrant as specified in its charter)

Florida	**0-24696**	**59-3248917**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

4730 North Habana Avenue, Suite 205, Tampa, Florida 33614
(Address of Principal Executive Office) (Zip Code)

(813) 264-2241
(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act: **None**

Securities registered under Section 12(g) of the Exchange Act:
Common Stock, without par value
(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for a 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 [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSBor any amendment to this Form 10-KSB. [ ]

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Act): Yes [ ] No [X]

State issuer's revenue for its most recent fiscal year: $225,086

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $7,630,575 as of May 1, 2007. The shares of Common Stock held by each current executive officer and director and by each person who is known to the Company to own 5% or more of the outstanding Common Stock have been excluded from this computation on the basis that such persons may be deemed affiliates. The determination of affiliate status is not a conclusive determination for other purposes.

As of May 1, 2007 there were 247,476,426 shares of the Registrant's Common Stock outstanding.

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PART I

Item 1. Business

Nanobac Pharmaceuticals, Incorporated and its subsidiaries (which may be referred to as “Nanobac”, “the Company”, “NNBP”, “we”, “us”, or “our”) is a research-based bio-lifescience company formed in 1994 as a Florida corporation. The current business described below commenced in June 2003 with the acquisition of NanobacLabs Pharmaceuticals, Inc.

We are a life science company dedicated to the discovery and developments of products and services to improve people's health through the detection and treatment of Calcifying Nanoparticles (“CNPs”), otherwise known as "nanobacteria". The Company's pioneering research is establishing the pathogenic role of nanobacteria in soft tissue calcification, particularly in coronary artery heart disease, prostatitis and vascular disease.

Nanobac’s drug discovery and development is focused on new and existing compounds that effectively inhibit, destroy or neutralize CNPs. Nanobac manufactures and markets In Vitro Diagnostic (IVD) kits and reagents for detecting calcifying nanoparticles. IVD products include assays, proprietary antibodies and reagents for uniquely recognizing CNPs. Nanobac's BioAnalytical Services works with biopharmaceutical partners to develop and apply methods for avoiding, detecting, and inactivating or eliminating CNPs from raw materials. Nanobac's drug discovery and development efforts are focused on developing new and existing compounds that effectively inhibit, destroy or neutralize CNPs.

Calcification is a significant feature in most diseases that are leading causes of death, including heart disease. Calcification is shown in numerous studies to block circulation, cause inflammation and cell disruption, and is a sign of various cancers. We have decided to have a sharpened focus on drug therapy based on findings by Nanobac scientists that certain drugs, when combined, are effective at halting the calcification process. Some of these drug combinations have not been tested in animals or humans. However, the Company has an advantage in that each of these drugs on its own has an FDA-approved record of being safe; therefore regulatory hurdles are significantly lower in every national jurisdiction.

Our plan is to focus on the following priorities over the next twelve months:

- **Therapy -** We are entering into agreements to support the FDA PIND to test our proprietary drug combinations to treat stone-forming diseases, with a preliminary focus on prostatitis, which affects millions of men and currently is largely untreatable. We will also conduct tests with other stone forming diseases such as gallstones and kidney stones.

- **Infection -** The gold standard for proving that something is infectious is Koch's postulates. We intend to validate earlier findings on Koch's postulates with calcifying nanoparticles in laboratory animals, including testing whether the infection can be prevented or treated with a proprietary drug combination. In June 2006, a new study published by independent scientists in a peer reviewed journal demonstrated key elements of Koch’s postulates by showing that CNPs are implicated in formation of black pigment gallstones in an animal model. In August 2006, we announced that we entered into an agreement to validate this finding with the same scientists including Dr. LiMin Wang from Shantou University Medical College, Guangdong, China, who will be the Principle Investigator

- **Characterization -** We have preliminary photographic and biochemical evidence that calcifying nanoparticles self-replicate in non-precipitating conditions, suggesting further that they have a self-sustaining mechanism and might be infectious. In a recent agreement with Fetzer Memorial Trust, we have begun experiments at our NASA laboratory in Houston to demonstrate this replication via time-lapse photography using award-winning CytoViva microscope technology capable of breaking through the 200 nanometer (nm) barrier for light microscopes. Our Scientific Director at NASA’s Johnson Space Center has recently taken preliminary photographs of CNPs at

magnifications that we believe had not been previously achieved. We own the intellectual property arising from the above experiments.

- **Thrombosis -** Thrombosis is the cause of death in most hemodialysis patients. We intend to validate findings that calcifying nanoparticles discovered in human blood provoke thrombosis and might be preventable.

