

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

DOR BIOPHARMA INC  
Form 10KSB  
March 31, 2003

-----  
AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON \_\_\_\_\_, 2003  
=====

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
-----

FORM 10-KSB  
-----

(MARK ONE)

ANNUAL REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2002  
OR  
 TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_  
COMMISSION FILE NO. 1-14778  
-----

DOR BIOPHARMA, INC.  
(NAME OF SMALL BUSINESS ISSUER IN ITS CHARTER)  
-----

DELAWARE  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

41-1505029  
(I.R.S. EMPLOYER  
IDENTIFICATION NUMBER)

28101 BALLARD DRIVE, SUITE F  
LAKE FOREST, IL 60045  
847-573-8990

(ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE  
NUMBER, INCLUDING AREA CODE OF  
REGISTRANT'S PRINCIPAL EXECUTIVE OFFICES)  
-----

SECURITIES REGISTERED UNDER SECTION 12(b) OF THE EXCHANGE ACT:  
=====

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	NAME OF EACH EXCHANGE ON WHICH REGISTERED
Common Stock, par value \$.001 per share	American Stock Exchange

SECURITIES REGISTERED UNDER SECTION 12(G) OF THE SECURITIES EXCHANGE ACT:  
=====

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	NAME OF EACH EXCHANGE ON WHICH REGISTERED
-------------------------------------------------------	----------------------------------------------

# Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

None

None

=====  
Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  
Yes  No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB.

Issuer's revenues for its most recent fiscal year: \$ 0

The aggregate market value of the common stock held by non-affiliates (assuming, for this purpose, that executive officers, directors and holders of 10% or more of the common stock are affiliates), computed by reference to the closing price of such stock as of March 15, 2003, was \$29,102,823.

At March 15, 2003, 26,622,300 shares of the registrant's common stock (par value \$.001 per share) were outstanding.

Transitional Small Business Issuer: Yes  No

Documents Incorporated by Reference

## PART I

### ITEM 1. DESCRIPTION OF BUSINESS.

This report contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this report that could cause actual results to differ materially from those indicated in any forward-looking statements, including those set forth in "Risk Factors" in this Annual Report Form 10-KSB. See "Cautionary Note Regarding Forward Looking Statements."

#### OVERVIEW

We are a pharmaceutical company specializing in the development of oral and nasal delivery of vaccines and drugs. Through collaborations, we are developing a proprietary oral and nasal vaccine delivery technology called the Microvax(TM) system, which we are applying to biodefense vaccines, including nasal vaccines against ricin toxins and anthrax and an oral delivered vaccine against botulinum toxin. In addition to our biodefense vaccines, we are developing orBec(R), an oral therapeutic product, that is currently in a pivotal Phase III clinical trial for the treatment of intestinal graft-vs-host disease, a life threatening complication of bone marrow transplantation. Also, using orBec(R), we are planning a Phase II clinical trial for the treatment of irritable bowel syndrome. We are also developing oral drug delivery systems, named the LPM(TM), PLP(TM), and LPE(TM) systems, for the delivery of proteins and water insoluble drugs. We have preclinical animal data demonstrating the oral delivery of the drug leuprolide, a FDA approved injectable anticancer product. We also have preclinical animal data demonstrating the oral delivery of the drug paclitaxel, a FDA approved injectable anticancer product.

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Our business strategy is to (1) identify, acquire and exploit rights to new technologies and compounds relating to biodefense and orally delivered compounds to treat gastrointestinal disorders; (2) enhance the value of those technologies through further out-sourced research and development, specifically preclinical and clinical testing towards regulatory approval; (3) market our therapeutics drugs through licensing agreements with major pharmaceutical companies; (4) market our biodefense vaccine products directly to the U.S. and European governmental agencies; and (5) work to develop additional promising compounds utilizing contract research organizations and collaborations with third parties such as our licensors at the University of Texas Southwestern Medical Center.

We have assembled an experienced management team that oversees the human clinical trials necessary to establish preliminary evidence of effectiveness and seek partnerships with pharmaceutical and biotechnology companies for late-stage development and marketing of our product candidates. We also supplement our management team through a network of consultants and contractors. By operating in this manner, we believe we can efficiently utilize our capital resources to advance our drug and vaccine products to market. We operate through various subsidiary companies: DOR Vaccines, Inc., which is the successor in interest to Innovaccines Corporation, our former joint venture, and formed the basis of our biodefense business initiative; Enteron Pharmaceuticals, Inc. and Oradel Systems, Inc., which formed the basis of our biotherapeutics initiative. Enteron is a majority owned subsidiary which holds the intellectual property relating to orBec(R). Oradel is a wholly-owned subsidiary which holds the intellectual property relating to the LPM(TM) drug delivery system. We plan to continue to develop our later stage product opportunities while seeking to manage our earlier stage product pipeline through collaborative licensing arrangements.

During 2002, our management and board of directors implemented a restructuring plan in which we reduced our headcount and capital expenditures. As part of this plan we acquired our joint venture

Innovaccines Corporation from Elan Pharmaceuticals, Plc., which had been developing the Microvax(TM) vaccine delivery system since 1998. This acquisition provided us with a vaccine delivery platform to enter into the biodefense vaccine industry. In September 2002, we began development of our first biodefense initiative to develop a vaccine against ricin toxin, one of the biological agents that could be potentially used in biological warfare. In further refocusing our development plan, we began an initiative to acquire the rights to key vaccines, including antigens as well as additional delivery technologies. To date, we have focused these efforts on negotiating licenses for the development of delivery technology related to nasal vaccine for anthrax and a novel vaccine for botulinum toxin. In our restructuring plan, we have continued clinical evaluation of orBec(R), our lead product, which is currently being evaluated in a multi-center pivotal trial for the treatment of intestinal graft-vs-host disease.

We were incorporated during 1984 as Immunotherapeutics, Inc., which was later changed to Endorex Corporation and began our operations during 1985. We changed our name to DOR BioPharma, Inc. in December 2001, following our acquisition of Corporate Development Technology, Inc., a specialty pharmaceutical company. Our corporate headquarters is located at 28101 Ballard Drive, Suite F, Lake Forest, Illinois 60045. Our phone number is 847-573-8990 and our website is located at [www.dorbiopharma.com](http://www.dorbiopharma.com).

# Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

## INDUSTRY BACKGROUND

### THE BIODEFENSE INDUSTRY

The potential use of biological agents in war or acts of terrorism is accompanied by an increased realization that our country is poorly prepared to prevent or treat the human damage that can be caused by these agents. The use of these agents as weapons, even on a small scale, has the potential for social and economic disruption and diversion of local and national resources to combat the threat, treat primary disease and clean up environmental contamination. The U.S. Center for Disease Control and Prevention has identified and classified over 30 of these biological threats in Categories A-C, based on the severity of the threat as well as the seriousness of the diseases that could be caused by their use in bioterrorist or biowarfare acts, with Category A being the highest threat. For example, smallpox, anthrax, plague and botulinum toxin are all Category A threats. Ricin is considered a Category B bioterror threat. For a majority of these agents, there are no effective vaccines to prevent and no effective treatments following exposure. Even where vaccines do exist, their supply may be currently limited, as in the case of the smallpox vaccine, and their use could pose significant safety risks. An effort and expenditure to scale up and manufacture greater supplies of the vaccines that are now available in only limited quantities will be required to vaccinate civilian and military populations.

We believe that vaccines to prevent the biological and human damage caused by these agents represent the best short and long-term alternative to dismantling the threat of their use. The FDA has recognized that it will be impossible to perform efficacy trials in humans with Category A-C biological agents and has indicated that it will license a vaccine based on animal correlates and limited human safety data. We envision a more rapid course to licensure for vaccines for these agents than the coverage applicable to our biotherapeutics products.

Where we believe the country is most vulnerable is in areas where no vaccines or antidotes exist. In many cases, the nature of the protective immune response in humans is not known or there have been no experimental vaccines that have proven to be safe and effective in preclinical animal studies. The National Institute of Health and other government agencies have recently increased their budgets for research and development into new vaccines, diagnostics and therapeutics for Category A-C biological agents. Recognizing that the course to vaccine development, manufacture and regulatory approval can be long and circuitous, we have initiated several programs for vaccine development based on our

2

Microvax(TM) vaccine delivery technology, with respect to vaccines where the Microvax(TM) technology has proven to be safe and efficacious in preclinical animal studies. Based on promising preclinical results, we are preparing to enter into a manufacturing and testing stage for our Microvax(TM) systems with several antigens. We have additionally selected for its first programs several biological agents from both Category A and Category B in the Centers for Disease Control and Prevention list, in which single antigens currently represent the best alternatives as antigen candidates.

### THE DRUG DELIVERY INDUSTRY

The drug delivery industry seeks to provide new, improved or alternative methods for delivery of drugs that enhance patient compliance, quality of life and ease-of-use. Additionally, major pharmaceutical companies

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

have extended the life of their effective market exclusivity periods for existing pharmaceutical products by licensing new, differentiated forms of their drugs and obtaining new patents based upon new formulations that are administered via alternative methods. As the drug delivery industry has grown and become more specialized, different companies have focused on core technologies to deliver drugs in unique ways, including transdermal - through the skin; nasal - through the nasal passages; implant - delayed release of injections for weeks or months at a time; and oral - either liquid, pills or a spray into the mouth. Generally, the regulatory hurdles for approval of a drug delivery system are less stringent than those for a new chemical entity or new pharmaceutical product because most drug delivery companies look at delivering already approved and marketed drugs where the safety and efficacy of the drug has been previously established.

Delivery of large molecule or macromolecular drugs based on peptides or proteins, to humans are primarily available today only in injectable form, although there are companies testing alternate routes such as oral, pulmonary, nasal and transdermal. Injectable therapy has two major limitations. First, many patients find injectable therapies unpleasant due to the pain associated with the injection. When injectable therapy is necessary for subchronic and chronic diseases, patient compliance often decreases, resulting in higher health costs due to an increase in medical complications. Second, studies from the Center for Disease Control have demonstrated that the drug itself is often only a small part of the total cost of administering the treatment, which includes the cost of medical personnel to administer the injection, the cost of the syringe, and the cost to dispose of the syringe.

While all of the new delivery options may offer advantages for the patient over the traditional injectable format, oral delivery is generally the patient-preferred format due to simplicity of use. However, from a technical perspective, oral delivery of drugs has been extremely difficult due to low effectiveness and the fragility of these drugs to withstand degradation as they move through the stomach and upper gastrointestinal tract.

We are developing drug delivery platforms based on the combination of lipids and polymers, which are synthetic compounds that are used to modify the properties of drug uptake and distribution in the body. These platforms, for both water-soluble drug/peptide delivery and water-insoluble drug solubilization and oral delivery, lend themselves to increased absorption of drugs/peptides that are otherwise poorly absorbed by the gastrointestinal tract. By employing proprietary lipid and polymer drug delivery systems that are able to encapsulate these drugs, many of these agents may be made orally available at therapeutic levels. While this class of drugs presents unique challenges to facilitating and enhancing safe and effective oral delivery and therapy, we believe that our expertise in lipids and polymers make us uniquely capable of improving the stability and preservation of these drugs as they transit the gastrointestinal tract and are absorbed into the vascular compartment.

We believe that our lipid based drug delivery systems constitute a platform technology that has the potential to satisfy a number of criteria necessary for a successful drug delivery system, including:

3

- flexibility for incorporating numerous drug types, including (both water soluble and insoluble drugs, as well as drugs of various molecular weight ranges and size);
- stability of the drug through the gastrointestinal tract;

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

- enhanced uptake of the drug
- compatibility of the delivery system with current manufacturing techniques; and
- safety, tolerability and convenience for the patient

We have successfully demonstrated the effectiveness of selected drugs when delivered using these lipids in animal models. We believe that oral versions of peptide-based drugs and water insoluble drugs could provide product differentiation, convenience and improved compliance. Daily oral delivery could offer an attractive alternative to multiple weekly injections or slow release injection formulations, particularly for chronic therapies.

Some classes of small molecule drugs also present delivery challenges and opportunities, particularly water-insoluble drugs, examples of which are cancer chemotherapy and immunosuppressants, a class of drugs used to suppress the immune system after organ transplant. We are evaluating such drugs to identify those that are compatible with our oral drug delivery systems for future development and ultimately entrance into human clinical trials.

### OUR PRODUCTS IN DEVELOPMENT

The following tables summarize the products that we are currently developing:

#### BIODEFENSE PRODUCTS

SELECT AGENT -----	CURRENTLY AVAILABLE COUNTERMEASURE -----	DOR BIODEFENSE -----
Ricin Toxin	No vaccine or antidote currently FDA approved	Nasal Ricin Vac
Ricin Toxin	No vaccine or antidote currently FDA approved	Injectable Ricci
Botulinum Toxin	No vaccine or antidote currently FDA approved	Oral Botulinum
Anthrax	BioThrax(R), 6 Injections over 18 months	Nasal Anthrax V

#### THERAPEUTIC PRODUCTS

PRODUCT -----	THERAPEUTIC INDICATION -----	STAGE OF DEVELO -----
orBec (R)	Treatment of moderate to severe intestinal graft versus host disease	Pivotal Phase I
orBec (R)	Treatment of Irritable Bowel Syndrome	Preclinical Ani
LPM(TM) Leuprolide (Lipid Polymer Micelles)	Endometriosis, prostate cancer	Preclinical
LPE(TM) /PLP(TM) Paclitaxel	Breast, ovarian and lung cancer	Preclinical

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

(Lipid Polymer Emulsions/  
Polymer Lipid Particles)

4

### BIODEFENSE PRODUCTS

#### THE MICROVAX(TM) SYSTEM

Our proprietary vaccine delivery technology named Microvax(TM) permits non-live vaccines to be delivered via oral and nasal routes, avoiding the need for needles and trained medical personnel to administer vaccines. Unlike injected vaccines, vaccines incorporating the Microvax(TM) technology can confer protection in the lungs and gastrointestinal tract, the body's first line of defense against potential bioterror agents. The Microvax(TM) system utilizes well-characterized and safe materials to create biodegradable microspheres that contain genetically engineered or killed vaccine antigens. Microvax(TM) microspheres stimulate and confer protection to the common lymphatic mucosal immune system consisting of the surface of the lungs, nasopharynx and gastrointestinal and urogenital tracts. Because of their release over time and biodegradable design, Microvax(TM) microspheres continue to provide immunity for weeks to months with a single dose. The Microvax(TM) system is supported by publications from university and military research groups that demonstrate the ability of Microvax(TM) to protect animals from exposure to lethal doses of such agents as ricin, anthrax and plague after oral or nasal vaccination.

The Microvax(TM) system is protected by worldwide issued patents under license to us from Southern Research Institute and the University of Alabama for use in orally administered vaccines. There are six U.S. patents and two patents in Europe and corresponding international patents issued elsewhere in the world that protect both the vaccine compositions and the processes and methods to make them.

#### NASAL RICIN VACCINE

On September 11, 2002, we announced the initiation of development of our first vaccine candidate utilizing the Microvax(TM) system, a vaccine against ricin toxin.

Ricin toxin is a heat stable toxin that is easily isolated and purified from the bean of the castor plant. As a bioterrorism agent, ricin toxin could be used in small-scale, as well as large-scale, attacks and could be used as an aerosol or to contaminate water and food supplies. The U.S. Centers for Disease Control and Prevention have classified ricin as a category B biological agent. Once exposed to ricin toxin, there is no effective therapy to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of the use of ricin toxin in a potential terrorist attack or the use of ricin as a weapon on the battlefield. Importantly, there is neither any approved nor any known antidote for ricin toxin exposure.

Using our Microvax(TM) delivery system, experimental nasal and oral ricin vaccines were developed, studied and published by researchers at the United States Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland. These vaccines, utilizing a non-toxic form of ricin, were shown to be capable of protecting 100% of animals against exposure to a lethal dose of ricin toxin one year after immunization.

We have executed an option agreement with the University of Texas

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Southwestern Medical Center to license non-toxic ricin vaccine invented and tested at University of Texas. The lead vaccine candidate consists of ricin toxin which has been genetically engineered to eliminate its toxic activity. We have begun a program to manufacture and test this ricin vaccine.

5

### ORAL BOTULINUM VACCINE

We are developing an oral, nontoxic modified botulinum toxin vaccine by exploiting a natural property of botulinum toxin to penetrate intestinal tissue. Our vaccine is based on segments of botulinum toxin that are completely non-toxic and induce immune responses that are capable of neutralizing botulinum toxin. Our oral vaccine candidate has been shown to protect animals against a lethal dose of botulinum. Botulinum toxin, produced by the bacterium *Clostridium botulinum*, is an extremely potent toxin that attacks the nervous system, and is the most poisonous biologic substance known to man. Exposure to botulinum toxin can shut down breathing within hours. The Centers for Disease Control and Prevention has classified botulinum toxin as a Category A agent, a high priority agent that could be used as a bioweapon. Botulinum toxin poses a substantial threat because of its extreme potency and lethality, its ease of production, transport and misuse, and the potential need for prolonged intensive care of affected persons. There is no currently available FDA approved vaccine or antidote to botulinum toxin exposure.

We have executed an exclusive option agreement with Thomas Jefferson University to license the technology which is protected by one issued US Patent and several pending U.S. and international patents. Our collaborators have also recently reported that an intranasal form of the vaccine is capable of protecting animals against up to 30,000 times the normal lethal dose of inhaled botulinum toxin. Based on these encouraging preclinical results, we have begun a development program, relying on Thomas Jefferson University for the development work, to manufacture the vaccine for an initial human clinical trial that we expect will confirm immunogenicity and safety.

### NASAL ANTHRAX VACCINE

We are developing a nasally administered anthrax vaccine by utilizing a form of a key antigen derived from the anthrax bacillus and microparticulate delivery technology. The delivery technology is a variation of the Microvax(TM) technology. A prototype version of this vaccine has been recently described by investigators, who demonstrated that an nasally delivered anthrax vaccine was capable of protecting animals against lethal exposure of anthrax spores. We have executed an exclusive option agreement to license patent applications covering this technology as well as related know-how, subject to us entering into a definitive license agreement with the U.K.'s Ministry of Defense. We are in the process of initiating a collaborative research and development agreement with the University of London to help us develop the intranasal anthrax vaccine. Upon successful preclinical testing of the prototype vaccines, we expect to manufacture the vaccine for clinical evaluation under a U.S. investigational new drug application.

Anthrax, the disease caused by the spore-forming bacterium *Bacillus anthracis*, occurs in the three distinct forms, cutaneous, gastrointestinal and pulmonary, depending upon the routes of infection. Anthrax is described by the Centers for Disease Control and Prevention as a Category A bioterror threat. The current FDA approved anthrax vaccine, BioThrax(TM) (BioPort, Inc., Lansing, MI) is administered by six injections, given over 18 months, followed by annual boosters. These injections are painful, require a visit to a physician and are



## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

associated with numerous side effects, such as, muscle aches, joint aches, headaches, rash, chills, fever, nausea, loss of appetite, malaise or related symptoms.

6

### THERAPEUTICS PRODUCTS

#### ORBEC(R) (ORAL BECLOMETHASONE DIPROPIONATE)

We are developing an oral therapeutic product, orBec(R), a dual tablet formulation of beclomethasone dipropionate, for the treatment of intestinal graft-vs.-host disease, a life threatening complication associated with bone marrow transplantation. orBec(R) uses beclomethasone dipropionate as its active pharmacologic agent. Beclomethasone dipropionate is an off-patent potent drug which has been previously approved by the FDA and sold as Beconase(R) by GlaxoSmithkline only in an inhaled and nasal formulation for the treatment of asthma, allergic rhinitis and nasal polyposis. Worldwide sales of Beconase(R) and inhaled beclomethasone dipropionate make it one of the leading selling drugs for the treatment and prevention of asthma.

#### ORBEC(R) FOR INTESTINAL GRAFT-VS.-HOST DISEASE

orBec(R) is currently the subject of a pivotal, 130 patient, multi-center, placebo controlled phase III clinical trial, using orBec(R) vs. standard of care for the treatment of intestinal graft-vs.-host disease. A previous 68 patient randomized phase II clinical trial of orBec(R) in treatment of intestinal graft-vs.-host disease demonstrated met its predetermined statistically significant primary endpoint ( $p=.02$ ). If the current phase III clinical trial is successful, we should be able to file a New Drug Application with the FDA for marketing approval of orBec(R) in the U.S. On February 28, 2003, we announced 50% enrollment in this clinical trial.

