DOR BIOPHARMA INC
Form 10KSB
April 01, 2002

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

(Mark One)

ý **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2001

OR

o **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	**41-1505029**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
28101 BALLARD DRIVE, SUITE F, LAKE FOREST, IL	**60045**
(Address of principal executive offices)	(Zip Code)

Issuer's telephone number, including area code: **(847) 573-8990**

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	**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 class)

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 ý No o

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. o

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 1, 2002, was $16,480,829.

At March 1, 2002, 20,825,742 shares of the registrant's common stock (par value $.001 per share) were outstanding.

Transitional Small Business Issuer: Yes o No ý

Documents Incorporated by Reference

The definitive proxy statement of Endorex Corporation in connection with its 2002 annual meeting of stockholders is incorporated by reference into Part III of this Form 10-KSB.

PART I

Item 1. 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 which 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.

Overview

DOR BioPharma, Inc. is a drug delivery company developing both drugs and platform delivery systems for medicines that have long been considered by the pharmaceutical industry as the "Holy Grail" of the industry: the technological challenge of transforming drugs that have traditionally been administered in non-oral formats (mostly injected) into an orally bioavailable format. DOR BioPharma's expertise in this area is focused on the oral delivery of biopharmaceuticals (which includes many of the new drugs being developed by the biotech industry as well as drugs that are already being marketed) and water insoluble drugs. Both classes of drugs represent delivery challenges, the common link being their poor absorption in the gastrointestinal tract. Examples of these classes of drugs include peptide (large molecule) drugs and cancer chemotherapeutics (water insoluble drugs). Additionally, there are numerous drugs for which a new delivery modality enables the drug to be used for the treatment of other diseases, outside of the original use of the drug.

We believe the market potential for such products is extensive**.** Sales in 2002 of the top 20 injectable drugs (not available in oral) for which DOR's technology may be applicable is approximately $7.7 billion in the U.S. This market is even larger when taking into consideration opportunities in the rest of the world. Many of these drugs are administered over a protracted period of time (chronic administration) requiring multiple injections over many months and sometimes years. This mode of administration is painful and more often than not requires physician intervention, adversely affecting and impacting the patient's quality of life. There appears to be a direct correlation between the decrease in the patient***'s*** quality of life and the willingness of the patient to continue on therapy (patient compliance). Patients who fail to complete therapy run the risk of disease recurrence, and additional healthcare costs.

Patients prefer to take drugs orally. It is the simplest and most convenient format. DOR BioPharma has been focusing on the development of drugs targeted to the gastrointestinal ("GI") tract to either treat GI diseases or enhance the absorption of drugs from the GI system. Our drug pipeline includes a number of GI and automimmune diseases, as well as cancer therapeutics. Our lead drug is an oral form of

beclomethasone (orBec) which commenced a multicenter pivotal phase III trial for graft versus host disease during 2001. Beclamethasone has been granted FDA "fast track" designation and designated orphan drug status**.** In addition, orBec is also in phase II for another GI disorder, Crohn's disease. Our second drug Oraprine also represents a novel oral formulation of the drug azathioprine and has completed phase I trials. DOR also has two drugs, leuprolide and paclitaxel, in preclinical development utilizing its proprietary oral delivery platforms.

The Company

DOR BioPharma was originally founded as Immunotherapeutics, Inc. in 1987 and headquartered in Fargo, North Dakota. During the period from 1987 to 1997, the Company developed new cancer therapy based on proprietary peptide-based immunomodulators (drugs which stimulate the immune system to fight against cancer). These immunomodulators were formulated in liposomes to improve the side effect profile for the patient. In 1996, majority ownership of the Company was acquired by the

Aries Funds, managed by Paramount Capitol, Inc. A new management team, including a new president and chief executive officer and board of directors, was recruited to identify and acquire new products and technology. Subsequently, the Company's name was changed to Endorex Corporation to reflect the new direction of the company. The new management team established executive offices in Lake Bluff, Illinois, a Chicago suburb, and then relocated all company operations to the new headquarters in Lake Forest, Illinois, in early 1998.