- **Diagnostics** - We believe that our proprietary Elisa antibody test uniquely recognizes calcifying nanoparticles known as nanobacteria, and plan to further validate the functionality of this diagnostic test.

During September 2006, we announced our agreement with Mayo Clinic to study whether calcifying nanoparticles, already found in atherosclerotic plaque, are infectious and contribute to the onset of heart diseases

We will continue optimizing our proprietary diagnostics, with a clear focus on developing effective therapies in cooperation with well-established partners including NASA, Mayo Clinic, Cleveland Clinic, and numerous other institutions. Once these experiments are completed, we expect to have a compelling and well-rounded scientific basis for the Company to move forward.

Patents - We have filed applications for a number of patents, have been granted patents, and await prosecution of pending application in the US and International Stages.

Patent		General Subject Matter	Expiration Date
US 5,135,851	U.S.	-Method for the culture and detection of nanobacteria also known as calcifying nanoparticles (issued in 1992)	August 11, 2010
US 6,706,290 PCT/EP1999/004555	U.S. & International Application (PCT)	-Methods for the eradication of Nanobacteria from articles and animals using various novel combinations of systems, chemicals, compounds, drugs, prodrugs, supplements, etc. (issued in 2004)	Jul 6, 2018
	U.S. & PCT Applications Filed	-Methods and Compositions (combinations) for treating diseases characterized by pathological calcification (Filed in 2004)	
	U.S. & PCT Applications Filed	-Methods and combinations of compositions including Bisphosphonates, chelators, and citrates (Filed in 2004)	
	U.S.	-Methods for the treatment of disease associated with calcification and/or plaque formation (Filed in 2004)	
	U.S. & PCT Application Filed	-Detection of antibodies against compositions of conformationally changed proteins comprising calcium binding protein hydroxy apatite complexes and novel in vitro test methods (Filed in 2005)	
	U.S. & PCT Applications filed	-Methods and compositions to detect calcifying nanoparticles including the identification and quantification of proteins thereon and correlation to diseases thereof	

		(Filed in 2005)	

There can be no assurance that our patents or pending applications will afford legal protection against competitors or provide significant proprietary protection or competitive advantage. In addition, our patents or pending applications could be held invalid or unenforceable by a court, or infringed or circumvented by others, or others could obtain patents that we would need to license or circumvent. Competitors or potential competitors may have filed patent applications or received patents, and may obtain additional patents and proprietary rights relating to proteins, small molecules, compounds, or processes competitive with ours. Additionally, for certain of our product candidates, competitors, or potential competitors may claim that their existing or pending patents prevent us from commercializing such product candidates in certain territories. Further, when our patents expire, other companies could develop new competitive products to our products.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require our staff members, material consultants, scientific advisors, and parties to collaboration and licensing agreements to execute confidentiality agreements upon the commencement of employment, the consulting relationship, or the collaboration or licensing arrangement with us. However, others could either develop independently the same or similar information or obtain access to our information.

Research

Nanobacterial research is ongoing around the world. Our lead scientists Olavi Kajander and Neva Ciftcioglu, have formed multidisciplinary alliances with top researchers including: Marshall Stoller, University of California San Francisco; Rune Eliasson, Sweden; Hojatollah Vali, McGill University, Canada; Mayo Clinic, Rochester, Minnesota; University of South Florida; Iowa State University; D. Shoskes, Cleveland Clinic; Garcia-Cuerpo, Spain; China Ghangsha group; Sommer, Univ. of Ulm; Pretorius, South-Africa; G. Epstein/J.T. Salonen; Tom & Marcia Hjelle, Univ. of Illinois; Y. Av-Gay, University of British Columbia; and R. Berger, Miami Heart Institute, Miami FL. We intend to serve as the nexus for research scientists and become the premier leader in nanobacterial research and distribution of knowledge. We generally retain the rights for the commercialization of intellectual property that result from these collaborative studies.

To date, these collaborations have resulted in the publishing of over 86 articles, numerous abstracts and book chapters. Example publications since 1998 include articles in Science, Nature and Nature Medicine, Proceedings of the National Academy of Sciences, Lancet, Urology, New Scientist, Molecular Medicine, PDA Journal, Kidney International, Circulation, Journal of Pathophysiology, and American Society for Microbiology.