Due to the nature of this small patient population, the FDA has agreed that only one phase III clinical trial would be necessary for FDA approval. The FDA has also designated orBec(R) "Fast Track" status, allowing for an expedited 6 month review cycle following an New Drug Application submission. orBec(R) has also been granted "Orphan Drug" status by the FDA for the treatment of intestinal graft-vs-host disease and for the prevention of graft-vs.-host disease. In Europe, the EMEA has designated orBec(R) an "Orphan Drug" for the treatment of intestinal graft-vs.-host disease.

#### ORBEC(R) FOR IRRITABLE BOWEL SYNDROME

The Company is simultaneously testing and developing orBec(R) for much larger patient populations such as inflammatory bowel disease and irritable bowel syndrome that may allow it to file a Supplemental New Drug Application for one or more of these indications in an efficient and cost effective manner. According to published literature, irritable bowel syndrome affects approximately 25 to 55 million patients per year in the U.S. We are currently testing orBec(R) in post-colitis animal models of functional bowel pain, a model which closely mimics the symptoms of irritable bowel syndrome. Following the completion of positive preclinical experiments, we have plans to initiate a phase II clinical trial using orBec(R) to treat irritable bowel syndrome. Developing orBec(R) for larger disease segments, such as irritable bowel syndrome, would allow greatly enhance the market potential for the product.

LPM(TM), LPE(TM) AND PLP(TM)

During 2002, we formed Oradel Systems, Inc., a wholly owned subsidiary

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

of the Company. We transferred all of our patent applications relating to the LPM(TM), LPE(TM) and PLP(TM) delivery systems to Oradel in order to establish a corporate partnership with another drug delivery company to further develop our oral drug delivery system.

### LPM(TM) LEUPROLIDE

We are developing an oral dosage formulation of the peptide drug, leuprolide, a hormone-based drug that is among the leading drugs used to treat endometriosis and prostate cancer, by utilizing a novel drug delivery system, the LPM(TM) system, composed of safe and well characterized ingredients to enhance

7

intestinal absorption. The LPM(TM) system incorporates biocompatible lipids and polymers and it is potentially useful for a wide variety of molecular structures of water-soluble drugs, particularly those based on peptides. Although both small molecules and large molecules can be incorporated into our system, there is a molecular size cutoff for a commercially viable oral bioavailability enhancement, and this system is most effective with drugs/peptides. Using a simple and scalable manufacturing process, aqueous solutions of peptides can be incorporated into lipid-polymer mixtures forming stable micelles.

According to IMS data, leuprolide, an FDA approved product, which generated more than \$800 million in U.S. sales, and is presently administered solely by depot injection. In preclinical studies, we have demonstrated that LPM(TM) has been able to demonstrate promising intestinal absorption enhancement of leuprolide. Based on our promising preclinical data, we plan further development of LPM(TM)-leuprolide through a corporate licensing partner, which we expect will lead to clinical studies for the treatment of endometriosis.

Endometriosis is a condition in which the tissue that normally lines the uterus grows in other areas of the body, causing pain, irregular bleeding, and frequently, infertility. It is estimated that between 5 million and 5.5 million women in the U.S. and Canada have endometriosis, and in the U.S. approximately 300,000 new cases are diagnosed annually. Our preclinical studies, have demonstrated consistent bioavailability in both LHRH and leuprolide. We plan to conduct appropriate toxicology and scale up studies to complete a filing for an Investigational New Drug Application with the FDA by year-end to enable us to initiate human clinical trials.

In addition to leuprolide, we plan to evaluate other classes of water-soluble drugs/peptides with the LPM(TM) system. Two initial patent applications covering broadly LPM(TM) for oral water-soluble drug/peptide delivery have been filed in 2001.

### LPE(TM) AND LPP(TM) SYSTEMS FOR WATER-INSOLUBLE DRUGS

We are developing two lipid-based systems, LPE(TM) and PLP(TM), to support the oral delivery of small molecules of water insoluble drugs. Such drugs include most kinds of cancer chemotherapeutics currently delivered intravenously. The LPE(TM) system is in the form of an emulsion or an emulsion pre-concentrate incorporating lipids, polymers and co-solvents, particularly perillyl alcohol. We have filed for patent applications on the use of POH as a solvent, surfactant and absorption enhancer for lipophilic compounds. The polymers used in these formulations can either be commercially available or proprietary polymerized lipids and lipid analogs.

We have utilized both LPE(TM) and PLP(TM) systems to develop an oral dosage form of paclitaxel, the active ingredient in the anticancer product

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Taxol(R). Three initial patent applications covering broadly LPE(TM) and PLP(TM) for oral water-insoluble drug/peptide delivery have been filed.

### THE DRUG APPROVAL PROCESS

#### GENERAL

Before marketing, each of our products must undergo an extensive regulatory approval process conducted by the FDA and applicable agencies in other countries. Testing, manufacturing, commercialization, advertising, promotion, export and marketing, among other things, of the proposed products are subject to extensive regulation by government authorities in the United States and other countries. All products must go through a series of tests, including advanced human clinical trials, which the FDA is allowed to suspend as it deems necessary.

8

Our products will require, prior to commercialization, regulatory clearance by the FDA and by comparable agencies in most foreign countries. The nature and extent of regulation differs with respect to different products. In order to test, produce and market certain therapeutic products in the United States, mandatory procedures and safety standards, approval processes, and manufacturing and marketing practices established by the FDA must be satisfied.

An Investigational New Drug Application, referred to as an IND, is required before human clinical use in the United States of a new drug compound or biological product can commence. The IND includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

Clinical trials are normally done in three phases, although the phases may overlap. Phase I trials are concerned primarily with the safety of the product. Phase II trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase III trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship, discover less common side effects and adverse reactions, and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase IV, or post-marketing, studies to be conducted.

With certain exceptions, once successful clinical testing is completed, the sponsor can submit a new drug application for approval of a drug. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant an approval on a timely basis, or at all. The FDA may deny a New Drug Application, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing regulations. In complying with standards contained in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase IV post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes may be required to be submitted to the FDA or foreign regulatory authority.

In the United States, the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Federal Trade Commission Act, and other federal and state statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, refusal to

9

permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow the Company to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess civil penalties for violations of the Federal Food, Drug, and Cosmetic Act involving medical devices.

### NEW BIODEFENSE LEGISLATION AND REGULATIONS

In June 2002, in response to the threat of bioterrorism, the FDA eased regulatory requirements for new drug and biological products used to reduce or prevent the toxicity of chemical, biological radiological, or nuclear substances. They may be approved for use in humans based on evidence of effectiveness derived only from appropriate animal studies and any additional supporting data. With this change in FDA policy, we believe it is possible to develop vaccines for biodefense without the need for human efficacy trials. More recently, on January 28, 2003, President Bush announced a proposal now introduced to Congress as the Project BioShield Act of 2003, a \$6 billion initiative to stimulate the private sector to rapidly contract, manufacture, develop, stockpile and make available new advanced bioterror countermeasures on behalf of the U.S. government. As a result of these proposed changes, we believe we may have a vaccine available for delivery to the Centers for Disease Control and Prevention Strategic National Stockpile and ready for investigational use and initial payment within 18 months. As proposed by the Project BioShield Act of 2003, upon subsequent FDA licensure of any delivered investigational vaccines, if we entered into government contracts relating to those vaccines, we would become eligible for additional premium product pricing.

### MARKETING STRATEGIES

Our marketing strategy for therapeutic products is to add value to drug compounds that have been approved by the FDA which have already reached the end of their initial patent life (or are reaching the end of such patent life) by developing proprietary therapeutic indications and/or proprietary new delivery modalities to enhance patient ease of treatment and enhance treatment compliance.

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

During 2003, we believe we will be able to identify a marketing partner for orBec(R) for marketing in the U.S. and Europe for the initial therapeutic indication of this drug, intestinal graft-vs.-host disease. Although this is a niche market, the additional gastrointestinal disorders for which orBec(R) is being evaluated represent substantially larger and more attractive market segments for marketing partners. Our strategy for drug delivery technology commercialization is to demonstrate initial clinical efficacy and safety in human clinical trials (human "proof of concept" data) with novel oral formulations of well-known and established drugs that have reached the end of their patent life or that are nearing the end of their patent life. We believe that we can then attract pharmaceutical partners that would like to extend the commercial life of their products or compete effectively against the original product about to go off-patent. By licensing DOR technology, our strategy is to negotiate agreements with potential corporate partners for up-front payments, milestone payments, a percentage of net product sales, or a combination of these payment schemes. The revenues that we derive from these products and technology will depend on the degree of success achieved by our corporate partners in licensing, manufacturing, distributing, and marketing those products.

We intend to market our biodefense vaccine products directly to government agencies. We believe that both military and civilian health authorities of the U.S. government will increase their activities in the stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions caused by the intentional release of bioterrorism agents. We intend to develop stockpiles of vaccines of our lead products that we will sell directly to the government. In some cases, the government may be willing to purchase stockpiles before final approval by the FDA to further the testing of the vaccine. We will also receive revenues from the sale of stockpiled vaccines to foreign governments.

10

### COMPETITION

The pharmaceutical industry and specifically the gastroenterology and vaccine delivery segment of the industry, is highly competitive. Our competitors are not only major pharmaceutical and biotechnology companies, most of whom have considerably greater financial, technical, and marketing resources than we currently have, but also other biotechnology and biopharmaceutical companies. Another source of competing technologies is universities and other research institutions, and we face competition from other companies to acquire rights to those technologies.

#### BIODEFENSE VACCINE COMPETITION

We feel that we face intense competition in the area of biodefense from various public and private companies, universities and governmental agencies, such as the US Army may have their own proprietary technologies which may directly compete with the Company's technologies. Avant Immunotherapeutics, Inc., Bioport Corporation, VaxGen, Inc., Chimerix, Inc., ID Biomedical Corporation, Human Genome Sciences, Inc., Avanir Pharmaceuticals, Inc., Antex Biologics, Inc. and others all have announced vaccine or countermeasure development programs for biodefense. Some of companies have substantially greater human and financial resources at their disposal and many of them have already received grant or government contracts to develop anti-toxins and vaccines against bioterrorism. For example, Avant Immunotherapeutics, Inc. has announced that they have received an \$8 million contract to develop an oral plague and oral anthrax vaccines. Vaxgen and Avecia Biotechnology, Inc. have both received NIH contracts to develop a next generation injectable anthrax vaccine. CpG Immunotherapeutics, Inc. has also received a \$6 million Department

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

of Defense grant to develop vaccine enhancement technology. ID Biomedical Corporation, has entered into an \$8 million contract to develop a plague vaccine. We have not yet been awarded any such funding. Another anthrax vaccine candidate is currently marketed by Bioport Corporation, under the tradename of BioThrax(R). Additionally, we face competition from other companies which have existing governmental relationships, such as Dynport Vaccine Company, LLC, a prime contractor to the U.S. Department of Defense. Dynport currently has a \$300 million contract to develop vaccines for the U.S. Military, including anthrax, and botulinum toxin vaccines.

We believe that our Microvax(TM) delivery system is able to deliver vaccines in a needleless and cost effective route of administration to patients. In the area of anthrax vaccines, the Company faces competition from Bioport Corporation, the manufacturer of BioThrax(R), which is the only FDA approved anthrax vaccine. It is an injectable vaccine, which requires 6 injections over an 18-month period with annual booster injections. While effective, this form of vaccination requires injections, which are typically administered in a hospital and/or physician office and it is unpractical to vaccinate large populations rapidly. The Company is also developing vaccines for which there aren't commercial vaccines, antidotes or countermeasures, such as botulinum toxin, and ricin toxin.

### ORBEC (R) COMPETITION

Competition is intense in the gastroenterology and transplant areas being addressed by our company. Companies are attempting to develop technologies to treat graft-vs.-host disease by suppressing, through various mechanisms, the immune system. Some companies, including Sangstat, Abgenix, and Protein Design Labs, Inc., are developing monoclonal antibodies to treat graft-vs.-host disease. Biotransplant, Novartis, Medimmune, and Ariad are developing both gene therapy products and small molecules to treat graft-vs.-host disease. All of these products are in various stages of development. For example, Novartis currently markets Cyclosporin, and Sangstat currently markets Thymoglobulin, for transplant related therapeutics.

11

Competition is also intense in the therapeutic area of irritable bowel syndrome and Crohn's disease. Several companies, including Centocor, Immunex, and Celgene, have products that are currently FDA approved. For example, Centocor, a subsidiary of Johnson & Johnson, markets the drug product Remicade(R) for Crohn's disease. Other drugs used to treat inflammatory bowel disease include another orally-active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada under the tradename of Entocort. Entocort is structurally similar to beclomethasone dipropionate, and the FDA approved Entocort for Crohn's disease late in 2001. In Italy, Cheisi Pharmaceuticals markets an oral formulation of beclomethasone dipropionate, the active ingredient of orBec(R) for ulcerative colitis and may seek marketing approval for their product in countries other than Italy including the United States. In addition, Salix Pharmaceuticals, Inc. markets an FDA-approved therapy for ulcerative colitis.

Several companies have also established various colonic drug delivery systems to deliver therapeutic drugs to the colon for treatment of Crohn's disease. These companies include Ivax Corporation, Incline Pharmaceutical Corporation, and Elan Pharmaceuticals, Inc. Other approaches to treat gastrointestinal disorders include antisense and gene therapy. Isis Pharmaceuticals, Inc. is in the process of developing antisense therapy to treat Crohn's disease.

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

We believe that the low dosage, tablet formulation for orBec(R), combined with the low systemic side effects, along with the clinical success demonstrated, will make orBec(R) an attractive alternative to existing therapies for inflammatory diseases of the gastrointestinal tract and other pan-intestinal diseases, such as irritable bowel syndrome.

### PATENTS AND OTHER PROPRIETARY RIGHTS

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements, which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

We have been successful in obtaining "Orphan Drug" designations in the U.S. and in Europe. Orphan Drug status provides for 7 seven years of marketing exclusivity for orBec(R) for the use in the treatment of intestinal graft-vs. host-disease. We have also been successful in obtaining "Orphan Drug" designation in the US for the prevention of graft-vs.-host-disease.

Under the Waxman-Hatch Act, a patent which claims a product, use or method of manufacture covering drugs and certain other products may be extended for up to five years to compensate the patent holder for a portion of the time required for development and FDA review of the product. The Waxman-Hatch Act also establishes periods of market exclusivity, which are periods of time ranging from 3 to 5 years following approval of a drug during which the FDA may not approve, or in certain cases even

12

accept, applications for certain similar or identical drugs from other sponsors unless those sponsors provide their own safety and effectiveness data.

### ORBEC (R) LICENSE AGREEMENT

In October 1998, our subsidiary, Enteron Pharmaceuticals, Inc. entered into an exclusive, worldwide, royalty bearing license agreement with George B. McDonald, M.D., including the right to grant sublicenses, for the rights to the intellectual property and know-how relating to orBec(R). Enteron also executed an exclusive option to license patent applications for "Use of Anti-Inflammatories to Treat Irritable Bowel Syndrome" from the University of Texas Medical Branch-Galveston. Under the license, we would be obligated to make

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

performance-based milestone payments, upon the filing for approval and the receipt of FDA approval, as well as royalty payments on net sales of orBec(R). In addition, Dr. McDonald receives \$40,000 per annum as a consultant to us.

### MICROVAX(TM) INTELLECTUAL PROPERTY

During 1998, our former joint venture with Elan Pharmaceuticals, Inc., Innovaccines Corporation acquired broadly issued U.S. and International patents relating to the mucosal administration of vaccines. Microspheres of these dimensions are preferentially absorbed by lymphoid tissues in the gastrointestinal tract and other mucosal lymphoid tissue, resulting in higher efficacy for orally and mucosally applied vaccines. Microsphere technology also protects vaccines against inactivation by environmental factors. The United States patents, assigned jointly to UAB and SRI #6,024,983, #5,942,252, #5,853,763, #5,820,883, #5,814,344, and #5,811,128 protect the microencapsulation technology and have terms that expire 2015 through 2018. European patents EP 0 333 523 B1 and EP 0 266 119 protect the technology in Europe until 2008 and equivalent patents are issued in other selected countries of the world. During 2002, we acquired Elan's interest in Innovaccines and reassigned the rights under these patents to a wholly owned subsidiary named DOR Vaccines, Inc. During 2002, DOR Vaccines entered into a binding letter of intent to expand its license agreement with SRI to include nasal vaccine delivery. Upon the execution of an amendment, we have agreed to provide \$250,000 per annum for 4 years in sponsored research support. The Company also agreed to a \$50,000 per annum consulting agreement with one of the inventors of the Microvax(TM) technology. We have also agreed to grant options to acquire 100,000 shares of our common stock to that individual.

During January 2003, we executed a binding letter of intent to exclusively license patent applications covering the use of microencapsulated anthrax and plague vaccines. These included patent application numbers WO 00/56282; WO 00/56362; WO 00/56361 and WO 01/70200. Upon execution of a royalty bearing license agreement, we would be obligated to pay a license issue fee \$100,000, as well as a \$25,000 license fee payable on the first anniversary of the license agreement and an additional \$25,000 license fee payable 18 months later. We would also provide \$100,000 of sponsored research support for a one-year period.

### RICIN VACCINE INTELLECTUAL PROPERTY

During January 2003, we executed a worldwide exclusive option to license patent applications with the University of Texas Southwestern Medical Center for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. During February 2003, we executed a binding, 90 day right of first negotiation agreement with UT Southwestern to obtain the injectable rights to the ricin vaccine. Until January 2004, we may choose to exercise the option to license the nasal, pulmonary, and oral rights to the non-toxic ricin vaccine with a license fee payment of \$100,000.

13

### BOTULINUM TOXIN VACCINE INTELLECTUAL PROPERTY

We executed a letter of intent with Thomas Jefferson University to exclusively license issued U.S. Patent No. 6,051,239 and corresponding international patent applications broadly claiming the oral administration of nontoxic modified botulinum toxins as vaccines. The intellectual property also includes patent applications covering the inhaled and nasal routes of delivery of the vaccine. Upon execution of the license agreement, we would have to pay a license fee of \$160,000, payable in \$130,000 of restricted common stock and \$30,000 in cash. Upon the execution of the license agreement with TJU, we would



## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

also enter into a one year sponsored research agreement in which we would provide \$300,000 in research support payable quarterly. Upon the execution of the license agreement with Thomas Jefferson University, we would also enter into a consulting agreement with Dr. Lance Simpson, the inventor of the botulinum toxin vaccine for a period of three years under, which Dr. Simpson would receive options to purchase 100,000 shares of our common stock, vesting over three years.

### EMPLOYEES

As of March 1, 2003, we had five employees, four of whom were full-time employees.

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933, that reflect our current expectations about our future results, performance, prospects and opportunities. These forward-looking statements are subject to significant risks, uncertainties, and other facets, including those identified in "Risk Factors" below, which may cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements. The forward-looking statements within this Form 10-KSB may be identified by words such as "believes," "anticipates," "expects," "intends," "may," "would," "will" and other similar expressions. However, these words are not the exclusive means of identifying these statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances occurring subsequent to the filing of this form 10-KSB with the SEC or for any other reason. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

### RISK FACTORS

You should carefully consider the risks, uncertainties and other factors described below because they could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock. Also, you should be aware that the risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in and incorporated by reference into this Annual Report on Form 10-KSB, including our financial statements and the related notes.

14

### RISKS RELATED TO OUR BUSINESS AND OUR INDUSTRY

WE HAVE HAD SIGNIFICANT LOSSES AND ANTICIPATE FUTURE LOSSES; IF ADDITIONAL FUNDING CANNOT BE OBTAINED, WE MAY REDUCE OR DISCONTINUE OUR PRODUCT DEVELOPMENT AND COMMERCIALIZATION EFFORTS AND WE MAY BE UNABLE TO CONTINUE OUR OPERATIONS.

We are a development stage company that has experienced significant losses since inception and have a significant accumulated deficit. We expect to

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

incur additional operating losses in the future and expect our cumulative losses to increase. All of our products are currently in development, preclinical studies or clinical trials, and we have not generated any revenues from sales or licensing of these products. Through February 28, 2003, we have expended approximately \$1.6 million developing our current product candidates and for our clinical trials, and we currently have commitments to spend approximately \$1.1 million over the next two years in connection with development of our oral delivery systems, licenses, employee agreements and severance arrangements, and consulting agreements. Unless and until we are able to generate licensing revenue from orBec(R), our leading product candidate, or another one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. We may not be able to obtain additional required funding on terms satisfactory to our requirements, if at all. If we are unable to raise additional funds when necessary, we may have to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates or take other cost-cutting steps that could adversely affect our ability to achieve our business objectives. If additional funds are raised by our issuing equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by our issuing debt, we may be subject to limitations on our operations.