In December 1996, drug delivery became a central focus of the Company after licensing a new technology from the Massachusetts Institute of Technology ("MIT"). This new drug delivery technology was intended to enable the oral delivery of large molecule drugs (based on proteins and peptides) normally delivered via injection. This delivery system, based on novel polymerized liposomes (fat globules that can entrap or encapsulate drug particles) was designed to increase the ability of the liposome to withstand the acids and enzymatic activity of the stomach and upper gastrointestinal tract thereby protecting the protein- or peptide-based drug from degradation before it can be absorbed through the stomach or intestinal lining. Commercial development of this delivery system, called the Orasome system, commenced in 1997.

In 1997, The Company licensed a new cancer drug, perillyl alcohol, from the Wisconsin Alumni Research Foundation ("WARF"), the repository of new technology and intellectual property of the University of Wisconsin-Madison. Phase I trials, to evaluate perillyl alcohol, part of a new class of anti-cancer agents called monoterpenes, were being completed. Several phase II trials for treatment of different types of cancer were subsequently initiated during 1998.

In 1998, the Company formed two drug delivery joint ventures with Elan Corporation, plc ("Elan"). The purpose of the first joint venture, InnoVaccines Corporation ("InnoVaccines"), was to develop and commercialize novel vaccine delivery systems for the human and veterinary vaccine markets. The second joint venture, Endorex Newco, Ltd. ("Newco"), focused on the utilization of Elan's microinfusion pump, MEDIPAD®, to deliver iron chelator therapy for the treatment of a series of genetic blood disorders known as iron overload disorders (whereby patients have an inability to eliminate excess iron in their body).

In 1999, InnoVaccines expanded its delivery platforms by acquiring the exclusive license rights and corresponding patents to another vaccine delivery system, based on polylactide-co-glycolide ("PLGA") microspheres, for encapsulating and protecting vaccine antigens in the gastrointestinal tract. This vaccine delivery technology was owned by and invented at the Southern Research Institute, or SRI, and the University of Alabama at Birmingham, or UAB. Additionally, InnoVaccines licensed a mucosal tissue-targeting technology from Elan that had the potential to enhance the uptake of oral and/or nasal vaccines. The Company also initiated a research and option agreement with the Danish pharmaceutical company, Novo Nordisk A/S ("Novo"), to develop an oral form of Novo's human growth hormone product, Norditropin®.

In 2000, the Company announced its intention to further concentrate on drug delivery, and began the process of exiting its existing oncology business due to the lack of efficacy of these products. Additionally, Newco executed a license agreement with Schein Pharmaceutical (Bermuda) Ltd. ("Schein") to develop and market the MEDIPAD® microinfusion pump to deliver Schein's iron chelator drug for the treatment of iron overload disorders. Schein subsequently became a subsidiary of Watson Pharmaceuticals Inc. ("Watson"). InnoVaccines began evaluating the SRI vaccine technology for oral vaccines combined with a vaccine adjuvant.

In February 2001, the Company signed a letter of intent to acquire a privately-held specialty pharmaceutical company, Corporate Technology Development, Inc. ("CTD") to enhance its critical mass and product portfolio. CTD was developing innovative oral and mucosal formulations and new therapeutic indications of drugs that previously have been approved by the FDA for marketing in the United States. CTD's lead products, orBec and Oraprine , were in clinical trials: orBec was about

to initiate a multicenter phase III clinical trial to treat intestinal Graft-Versus-Host Disease patients, and a phase II trial to treat Crohn's disease. Oraprine was completing a phase I clinical bioequivalency trial.

In August 2001, the Company executed a merger agreement with, and in November 2001, Endorex completed its acquisition of CTD, after receiving stockholder approval. In December 2001, we changed our name to DOR BioPharma, Inc. The new name, an acronym for (**D**)elivery of (**Or**)al (**Biopharma**)ceuticals, signaled our intent to further focus on drug delivery.