In 2004, we entered into a Space Act Agreement with NASA's Johnson Space Center ("JSC"), Houston Texas, to collaborate on the research of nanobacterium sanguineum and its nature and role in pathological calcification, including the detection and treatment of the pathogen. Since Astronauts may be more prone to an increased rate of pathological calcification while in a zero gravity environment, the collaboration will support NASA's need to better understand the effects of long-term space travel on humans. In addition, Nanobac's work provides a model for studying mineralized organic matters that could aid NASA in the search for extraterrestrial life.

Nanobac co-founder and Director of Science, Neva Ciftcioglu, Ph.D. will remain at NASA JSC as Staff Scientist and principal researcher. Under the agreement, NASA will provide workspace at JSC for Nanobac's personnel located at JSC. The agreement further provides Nanobac the opportunity to work together with a multidisciplinary team of NASA researchers while having access to basic laboratory services for CNPs science, including electron microscopy, molecular biology and geology-mineralogy research facilities. Projects ranging from searching for CNPs biosignatures in earth fossils and in Mars meteorites to diagnosing and treating CNPs are anticipated. Nanobac will provide JSC with equipment and specialty supplies for CNP research and apply its pioneering diagnostic and treatment experience in the field.

We own the rights for the commercialization of intellectual property that results from our collaborative research at NASA JSC. However, the U.S. Federal Government retains the right to use this intellectual property for U.S. Government purposes without compensation to us.

The Role of CNPs in Calcification Associated Diseases

Urological Diseases

Researchers have shown a relationship between CNPs and urological diseases such as chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), kidney stones, and PKD. Until these studies, no single infection, viral or bacterial, had been identified that could have caused the progression of these diseases.

Nanobac has focused on investigating the relationship between CNPs and these urological diseases.

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS)

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a disease in males defined by pelvic pain and/or ejaculatory and/or urinating pain/discomfort lasting longer than 3 months. At any time 2-10% of adult men are suffering from CP symptoms and 15% of men will suffer from CP symptoms at some point of their lives. In the United States, more than 2 million men per year will visit their physician for CPPS. The cause for CP/CPPS is frequently unknown and thus the therapies are mostly empirical and target the symptoms. Antimicrobial and anti-inflammatory agents and a-adrenergic receptor blockers are frequently used, and seem to relieve the symptoms in many patients. However, men with refractory long-standing symptoms present a substantial problem to general practioners, internists and urologists, as the current therapies have inconsistent effects on the patient's symptoms. Persistent unknown cause behind the symptoms leads to a situation where no evidence based medicine can be used as a basis for therapeutic efforts.

The prostatitis syndromes are a group of disorders with varying symptoms and probably diverse etiologies. Prostatitis is divided into four types. CP/CPPS type III accounts for the majority of CP/CPPS patients seen in an average urology practice. These patients often have prostatic calcification. The presence of prostatic calculi in younger men is associated with both inflammation and symptoms of CPPS. While prostatic calcification is often detected in asymptomatic older men who undergo prostate biopsy, the presence and degree of calcification in younger CP/CPPS patients can be striking. One hypothesis is that prostatic calculi in the prostatic ducts may increase intraprostatic pressures and lead to pain and swelling. Furthermore, the core of prostatic calculi is typically calcium apatite, which is the hallmark of CNPs action. This association led researchers to postulate a role for CNPs in the development of CP/CPPS. Indeed, preliminary research comparing serum of men with a diagnosis of prostatitis with serum from unaffected men revealed significantly higher rates of CNP antigen by ELISA analysis in the prostatitis group.

Kajander and Ciftcioglu proposed a new etiology for CP/CPPS, simply because we have found that these patients very often have very high levels of CNPs in their blood. CNPs carry important players of inflammation and cell death on their surface. It has been shown *in vitro* that CNPs can kill cultured mammalian cells and can cause cell damage.

When 15 human diseases were investigated for the presence of CNPs in peripheral blood, CP/CPPS patients showed the highest values of CNPs. A strategy to treat CP/CPPS should be based upon a new understanding of the basic disease process calcific inflammation.

A recent observational study of prostatitis patients, led by Daniel A. Shoskes, M.D., of Cleveland Clinic Florida, published in the leading peer-reviewed urology journal, The Journal of Urology, demonstrated a significant improvement in the symptoms of chronic prostatitis / chronic pelvic pain syndrome for those patients who took Nanobac Supplements for a period of three months. The treated group of 16 patients had prostatic stones and longstanding Chronic Pelvic Pain Syndrome ("CPPS") symptoms that were not responsive to prior conventional therapies. Two of the patients in the test group who had been on complete medical disability have returned to work.