IF WE ARE UNSUCCESSFUL IN DEVELOPING OUR PRODUCTS, OUR ABILITY TO GENERATE REVENUES WILL BE SIGNIFICANTLY IMPAIRED.

To be profitable, our organization must, along with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and pre-clinical development and will require significant further funding, research, development, preclinical and/or clinical testing, regulatory approval and commercialization testing, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to orBec(R) or any of our other product candidates:

- that we will not be able to maintain our current research and development schedules;
- that we will encounter problems in clinical trials; or
- that the technology or product will be found to be ineffective or unsafe.

If any of the risks set forth above occurs, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may not be able to successfully develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of orBec(R) or any other technology we develop, even if it is shown to be effective, if:

- it is uneconomical or the market for the product does not develop or diminishes;

- we are not able to enter into arrangements or collaborations to manufacture and/or market the product;

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

- the product is not eligible for third-party reimbursement from government or private insurers;
- others hold proprietary rights that preclude us from commercializing the product;
- others have brought to market similar or superior products; or
- the product has undesirable or unintended side effects that prevent or limit its commercial use.

OUR BUSINESS IS SUBJECT TO EXTENSIVE GOVERNMENTAL REGULATION, WHICH CAN BE COSTLY, TIME CONSUMING AND SUBJECT US TO UNANTICIPATED DELAYS.

All of our product offerings, as well as the processes and facilities by which they are manufactured, are subject to very stringent United States, federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change.

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. We may be unable to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product. Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed. For example, clinical trials of OrBec(R) began in 2001 and are expected to continue for at least one more year. We do not expect to complete clinical testing of any of our product candidates within the next 6 months.

Following any regulatory approval, a marketed product and its manufacturer are subject to continual regulatory review. Later discovery of problems with a product or manufacturer may result in restrictions on such product or manufacturer. These restrictions may include withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export, among other things, of a product are subject to extensive regulation by governmental authorities in the United States and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and/or criminal prosecution.

WE WILL BE DEPENDENT ON GOVERNMENT FUNDING, WHICH IS INHERENTLY UNCERTAIN, FOR THE SUCCESS OF OUR BIODEFENSE OPERATIONS.

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of our products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments.

OUR PRODUCTS, IF APPROVED, MAY NOT BE COMMERCIALY VIABLE DUE TO HEALTH CARE CHANGES AND THIRD PARTY REIMBURSEMENT LIMITATIONS.

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

WE MAY NOT BE ABLE TO RETAIN RIGHTS LICENSED TO US BY THIRD PARTIES TO COMMERCIALIZE KEY PRODUCTS OR TO DEVELOP THE THIRD PARTY RELATIONSHIPS WE NEED TO DEVELOP, MANUFACTURE AND MARKET OUR PRODUCTS.

We currently rely on license agreements from Southern Research Institute, the University of Alabama Research Foundation, the University of Texas Southwestern Medical Center, the University of Texas Medical Branch at Galveston and George B. McDonald for the rights to commercialize key product candidates. These agreements require that we use our best efforts to commercialize at least two products in the next 5 years. Our failure to meet the requirement would allow the licensors to terminate the licenses, whereas our meeting this milestone would trigger payment obligations on our part. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, or at all. We have also entered into letters of intent or option agreements with Southern Research Institute, the University of Alabama Research Foundation, Thomas Jefferson University, Ministry of Defence of the United Kingdom, the University of Texas Southwestern Medical Center and the University of Texas Medical Branch--Galveston, under which we plan to license issued patent and pending patent applications for technologies relating to botulinum toxin, intranasal anthrax and ricin vaccines. Although these letters of intent and option agreements provide for defined business terms, we may not be able to come to definitive agreements with the institutions and, as a result, may not obtain critical intellectual property rights on which we expect to rely.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract with outside researches, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are successfully developed and approved for commercialization, then we will need to enter into collaboration and other agreements with third parties to

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or

17

preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights might limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

Additionally, if we do not enter into relationships with third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force. Development of an effective sales force would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

WE MAY SUFFER PRODUCT AND OTHER LIABILITY CLAIMS; WE MAINTAIN ONLY LIMITED PRODUCT LIABILITY INSURANCE, WHICH MAY NOT BE SUFFICIENT.

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of \$5 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

WE MAY NOT BE ABLE TO COMPETE SUCCESSFULLY WITH OUR COMPETITORS IN THE BIOTECHNOLOGY INDUSTRY.

The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Virtually all of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in the therapeutic area of inflammatory bowel disease. We face intense competition in the area of biodefense from various public and private companies, universities and governmental agencies, such as the U.S. Army may have their own proprietary technologies which may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to compete successfully with our existing and future competitors.

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

WE MAY BE UNABLE TO COMMERCIALIZE OUR PRODUCTS IF WE ARE UNABLE TO PROTECT OUR PROPRIETARY RIGHTS AND WE MAY BE LIABLE FOR SIGNIFICANT COSTS AND DAMAGES IF WE FACE A CLAIM OF INTELLECTUAL PROPERTY INFRINGEMENT BY A THIRD PARTY.

Our success depends in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. For example, we currently hold the rights to a patent for our Microvax(TM) technology in the field of mucosally and orally administered vaccines. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and

18

technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

Although we have filed various patent applications covering the uses of our product candidates, we may not be issued patents from the patent applications already filed or from applications we may file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and recently has been the subject of much litigation. Any patents we have obtained, or may obtain in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the United States Patent and Trademark Office regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the United States are maintained in secrecy until patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The Patent and Trademark Office may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents.

It is also possible that our patented technologies may infringe on patents or other rights owned by others, licenses to which may not be available to us. We are aware of at least one issued U.S. patent assigned to the U.S. Government relating to one component of one of our vaccine candidates that we may be required to license in order to commercialize those vaccine candidates. We may not be successful in our efforts to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

OUR BUSINESS COULD BE HARMED IF WE FAIL TO RETAIN OUR CURRENT PERSONNEL OR IF THEY ARE UNABLE TO EFFECTIVELY RUN OUR BUSINESS.

We have only five employees: Dr. Ralph Ellison, our Chief Executive Officer and President; Steve Kanzer, our Vice Chairman; William Milling, our Controller, Treasurer and Corporate Secretary; Robert Brey, our Vice President and Research and Development; and Robin Simuncek, our Clinical Project Manager and Administrative Assistant. We depend upon these five employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. Furthermore, these few employees on whom our business depends have very limited experience in managing and operating our business. Dr. Ellison was hired in March 2003; Mr. Kanzer became our Vice Chairman in March, 2003; Mr. Milling was hired in September 2002; and Mr. Brey was hired in December 2002. In addition, Alexander Haig, our Chairman of the Board was

19

appointed in January 2003. Because of this inexperience in operating our business, there is significant uncertainty as to how our management team will perform. Furthermore, our management team may need to devote a significant amount of time to learning about our business and its markets, which could limit their effectiveness in managing our business for a period of time. We will not be successful if this new management team cannot effectively manage and operate our business.

WE HAVE CERTAIN RELATIONSHIPS THAT PRESENT CONFLICTS OF INTEREST.

Our Vice Chairman of the Board of Directors, Steve H. Kanzer, is Chairman and Chief Executive Officer of Accredited Ventures, Inc., which in the regular course of its business, identifies, evaluates and pursues investment opportunities in biomedical and pharmaceutical products, technologies and companies. However, Accredited is under no obligation to make any additional products or technologies available to us. Therefore, we may lose to Accredited opportunities of which Mr. Kanzer is aware that would be beneficial to our business. In addition, our officers and directors and officers or directors appointed in the future may from time to time serve as officers, directors or consultants of other biopharmaceutical or biotechnology companies and those companies may have interests that conflict with our interests. As a result of our recent management changes, which highlighted some of the actual and potential conflicts, we have not yet developed policies to address the conflicts of interest, but we plan to do so in the near future.

RISKS RELATED TO AN INVESTMENT IN OUR COMMON STOCK

OUR STOCK PRICE IS HIGHLY VOLATILE AND OUR STOCK IS THINLY TRADED.

The market price of our common stock, like that of many other development stage public pharmaceutical and biotechnology companies, has been highly volatile and may continue to be so in the future due to a wide variety of factors, which include, actual or anticipated fluctuations in our results of operations, announcements of innovations by us or our competitors, additions or departures of key personnel or general market conditions. For example, when we announced the we were entering the biodefense industry on January 6, 2003, our

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

stock price went from \$0.58 per share to \$1.05 per share in one day and has fluctuated between \$0.80 per share and \$1.57 per share from that date through March 28, 2003. From July 1, 2000 through December 31, 2002, the per share price of our common stock ranged from a high of \$9.44 per share to a low of \$0.11 per share, including a 2002 high of \$2.10 per share and low of \$0.11 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

Since it commenced trading on the American Stock Exchange on August 6, 1998, our common stock has been thinly traded. The average trading volume for our common stock has averaged approximately 33,716 shares per day from January 1, 2001 to March 25, 2003. The relatively illiquid market for our shares may have an adverse effect on the market price for our shares and on stockholders' ability to sell our common stock at the prevailing market price. A more active trading market for our common stock may not develop.

### OUR STOCK MAY NOT REMAIN LISTED ON THE AMERICAN STOCK EXCHANGE.

Because we continue to incur losses from continuing operations in fiscal 2003, the stockholders' equity standard applicable to us of AMEX's continued listing requirements will increase to \$6 million for fiscal years ending 2003 and beyond. Although not yet applicable, our net equity of \$4.3 million as of December 31, 2002 would not allow it to meet these increased requirements. If, for this reason or for any other reason, our stock were to be delisted from the American Stock Exchange, we may not be able to list our common stock on another national exchange or market. If our common stock is not listed on a national exchange or market, the trading

20

national exchange or market, the trading market for our common stock may be even more illiquid. Upon any such delisting, our common stock would become subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than \$5.00 per share, other than securities registered on certain national securities exchanges or quoted on the Nasdaq system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, before a transaction in a penny stock that is not otherwise exempt from such rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. As a result of these requirements, if our common stock were to become subject to the penny stock rules it is likely that the price of our common stock would decline and that our stockholders would find it more difficult to sell their shares.

### INVESTORS MAY SUFFER SUBSTANTIAL DILUTION.

We have a number of agreements or obligations that may result in dilution to investors. These include:

- warrants to purchase a total of approximate 5.2 million shares of our common stock at a current weighted average exercise price of



## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

approximately \$2.50.

- conversion rights and dividend rights of preferred stock, consisting of 117,118 shares of Series B preferred stock (\$8.0 million original liquidation value) bearing an 8% cumulative payment-in-kind dividend and convertible at the liquidation value into common stock at \$7.38 per share;
- anti-dilution rights under the above warrants and preferred stock, which can permit purchase of additional shares and/or lower exercise/conversion prices under certain circumstances; and
- options to purchase approximately 6,077,042 shares of common stock of a current weighted average exercise price of approximately \$0.95.

To the extent that anti-dilution rights are triggered, or warrants, options or conversion rights are exercised, our stockholders will experience substantial dilution and our stock price may decrease.

### ITEM 2. DESCRIPTION OF PROPERTY

Our executive offices and research and development center are located in a leased facility of approximately 7,500 square feet in Lake Forest, Illinois. The lease expires on December 31, 2003. We believe that our current leased facilities are sufficient to meet our current and foreseeable needs.

### ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any legal proceedings.

21

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

We did not submit any matters to a vote of the stockholders in the fourth quarter of 2002.

22

## PART II

### ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Our common stock is traded on the American Stock Exchange under the symbol "DOR." The table below sets forth the high and low sales prices, as provided by the American Stock Exchange, for the period from January 1, 2001 through December 31, 2002. The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.

Period	Price Range	
	High	Low
-----	----	---

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Fiscal Year Ending December 31, 2001

First Quarter	\$1.75	\$0.80
Second Quarter	\$1.30	\$0.75
Third Quarter	\$1.40	\$0.80
Fourth Quarter	\$1.10	\$0.85

Fiscal Year Ending December 31, 2002

First Quarter	\$2.10	\$0.95
Second Quarter	\$1.25	\$0.25
Third Quarter	\$0.44	\$0.11
Fourth Quarter	\$0.60	\$0.35

As of March 1, 2003, we had approximately 1,100 registered stockholders of record. We have never paid any cash dividends, and currently intend to retain any earnings for use in our business and, therefore, do not anticipate paying any cash dividends in the foreseeable future.

In December 2002, we completed a private placement in which we issued and sold 3,093,569 shares of common stock, and warrants to purchase an additional 1,546,789 shares. In this private placement we received total proceeds of \$1,082,750. The Warrants are exercisable for a period of 5 years at \$0.75 per share and are callable by us at \$3.00 per share. Our net proceeds after deducting commissions and expenses of Atlas Capital Services, LLC, which acted as the placement agent for the private placement and Accredited Equities, Inc., which acted as a dealer in connection with the private placement, were approximately \$290 thousand.

In connection with the 2002 private placement, we issued to the placement agent and the dealer or their designees placement warrants allowing the purchase of up to 397,169 shares of common stock at prices ranging from \$0.35 to \$0.75 per share, until December 31, 2007. See "Item 12. -- Certain Relationships and Related Transactions" in this Annual Report on Form 10-KSB.

We issued these securities in transactions exempt from registration under the Securities Act of 1933 in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering. Each of the parties that acquired the securities represented to us that it was an "accredited investor" under Rule 501(a) of Regulation D.

### ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION.

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operation and financial condition. You should read this

23

analysis in conjunction with our audited consolidated financial statements and related note. This discussion and analysis contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions, and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this report which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Item 1. Business--Risk Factors" in this Annual Report on Form 10-KSB. See "Item 1. Business--Cautionary Note Regarding Forward-Looking Statements."

### PLAN OF OPERATION

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

During 2002, we made significant progress in the development of several of the company's core delivery technologies for both biotherapeutic drugs and vaccines. During the first half of 2002, we continued development of several our novel drug delivery platform technologies that are distinct and can be used for the oral delivery of large molecule drugs and water-insoluble drugs. Both these classes of drugs under today's delivery methods are absorbed poorly, if at all, from the gastrointestinal tract. During 2002, we filed additional patents to reinforce the filings initiated during 2001. We completed preclinical oral absorption studies in dogs and identified a lead oral formulation for future clinical evaluation of leuprolide, a drug used for the treatment of prostate cancer in men and endometriosis in women. Currently, our plans are to seek corporate partnerships to complete the preclinical toxicology and initiate human clinical trials with the lead leuprolide formulation. We believe that the current oral bioavailability data with leuprolide is extremely promising and will be substantiated in human clinical trials.

In June of 2002, we implemented a restructuring plan in which we significantly reduced our headcount and capital expenditures relating to early stage product opportunities. In October 2002, we acquired our former joint venture, Innovaccines Corporation from Elan Pharmaceuticals, Plc., and we refocused our resources on our near-term product opportunities, such as orBec(R) and our Microvax(TM) delivery system. In September 2002, we announced our intent to develop the Microvax(TM) delivery system in conjunction with novel vaccines to be used to combat biological agents listed by the Center for Disease control as among the highest bioterrorism threats. We believe that significant opportunities exist for the Microvax(TM) technology in the development of vaccines for agents that can be used as weapons of bioterrorism or biowarfare.

We are developing an oral therapeutic product, orBec(R) (oral beclomethasone dipropionate), a dual tablet formulation for the treatment of intestinal graft-vs.-host disease, a life threatening complication associated with bone marrow transplantation. Beclomethasone dipropionate is an off-patent drug which has been previously approved by the FDA and sold as Beconase(R) by GlaxoSmithkline only in an inhaled and nasal formulation for the treatment of asthma, allergic rhinitis and nasal polyposis. Worldwide sales of Beconase(R) and inhaled beclomethasone dipropionate make it one of the top selling drugs for the treatment and prevention of asthma. The Phase III trial for orBec(R) has enrolled more than half of the 130 patients needed to complete the trial. We anticipate that the trial will be fully enrolled by the end of 2003 and that a new drug application can be filed with the FDA soon thereafter, pending favorable results. We are simultaneously testing orBec(TM) for its potential to be used in other indications such as irritable bowel syndrome and plan to file investigational new drug applications with the FDA during 2003 in other patient populations where orBec(TM) has shown to be effective in corresponding preclinical studies.

By identifying and acquiring the most advanced research available and collaborating with the inventors for further research and formulation work, we plan to develop several of our biodefense vaccines during 2003. We have identified and are in the process of licensing intellectual property rights to a ricin vaccine candidate developed at the University of Texas Southwest Medical Center. We believe

that this candidate is the best technology for a ricin vaccine, since it consists of a non-toxic, safe, genetically engineered derivative of ricin toxin that has been shown to elicit effective immune responses in mice. Ricin is potentially deadly biological agent that has been recently found in London and Paris and is one of the agents that can be used in bioterrorism attacks. Based

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

on promising preclinical results, we have begun a development program to manufacture and test an investigational stockpile of this ricin vaccine. We have submitted several grant applications to the National Institutes of Health in November and December 2002 and in January 2003 to help fund our efforts in the producing a form of this vaccine that can be taken by inhalation through the nose. Separately, we are seeking funding for the development of ricin vaccine under the pending Project Bioshield Act of 2003. We are initially planning to produce an injectable form of this vaccine to demonstrate safety and immunogenicity in a small clinical trial and concurrently are developing the candidate using the Microvax(TM) delivery technology for a nasal vaccination. Investigators at Fort Detrick who demonstrated that nasal vaccination with another ricin vaccine candidate is feasible have used the Microvax(TM) delivery technology. We plan to use subcontractors for the scale-up and manufacture of the ricin vaccine antigen, which the part of ricin toxin that induces immunity, and for the manufacturer of Microvax(TM) formulations. We are also currently planning to utilize a nasal delivery device in conjunction with the clinical testing of the nasal form of ricin vaccine. We believe that the best vaccine against possible ricin intoxication will be one that stimulates immunity in the lungs and the gastrointestinal tract, since it will likely protect tissues against direct damage by ricin.

During 2003, we are also planning to develop a vaccine to protect against botulinum toxin poisoning. Botulinum is the most potent biological toxin known to man and is classified by the Center for Disease Control as one of the highest threats for bioterrorism. The current vaccine consists of a mixture of different types of detoxified botulinum toxins and lacks substantial efficacy. Only limited and experimental quantities of this particular vaccine are available. In February 2003, we entered into a letter of intent to licensing and sponsored research and development arrangements with Thomas Jefferson University for the development of oral botulinum vaccines. The technology relies on genetically engineered and non-toxic fragments of botulinum toxin, which retain the capacity to penetrate mucosal tissues and induce antibodies in the bloodstream that inactivate native botulinum toxin and protect against intoxication. We are planning to develop three candidate antigens, which are the part of botulinum that induces immunity, relating to types A, B, and E botulinum toxins. These are the most potent forms of botulinum toxins and are the ones that we believe could have the most impact as agents of bioterrorism.

We are developing the Microvax (TM) system in conjunction with the nasal ricin vaccine and also a novel vaccine for anthrax, using a non-live subunit of the anthrax bacterium. The Microvax(TM) vaccine delivery system is a technology based on over ten years of research and development, which has been shown by many independent investigators to be effective in enhancing surface, cellular and systemic immune responses with numerous vaccines and therapeutic drugs. Vaccines can be entrapped within the microspheres composed of biodegradable polymers, as well as attached to the particle surface. Vaccines delivered by the oral and nasal routes of delivery avoid the need for needles or the use of live viruses or bacterium. Unlike injected vaccines, Microvax(TM) vaccines have been shown to provide protection in the lungs and gastrointestinal tract, the body's first line of defense against potential bioterror agents, thus making them well suited as biodefense vaccines. We have acquired exclusive license to the technology for the development of orally and nasally administered vaccines from the Southern Research Institute and the University of Alabama. The Microvax(TM) technology is the subject of six patents issued in the US, two patents issued in Europe and equivalents in other countries.