The acquisition of CTD enhanced the company in four areas:

Provided a clinical pipeline (oral versions of drugs not previously available orally):

one product in phase 3 and phase 2 trials

one product in phase 1 trials

Expanded the patent portfolio with:

8 additional issued patents

10 additional pending patents

Strengthened the balance sheet with:

$3.3 million in cash and no debt

Enhanced the management team:

3 new board members affiliated with key investment groups

a new Chairman/CEO

Also during 2001, Schein indicated its intention to terminate the license agreement, as the Medipad® iron chelator product did not fit Schein's product marketing plans. In March 2002, Newco completed an agreement with Schein to terminate the license agreement and reimburse the joint venture for certain expenses. In light of this development, DOR and Elan have been in discussions to terminate Newco.

Although InnoVaccines' development activities during 2001 included further evaluation of oral/ mucosal delivery of tetanus and influenza vaccines with mucosal tissue targeting technology, the results of these studies were inconclusive. As a result, both JV partners initiated discussions to terminate the InnoVaccines joint venture. Additionally, Novo and the Company mutually terminated their research and option agreement for the development of oral human growth hormone.

Business Strategy

The objective of DOR BioPharma is to focus on the development of new therapeutic indications and improved delivery modalities of already commercialized FDA-approved drugs. These new indications (for other disease areas) are expected to be protected by proprietary patents for the new therapeutic use and the Company's delivery systems. Oral delivery of drugs has been demonstrated to be the patient-preferred form of administering drug medication, enhancing patient compliance by creating an easier, convenient manner to administer a drug. It is also possible that oral formulation could reduce overall healthcare expenses due to the elimination of needles, syringes, and medical personnel needed to administer such devices.

DOR BioPharma possesses a product pipeline combining both preclinical and clinical products, as well as drug delivery platform technologies that could generate multiple proprietary oral products.

The business strategy includes entering into corporate partnerships with pharmaceutical and/or biotech partners that will market our initial products, and with companies who have products or compounds in development that would benefit from our drug delivery technology. We believe the benefit for such partners would be the creation of a new, differentiated product form, which could potentially enhance patient compliance via an easier to use format, and extend our partners' product lives by combining their products with our unique, patented technology.

DOR BioPharma is endeavoring to develop delivery systems to enhance the therapeutic use of potential partners' products. Additionally, DOR seeks to in-license and develop compatible drug delivery systems and products from other institutions to enhance its delivery capability and portfolio. DOR BioPharma plans to develop product candidates through early clinical development and seek partnerships or corporate collaborations to continue later stage clinical development and commercialization.

The Drug Approval Process

The drug approval process is expensive and rigorously regulated by governmental agencies, including, in the United States, the Food and Drug Administration (the "FDA"). Each drug must undergo a series of preclinical and clinical trials before the FDA will consider approval for commercial sale. The FDA can discontinue drug trials at any time if it feels that patients are being exposed to an unacceptable health risk or if there is insufficient evidence that the drug is effective. The FDA may also require a company to provide additional information or conduct additional trials before it will permit a drug to proceed from one phase of trials to the next.

Advantages of Developing Approved Chemical Entities ("ACE") Drug Products

Our primary strategy in this process is to focus on developing: 1) new oral or mucosal formulations of ACE drugs, and 2) new therapeutic indications for ACE drugs. There are significant advantages to developing new formulations for drugs that have already been approved by the FDA.

Increased Likelihood of Multiple Uses

ACE products approved for the treatment of a specific disease are sometimes found to be effective in treating other medical conditions. Doctors and scientists that use or prescribe a given ACE have an understanding of the chemical and medicinal properties associated with that ACE and are often able to identify new disease targets for that ACE

Speed and Cost

The ACEs being developed by DOR already have well-established safety and therapeutic profiles, although such profiles are for uses that differ from the uses we plan for these drugs. Consequently, we anticipate that the approval process may be quicker and cheaper than would otherwise be the case for medicinal compounds that have not been approved by the FDA, known as new chemical entities ("NCE's"), since the FDA allows applicants developing ACE products to rely on previous study results to support safety and efficacy claims. To date the FDA has not requested that we duplicate any preclinical and safety studies, but instead, has allowed us to use existing data and peer review journal articles in support of the approval process. Consequently, the Company has been able to initiate human clinical trials sooner than otherwise would have been possible.