Kidney Stones:

Kidney stones are one of the most common disorders of the urinary tract. A kidney stone is a solid piece of material that forms in the kidney out of substances in the urine. A problem stone can block the flow of urine and cause great pain.

Several studies conducted by prominent medical researchers have collectively shown CNPs as a probable cause of kidney stone formation. Depending upon the patient population, researchers have found that 62% to 97% of kidney stones have CNPs. The presence of CNPs is independent of the type of kidney stone.

It is believed that CNPs create the calcific deposits that are physically present in the kidney stones and therefore may be the cause of kidney stone formation.

The Company has been working with scientists at NASA to research the effects of CNPs in the formation of kidney stones during space flights. Neva Ciftcioglu, the Company's Director of Science, and a team of NASA scientists used multiple techniques to determine that CNPs multiply faster in space flight simulated conditions than on Earth. This determination is especially important to NASA as it indicates that astronauts on future long-term missions to the moon and Mars are at an increased risk for developing kidney stones.

The Company is continuing its collaboration with NASA. The observation that CNPs grow faster in conditions simulating the microgravity conditions of space also allows researchers to grow cultures faster. A problem facing researchers in studying CNPs had been in developing a sufficient amount of material. CNPs double about once every three days compared to typical bacteria which doubles about every 20 minutes.

Polycystic Kidney Disease ("PKD"):

Polycystic kidney disease ("PKD") is a genetic disorder characterized by the growth of numerous cysts in the kidneys. PKD cysts can slowly replace much of the mass of the kidneys, reducing kidney function and leading to kidney failure.

Studies have shown that 100% of kidney cyst fluids and urine were positive for Nanobacteria. Nanobac plans to initiate research trials that will evaluate the link between Nanobacteria and PKD.

Cardiovascular Diseases

The most serious and widespread of the diseases caused by calcified plaque are atherosclerosis (hardening of the arteries) and coronary heart disease. Coronary heart disease is caused by a narrowing of the coronary arteries that feed the heart, which may be caused by the build-up of CNPs.

Many cardiovascular researchers have shown that atherosclerosis might be the life-long result of our bodies' various healing mechanisms and inflammatory responses to infection. Researchers have sought to isolate an infectious agent that is present in our tissues that could stimulate the development of atherosclerotic plaques. Until recently, no single infection, viral or bacterial, had been implicated.

Three recently published studies conducted by prominent medical researchers have collectively shown that CNPs might be the previously unidentified agent involved in the development of atherosclerotic heart disease. A group of researchers at the Mayo Clinic, led by Virginia Miller, PhD showed that CNPs are present in calcified atherosclerotic coronary arteries and heart valves.

Cardiovascular researcher Benedict Maniscalco, MD published a study that showed that patients with severe coronary artery disease tested positive for nanobacterial antigen. The study also indicated that a majority of cardiac patients that received the Nanobac Supplements had a decrease in their coronary artery calcium scores. Angina was decreased or ablated in 16 of 19 patients. Lipid (fats and fat like materials) profiles also improved in most patients. Dr. Maniscalco's study concluded that the coronary artery calcium scores of most coronary artery disease patients decreased during the period they used the Nanobac Supplements inferring regression of calcified coronary artery plaque volume. The patients tolerated the therapy well and their angina and lipid profiles improved.

Also, at a recent American Heart Association scientific session, one of the world's most prominent heart disease researchers, Stephen E. Epstein, MD, Director of the Cardiovascular Research Institute at Washington Hospital Medical Center in Washington D.C., reported that 94% of people with calcified coronary arteries have nanobacterial infection as measured by the Company's Nanobacterial Antibody Assay, and that antibody results correlated with coronary calcification scoring. Therefore, the Nanobacterial Antibody Assay may be a predictor of patients with high levels of calcium in their coronary arteries. These patients are at the highest risk for a heart attack. Thus, the Nanobacterial Antibody Assay could be used as a biomarker that may predict which patients are at greatest risk for a heart attack.

The collective weight of the three studies suggests that CNPs infection may be the previously unknown infectious agent associated with atherosclerotic plaque. The physical presence of CNPs in the diseased artherosclerotic tissues and the correlation with heart disease calcification levels suggests that long-term CNP presence may be involved in the development of the calcification in atherosclerotic heart disease.

Nanobac is continuing its research of the relationship between CNPs and heart disease and has expanded its research to include other diseases involving pathological calcification.

Other Opportunities

Calcifying Nano-Particles expose a risk for biopharmaceuticals containing human or animal blood components or blood and animal tissue derived raw materials or production substrates.