We are developing a vaccine against anthrax utilizing the Microvax(TM) system that can be administered orally or nasally utilizing a non-live subunit of anthrax, the protective part of anthrax that is the principal component of the licensed anthrax vaccine. Anthrax is considered by the Center for Disease Control as one of the highest threats for bioterrorism. The current vaccine is associated with undesirable

side effects and has to be administered by injections in six doses. We believe that an orally or nasally administered vaccine will be safer and elicit protective antibodies in the lungs, which could neutralize spores and prevent their transfer into the rest of the body. Recently, a prototype Microvax(TM)-PA vaccine has been evaluated and been shown to elicit protection in mice after two doses of an nasally administered vaccine. We are developing further prototypes of Microvax(TM) with a non-live subunit of anthrax and consider our current candidates to be the leading ones for the next generation of anthrax vaccines that could be self-administered with fewer doses than the current injected vaccines. We have recently signed a letter of intent to license patent applications and technology that we think will complement the Microvax(TM) technology for the development of select nasal vaccines. Our intranasal anthrax vaccine demonstrated that an experimental microencapsulated nasally delivered anthrax vaccine was capable of protecting 100% of animals against lethal challenge to anthrax spores with only two doses of the vaccine. We are currently negotiating under a binding letter of intent to collaborate with investigators are involved in developing vaccines and therapies for select agents. Using an nasal microparticle system, including some enhancements such as binding the vaccine to the outer shell of the microcapsules, researchers demonstrated that an nasally delivered anthrax vaccine was capable of protecting 100% of animals against lethal challenge to anthrax spores with only two doses of the vaccine.

In June 2002, the FDA eased regulatory requirements for certain new drug and biological products, including ricin, anthrax, and botulinum vaccines, that can be used to reduce or prevent the toxicity of chemical, biological radiological or nuclear substances. They may be approved for use in humans based on evidence of effectiveness derived only from appropriate animal studies and any additional supporting data. More recently, on January 28, 2003, President Bush announced a proposal, now introduced to Congress as the Project BioShield Act of 2003, for a \$6 billion initiative to stimulate the private sector to rapidly contract, manufacture, develop, stockpile and make available new advanced bioterror countermeasures on behalf of the U.S. Government. As a result of these proposals, we believe we may have products available for delivery to the Center for Disease Control's Strategic National Stockpile and ready for investigational use and initial payment within 18 months. As proposed by the Project BioShield Act of 2003, upon subsequent FDA licensure of any delivered investigational vaccines, if we enter into government contracts resulting to the vaccines, we would become eligible for additional premium product pricing.

#### CRITICAL ACCOUNTING POLICIES

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expense, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate these estimates. Currently, the most significant estimate or judgment that we make is whether or not to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in SFAS 2, "Accounting for Research and Development Costs". Accordingly, we capitalized all outside legal and filing costs incurred in the procurement and defense of patents, as well as amounts paid to Southern Research Institute and Elan allowing us to increase the range of our license on the Southern Research patents.

#### MATERIAL CHANGES IN RESULTS OF OPERATIONS

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

We are a development stage company and to date have not generated any material revenues from operating activities. Although our product portfolio includes a phase III drug that we believe may be

26

attractive to potential pharmaceutical partners, we have no active discussions under way with any such potential partners.

For the 12 months ended December 31, 2002, we had a net loss applicable to common stockholders of \$6,422,466 as compared to a \$16,117,676 net loss applicable to common stockholders for the 12 months ended December 31, 2001, a decrease of \$9,695,210, or 60.0%. Net loss applicable to common stockholders included the impact of preferred stock dividends, which totaled \$1,456,385 in 2002, as compared to \$1,486,501 in 2001. The small decrease in preferred stock dividends was due to the conversion of Series C preferred stock to common stock in November 2002.

Results for 2001 reflected a \$10,181,000 non-recurring expense for the write-off of acquired in-process research and development costs associated with the merger with CTD in November 2001. See note 5 in the Notes to Consolidated Financial Statements in this Annual Report on Form 10-KSB.

The 2002 results reflect a continued shift of research and development activities from joint venture R&D to in-house proprietary R&D activities through the first six months of the year. During the first six months of the year, our R&D spending increased by \$1,072,495 as compared to the first half of 2001. This increase was intended to accelerate the development of our pre-clinical drug delivery activities. However, during the second half of 2002 our R&D spending decreased by \$599,803 as compared to the second half of 2001. This decrease is a result of our restructuring June 2002, in which, we laid off our entire research staff. Almost All R&D spending in the last half of the year is for our orBec(TM) trial. This led to an overall, increase in R&D expense of \$472,692 or 19% to \$2,943,493 in 2002 from \$2,470,801 in 2001. Based on our current business model applied in the restructuring, we anticipate that our R&D expenditures will continue at a level much closer to that incurred in the last half of 2002.

General and administrative expenses for the 12 months ended December 31, 2002 were \$2,988,020 as compared to \$1,973,455 for the 12 months ended December 31, 2001, an increase of \$1,014,565, or 51.4%. The majority of this difference was due to increased administrative spending, including salaries, travel and consultants in the first six months of the year, as well as professional fees related to defense of the stockholder initiated consent solicitation in May and severance charges related to the restructuring. This restructuring reduced our general and administrative headcount from eleven people to two, therefore our General and Administrative spending was greatly diminished in the last half of the year, going from \$2,058,646 in the first six months of 2002 to 929,374 in the last half of 2002. We expect our 2002 general and administrative expenses to be at a level much closer to that incurred in the last half of 2002.

Equity in earnings/(losses) from joint ventures, representing our two joint venture operations with Elan, for the 12 months ended December 31, 2002 was a gain of \$868,859 as compared to a loss of \$401,699 for the same period in 2001, an increase of approximately \$1,270,528. The earnings were mostly a result of a closing out the joint ventures, causing a reduction in our liability to the joint venture, in addition to incurring no additional expenses. As the joint ventures are now closed out, we do expect to have any earnings or losses in this category in 2003.

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Interest income for the 12 months ended December 31, 2002 was \$105,676 as compared to \$424,032 for the 12 months ended December 31, 2001, a decrease of \$318,356 or 75.1%. This decrease was primarily due to the reduction in the cash balance available for investment and the sharp reduction in interest rates during 2002.

27

### FINANCIAL CONDITION

As of December 31, 2002 we had cash, cash equivalents and marketable securities of \$4,147,164 as compared to \$9,942,053 as of December 31, 2001 and working capital of \$3,046,775 as compared to \$6,766,704 as of December 31, 2001. For the 12 months ended December 31, 2002, our cash used in operating activities or "net cash burn," was approximately \$6 million, which we believe will be substantially lower in 2002 due to the decrease in personnel, and overhead that occurred in the June 2002 restructuring.

The following table summarizes our expected expenditures under existing product development agreements and license agreements we expect to enter into pursuant to letters of intent and option agreements:

LICENSOR	DESCRIPTION	2003 EXPENDITURES*		
		2ND QUARTER	3RD QUARTER	4TH QUARTER
Thomas Jefferson University (1,2)	License fee	\$ 30,000	\$	\$
Thomas Jefferson University (2)	Sponsored research	75,000	75,000	75,000
Ministry of Defense (3,2)	License fee	100,000	--	--
Ministry of Defense (2)	Sponsored research	25,000	25,000	25,000
University of Texas (2)	License fee	100,000	--	--
Southern Research Institute (4,2)	License fee	175,000	--	--
Southern Research Institute (2)	Sponsored research	250,000	--	--
Southern Research Institute (2)	Scientific advisory fee	12,500	12,500	12,500
Southern Research Institute (5)	Royalty			320,000
	TOTAL	\$ 777,500	\$ 112,500	\$ 432,500
		=====	=====	=====

\* There are no expenditures for licenses in the first quarter.

- (1) We paid a \$10,000 non-refundable fee in February 2003 for a binding letter of intent.
- (2) Contract is currently proposed and changes may take place before being finalized.
- (3) We paid a \$25,000 non-refundable fee in January 2003 for a binding letter of intent.
- (4) We paid a \$175,000 non-refundable fee in December 2002 as a down payment for the agreement.
- (5) The current contract calls for a \$140,000 dollar payment in December; the remaining amount would be payable is under a proposed new contract

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

In 2002 we spent approximately \$1.2 million on orBec(R), in 2003 we anticipate spending an additional \$452,000 and approximately \$1 million after 2003. We also spent \$330,000 in 2002 on our current and proposed license agreements, however since these are either new or not finalized, we do not have a reliable estimate as to the future costs, beyond the table shown above.

As of December 31, 2002, we have a total of \$579,742 as a liability, which represents the entire remaining amounts payable in connection with our Newco and Innovaccines joint ventures. We are required to make payments of \$231,897 in June 2003, \$231,897 in June 2004 and \$115,948 in December 2004. Both Newco and InnoVaccines have been closed, and we acquired all rights and property in InnoVaccines in exchange for 500,000 shares of our stock valued at \$250,000.

28

The following summarizes our contractual obligations at December 31, 2002, not including the product development and license related amounts reflected in the table above, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

CONTRACTUAL OBLIGATIONS (1)	TOTAL	2003	2004
Non-cancelable operating lease obligations	\$ 62,978	\$ 62,978	\$ --
Debt (2)	729,967	377,151	352,816
	-----	-----	-----
Total contractual obligations	\$792,945	\$440,129	\$352,816
	=====	=====	=====

(1) None of these contractual obligations extend beyond 2004.

(2) Debt consists of payments due to Elan as part of the dissolution of the joint ventures, and the final year of a bank loan used to purchase equipment in 2001.

We supplemented our cash position in December with a private placement netting approximately \$970 thousand after placement fees and expenses. The shares were offered at \$0.35 each with 0.5 warrants attached to each share, where 1 warrant equals the right to buy one share of common stock at a price of \$0.75. We believe our current cash position of \$4,147,164 will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. However, within this period, possibly in the very near term, we may decide to seek additional capital in the private and/or public equity markets to support a higher level of growth, to respond to competitive pressures, to develop new products and services and to support new strategic partnership expenditures. After that 12-month period, if cash generated from operations are insufficient to satisfy our liquidity requirements, we may need to raise additional funds through public or private financing, strategic relationships or other arrangements. If we receive additional funds through the issuance of equity securities, stockholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. Further, we may not be able to obtain additional



## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

financing when needed or on terms favorable to our stockholders or us. If we are unable to obtain additional financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities or respond to competitive pressures.

### ITEM 7. FINANCIAL STATEMENTS.

The financial statements listed in Part III Item 13, with the reports of independent accountants, are included in this Form 10-KSB on pages F-1, et seq.

### ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

## PART III

### ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT.

In June, 2002, following an aborted attempt by Mr. Kanzer to remove certain directors and replace them with his own nominees, we completed a restructuring of our operations. In connection with that restructuring, Dr. Colin Bier, who was then serving as our Chairman and Chief Executive Officer, and Michael Rosen, who was serving as our President and Chief Operating Office and as a director, resigned their positions. In addition, the employment of our other executive officers terminated, and a number of the other members of our Board of Directors resigned. Steve H. Kanzer, currently our Vice

29

Chairman of the Board, served, without additional consideration, as our Interim President from June 30, 2002 through January 4, 2003. David Kent then served as of Chief Executive Officer and President from January 4, 2003 through March 15, 2003, when he was replaced by Dr. Ralph Ellison, our current Chief Executive Officer and President. The following table contains information regarding the current members of the Board of Directors and executive officers of the Company:

NAME	AGE	POSITION
General Alexander M. Haig, Jr.	76	Chairman of the Board
Steve H. Kanzer, CPA., Esq.	39	Vice Chairman of the Board
Ralph M. Ellison, M.D., M.B.A.	41	Chief Executive Officer and President
Robert N. Brey, Ph.D.	50	Vice President, Research and Development
William Milling, CPA	36	Controller, Secretary and Treasurer
Larry J. Kessel, M.D.	48	Director
Arthur Asher Kornbluth, M.D.	42	Director
Evan Myrianthoupoulos	38	Director
Paul Rubin, M.D.	49	Director
Peter Salomon, M.D., FACG	43	Director

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

ALEXANDER M. HAIG, JR., Chairman of the Board

Mr. Haig currently serves as our non-employee Chairman of the Board. Since 1984, Mr. Haig has been Chairman and President of Worldwide Associates, Inc., a Washington D.C. based international advisory firm. He served as Secretary of State (1981-82), President and Chief Operating Officer of United Technologies Corporation (1978-81), and Supreme Allied Commander in Europe (1974-79). Before that, he was White House Chief of Staff, Vice Chief of Staff, Vice Chief of Staff of the U.S. Army, and Deputy National Security Advisor. Mr. Haig currently serves on the Board of Directors of MGM Mirage, Inc.; Indevus Pharmaceuticals, Inc.; SDC International, Inc.; and Metro-Goldwyn\_Mayer, Inc. He is also the host of his own weekly television program, "World Business Review". Mr. Haig is also a consultant to the company.

STEVE H. KANZER, CPA., ESQ., Vice Chairman of the Board

Mr. Kanzer currently serves as our non-employee Vice Chairman after having served as our Interim President from June 30, 2002 through January 4, 2003 and a member of the board of directors since 1996. He was a co-founder of Paramount Capital, Inc. in 1991 and served as Senior Managing Director - Head of Venture Capital of Paramount Capital until December 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of numerous biotechnology companies, including us and Corporate Technology Development, Inc. Mr. Kanzer was Chief Executive Officer of CTD from 1997 until its acquisition by us in November 2001. Since December 2000, he has served as Chairman of Accredited Ventures Inc. and Accredited Equities Inc., respectively, a venture capital and NASD member firm specializing in the biotechnology industry. He also serves as President of several private biotechnology companies. From 1997 until December 2000, Mr. Kanzer was founding President of PolaRx Biopharmaceuticals, Inc., a privately held pharmaceutical company developing arsenic trioxide as a treatment for acute leukemia. PolaRx was subsequently acquired by Cell Therapeutics, Inc., a public biotechnology company, which currently markets arsenic trioxide under the name Trisenox(R). From 1995

30

until June 1999, Mr. Kanzer was a founder and Chairman of Discovery Laboratories, Inc., a public biotechnology company.

RALPH M. ELLISON, M.D., M.B.A., Chief Executive Officer and President

Dr. Ellison became our Chief Executive Officer and President in January 2003. He was a co-founder, Chief Executive Officer and Director of PolaRx Biopharmaceuticals, Inc., an oncology focused drug development company that developed Trisenox(R) (arsenic trioxide) for the treatment of cancer. Following the successful completion of PolaRx's pivotal phase III clinical trial, PolaRx was acquired by Cell Therapeutics, Inc., a public biopharmaceutical company based in Seattle, Washington. During his tenure as the Chief Executive Officer of PolaRx, Dr. Ellison was responsible for all aspects of PolaRx's drug development program from IND filing through the end of phase III testing. Trisenox(R) currently holds the record as the fastest drug developed and approved the FDA. Dr. Ellison then worked closely with Cell Therapeutics during the preparation and filing of the new drug application for Trisenox(R), which was ultimately approved by the FDA for the treatment of relapsed acute promyelocytic leukemia (APL), a life-threatening cancer of the blood. Trisenox(R) is currently in clinical trials to treat more than 10 types of

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

cancer, including multiple myeloma, myelodysplasia and chronic myeloid leukemia. Before founding PolaRx, Dr. Ellison started and ran a contract research organization, which was a division of RTL, INC., a drug testing facility based in New York. At RTL he spent five years designing, implementing and completing clinical trials for both large and small pharmaceutical companies. Dr. Ellison's experience includes the development of anticancer compounds, antifungals, analgesics, anti-inflammatories, antibiotics and drug delivery systems. Dr. Ellison holds a degree of Doctor of Medicine from the University of the Witwatersrand in South Africa and a Masters of Business Administration from the University of Cape Town South Africa.

ROBERT N. BREY, PH.D., Vice President, Research and Development

Since 1996, Dr. Brey has held various positions within our company, including Vice President, Vaccine Development and Vice President, Research and Development, as well as principal vaccine consultant. He also has held scientific, management and project management positions in the Lederle-Praxis division of American Cyanamid, now a division of Wyeth, which has developed a commercially successful vaccine for Haemophilus influenzae meningitis, and a vaccine for pneumonia. While at Lederle-Praxis, Dr. Brey was manager of Molecular Biology research for vaccines and project manager for development of oral vaccines from 1985 through 1993, including projects for non-typable Haemophilus, Salmonella, B. pertussis and malaria. From 1993 through 1994, Dr. Brey served as director of research and development of Vaxcel, a company formed to exploit adjuvant technology and formulations for improved vaccines. From 1994 through 1996, Dr. Brey established an independent consulting group, Vaccine Design Group, to identify and develop novel vaccine technologies and platforms. From 1996 through 1998, in addition to serving as our Vice President, he served as Corporate Vice President of InnoVaccines Corporation, our joint venture with Elan Pharmaceutical Technologies. Before entering into drug and vaccine delivery, he held senior scientific positions at Genex Corporation from 1982 through 1986, one of the first biotechnology companies formed to exploit genetic engineering. He has been instrumental in the development of several commercial human vaccines, including HibTiter and pediatric combinations. Dr. Brey received an undergraduate degree in biology from Trinity College in Hartford, Connecticut, his Ph.D. in microbiology from the University of Virginia and performed postdoctoral studies at MIT with Nobel laureate Salvador Luria. Dr. Brey is an inventor or co-inventor of 10 U.S. patents in the area of vaccines. He is currently editing several theme issues of Advanced Drug Delivery Review on the topic of biodefense vaccines.

31

WILLIAM MILLING, CPA, Controller, Treasurer and Secretary

Before joining DOR BioPharma in September 2002, Mr. Milling spent six years with CCH, a legal publishing company, in various positions in the finance area. His final position was that of Accounting Administrator where he worked with integrating acquired companies and setting up new policies and corporate structures. He also spent two years at Northwestern Memorial Hospital working in the finance area associated with construction of their new \$800 million hospital. Mr. Milling graduated from Eastern Illinois University and passed the CPA examination in Illinois.

LARRY J. KESSEL, M.D., Director

Dr. Kessel is president of a five physician practice specializing in Internal Medicine and Geriatrics since 1984. He graduated Magna Cum Laude with a B.S. degree from the University of Pittsburgh as an honors major in Biology and

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

subsequently graduated with an MD degree from Temple Medical School. He completed a formal residency in Internal Medicine at Abington Memorial Hospital, and is board certified in Internal Medicine with added qualifications as a diplomat in Geriatric Medicine. He is an active staff attending and Clinical Instructor at Chestnut Hill Hospital (University of Pennsylvania affiliate) and Roxborough Memorial Hospital in Philadelphia Pennsylvania. Dr Kessel is a Board Reviewer for the American Board of Internal Medicine, as well as a fellow of the American College of Physicians. He also serves on the advisory board of Independence Blue Cross. Dr. Kessel Presently serves as a director to Cypress Biosciences, Inc of San Diego, California, NovaDel Pharma Inc., of Flemington, New Jersey. He previously served on the Board of Genta Inc.

ARTHUR ASHER KORNBLOTH, M.D., Director

Dr. Kornbluth is a Board Certified Gastroenterologist and Associate Clinical Professor of Medicine at Mount Sinai Medical Center and School of Medicine in New York City, an internationally recognized leading center in the clinical research and management of inflammatory bowel disease. Dr. Kornbluth is an active clinical investigator and practicing clinician with a large practice specializing in the management of patients with complex inflammatory bowel disease. He has published extensively in peer-reviewed journals regarding the pharmacologic and biologic treatments of inflammatory bowel disease. He is the author of several book chapters regarding the diagnosis and management of inflammatory bowel disease. He is the principal author of the American College of Gastroenterology's "Ulcerative Colitis Practice Guidelines in Adults." He has taught and lectured extensively throughout the United States and has received numerous awards as a medical educator. Dr. Kornbluth received his undergraduate degree from Brooklyn College and his medical degree from Downstate Medical Center. He completed his postgraduate training in internal medicine at the Albert Einstein College of Medicine where he was chosen as chief medical resident. He performed his gastroenterology fellowship at the Mount Sinai Medical Center in New York City. He is a member of the American Gastroenterology Association, the American College of Gastroenterology, the Alpha Omega Alpha Honor Medical Society for which he was selected as both an educator and clinician at the Mount Sinai School of Medicine. He is a member of the Crohn's and Colitis Foundation of America and is a member of the that foundation's Clinical Research Alliance, has served on their Clinical Trials Protocol Review Committee and currently serves on the Clinical Research Agenda Task Force.

EVAN MYRIANTHOPOULOS, Director

Mr. Myriantopoulos is currently the President of CVL Advisors, LLC, a financial consulting firm he founded that specializes in the biotechnology sector. Before founding CVL Advisors, Mr. Myriantopoulos was a co-founder of Discovery Laboratories, Inc., a public specialty pharmaceutical company developing respiratory therapies. While at Discovery, Mr. Myriantopoulos held the positions

32

of Chief Financial Officer and Vice President of Finance. Before co-founding Discovery, Mr. Myriantopoulos was a Technology Associate at Paramount Capital Investments, L.L.C., a New York City based biotechnology venture capital and investment banking firm.

PAUL RUBIN, M.D., Director

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Dr. Rubin is a member of the board of DOR BioPharma, Inc. and has served as a member of the board of directors of the Company since November 1997. Dr. Rubin is currently the Chief Executive Officer and President of Critical Therapeutics, Inc. Before joining Critical Therapeutics, he was Executive Vice President for Drug Development at Sepracor, Inc., having been the Senior Vice President since 1996. He was responsible for managing research and development programs for Sepracor's improved chemical entities portfolio, which includes the management of Discovery Research, Regulatory, Clinical, Preclinical, and Project Management teams. Dr. Rubin has also played a key role in the evaluation of external technology and licensing opportunities. From 1993 to 1996, Dr. Rubin was the Vice President and Worldwide Director of Early Clinical Development and Clinical Pharmacology at Glaxo Wellcome. Before joining Glaxo, Dr. Rubin held various executive research positions at Abbott Laboratories. Dr. Rubin received his M.D. from Rush Medical College in Chicago and completed his residency in Internal Medicine at the University of Wisconsin Hospitals and clinics in Madison, Wisconsin.

PETER SALOMON, M.D., F,A.C.G., Director

Dr. Salomon is a Board Certified gastroenterologist and has been in private practice with Gastroenterology Associates of South Florida for the last 11 years. An active clinical researcher in the treatment of Crohn's disease, Dr. Salomon has had several thousand patients suffering from inflammatory bowel disease. Dr. Salomon has authored numerous peer-reviewed publications on the subject of Crohn's disease and is co-author of the chapter of a leading gastroenterology textbook, Sleisinger & Fordtran's, Gastrointestinal & Liver Diseases. Dr. Salomon received his undergraduate degree from New York University in 1981 and his Medical Degree from New York University in 1985. Dr. Salomon received his training in Internal Medicine and Gastroenterology at The Mount Sinai Hospital in New York, where he also held a grant from the Crohn's and Colitis Foundation to perform research in inflammatory bowel disease. Dr. Salomon has previously been a member of the Board of Directors of Genta Inc. and PolaRx and has been a scientific advisor to Cypress Biosciences Inc.

### SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

We are required to identify each person who was an officer, director or beneficial owner of more than 10% of its registered equity securities during its most recent fiscal year and who failed to file on a timely basis reports required by Section 16(a) of the Securities Exchange Act of 1934. Based solely on our review of the copies of such reports received by us, and representatives from certain reporting persons, we believe, that during the year ended December 31, 2002, our directors, executive officers and beneficial owners of more than 10% of our capital stock have complied with all such filing requirements applicable to them, except that: (a) William Milling filed one late Form 3 and one late Form 4 reporting one transaction; (b) Steve Kanzer filed one late Form 4 reporting one transaction; (c) Peter Salomon filed one late Form 4 reporting one transaction; (d) Paul Rubin filed one late Form 4 reporting one transaction; (e) Larry Kessel filed one late Form 4 reporting one transaction and (f) Arthur Asher Kornbluth filed one late Form 4 reporting one transaction.

### ITEM 10. EXECUTIVE COMPENSATION.

The following table contains information concerning the compensation paid during the Company's fiscal years ended December 31, 2000, 2001 and 2002, to the two persons who served as our Chief Executive Officers during 2002, and the two other most highly compensated (based on combined salary and bonus)

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

persons who served as executive officers during the year exceeded \$100,000 for the year (collectively, the "Named Executive Officers").

### SUMMARY COMPENSATION TABLE

NAME AND PRINCIPAL POSITION	YEAR	ANNUAL COMPENSATION		LONG TERM
		SALARY (\$)	BONUS (\$)	COMPENSATION AWARDS SECURITIES UNDERLYING OPTIONS
Steve H. Kanzer Interim President (3)	2002	--	--	250,000
	2001	--	--	--
	2000	--	--	--
Colin Bier, Ph.D Former Chairman & CEO(1)	2002	\$103,124	\$ 47,948	--
	2001	\$ 24,863	--	700,000
	2000	--	--	--
Michael S. Rosen Former President & COO (2)	2002	\$116,691	\$ 25,000	--
	2001	\$254,600	\$ 25,000	160,000
	2000	\$249,600	\$ 25,000	--
Panos Constantides(4) Former Vice President Research and Development	2002	\$ 90,099	\$ 39,000	--
	2001	\$163,000	--	60,000
	2000	--	--	--

-----

- (1) Dr. Bier joined our company in November 2001 and resigned from the Company on June 30, 2002.
- (2) Mr. Rosen resigned from our company on June 30, 2002.
- (3) Mr. Kanzer assumed the role of Interim President from June 31, 2002 through January 4, 2003 for no compensation. Mr. Kanzer received 250,000 options in connection with his role as a director.
- (4) Mr. Constananides joined our company in February of 2001, and left in July 2002.
- (5) All other compensation consists solely of severance payments and obligations to pay.

The following table contains information concerning options granted to the Named Executive Officers during the fiscal year ended December 31, 2002. No SARs were granted during 2002.

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

	NUMBER OF SECURITIES UNDERLYING OPTIONS GRANTED (#)	PERCENTAGE OF TOTAL OPTIONS GRANTED TO EMPLOYEES IN FISCAL YEAR(1)	EXERCISE PRICE (\$/SHARE) (2)	EXPIRATION DATE
Steve Kanzer(3)	250,000	30.5%	\$ 0.20	10/23/1
Colin Bier	--	--	--	--
Michael S. Rosen	--	--	--	--
Panos P. Constantinides(4)	30,000	0.8%	\$ 1.29	10/31/0

-----

- (1) Based on options to purchase an aggregate of 821,000 shares of our common stock granted to employees and non-employee board members in the fiscal year ended December 31, 2002, including all options granted to the Named Executive Officers in all capacities.
- (2) The exercise price of each grant is equal to the fair market value of the Company, Inc.'s common stock on the date of the grant.
- (3) Mr. Kanzer's options were fully vested on the date of grant
- (4) Mr. Constantinides' options are for his services to the Company in all capacities and were granted in 2002 and expired on October 31,2002, 90 days after the termination of his employment.

The following table contains information concerning stock options held as of December 31, 2002 by each of the Named Executive Officers: None of the Named Executive Officers exercised any options during 2002. There were no SARs exercised in, or outstanding at the end of, 2002.

FISCAL YEAR-END OPTION VALUES

NAME	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT 12/31/02 (#)	VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS AT 12/31/02 (\$)(1)
	EXERCISABLE/UNEXERCISABLE	EXERCISABLE/UNEXERCISABLE
Steve Kanzer	666,800/--	50,000/--
Colin Bier	213,572/--	--/--
Michael S. Rosen	835,000/--	--/--
Panos P. Constantinides	--/--	--/--

-----

- (1) Based on the difference between the closing price on December 31, 2002 of \$0.47, as reported on the American Stock Exchange, and the exercise price of outstanding options.

EMPLOYMENT AND SEVERANCE AGREEMENTS

Following the implementation of our restructuring plan, the Company entered into Separation Agreements and General Release Agreements with Dr. Colin Bier, our former Chairman and Chief Executive Officer, and Michael S. Rosen, our

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

former President and Chief Operating Officer. Pursuant to these agreements, our former executives were to receive six month's severance and any options to purchase our Common Stock, that were vested at the time of termination, for one year following the execution of their agreements. In the event that these executives did not obtain other employment with a pay rate at least as much as they had been receiving from us, they were entitled to receive an additional severance beginning six months after termination and paid bi-monthly for six months.

On September 20, 2002, the Company entered into a letter agreement with William Milling, CPA, our Controller, Secretary and Treasurer. Under this agreement, we agreed to pay Mr. Milling a base salary of \$95,000 per year and we granted Mr. Milling options to purchase 200,000 shares of our common stock vesting over 3 years.

On October 7, 2002, the Company entered into a letter agreement with Robin Simuncak, our Director of Clinical Affairs. Under the this agreement, we agreed to pay Ms. Simuncak a base salary of \$90,000 per year and we granted Ms. Simunceck options to purchase 100,000 shares of our common stock vesting over 3 years.

35

On December 10, 2002, the Company entered into a letter agreement with Robert N. Brey, Ph.D., our Vice President of Research and Development. Under this agreement, we agreed to pay Dr. Brey a base salary of \$155,000 per year and we granted Dr. Brey options to purchase 100,000 shares of our common stock vesting over 3 years.

During March 2003, we entered into a three year employment agreement with Ralph M. Ellison M.D., M.B.A. Pursuant to this Employment Agreement we agreed to pay Mr. Ellison a base salary of \$200,000 per year. Upon the completion of an equity financing for, Dr. Ellison would receive an increase in base salary to \$300,000 per year, as well as a bonus of 30% of his base salary. We agreed to issue options to purchase 2,000,000 shares of our Common Stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "just cause" as defined by this agreement, we would pay Dr. Ellison 6 months severance, as well as any unpaid bonuses and all options would immediately become vested.

### BOARD OF DIRECTORS AGREEMENTS

On December 23, 2002, we entered into a letter agreement with General Alexander M. Haig, Jr. to serve as the Chairman of the Board of Directors of the Company. We agreed to pay General Haig a retainer of \$50,000 per year, and issue 2,000,000 options to purchase Common Stock.

### DIRECTOR COMPENSATION

Directors who are compensated as full-time employees receive no additional compensation for service on our Board of Directors or its committees. During 2002, each director who is not a full-time employee was paid \$1,000 for each board or committee meeting attended (\$500 if such board meeting was attended telephonically). This rate applied until the October 23, 2002 Board meeting. At that meeting, the rate was changed to \$2,000 per meeting for each meeting attended (\$1,000 if such meeting was attended telephonically).

We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of the our Board of Directors who are not



## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

full-time employees receive an initial grant of fully vested options to purchase 50,000 shares of common stock, and subsequent yearly grants of fully vested options to purchase 50,000 shares of common stock after re-election to our Board of Directors. In addition, the Board of Directors received a one-time grant of fully vested options to purchase 100,000 shares of common stock on October 23, 2002.

In 2002, Mr. Haig received, instead of the regular initial grant, options to purchase an aggregate of 2,000,000 shares of our common stock, of which options to purchase 900,000 shares of common stock are subject to stockholder approval of an amendment to our option plan, in connection with our retention of him as Chairman of the Board (See "Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, Equity Compensation Plan Information.").

In addition, Mr. Kanzer also received additional options to purchase 100,000 shares of common stock in consideration for additional services provided to us and Mr. Haig will receive an additional \$50,000 for consulting services outside of his service as Chairman of the Board.

36

### ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The table below provides information regarding the beneficial ownership of the Common Stock and Series B Convertible Preferred Stock as of March 21, 2003. The table reflects ownership by: (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock or series B preferred stock; (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them. Except as otherwise indicated, each stockholder's percentage ownership of our common stock in the following table is based on 26,457,112 shares of common stock outstanding.

NAME OF BENEFICIAL OWNER -----	SHARES OF COMMON STOCK BENEFICIALLY OWNED -----	PERCENT OF CLASS -----	SHARES OF SERIES CONVERTIBLE PREFERRED STOCK BENEFICIALLY OWNED -----
Aries Select, Ltd.(1)	2,326,652	8.76%	-
Nomura Bank (2)	1,390,358	5.26%	-
TVM Techno Venture Management (3)	1,310,663	4.95%	-
Aries Select I LLC (4)	1,052,747	3.97%	-
Elan International Services, Ltd.(5)	3,347,750	12.54%	108,442
Lindsay A. Rosenwald, M.D.(6)	5,882,680	21.07%	-
Paramount Capital Asset Management, Inc.(7)	3,399,684	12.85%	-
Steve H. Kanzer (8)	1,912,712	6.91%	-
Alexander M. Haig, Jr. (9)	1,100,000	7.03%	-
Ralph M. Ellison, M.D., M.B.A. (10)	881,286	3.24%	-
Paul Rubin M.D. (11)	204,000	*	-
Arthur Asher Kornbluth, M.D. (12)	150,000	*	-

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Evan Myriantopoulos (13)	215,454	*	-
Peter Salomon, M.D.(14)	315,000	1.18%	-
Larry Kessel, M.D.(15)	364,286	1.37%	-
William Milling (16)	75,000	*	-
Robert Brey (17)	115,000	*	-
All directors and executive officers as a group (10 persons)	6,232,738	19.80%	-

Except as otherwise set forth therein, each stockholder's percentage ownership in the following table is based on 26,457,112 shares of Common Stock outstanding.

-----

\*Less than 1%.

- (1) Number of shares beneficially owned includes 112,159 shares of common stock issuable upon exercise of warrants until April 16, 2003. The address of Aries Select, Ltd. is 787 Seventh Avenue, New York, NY 10019
- (2) The address of Nomura Bank is Kasamari Strasse I, CH 8021, Zurich, Switzerland.
- (3) As reported on a Schedule 13G filed with the SEC on February 14, 2003 by TVM Medical Ventures GmbH & Co. KG. According to the Schedule 13G, TVM Medical Ventures GmbH & Co. KG has sole voting and

37

dispositive power with respect to 1,310,663 shares. The address of TVM Medical Ventures GmbH & Co. KG is 101 Arch Street, Suite 1950, Boston, MA 02110.

- (4) Number of shares beneficially owned includes 56,533 shares of common stock issuable upon exercise of warrants until April 16, 2003. The address of Aries Select I LLC is 787 Seventh Avenue, New York, NY 10019.
- (5) Number of shares beneficially owned includes 1,564,101 shares of common stock issuable upon conversion of Series B preferred stock, and 230,770 shares of common stock issuable upon exercise of warrants until January 21, 2004. The Address of Elan International is 102 St. James Court, Fletts Smith, SC, 04 Bermuda.
- (6) Lindsay A. Rosenwald, M.D., is the Chairman and Chief Executive Officer of Paramount Capital Asset Management, Inc. ("PCAM"). PCAM is the investment manager of Aries Select, Ltd and is the managing member of Aries Select I LLC. Dr. Rosenwald and PCAM share the power to vote and/or dispose of the shares held by Aries Select, Ltd. and Aries Select I LLC. The securities beneficially owned by Dr. Rosenwald include 1,392,783 shares of common stock issuable upon exercise of warrants exercisable until April 16, 2008, 66,931 shares of Common Stock issuable upon exercise of warrants exercisable until October 2007, 2,326,652 shares beneficially owned by Aries Select I LLC, 1,052,747 shares beneficially owned by Aries Select, Ltd. and 20,284 shares beneficially owned by Aries Select II LLC. The securities beneficially owned by Dr. Rosenwald also include 682,774 shares of common stock owned by Paramount Capital Drug Development Holdings, LLC

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

and 13,572 shares of common stock owned by each of June Street Corporation and Huntington Street Corporation. The address of Dr. Ronsenwald is 787 Seventh Avenue, New York, NY 10019.

- (7) Includes the 2,326,652 of common stock shares beneficially owned by Aries Select, Ltd. and the 1,52,748 shares beneficially owned by Aries Select I LLC and 20,284 shares of common stock beneficially owned by Aries Select II, LLC. The address of Paramount Capitol Asset Management, Inc. is 787 Seventh Avenue, New York, NY 10019.
  - (8) Includes 403,095 shares of common stock owned by Mr. Kanzer, 285,714 total shares of common stock upon the exercise of warrants exercisable until December 31, 2007 which are held by Accredited Venture Capital, LLC, a company controlled by Mr. Kanzer, 80,913 shares of common stock issuable upon the exercise of warrants exercisable until December 31, 2007, and 1,000,133 shares of common stock issuable upon the exercise options within 60 days of March 21, 2003. The address of Mr. Kanzer is 28101 N. Ballard Drive, Suite F, Lake Forest, IL 60045.
  - (9) Includes 1,100,000 shares of common stock issuable upon the exercise of options within 60 days of March 21, 2003. Excludes 900,000 shares of common stock issuable upon the exercise of options issued pending stockholder approval. The address of Mr. Haig is c/o Worldwide Associates, Inc., 1155 15 Street, N.W. Suite 800, Washington, D.C. 20005.
  - (10) Includes 142,857 shares of common stock owned by Ralph M. Ellison, M.D., MBA, 71,429 shares issuable upon the exercise of warrants until December 31, 2007, and 667,000 shares of common stock issuable upon the exercise of options within 60 days of March 21, 2003. The address of Mr. Ellison is 28101 N. Ballard Drive, Suite F, Lake Forest, IL 60045.
  - (11) Includes 204,000 options to purchase common stock within 60 days of March 15, 2003. The address of Mr. Rubin is c/o Critical Therapeutics, 675 Massachusetts Ave., 14th Floor, Cambridge, MD 02139.
  - (12) Includes 150,000 options to purchase common stock within 60 days of March 15, 2003. The address of Mr. Kornbluth is c/o Mt. Sinai Medical Center, 1751 York Avenue, New York, NY 10178.
  - (13) Includes 150,000 shares of common stock issuable upon the exercise of options and 65,454 shares of common stock issuable upon the exercise of warrants until December 31, 2007. The address of Mr. Myriantopoulos is c/o COL Advisors 305 Fifth Avenue, Suite 5411, New York, NY 10018.
  - (14) Includes 150,000 shares of common stock issuable upon the exercise of options within 60 days of March 21, 2003, and 5,000 shares issuable upon the exercise of warrants exercisable until December 31, 2007. Excludes 150,000 shares of common stock issuable upon exercise options issued pending stockholder approval. The address of Peter Salomon is c/o Gastroenterology Consultants, 951 N.W. 13th St., Boca Raton, FL 33486.
- 38
- (15) Includes 150,000 shares of common stock issuable upon the exercise of options within 60 days of March 15, 2003, and 21,429 shares issuable upon the exercise of warrants exercisable until December 31, 2007. Excludes 150,000 shares of common stock issuable upon exercise options issued pending stockholder approval. The address of Mr. Kossel is 4114 Hain Drive, Lafayette Hill, PA 19444-1514.
  - (16) Includes options to purchase 75,000 of common stock within 60 days of

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

March 15, 2003. The address of Mr. Milling is 28101 W. Ballard Drive, Suite F, Lake Forest, IL 60045.

- (17) Includes options to purchase 115,000 Shares of common stock within 60 days of March 15, 2003. The address of Mr. Brey is 28101 W. Ballard Drive, Suite F, Lake Forest, IL 60045.

### EQUITY COMPENSATION PLAN INFORMATION

As of December 31, 2002, we maintained our 1995 Amended and Restated Omnibus Incentive Plan, which was approved by our stockholders. In December 2002, our board of directors approved an amendment to our 1995 Plan to increase the number of shares available for issuance under the 1995 Plan to 11,000,000 and increased the number of shares available for issuance to a single participant under the 1995 Plan to 2,500,000. Because that amendment, and options issued based upon that amendment, are subject to stockholder approval, the additional shares and those options are included in the category "Equity Compensation Plans Not Approved by Security Holders" and a summary description of the 1995 Plan is provided below.

Plan Category	(a)	(b)	Number remaini future equity (exclud reflect
-----	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted - average exercise price of outstanding options, warrants and rights	-----
Equity compensation plans approved by security holders	4,721,462	\$0.95	
Equity compensation plans not approved by security holders	1,342,375	\$0.35	
Total	6,063,837	\$0.82	

### 1995 OMNIBUS INCENTIVE PLAN

Our 1995 Omnibus Incentive Plan was initially adopted in April 1995. The 1995 Plan was subsequently amended in July 1996, October 1997, February 1998, February 2001 and December 2002 to effect increases to the share reserve and certain other amendments; all such amendments, other than the December 2002 amendment, have been approved by the stockholders. An aggregate of 11,000,000 shares of common stock have been reserved for issuance over the term of the 1995 Plan, subject to stockholder approval of the December 2002 Amendment. The purpose of the 1995 Plan is to attract and retain employees, consultants and directors and to provide these persons with incentives and rewards for superior performance. The 1995 Plan consists of four separate equity incentive programs: (1) the Discretionary Option Grant Program, (2) the Salary Investment Option Grant Program, (3) the Automatic Option Grant Program for non-employee board members and (4) the Director Fee Option Grant Program for non-employee board members. Under the Discretionary Option Grant Program, our compensation committee has complete discretion to issue options and the terms these options will be issued upon. Under the Salary Investment Option Grant Program, our compensation committee has complete discretion to issue options to employees who choose to reduce their base salary by at least \$10,000. Under the

Automatic Option Grant Program, eligible non-employee board members receive a series of option grants over their period of board service. Under the Director Fee Option Grant Program, our compensation committee has complete discretion to issue options to non-employee directors who choose to all or a portion of their cash retainer fee.