Nanobac BioAnalytical Services develop and apply methods for avoiding, detecting, and inactivating or eliminating CNPs from raw materials or production substrates. Our contamination control program focuses on host cell lines, animal and human derived materials, raw materials, availability of diagnostic procedures and downstream processes capable of inactivating or removing contaminants. We are considering enlisting biopharmaceutical partners to further this line of business.

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Calcifying Nano-Particle (CNP) Background and Description

CNPs were discovered in 1988 by Finnish researcher Olavi Kajander, M.D., PhD. Dr. Kajander was carrying out mammalian cell research when a routine mammalian cell culture experiment, using commercially available fetal bovine serum as the growth media, just wasn't getting off the ground. The cells weren't thriving and dividing like they should; the cells were sickly and died off before any study could be done. Strange vacuoles were forming up in many of the cells, and these cells subsequently died. Dr. Kajander, like all basic cell researchers, had encountered this problem before; sometimes their cell cultures worked, and sometimes they didn't. Dr. Kajander researched this further and after several weeks of culture, turbidity developed in one of the flasks. We believe this represented the first isolation of CNPs.

In 1991 Dr. Kajander was joined by microbiologist Neva Ciftcioglu, Ph.D. at the University of Kuopio, Finland. Their research established that the blood-borne CNPs form slow-growing calcified colonies in arteries and organs, much as coral reefs are formed. CNPs have been found in human and animal blood, urine and saliva. The name "nanobacteria" was introduced and patented by Dr. Olavi Kajander as the name for very small mineral-associated bacteria-like particles now referred to as CNPs.

Competition

The market for providing physicians and managed care organizations with nanobacteria related disease management and services is just emerging, and we believe are currently the only company providing a comprehensive approach to managing nanobacterial diseases.

The general market for academic researchers and clinical laboratories with In Vitro diagnostic test kits is highly competitive and includes diagnostic companies such as, Roche, Abbott, Bayer, Johnson & Johnson, and Dade Behring.

The general market for pharmaceuticals is also highly competitive and includes Fortune 500 pharmaceutical companies as well as small to medium sized pharmaceutical and dietary supplement companies.

Nanobac believes that it will be able to grow and defend the specialized nanobacteria related disease market niche due to its expertise in the field, its disease management approach, and its technology leadership.

Government Regulation

Clinical Reference Laboratory

Clinical reference laboratories in the United States are regulated under the federal Clinical Laboratory Improvement Act (CLIA). Our reference laboratory is located in Kuopio Finland and is regulated by European Union and Finland laws and is not regulated by CLIA.

In Vitro Diagnostics

The FDA regulates in vitro diagnostic kits and reagents. We intend to begin clinical studies to support an FDA filing for our assays. The timing of our clinical trials and FDA approval is dependent on future funding and preliminary research results. We received notification that our NANO-CAPTURE and NANO-SERO assays meet the criteria for CE Mark in Europe.

Environmental Matters

We have not been impacted financially or operationally by environmental laws.

Geographic

We will initially focus our drug discovery business in the United States. To date, over 90% of our revenue is from the United States. We may also develop markets in the European Union through the operations of our Finnish Subsidiary, Nanobac OY.

Employees

We have three employees in our corporate headquarters in Tampa, Florida, two employees at the NASA facility in Houston Texas and five employees in Finland.

Factors That May Affect the Company

We operate in a rapidly changing environment that involves a number of risks, uncertainties, and assumptions, many of which are beyond our control. For a discussion of some of these risks, see "—Risk Factors" in Item 6 of this report. Other risks are discussed elsewhere in this Form 10-KSB.

Investor Information

We are subject to the information requirements of the Securities Exchange Act of 1934 (the "Exchange Act"). Therefore, we file periodic reports, proxy statements, and other information with the Securities and Exchange Commission (the "SEC"). Such reports, proxy statements, and other information may be obtained by visiting the Public Reference Room of the SEC at 450 Fifth Street, NW, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

Financial and other information about the Company is available on our website (http://www.nanobac.com). We make available on our website, through links to the SEC website, copies of our annual report on Form 10-KSB, quarterly reports on Form 10-QSB, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC.

Item 2. Properties

The following table sets forth a description of our facilities:

Location	Square Feet (Approx)	Lease Expiration	Function
Tampa, Florida	1,700	December 2007	Headquarters for Nanobac
Tampa, Florida	4100	June 2007	Former Headquarters for Nanobac operations - space is currently vacant