ADDITIONAL OPTION ISSUED TO ALEXANDER HAIG

In connection with our retention of Mr. Haig as our Chairman of the Board, we issued to him options to purchase a total of 1,544,420 shares of our common stock under the 1995 Plan, of which options to purchase a total of 900,000 shares of common stock are subject to stockholder approval of the amendment to the 1995 Plan, as disclosed above. In addition to those options issued to Mr. Haig under the 1995 Plan, we issued to Mr. Haig an option to purchase 442,375 shares of our common stock as a further inducement to him to accept the position of Chairman of the Board. That option, which is not issued under the 1995 Plan nor subject to approval by our stockholders, is fully-vested exercisable for ten years at an exercise price of \$0.35 per share.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

In December 2002, we completed a private placement of 3,093,569 shares of our common stock and warrants to purchase 1,546,789 shares of our common stock. In this private placement we received total proceeds of \$1,082,750. Purchasers in this private placement included David M. Kent, our former Chief Executive Officer and President, Ralph M. Ellison our current Chief Executive Officer, and Steve H. Kanzer, Lawrence Kessel and Peter Salomon, each of whom is a member of our Board of Directors. In addition, we issued warrants to purchase 463,073 shares of our common stock to certain individuals and entities, including warrants to purchase 80,913 shares to Mr. Kanzer, in consideration for placement services rendered in connection with this private placement.

On January 4, 2003, the Company entered into a two-year employment agreement with David M. Kent. Pursuant to the agreement, we agreed to pay a base salary of \$180,000 per year. The Company agreed to issue options to purchase 600,000 shares of our common stock, with one third immediately vesting and the remainder vesting over two years. If the price of our common stock trades above \$3 and \$5 dollars per share, Mr. Kent would be entitled to accelerated vesting of the options. In the event that Mr. Kent is terminated within the first year of employment, we would be obligated to pay three months severance. In the event that Mr. Kent were terminated after the first year of employment, we would be obligated to pay six months' severance. On March 7, 2003, Mr. Kent resigned from the Company and entered into a separation agreement and general release in which we agreed to pay Mr. Kent six months' severance and Mr. Kent has one year to exercise the 200,000 vested options received pursuant to the his employment agreement.

In connection with our 2002 private placement of units, Evan Myriantopoulos, one of our Directors acted as a finder to introduce certain investors to the Company. Mr. Myriantopoulos received \$15,375 cash compensation and 65,454 Warrants to acquire our Common Stock.

ITEM 13. EXHIBITS, LIST AND REPORTS ON FORM 8-K.

(a) The following financial statements and exhibits are filed as part of this report:

(1) Financial Statements:

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

(i) Independent Accountants' Report.

40

(ii) Balance Sheets as of December 31, 2002 and December 31, 2001.

(iii) Statement of Operations for the periods ended December 31, 2002 and 2001 and cumulative from February 15, 1985 (date of inception) to December 31, 2002.

(iv) Statement of Cash Flows for the periods ended December 31, 2002 and 2001 and cumulative from February 15, 1985 (date of inception) to December 31, 2002.

(v) Statement of Stockholders' Equity for the period from February 15, 1985 (date of inception) to December 31, 2002.

(vi) Notes to Financial Statements.

### (2) Exhibits

- 3.1 Amended and Restated Certificate of Incorporation.(2)
- 3.2 By-laws.(3)
- 4.1 Specimen Common Stock Certificate.(3)
- 4.2 Form of Subscription Agreement by and between the Company and each investor dated as of April 11, 2000.(4)
- 4.3 Form of Amendment and Supplement to Subscription Agreement entered into by each investor as of April 11, 2000.(4)
- 4.4 Form of Second Amendment and Supplement to Subscription Agreement entered into by each investor as of April 11, 2000.(4)
- 4.5 Form of Investor Warrant issued to each investor dated as of April 12, 2000.(4)
- 4.6 Form of Finder Warrant issued to Paramount Capital, Inc. dated as of April 12, 2000.(4)
- 4.7 Warrant issued to Aries Fund dated as of May 19, 1997.(4)
- 4.8 Warrant issued to Aries Domestic Fund, L.P. dated as of May 19, 1997.(4)
- 4.9 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997.(5)
- 4.10 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997.(5)
- 4.11 Warrant issued to Elan International Services, Ltd. dated January 21, 1998.(6)
- 4.12 Form of Warrant to be issued to CTD warrant holders.(12)

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

10.1 Patent License Agreement dated December 16, 1996 between the Company and Massachusetts Institute of Technology.(7)

41

10.2 Purchase Agreement among Dominion Resources, Inc., The Aries Fund, a Cayman Island Trust, The Aries Domestic Fund, L.P., and the Company dated as of June 13, 1996.(4)

10.3 Purchase Agreement dated as of June 26, 1996 between the Company, The Aries Fund and The Aries Domestic Fund, L.P.(7)

10.4 Amended and Restated 1996 Omnibus Incentive Plan.(8)

10.5\* Amended and Restated 1995 Omnibus Incentive Plan, as approved by shareholders of the Company on November 29, 2001.(14)

10.6 Lease dated December 19, 1997 between the Company and Howard M. Ruskin.(5)

10.7 Joint Development and Operating Agreement, dated as of January 21, 1998, between the Company, Elan Corporation, plc, Orasomal Technologies, Inc. and Endorex Vaccine Delivery Technologies, Inc.(5)

10.8 Securities Purchase Agreement, dated as of January 21, 1998, between the Company and Elan International Services, Ltd.(6)

10.9 Registration Rights Agreement, dated as of January 21, 1998, between the Company and Elan International Services, Ltd.(6)

10.10+ License Agreement, dated as of January 21, 1998, between Elan Pharmaceuticals, plc, and Endorex Vaccine Delivery Technologies, Inc.(6)

10.11+ License Agreement, dated as of January 22, 1998, between Orasomal Technologies, Inc., Endorex Vaccine Delivery Technologies, Inc. and the Company.(6)

10.12 Securities Purchase Agreement, dated as of October 21, 1998, between the Company and Elan International Services, Ltd.(9)

10.13 Registration Rights Agreement, dated as of October 21, 1998, between the Company and Elan International Services, Ltd.(9)

10.14+ License Agreement, dated as of October 21, 1998, between the Company, Elan Corporation, plc, Endorex Newco. Ltd., and Elan Medical Technologies Ltd.(9)

10.15+ Joint Development and Operating Agreement, dated as of October 21, 1998, between the Company, Elan Corporation, plc, Elan International Services, Ltd. and Endorex Newco, Ltd.(9)

10.17+ Development License and Supply Agreement, dated February 2, 2000, between the Company Newco, Ltd. and Schein Pharmaceutical (Bermuda), Ltd.(10)

10.20\* Employment Agreement dated October 21, 2001 between the Company and Michael Rosen.(14)

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

42

- 10.21\* Employment Agreement between the Company and Steve Koulogeorge dated September 19, 2000.(8)
- 10.22\* Employment Agreement between the Company and Panayiotis Constantinides dated January 4, 2001.(8)
- 10.23\* Employment Agreement between the Company and John McCracken dated February 21, 2001.(8)
- 10.24 Financial Advisory Agreement between the Company and Paramount Capital, Inc. dated as of October 18, 2001.(14)
- 10.25 Form of Affiliate Agreement dated as of August 15, 2001 by and between the Company and the affiliates of CTD.(13)
- 10.26 Escrow Agreement to be entered into by and among the Company, the stockholders of CTD, Peter O. Kliem, and Wells Fargo Bank Minnesota, National Association.(13)
- 10.27 Amendment No. 1 to Escrow Agreement dated November 29, 2001 by and among the Company, Paramount Capital Drug Development Holdings LLC, Peter Kliem and Wells Fargo.(13)
- 10.28\* Employment Agreement between the Company and Colin Bier dated November 29, 2001.(14)
- 10.29\* Consulting Agreement entered into by and among the Company, CTD and Nicholas Stergiopoulos dated as of November 29, 2001.(14)
- 10.30\* Noncompetition and Nonsolicitation Agreement entered into by and among the Company, CTD and Steve H. Kanzer dated as of November 29, 2001.(14)
- 10.31 Master Loan and Security Agreement, dated as of December 23, 1998, between FINOVA Technology Finance, Inc. and the Company.(14)
- 10.32 Amendment dated as of December 30, 1999, to the Patent License Agreement dated December 16, 1996 between the Company and Massachusetts Institute of Technology.(7)
- 10.33 Termination and Release Agreement, dated March 7, 2002, by and between Schein Pharmaceutical (Bermuda) Ltd., and Endorex Newco.(1)
- 10.34\* Termination agreement between the Company and Colin Bier dated June 16, 2002.
- 10.35\* Termination agreement between the Company and Michael Rosen Dated June 14, 2002.
- 10.36 Letter of intent between the Company, Southern Research Institute, and the University of Alabama to increase licensed rights to patents dated December 20, 2002.



Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

43

- 10.37 Termination of the Endorex Newco joint venture between the Company , Elan Corporation, Elan international services, and Elan Pharmaceutical Investments dated December 12, 2002.
- 10.38\* Amendment to the 1995 Omnibus Incentive Plan (subject to stockholder approval).
- 10.39\* Option Agreement with General Alexander M. Haig Jr.
- 10.40\* Employment agreement between the Company and Ralph Ellison dated March 13, 2003
- 10.41 Letter of Intent between the Company and Thomas Jefferson University for sponsored research
- 10.42 Consulting agreement between the Company and The School of Pharmacy, University of London
- 10.43 Consulting agreement between the Company and Lance Simpson of Thomas Jefferson University
- 21.1 Subsidiaries of the Company
- 23.1 Consent of Ernst & Young LLP.
- 99.1 Certification of the Chief Executive Officer pursuant to section 906 of the Sabanes Oxley Act of 2002.
- 99.2 Certification of the Chief Financial Officer pursuant to section 906 of the Sabanes Oxley Act of 2002.

-----  
\*Management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report.

+ Endorex was granted Confidential Treatment of portions of this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

- (1) Incorporated by reference from our Quarterly Report on Form 10-QSB for the fiscal quarter ended June 30, 2002.
- (2) Incorporated by reference to our Quarterly Report on Form 10-QSB, for the fiscal quarter ended June 30, 2001.
- (3) Incorporated by reference to our Registration Statement on Form S-1, as amended (File No. 33-13492).
- (4) Incorporated by reference to our Registration Statement on Form S-3 (File No. 333-36950), as amended on December 29, 2000.
- (5) Incorporated by reference to our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 1997.
- (6) Incorporated by reference to our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 1997.
- (7) Incorporated by reference to our Annual Report on Form 10-KSB, as amended, for the transition period ended December 31, 1996.
- (8) Incorporated by reference to our Annual Report on Form 10-KSB for the

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

fiscal year ended December 31, 2000, as amended.

- (9) Incorporated by reference to our Quarterly Report on Form 10-QSB for the fiscal quarter on Form 10-QSB for the fiscal quarter ended September 30, 1998.
- (10) Incorporated by reference to our Annual Report on Form 10-KSB for the fiscal year ended December 31, 1999, as amended.
- (11) Incorporated by reference to our current report on Form 8-K filed on November 9, 2000.
- (12) Incorporated by reference to our Registration Statement on Form S-4 filed on October 2, 2001.
- (13) Incorporated by reference to our current report on Form 8-K filed on December 14, 2001.

44

- (14) Incorporated by reference to our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001, as amended.

(b) Reports on Form 8-K

We did file any current reports on Form 8-K during the fourth quarter of 2002.

### ITEM 14. CONTROLS AND PROCEDURES

(a) Our Chief Executive Officer and Controller (our principal executive officer and principal financial officer, respectively) have concluded, based on their evaluation as of a date within 90 days prior to the date of the filing of this report, that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports filed or submitted by us under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports is accumulated and communicated to the our management, including our Chief Executive Officer and Controller, as appropriate to allow timely decisions regarding required disclosure.

(b) There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation."

45

DOR BioPharma, Inc.

Consolidated Balance Sheets

DECEM

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

	2002
	-----
ASSETS	
Current assets:	
Cash and cash equivalents	\$ 4,147,164
Receivable from related party	--
Prepaid expenses	104,333
	-----
Total current assets	4,251,497
Leasehold improvements and equipment, net of accumulated amortization of \$1,162,247 and \$976,860	262,921
Licenses and patent costs, net of accumulated amortization of \$46,100 and \$15,091	1,097,341
Amortizable intangible assets, net of accumulated amortization of \$137,710 and \$8,611	226,441
	-----
Total assets	\$ 5,838,200
	=====
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable and accrued expenses	\$ 698,120
Accrued compensation	124,480
Due to joint ventures	--
Current portion of long-term debt	382,122
	-----
Total current liabilities	1,204,722
Long-term debt	347,845
	-----
Total liabilities	1,552,567
Series C exchangeable convertible preferred stock, \$.05 par value Authorized 200,000 shares; 0 and 104,435 issued and outstanding, at liquidation value	--
Stockholders' equity (deficit):	
Preferred stock, \$.001 par value. Authorized 4,600,000 shares; none issued and outstanding	--
Series B convertible preferred stock, \$.05 par value. Authorized 200,000 shares; 117,118 and 108,443 issued and outstanding, at liquidation value	11,711,822
Common stock, \$.001 par value. Authorized 50,000,000 shares; 26,794,642 and 20,944,384 issued, 26,622,300 and 20,825,742 outstanding	26,795
Additional paid-in capital	61,315,985
Common stock to be issued, 375,498 and 1,350,000 shares	436,812
Unearned compensation	(50,148)
Deficit accumulated during the development stage	(68,687,366)
	-----
Less: Cost of 172,342 and 118,642 shares of common stock in treasury	4,753,900
	(468,267)
	-----
Total stockholders' equity (deficit)	4,285,633
	-----
Total liabilities and stockholders' equity (deficit)	\$ 5,838,200
	=====

The accompanying notes are an integral part  
of the consolidated financial statements.

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

F-1

DOR BioPharma, Inc.

Consolidated Balance Sheets

	YEAR ENDED DECEMBER 31		CUMULATIVE FEBRUARY (INCEP DECEMB 20
	2002	2001	20
	-----	-----	-----
SBIR contract revenue	\$ --	\$ --	\$ 100
Expenses:			
SBIR contract research and development	--	--	86
Proprietary research and development	2,943,493	2,470,801	20,247
General and administrative	2,988,020	1,973,455	18,033
Write-off of acquired in-process research and development	--	10,181,000	10,181
	-----	-----	-----
Total expenses	5,931,513	14,625,256	48,547
	-----	-----	-----
Loss from operations	(5,931,513)	(14,625,256)	(48,447)
Equity in earnings (losses) of joint ventures	868,859	(401,699)	(22,179)
Other income	--	7,588	262
Interest income	105,676	424,032	3,571
Interest expense	(9,103)	(35,840)	(358)
	-----	-----	-----
Net loss	(4,966,081)	(14,631,175)	(67,151)
Preferred stock dividends	(1,456,385)	(1,486,501)	(6,323)
	-----	-----	-----
Net loss applicable to common stockholders	\$ (6,422,466)	\$ (16,117,676)	\$ (73,474)
	=====	=====	=====
Basic and diluted net loss per share applicable to common shareholders	\$ (0.29)	\$ (1.20)	
Basic and diluted weighted average common shares outstanding	22,498,894	13,450,579	

The accompanying notes are an integral part of the consolidated financial statements.

F-2

DOR BioPharma, Inc.

Consolidated Statements of Stockholders' Equity



Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

The accompanying notes are an integral part of the consolidated financial statements.

F-3

DOR BioPharma, Inc.

Consolidated Statements of Stockholders' Equity (continued)

	Common Stock		Common Stock to be Issued		Preferred Stock		Add Pa Ca
	Shares	Par Value	Shares	Stated Value	Shares	Stated Value	
Nonqualified stock options exercised in 1988	18	\$ --	--	\$ --	--	--	\$ --
Stock warrants exercised in 1988	1	--	--	--	--	--	--
Common stock redeemed and retired in 1988	(10)	--	--	--	--	--	--
Excess of fair market value over option price of nonqualified stock options granted in 1988	--	--	--	--	--	--	--
Amortization of unearned compensation in 1988	--	--	--	--	--	--	--
Nonqualified stock options exercised in 1989	71	--	--	--	--	--	--
Common stock redeemed and retired in 1989	(12)	--	--	--	--	--	--
Excess of fair market value over option price of nonqualified stock options granted in 1989	--	--	--	--	--	--	--
Net proceeds from secondary public stock offering in April 1989 at \$525 per share, less issuance cost	2,174	2	--	--	--	--	--
Amortization of unearned compensation in 1989	--	--	--	--	--	--	--
Common stock issued for cash in October 1990 through January 1991 at \$9.00 per share	5,694	6	--	--	--	--	--
Excess of fair market value over option price of nonqualified stock options granted in 1990	--	--	--	--	--	--	--
	Treasury Stock		Unearned		Note		
	Equity	Cost	Compensation		Receivable		

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Nonqualified stock options exercised in 1988	--	\$ --	\$ --	\$ --
Stock warrants exercised in 1988	--	--	--	--
Common stock redeemed and retired in 1988	--	--	--	--
Excess of fair market value over option price of nonqualified stock options granted in 1988	--	--	--	--
Amortization of unearned compensation in 1988	--	--	19,113	--
Nonqualified stock options exercised in 1989	--	--	--	--
Common stock redeemed and retired in 1989	--	--	--	--
Excess of fair market value over option price of nonqualified stock options granted in 1989	--	--	--	--
Net proceeds from secondary public stock offering in April 1989 at \$525 per share, less issuance cost	--	--	--	--
Amortization of unearned compensation in 1989	--	--	1,650	--
Common stock issued for cash in October 1990 through January 1991 at \$9.00 per share	--	--	--	--
Excess of fair market value over option price of nonqualified stock options	--	--	--	--

The accompanying notes are an integral part of the consolidated financial statements

F--4

DOR BioPharma, Inc.

Consolidated Statements of Stockholders' Equity (continued)

	Common Stock		Common Stock to be Issued		Preferred Stock	
	Shares	Par Value	Shares	Stated Value	Shares	Stated Value
Common stock issued for cash in February 1991 through April 1991 at \$9.00 per share	2,772	\$ 3	--	\$ --	--	\$ --
Common stock issued for cash and services in November 1991 at \$1.50 per share	15,333	15	--	--	--	--
Common stock issued for cash and note in December 1991 at \$0.75 per share	296,949	297	--	--	--	--

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Excess of fair market value over option price of nonqualified stock options granted in 1991	--	--	--	--	--	--
Nonqualified stock options exercised in 1991	1	--	--	--	--	--
Payments on note receivable in 1992	--	--	--	--	--	--
Net proceeds from secondary public stock offering in August 1992 at \$112.50 per share, less issuance costs	66,666	66	--	--	--	--
Nonqualified stock options exercised in 1992	2,000	2	--	--	--	--
Excess of fair market value over option price of nonqualified stock options granted in 1993	--	--	--	--	--	--
Amortization of unearned compensation in	--	--	--	--	--	--
Nonqualified stock options exercised in 1993	67	--	--	--	--	--
Collection of note receivable in 1993	--	--	--	--	--	--

	Other Comprehensive Income	Treasury Stock ----- Shares	Cost	Unearned Compensation
	-----	-----	-----	-----
Common stock issued for cash in February 1991 through April 1991 at \$9.00 per share	\$ --	--	\$ --	\$ --
Common stock issued for cash and services in November 1991 at \$1.50 per share	--	--	--	--
Common stock issued for cash and note in December 1991 at \$0.75 per share	--	--	--	--
Excess of fair market value over option price of nonqualified stock options granted in 1991	--	--	--	--
Nonqualified stock options exercised in 1991	--	--	--	--
Payments on note receivable in 1992	--	--	--	--
Net proceeds from secondary public stock offering in August 1992 at \$112.50 per share, less issuance costs	--	--	--	--
Nonqualified stock options exercised in 1992	--	--	--	--
Excess of fair market value over option price of nonqualified stock options granted in 1993	--	--	--	(126,000)
Amortization of unearned compensation in	--	--	--	40,750
Nonqualified stock options exercised in 1993	--	--	--	--
Collection of note receivable in 1993	--	--	--	--

The accompanying notes are an integral part of the consolidated financial statements.



Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

DOR BioPharma, Inc.

Consolidated Statements of Stockholders' Equity (continued)

	Common Stock		Common Stock to be Issued		Preferred Stock		Addi- tional Paid- in- Cap-
	Shares	Par Value	Shares	Stated Value	Shares	Stated Value	
Acquisition of treasury stock in 1994	--	\$ --	--	\$ --	--	\$ --	\$
Forfeiture of nonqualified stock options granted in 1994	--	--	--	--	--	--	(
Amortization of unearned compensation in 1994	--	--	--	--	--	--	
Acquisition of treasury stock in 1995	--	--	--	--	--	--	
Forfeiture of nonqualified stock options granted in 1995	--	--	--	--	--	--	
Amortization of unearned compensation in 1995	--	--	--	--	--	--	
Common stock issued at \$0.975 per share in 1996	333,333	333	--	--	--	--	3
Common stock issued at \$3.00 per share in 1996	333,333	333	--	--	--	--	9
Nonqualified stock options exercised in 1996	145,283	146	--	--	--	--	3
Warrants exercised at \$1.20 per share in 1997	1,173	1	--	--	--	--	
Proceeds on exercise of stock options in 1997	--	--	--	--	--	--	
Warrants issued in 1997	--	--	--	--	--	--	5,4
Net proceeds for private placement at \$2.3125 per share, less issuance cost in 1997	8,648,718	8,650	--	--	--	--	15,1

	Treasury Stock		Unearned Compensation	Note Receivable
	Shares	Cost		
Acquisition of treasury stock in 1994	41,975	\$ (300,000)	\$ --	\$ --
Forfeiture of nonqualified stock options granted in 1994	--	--	22,402	--
Amortization of unearned compensation in 1994	--	--	49,348	--
Acquisition of treasury stock in 1995	76,667	(143,750)	--	--
Forfeiture of nonqualified stock options granted in 1995	--	--	1,379	--
Amortization of unearned compensation in 1995	--	--	12,121	--
Common stock issued at \$0.975 per share in 1996	--	--	--	--
Common stock issued at \$3.00 per share	--	--	--	--

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

in 1996	--	--	--	--
Nonqualified stock options exercised in 1996	--	--	--	--
Warrants exercised at \$1.20 per share in 1997	--	--	--	--
Proceeds on exercise of stock options in 1997	--	--	--	--
Warrants issued in 1997	--	--	--	--
Net proceeds for private placement at \$2.3125 per share, less issuance cost in 1997	--	--	--	--

The accompanying notes are an integral part of the consolidated financial statements.

F-6

DOR BioPharma, Inc.

Consolidated Statements of Stockholders' Equity (continued)

	Common Stock		Common Stock to be Issued		Sha
	Shares	Par Value	Shares	Stated Value	
Net proceeds from issuance of common stock and warrants in January 1998	307,692	\$ 308	-	\$ -	\$
Proceeds from exercise of stock options in 1998	25,000	25	-	-	
Purchase and retirement of common stock in 1998	(133,335)	(134)	-	-	
Net proceeds from issuance of Series B preferred stock at \$100 per share in March 1998	-	-	-	-	80,
Accrued preferred stock dividends in 1998	-	-	-	-	5,
Proceeds from exercise of stock options in 1999	334	4	-	-	
Common stock dividends issued in 1999	819,319	819	-	-	
Accrued preferred stock dividends in 1999	-	-	-	-	6,
Net proceeds from private placement at \$4.725 per share, less issuance costs in 2000	1,809,520	1,810	-	-	
Issuance of options issued in exchange for financial advisory services in 2000	-	-	-	-	
Issuance of options issued in exchange for consulting services in 2000	-	-	-	-	
Amortization of unearned compensation					

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

in 2000	-	-	-	-	
Proceeds from exercise of stock options					
in 2000	71,722	69	-	-	
Noncash exercise of warrants in 2000	104,963	104	-	-	
Accrued preferred stock dividends					
in 2000	-	-	-	-	7,
Net loss from inception, February 15, 1985 to December 31, 2000	-	-	-	-	
Unrealized gain on marketable securities in 2000	-	-	-	-	
Comprehensive loss	-	-	-	-	
Balance at December 31, 2000	12,860,500	12,861	-	-	100,

	(Deficit) Accumulated During the Development Stage	Other Comprehensive Income	Treasury Stock ----- Shares      Cost	
Net proceeds from issuance of common stock and warrants in January 1998	-	\$ -	\$ -	\$ -
Proceeds from exercise of stock options in 1998	-	-	-	-
Purchase and retirement of common stock in 1998	-	-	-	-
Net proceeds from issuance of Series B preferred stock at \$100 per share in March 1998	-	-	-	-
Accrued preferred stock dividends in 1998	-	-	-	-
Proceeds from exercise of stock options in 1999	-	-	-	-
Common stock dividends issued in 1999	(1,536,222)	-	-	-
Accrued preferred stock dividends in 1999	-	-	-	-
Net proceeds from private placement at \$4.725 per share, less issuance costs in 2000	-	-	-	-
Issuance of options issued in exchange for financial advisory services in 2000	-	-	-	-
Issuance of options issued in exchange for consulting services in 2000	-	-	-	-
Amortization of unearned compensation in 2000	-	-	-	-
Proceeds from exercise of stock options in 2000	-	-	-	-
Noncash exercise of warrants in 2000	-	-	-	-
Accrued preferred stock dividends in 2000	-	-	-	-
Net loss from inception, February 15, 1985 to December 31, 2000	(47,553,888)	-	-	-

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Unrealized gain on marketable securities in 2000	-	75	-
Comprehensive loss	-	-	-
Balance at December 31, 2000	(49,090,110)	75	118,642 (443,75)

Total  
Stockholders'  
Equity

Net proceeds from issuance of common stock and warrants in January 1998	\$ 1,871,845
Proceeds from exercise of stock options in 1998	61,750
Purchase and retirement of common stock in 1998	(130,000)
Net proceeds from issuance of Series B preferred stock at \$100 per share in March 1998	8,010,000
Accrued preferred stock dividends in 1998	(114,521)
Proceeds from exercise of stock options in 1999	351
Common stock dividends issued in 1999	-
Accrued preferred stock dividends in 1999	(596,778)
Net proceeds from private placement at \$4.725 per share, less issuance costs in 2000	7,774,548
Issuance of options issued in exchange for financial advisory services in 2000	-
Issuance of options issued in exchange for consulting services in 2000	-
Amortization of unearned compensation in 2000	95,307
Proceeds from exercise of stock options in 2000	215,754
Noncash exercise of warrants in 2000	-
Accrued preferred stock dividends in 2000	(638,500)
Net loss from inception, February 15, 1985 to December 31, 2000	(47,553,888)
Unrealized gain on marketable securities in 2000	75
Comprehensive loss	(47,553,813)
Balance at December 31, 2000	880,633

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

The accompanying notes are an integral part of the consolidated financial statements.

F-7

DOR BioPharma, Inc.

Consolidated Statements of Stockholders' Equity (continued)

	Common Stock		Common Stock to be Issued		Share
	Shares	Par Value	Shares	Stated Value	
Issuance of common stock for the acquisition of CTD	8,083,884	8,084	1,350,000	1,687,500	
Additional costs related to 2000 private placement	-	-	-	-	
Issuance of options issued in exchange for advisory services and consulting fees	-	-	-	-	
Amortization of unearned compensation	-	-	-	-	
Accrued preferred stock dividends	-	-	-	-	8,03
Net loss	-	-	-	-	
Unrealized loss on marketable securities	-	-	-	-	
Comprehensive loss	-	-	-	-	
Balance at December 31, 2001	20,944,384	20,945	1,350,000	1,687,500	108,44
Issuance of common stock, net	3,593,569	3,593	-	-	
Issuance of options issued in exchange for advisory services and consulting fees	-	-	-	-	
Amortization of unearned compensation	-	-	-	-	
Accrued preferred stock dividends	-	-	-	-	8,67
Conversion of redeemable preferred stock to common stock	1,245,187	1,245	-	-	
Issuance of restricted stock for consulting services	-	-	37,000	13,690	
Acquisition of treasury stock	-	-	-	-	
Release of shares to be issued	1,011,502	1,012	(1,011,502)	(1,264,378)	
Net loss	-	-	-	-	
Balance at December 31, 2002	26,794,642	\$26,795	375,498	\$ 436,812	117,11

(Deficit)  
Accumulated  
During the                      Other                      Treasury Stock

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

	Development Stage	Comprehensive Income	Shares	Cost	U Com
Issuance of common stock for the acquisition of CTD	-	-	-	-	
Additional costs related to 2000 private placement	-	-	-	-	
Issuance of options issued in exchange for advisory services and consulting fees	-	-	-	-	(25)
Amortization of unearned compensation	-	-	-	-	30
Accrued preferred stock dividends	-	-	-	-	
Net loss	(14,631,175)	-	-	-	
Unrealized loss on marketable securities	-	(75)	-	-	
Comprehensive loss	-	-	-	-	
Balance at December 31, 2001	(63,721,285)	-	118,642	(443,750)	
Issuance of common stock, net	-	-	-	-	
Issuance of options issued in exchange for advisory services and consulting fees	-	-	-	-	(368)
Amortization of unearned compensation	-	-	-	-	318
Accrued preferred stock dividends	-	-	-	-	
Conversion of redeemable preferred stock to common stock	-	-	-	-	
Issuance of restricted stock for consulting services	-	-	-	-	
Acquisition of treasury stock	-	-	53,700	(24,517)	
Release of shares to be issued	-	-	-	-	
Net loss	(4,966,081)	-	-	-	
Balance at December 31, 2002	\$(68,687,366)	\$ -	172,342	\$(468,267)	\$(50)

The accompanying notes are an integral part of the consolidated financial statements.

F-8

DOR BioPharma, Inc.

Consolidated Statement of Cash Flows

	YEAR ENDED DECEMBER 31		CUMU FEBR (I D
	2002	2001	
OPERATING ACTIVITIES:			
Net loss	\$ (4,966,081)	\$(14,631,175)	\$

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	345,495	188,526
Gain on sale of marketable securities	--	--
Noncash stock compensation	332,378	30,405
Equity in (earnings) losses of joint ventures	(868,859)	401,699
Amortization of fair value of warrants	--	--
Gain on sale of assets	--	--
Write-off patent issuance cost	--	--
Write-off of acquired research and development	--	10,181,000
Change in operating assets and liabilities:		
Receivable from related party	44,447	82,091
Prepaid expenses	(54,392)	12,884
Accounts payable and accrued expenses	(158,067)	68,821
Accrued compensation	(81,489)	58,764
Due to joint ventures	(594,232)	(369,579)
Total adjustments	(1,034,719)	10,654,611
Net cash used in operating activities	(6,000,800)	(3,976,564)
INVESTING ACTIVITIES:		
Cash received in acquisition of CTD, net	--	1,392,108
Patent issuance costs	(593,931)	(34,835)
Investment in joint ventures	--	--
Organizational costs incurred	--	--
Purchases of leasehold improvements and equipment	(83,089)	(139,656)
Proceeds from assets sold	--	--
Purchases of marketable securities	--	--
Proceeds from sale of marketable securities	--	2,014,909
Net cash provided by (used in) investing activities	(677,020)	3,232,526

The accompanying notes are an integral part of the consolidated financial statements.

F-9

DOR BioPharma, Inc.

Consolidated Statement of Cash Flows (continued)

YEAR ENDED  
DECEMBER 31

2002 2001

FINANCING ACTIVITIES:

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

Net proceeds from issuance (costs incurred related to issuance) of common stock	974,069	(21,871)
Proceeds from exercise of options	--	--
Proceeds from borrowings under line of credit	--	--
Repayment of amounts due under line of credit, notes payable and capital lease obligations	(66,621)	(123,304)
Repayment of long-term receivable	--	--
Repayment of note payable issued in exchange for legal services	--	--
Purchase and retirement of common stock	--	--
Purchase of common stock for treasury	(24,517)	--
	-----	-----
Net cash provided by (used in) financing activities	882,931	(145,175)
	-----	-----
Net increase (decrease) in cash and cash equivalents	(5,794,889)	(889,213)
Cash and cash equivalents at beginning of period	9,942,053	10,831,266
	-----	-----
Cash and cash equivalents at end of year	\$ 4,147,164	\$ 9,942,053
	=====	=====
Supplemental disclosure of cash flow:		
Cash paid for interest	\$ 9,103	\$ 35,840
Non-cash transactions:		
Issuance of preferred stock dividends in kind	\$ 1,456,385	\$ 1,486,501
Issuance of common stock, options and warrants in acquisition	--	12,214,207
Capital lease acquisitions	--	17,195
Issuance of note payable for joint venture termination	579,742	--
Issuance of common stock for patent rights	250,000	--

The accompanying notes are an integral part of the consolidated financial statements.

F-10

BioPharma, Inc.

Notes to Consolidated Financial Statements

December 31, 2002

### 1. ORGANIZATION AND NATURE OF BUSINESS

#### PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include DOR BioPharma, Inc. and its subsidiaries (DOR or the Company). All significant intercompany accounts and transactions have been eliminated in consolidation.

#### NATURE OF BUSINESS

DOR is a pharmaceutical company specializing in the development of oral and nasal delivery of vaccines and drugs for unmet medical needs. The Company is developing a proprietary oral and intranasal vaccine delivery technology called the Microvax™ system, which they are applying to the delivery of intranasal and oral biodefense vaccines. Utilizing this Microvax™ system, the Company is



## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

developing intranasal vaccines against ricin toxin and anthrax. The Company is also developing an oral vaccine against botulinum toxin.

In addition to its biodefense vaccines, the Company is developing orBec(R) (oral beclomethasone dipropionate), an oral therapeutic product that is currently in a pivotal Phase III clinical trial for the treatment of intestinal graft-vs-host disease, a life threatening complication of bone marrow transplantation. Using orBec(R), the Company is also planning a Phase II clinical trial for the treatment of irritable bowel syndrome.

### 2. DEVELOPMENT STAGE ENTERPRISE

The Company's activities to date principally have been conducting research and development in conjunction with developing new products. Consequently, as shown in the accompanying financial statements, the Company has not realized substantial revenue and has a deficit accumulated during the development stage for the period from inception, February 15, 1985, through December 31, 2002 of \$68,687,366. The Company will continue to be a development stage company, as defined in Statement of Financial Accounting Standards (SFAS) No. 7, "Accounting and Reporting by Development Stage Enterprises," until it begins sales of its anticipated products.

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### SEGMENT AND GEOGRAPHIC INFORMATION

The Company operates in the biotechnology drug delivery industry and does not have any reportable operating segments.

#### CASH AND CASH EQUIVALENTS

The Company considers all highly liquid investments with a maturity of 90 days or less when purchased to be cash equivalents.

F-11

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

#### RESEARCH AND DEVELOPMENT COSTS

In accordance with SFAS No. 2, "Accounting for Research and Development Costs," research and development costs are charged to expense when incurred. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries and employee benefits, equipment depreciation and allocations of various corporate costs. Purchased in-process research and development expense (IPR&D) represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition. In accordance with SFAS No. 2, as clarified by Financial Accounting Standards Board Interpretation No. 4, amounts assigned to IPR&D meeting the above stated criteria are charged to expense.

#### LICENSES AND PATENT COSTS

Patent costs, principally legal fees, are capitalized and, upon issuance of the patent, are amortized on a straight-line basis over the shorter of the estimated useful life of the patent or the regulatory life. Licenses of technology with

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

alternative future use are capitalized and are amortized on a straight-line basis over the shorter of the estimated useful life or the regulatory life. Licenses of technology with no alternative future use are expensed as incurred. The useful lives of licenses and patent costs at December 31, 2002 ranged from 15 to 17 years.

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

#### IMPAIRMENT OF LONG-LIVED ASSETS

Equipment, leasehold improvements, licenses and patent costs, and amortizable intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

#### NET LOSS PER SHARE

In accordance with accounting principles generally accepted in the United States, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the respective periods (excluding shares that are not yet issued). The effect of stock options, warrants and convertible preferred stock is antidilutive for all periods presented.

#### INCOME TAXES

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the current tax payable for the period plus or minus the change during the period in deferred tax assets and liabilities. No current or deferred income

F-12

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

taxes have been provided through December 31, 2002 because of the net operating losses incurred by the Company since its inception.

#### STOCK BASED COMPENSATION

The Company has stock-based compensation plans (see Note 8). SFAS No. 123, "Accounting for Stock-Based Compensation," encourages, but does not require companies to record compensation cost for stock-based employee compensation plans at fair value. The Company has chosen to continue using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations, in accounting for its stock option plans. Had compensation cost been determined based upon the fair value at the grant date for awards under the plans based on the provisions of SFAS No. 123, the Company's SFAS No. 123 pro forma net loss and net loss per share would have been as follows:

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

	YEAR ENDED DECEMBER 31	
	2002	2001
Net loss applicable to common stockholders:		
As reported	\$ (6,422,466)	\$ (16,117,67
Add: Stock-based employee compensation expense related to stock options determined under fair value based method	(577,326)	(1,273,69
SFAS No. 123 Pro forma	\$ (6,999,792)	\$ (17,391,37
Net loss per share:		
As reported, basic and diluted	\$ (0.29)	\$ (1.2
SFAS No. 123 pro forma, basic and diluted	(0.31)	(1.2

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was \$0.26 and \$0.83 for 2002 and 2001, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 148% and 105% in 2002 and 2001, respectively and average risk-free interest rates in 2002 and 2001 of 4.0% and 4.5%, respectively.

Stock compensation expense for options granted to nonemployees has been determined in accordance with SFAS 123 and Emerging Issues Task Force (EITF) 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is periodically remeasured as the options vest.

FAIR VALUE OF FINANCIAL INSTRUMENTS

Accounting principles generally accepted in the United States require that fair values be disclosed for the Company's financial instruments. The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, current liabilities and debt obligations are considered to be representative of their respective fair values.

F-13

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

USE OF ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

RISK AND UNCERTAINTIES

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, litigation, product liability, development of new technological innovations, dependence on key personnel, protections of proprietary technology, and compliance with FDA regulations.

### NEW ACCOUNTING PRONOUNCEMENTS

During 2002, the Financial Accounting Standards Board issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," and SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." The provisions of SFAS No. 144, which was adopted on January 1, 2002, were applied by the Company and did not have a material impact on the Company's consolidated financial statements. SFAS No. 146 will be effective for exit or disposal activities initiated after December 31, 2002. Adoption of this statement is not expected to have a material impact on the Company's consolidated financial statements. Effective December 31, 2002, the Company made the disclosures required under SFAS No. 148.

### 4. INVESTMENT IN JOINT VENTURES AND PREFERRED STOCK

In 1998, the Company formed two joint ventures with Elan International Services, Ltd. (Elan) as follows:

#### INNOVACCINES CORPORATION

InnoVaccines was established in January 1998 pursuant to agreements between the Company and Elan. At closing, the Company issued to Elan 307,692 shares of common stock and a six-year warrant to purchase an additional 230,770 shares of common stock at an exercise price of \$10.00 per share for an aggregate recorded value of \$2.0 million. In addition, Elan purchased \$8.0 million of DOR Series B convertible preferred stock, which is convertible into common stock at a price of \$7.38 per share, subject to adjustment, with automatic conversion at such point that the common stock trades at over 100,000 shares per day at a closing price of at least \$9.75 per share for 20 out of 30 consecutive trading days. The Series B convertible preferred stock pays an 8% annual in-kind dividend, which was \$867,542 and \$803,280 in 2002 and 2001, respectively.

InnoVaccines was owned 80.1% by DOR and 19.9% by Elan. Although DOR was the majority shareholder, the joint development agreement of InnoVaccines gave management participation to both DOR and Elan equally. Therefore, because the minority shareholder, Elan, had substantive participating veto rights, DOR accounted for its investment in the joint venture using the equity method of accounting in accordance with EITF-96-16 "Investor's Accounting for an Investee, When the Investor Has a Majority of the Voting Interest but the Minority Shareholder or Shareholders Have Certain Approval or Veto

F-14

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

Rights." InnoVaccines licensed certain technology from Elan and certain other technology from DOR. DOR and Elan originally invested \$8.0 and \$2.0 million in the joint venture, respectively.

At closing, InnoVaccines paid Elan an initial \$10.0 million license payment. As the technology did not yet represent a commercial product, the joint venture

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

recorded an expense in 1998 for the initial license fee. The Company recorded its \$8.0 million share of the license fee expense in accordance with the equity method.

InnoVaccines contracted with both DOR and Elan, which performed research and development on behalf of the joint venture. Elan and DOR each funded research and development related to InnoVaccines technology equally from the inception of the joint venture through March 31, 1999, in accordance with the joint development and operating agreement. Such payments were not funded through the joint venture and DOR expensed its payments. Subsequent to April 1, 1999, DOR and Elan were responsible for funding joint venture expenditures in proportion to their respective ownership levels through the joint venture entity (as a loan). During the years ended December 31, 2002 and 2001, DOR incurred research and development and general and administrative expenditures aggregating \$0 and \$.4 million, respectively, which were billed to InnoVaccines.

DOR and Elan also incurred approximately \$139,000 and \$246,000 of expenditures during the years ended December 31, 2002 and 2001, respectively, related to certain licenses that DOR and Elan acquired for further development on behalf of InnoVaccines. Elan and DOR each agreed to pay 50% of the license costs outside of the joint venture entity. The receivable from related party of \$44,447 at December 31, 2001 on the accompanying consolidated balance sheet represented reimbursements that were received from Elan in 2002. The Company's portion of the license costs through the dissolution of the joint venture, \$69,732 in 2002 and \$123,103 in 2001, was included in equity in losses from joint ventures in the accompanying statements of operations. In November 2002, the Company purchased Elan's ownership interest in the license for 500,000 shares of common stock, recorded at \$250,000, which was capitalized because the technology at the time of purchase was determined to have alternative future use.

ENDOREX NEWCO, LTD.

Newco was established in October 1998 pursuant to agreements between DOR and Elan. At closing, DOR and Elan paid \$8.4 million and \$2.1 million to purchase Newco's common stock, respectively. In addition, Elan purchased \$8,410,500 of DOR Series C Convertible Preferred Stock. The Series C Preferred Stock was exchangeable at Elan's option for an additional 30.1% ownership interest of Newco's common stock, which caused the classification of the Series C Preferred Stock to be outside of equity. The Series C Preferred Stock automatically converted to common stock at the conversion price of \$8.86 on October 21, 2002. Conversion of Series C Preferred Stock caused total stockholders' equity to increase by the liquidation value of the Series C Preferred Stock. The Series C Preferred Stock paid a 7% annual in-kind dividend, which was \$588,843 and \$683,221 in 2002 and 2001, respectively.

Newco was owned 80.1% by DOR and 19.9% by Elan. Although DOR was the majority shareholder, the joint development agreement of Newco gave management participation to both DOR and Elan equally. Therefore, because the minority shareholder, Elan, had substantive participating veto rights, DOR accounted for its investment in the joint venture using the equity method of accounting in accordance with EITF-96-16. At closing, Newco paid Elan an initial \$10.0 million license payment. Because the technology did not represent a commercial product, Newco recorded an expense in 1998 for the initial

F-15

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

license fee expense. The Company recorded its \$8.0 million share of the license fee in accordance with the equity method.

The Newco joint venture entity contracted with both DOR and Elan, which performed research and development on behalf of the joint venture. During 2002 and 2001, Elan and DOR were required to fund Newco expenditures according to their respective ownership interests. During the years ended December 31, 2002 and 2001, DOR incurred research and development and general and administrative expenditures aggregating \$0 and \$45,000, respectively, related to the joint venture and billed to Newco.

Newco entered into an agreement with Schein Pharmaceuticals (Bermuda) Ltd. (Schein) for the manufacture of the MEDIPAD. In 2001, Schein terminated the agreement and agreed to pay Newco \$300,000 as a settlement. DOR recorded its portion of the settlement amount, \$240,000, as a reduction of joint venture related expenses.

### DISSOLUTION OF THE ELAN JOINT VENTURES

On June 29, 2002, DOR and Elan signed a definitive agreement for the dissolution of InnoVaccines and Newco. In connection with this settlement, the Company's balance of \$2,042,833 due to joint ventures (which had been recorded as a current liability) at December 31, 2001 was restructured into payments totaling \$1,104,242: \$524,500 paid immediately in cash and the remaining \$579,742 payable under a note with scheduled payments of principal and interest of \$231,897 (June 30, 2003), \$231,897 (June 30, 2004) and \$115,948 (December 30, 2004), respectively (see Note 10). The resulting gain of \$938,591 on the refinancing of the Company's payable has been reflected as "equity in earnings (losses) in joint ventures" in the accompanying statement of operations.

### UNAUDITED CONDENSED FINANCIAL STATEMENTS FOR JOINT VENTURES

Condensed, unaudited financial statement information of the joint ventures is stated below. The joint ventures had no revenues in any period.

	DECEMBER 31	
	2002	2001
InnoVaccines net loss	\$ -	\$ (586,828)
Newco net income	-	44,421
<b>Total net loss</b>	<b>\$ -</b>	<b>\$ (542,407)</b>
Reconciliation of joint venture net losses to equity in losses from joint ventures recorded by DOR:		
Total joint venture net losses	\$ -	\$ (542,407)
DOR mark-up (a)	-	155,872
Elan minority interest	-	107,939
InnoVaccines costs incurred by DOR, outside of joint venture	(69,732)	(123,103)
Gain on dissolution of joint ventures	938,591	-
Equity in earnings (losses) from joint venture - DOR	\$ 868,859	\$ (401,699)

# Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

DOR BioPharma, Inc.

## Notes to Consolidated Financial Statements (continued)

(a) The Company invoiced the joint venture at cost, plus a mark-up that was agreed to by Elan and was intended to approximate overhead costs.

### 5. ACQUISITION

On November 29, 2001, the Company acquired all of the capital stock of CTD, a development stage company. A director of DOR was also President, Chief Executive Officer and a director of CTD. Additionally, stockholders of DOR were also shareholders of CTD. Pursuant to the Merger Agreement, an aggregate of 9,433,884 shares of DOR common stock valued at \$1.25 per share were issued in exchange for all of the issued and outstanding capital stock of CTD; however, 1,350,000 of the shares were held in escrow to cover any potential damages for breach of contract by CTD and were to be issued through March 31, 2003. In 2002, the Company released 1,011,502 shares from escrow and the remainder were released in March 2003. The escrowed shares were included in the cost of CTD on the date of purchase because the issuance of the escrowed shares was considered probable. In addition, options and warrants to purchase 566,121 shares of DOR common stock were issued to replace existing vested CTD options and warrants and were valued at \$421,852. As part of the acquisition, the Company incurred \$1,500,000 and \$417,852 in direct acquisition costs and equity issuance costs, respectively.

The total purchase price of \$14,132,059 was allocated based on the fair market value of the assets acquired and liabilities assumed as follows:

Cash	\$ 3,309,960
Prepaid expenses	4,022
Intangible assets	364,151
Accounts payable	(144,926)
Acquired IPR&D	10,181,000
Equity issuance costs	417,852
	-----
Total	\$ 14,132,059
	=====

The acquisition was accounted for as a purchase and, accordingly, the results of operations have been included in the consolidated financial statements from November 29, 2001, the effective date of the acquisition. The purchase price has been allocated to the acquired assets and assumed liabilities on the basis of their estimated fair values at the acquisition date, with intangible assets determined in an independent appraisal. Intangible assets acquired consisted of contractual rights of \$364,151 and IPR&D of \$10,181,000. Contractual rights relate to a potential future milestone payment and were calculated based upon the estimated, probability-of-success-adjusted after-tax cash flows expected to be generated, using a 25% discount rate. The contractual rights are being amortized over a period of three years. IPR&D consists of the present value of the estimated after-tax cash flows expected to be generated by the purchased technology, which, at the acquisition dates, had not yet completed clinical trials with the FDA for their intended purpose and had no alternative future use at the purchase date. In valuing the purchased in-process technologies, the Company used probability-of-success-adjusted cash flows and a 25% discount rate. Cash inflows from the in-process products were assumed to commence between 2003 and 2005. Based on current information, the Company believes that the revenue projections underlying the purchase price allocation are substantially accurate. As with all pharmaceutical products, the probability of commercial success for any research and development project is highly uncertain.

# Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

F-17

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

## 6. LEASEHOLD IMPROVEMENTS AND EQUIPMENT

Office and lab equipment is stated at cost. Depreciation is computed on a straight-line basis over five years. Leasehold improvements are amortized utilizing the straight-line method over the term of the lease. Depreciation expense was \$186,387 and \$175,794 for the periods ended December 31, 2002 and 2001, respectively. Leasehold improvements and equipment consisted of the following at December 31:

	DECEMBER 31	
	2002	2001
Leasehold improvements	\$ 262,985	\$ 262,985
Laboratory equipment	927,189	857,560
Office equipment	234,994	220,534
Accumulated depreciation	1,425,168 (1,162,247)	1,341,079 (975,860)
	\$ 262,921	\$ 365,219

## 7. STOCKHOLDERS' EQUITY

### PRIVATE PLACEMENTS

In December 2002, the Company sold an aggregate of 3,093,569 shares of common stock in a private placement. Gross proceeds were \$1,085,844 (net after commissions was \$974,069). Commissions were paid to related parties who were agents for the private placement. Several directors and officers of the Company were investors in the private placement.

Investors in the December 2002 private placement also received warrants for the purchase of 1,546,789 shares of DOR common stock. The warrants issued to these investors are immediately exercisable at \$.75 per share and expire December 31, 2007. Also, as part of the compensation received for its assistance in the private placement, the placement agents/dealers received warrants to purchase an aggregate 463,073 shares of DOR common stock. These warrants are immediately exercisable at \$.35 - \$.75 per share and expire December 31, 2007. The Company has the right to call the warrants if the closing bid price of DOR's common stock equals or exceeds \$3.00 per share for at least 10 consecutive days.

In connection with an April 2000 private placement, the Company issued warrants to the investors for the purchase of 452,383 shares of its common stock. The warrants issued to these investors are immediately exercisable at \$5.91 per share and expire in April 2005. Also, as part of the compensation received for its assistance in the private placement, the placement agent received warrants to purchase 226,190 shares of DOR common stock. These warrants are immediately exercisable at \$5.25 per share, expire in October 2007 and the Company has the right to call the warrants if the closing bid price of DOR's common stock equals or exceeds \$13.125 per share for at least 20 consecutive trading days.



## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

In connection with a 1997 private placement, the Company issued warrants for the purchase of 864,865 shares of DOR common stock at an exercise price of \$1.65 per share to the placement agent, and certain of its affiliates and employees. The Company also issued warrants to purchase 1,297,297 shares of DOR common stock at an exercise price of \$1.65 per share to certain employees of the placement agent. The

F-18

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

warrants are exercisable and expire on April 16, 2003. Through December 31, 2002, 148,161 of these warrants have been exercised.

### STOCK COMPENSATION TO NON-EMPLOYEES

During 2002, the Company agreed to issue 37,000 shares of common stock in consideration for the termination of a consulting agreement. The shares were not yet issued at December 31, 2002; accordingly, they are included in common stock to be issued.

The Company granted 50,000 warrants to purchase DOR common stock to a consultant during 2002 exercisable at a price of \$0.40 through November 2003. The Company also granted another consultant 130,000 warrants to purchase DOR common stock exercisable at a price of \$0.35 through December 14, 2007.

### 8. STOCK OPTION PLANS

The Amended and Restated 1995 Omnibus Plan (the Plan) is divided into three separate equity programs: 1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock, 2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock, 3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and 4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant.

The rollforward of shares available for grant is as follows:

	DECEMBER 31	
	2002	2001
Shares available for grant at beginning of year	1,101,238	708
Increase in shares available based upon the annual Evergreen provision	208,257	127
Amendment to increase shares available in plan	6,500,000	2,165
Options granted under the Plan	(3,087,420)	(1,629)
Options forfeited	960,625	88
Options assumed in CTD acquisition	-	(359)
Shares available for grant at end of year	5,682,700	1,101

The Company also issued 442,375 options to a member of the Board of Directors which were not issued under the Plan. The amendment to increase shares available in the plan by 6,500,000 options is subject to stockholder approval. If the market price of the Company's common stock exceeds the option price on the date stockholder approval is obtained, the Company will be required to record compensation expense as the options vest for options granted from the amendment to increase shares by 6,500,000.

F-19

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

Option activity for the years ended December 31, 2002 and 2001 was as follows:

	Options	Weighted-Average Options Exercise Price
Balance at December 31, 2000	1,511,125	\$2.73
Granted	1,629,500	1.04
Assumed in CTD merger	359,042	0.74
Forfeited	(88,000)	3.51
Balance at December 31, 2001	3,411,667	1.69
Granted	3,626,000	0.33
Forfeited	(960,625)	1.27
Balance at December 31, 2002	6,077,042	\$0.95

The weighted-average exercise price, by price range, for outstanding options at December 31, 2002 is:

Price Range	Weighted-Average Remaining Contractual Life	Outstanding Options	Options Exercis
Price Range \$0.20 - \$0.40	9.94	3,495,000	3,157,813
Price Range \$0.74 - \$0.91	8.70	873,042	753,042
Price Range \$1.25 - \$2.00	6.24	463,500	446,125
Price Range \$2.47 - \$6.75	4.99	1,245,500	1,214,850

#### 9. INCOME TAXES

The types of temporary differences between tax bases of assets and liabilities and their financial reporting amounts that give rise to the deferred tax asset (liability) and their approximate tax effects are as follows:

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

	DECEMBER 31	
	2002	2001
	-----	
Deferred tax assets:		
Net operating loss carryforwards	\$ 21,712,000	\$ 15,810,000
Research and development credit carryforwards	1,910,000	1,890,000
Work opportunity credit carryforwards	260,000	260,000
Orphan drug credit carryforwards	2,552,000	1,547,000
Licensing fees	-	3,906,000
Other	-	65,000
	-----	
	26,434,000	23,478,000
Valuation allowance	(26,434,000)	(23,478,000)
	-----	
Net deferred tax assets	\$ -	\$ -
	=====	

At December 31, 2002, the Company had net operating loss carryforwards of approximately \$52.7 million for U.S. Federal and state tax purposes, which expire beginning in 2007. In the event of a change

F-20

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

in ownership greater than 50% in a three-year period, utilization of the net operating losses may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions.

10. LONG-TERM DEBT

Long-term debt is as follows:

	DECEMBER 31	
	2002	2001
	-----	
Note payable to Elan (see Note 4)	\$579,742	\$ -
Note payable to a bank	150,225	216,846
	-----	
	729,967	216,846
Less current portion	382,122	164,748
	-----	
	\$347,845	\$ 52,098
	=====	

The note payable to a bank has monthly principal and interest payments of \$12,878 with a final payment on December 31, 2003. The note bears interest at prime less .25% (4.0% at December 31, 2002) and borrowings are secured by a short-term certificate of deposit which is included in cash and cash equivalents.

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

### 11. LEASE COMMITMENTS

The Company leases its corporate office under an operating lease through December 2003, which provides for annual minimum rent and additional rent based on increases in operating costs and real estate taxes. Rent expense was \$61,262 in 2002 and \$63,967 in 2001.

Future minimum lease payments under the non-cancelable operating lease will be \$62,978 in 2003.

### 12. LICENSE AGREEMENTS

During 1998, Innovaccines (see Note 4), the Company's former joint venture with Elan, acquired a license to broadly issued U.S. and International patents relating to the oral administration of vaccines. Specifically, these patents claim the use of microencapsulation for oral and mucosal administration of vaccines using biocompatible microspheres below 10 microns in diameter. During 2002, the Company acquired Elan's interest in the patent license for 500,000 shares of common stock. Also during 2002, the Company entered into a binding letter of intent with Southern Research Institute (SRI) to expand its license to include intranasal vaccine delivery, which is considered by the Company to be better suited for biodefense vaccines. The Company capitalized the fair value of 500,000 shares (\$250,000) of common stock to Elan, as well as a \$175,000 payment to the Southern Research Institute for the expanded license because the acquired technology is considered to have alternative future uses. Upon execution of a royalty bearing license agreement, the Company will pay an additional license fee of \$175,000. The Company would also agree to provide \$250,000 of sponsored research during each of the calendar years 2003 to 2006 and would enter into a three year scientific advisory agreement with a consultant for \$50,000 per year.

F-21

DOR BioPharma, Inc.

Notes to Consolidated Financial Statements (continued)

As part of the acquisition of CTD in 2001 (see Note 5), the Company and its subsidiaries acquired the license to certain patents and "know-how," as defined in the respective license agreements with various individuals and corporations. Under the agreements, the Company is required to pay royalties ranging from 2% to 33% of the selling prices for products or processes that are covered by the licensed patents. There were no royalties in 2002 or 2001.

In connection with the sale of substantially all assets of a CTD subsidiary in 1999, the Company may receive a maximum of \$3,000,000 upon the approval by the Food and Drug Administration of various treatments.

### 13. SUBSEQUENT EVENTS (UNAUDITED)

#### MINISTRY OF DEFENSE LETTER OF INTENT

During January 2003, the Company executed a binding letter of intent to exclusively license patent applications from the Ministry of Defense of the United Kingdom covering the use of technology for delivery of vaccines for which the Company paid \$25,000 upon signing the letter of intent. Upon execution of a royalty bearing license agreement, the Company will be obligated to pay license fees of \$100,000 upon license execution, \$25,000 payable on the first anniversary of the license agreement and \$25,000 payable eighteen months thereafter. The Company would also agree to provide \$100,000 of sponsored

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

research support for a one-year period.

### UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER OPTION AGREEMENT

During January 2003, the Company executed a worldwide exclusive option to license patent applications from the University of Texas Southwestern Medical Center (UT Southwestern) for the intranasal, pulmonary and oral uses of a recombinant non-toxic ricin vaccine for which the company paid an option fee of \$50,000. During February 2003, the Company executed a binding, 90 day right of first negotiation agreement with UT Southwestern to obtain the injectable rights to the ricin vaccine. Until January 2004, the Company may choose to exercise the option to license the intranasal, pulmonary, and oral rights to the recombinant non-toxic ricin vaccine for a license fee payment of \$100,000.

### THOMAS JEFFERSON UNIVERSITY LETTER OF INTENT

During February 2003, the Company executed a letter of intent agreement with Thomas Jefferson University (Jefferson Agreement) to exclusively license certain U.S. and international patent applications related to the oral administration of nontoxic modified botulinum toxins as vaccines for which the Company paid a \$10,000 option fee. The intellectual property also includes patent applications covering the inhaled and intranasal routes of delivery of the vaccine. Upon execution of the Jefferson Agreement, the Company will have to pay a license fee of \$160,000, payable in \$130,000 of unregistered common stock of the Company and \$30,000 cash. Upon the execution of the license agreement, the Company would also enter into a one-year Sponsored Research Agreement in which the Company would provide \$300,000 in research support. Upon the execution of the license agreement, the Company would also enter into a consulting agreement with Dr. Lance Simpson, the inventor of the botulinum toxin vaccine, for a period of three years under which Dr. Simpson would receive options to purchase 100,000 shares of the Company's common stock vesting over three years.

F-22

### REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

To the Board of Directors and Shareholders of  
DOR BioPharma, Inc.  
(A Development Stage Enterprise)

We have audited the accompanying consolidated balance sheets of DOR BioPharma, Inc. (the Company, a development stage enterprise) as of December 31, 2002 and 2001, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and for the period February 15, 1985 (inception) through December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2002 and 2001 and the consolidated results of its operations and its cash flows for the years then ended and for the period February 15, 1985 (inception) through December 31, 2002, in conformity with accounting principles generally accepted in the United States.

Milwaukee, Wisconsin  
February 21, 2003

Ernst & Young LLP

F-23

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DOR BIOPHARMA, INC.

By: /s/ Ralph M. Ellison

-----  
Ralph M. Ellison, Chief Executive  
Officer and President

Date: March 31, 2003

In accordance with the Exchange Act, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated, on March 31, 2003.

Signature -----	Title -----
/s/ General Alexander M. Haig, Jr. ----- General Alexander M. Haig, Jr.	Chairman of the Board
/s/ Ralph M. Ellison ----- Ralph M. Ellison	Chief Executive Officer and President (executive officer)
/s/ Steve M. Kanzer ----- Steve M. Kanzer	Vice-Chairman of the Board
/s/ William D. Milling ----- William D. Milling	Controller, Treasurer and Corporate (principal financial and accounting)
/s/ Larry Kessel ----- Larry Kessel	Director
/s/ Arthur Asher Kornbluth ----- Arthur Asher Kornbluth	Director

Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

/s/ Evan Myrianthopoulos	Director
-----	
Evan Myrianthopoulos	
/s/ Peter Salomon	Director
-----	
Peter Salomon	
/s/ Paul D. Rubin	Director
-----	
Paul D. Rubin	

CERTIFICATION

I, Ralph M. Ellison M.D., certify that:

1. I have reviewed this annual report on Form 10-KSB of DOR BioPharma Inc.;

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, 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 in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

## Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: 03/31/2003

/s/ Ralph M. Ellison M.D.

-----  
Ralph M. Ellison M.D.  
CEO and President

I, William D. Milling, certify that:

1. I have reviewed this annual report on Form 10-KSB of DOR BioPharma Inc.;

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, 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 in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the



Edgar Filing: DOR BIOPHARMA INC - Form 10KSB

registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: 03/31/2003

/s/ William D. Milling

-----  
William D. Milling  
Controller  
(principal financial and accounting officer)