Proprietary Rights

Proprietary drug products can be distinguished from generic drug products because these drugs are protected by patents or other right of exclusivity. Generic drugs are drugs for which the patent has expired or been revoked, and have no market exclusivity. As such, these drugs are generally sold with

substantial price discounts to the original drugs. Generic drug companies generally rely on low-margin, high-volume sales strategy to achieve profits.

By developing new formulations of, or new therapeutic indications for, the ACEs to which we have obtained new patent rights, we may be able to gain an advantage over competitors by preventing them, for a period of time, from marketing that ACE. Our products represent new therapeutic uses for existing drugs. Although it is not possible to obtain composition-of-matter patents for these compounds, it is possible to secure method-of-use patent protection for those new therapeutic uses. A method-of-use patent covering use of a given drug to treat a certain disease prevents competitors from using that drug to treat that disease. A United States patent provides exclusivity for 20 years from the date the

patent application is filed.

Another source of exclusivity is the FDA's and the European community's "orphan drug" programs, which encourage the development of new treatments for rare diseases. This program has also recently started in Japan. Without special incentives, it is unlikely that drug companies would focus on a rare disease, as it represents a small market. Under the Orphan Drug Act of 1983, the FDA is permitted to grant "orphan drug" status to any drug products that are intended to treat a "rare disease or condition," defined as a disease or condition that affects fewer than 200,000 persons in the United States. A company developing an orphan drug is accorded up to seven years of market protection in the U.S. from competitors, as well as certain tax credits for the conduct of human clinical trials. Similarly, orphan drug protection is also provided in Europe, with up to 10 years of exclusivity. The FDA and the European Agency for the Evaluation of Medicinal Products ("EMEA") have each designated orBec as an orphan drug for a select disease; A similar designation for Oraprine has been achieved in the U.S.

An additional form of exclusivity can be obtained via the Hatch-Waxman Amendments which include exclusivity provisions that DOR believes may apply to its ACE drug products. One such amendment allows for a three-year exclusivity period for a new drug application ("NDA") that the FDA approves for ACE drug products supported by new clinical investigations. Another amendment allows for a three-year exclusivity period for a supplemental new drug application ("sNDA") that the FDA approves for ACE drug products supported by new clinical investigations that supplement an existing NDA. These exclusivity periods run concurrently with any period of market protection accorded to any of our products under the FDA's orphan drug products program. If we develop orBec or Oraprine for additional uses and file supplemental NDAs, those products may be eligible to qualify for this extra exclusivity.

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 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: 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) delivery comprise some of the new delivery pathways. Generally, the regulatory hurdles for approval of a drug delivery system are less stringent than that of 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 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 bioavailability and the fragility of these drugs to withstand degradation as they transit through the stomach and upper gastrointestinal tract.

Oral Drug Delivery Technology

DOR BioPharma is developing drug delivery platforms based on the combination of lipids and polymers. 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 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, DOR BioPharma believes that its expertise in lipids and polymers make it uniquely capable to improve 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:

- Flexibility for incorporating numerous drug types (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;
- Enhanced mucosal uptake of the drug
- Compatibility of the delivery system with current manufacturing techniques; and
- No apparent toxicity of the lipids in animal studies to date (additionally, the lipids used are "GRAS" generally recognized as safe.)

We have successfully demonstrated the bioavailability and bioactivity 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 depot 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. DOR is evaluating such drugs to identify those that are compatible with its oral drug delivery systems for future development and ultimately entrance into human clinical trials.

Product Candidates Currently in Development

Product	Indication	Developmental Status
orBec	Treatment of intestinal GVHD (Graft vs. Host Disease)	Phase III initiated Q3/01 in U.S. Phase III to be initiated in Europe
	Treatment of Crohn's disease	Phase II initiated Q4/01
	Treatment of ulcerative colitis	Phase II under evaluation
	Prevention of GVHD	Phase I/II under evaluation
Oraprine	Phase I Bioequivalency trial	completed
	Rheumatoid arthritis, organ transplantation Oral GVHD	Phase I/II oral autoimmune disorders completed
LPM *Leuprolide* (**L**ipid **P**olymer **M**icelles)	Endometriosis, prostate cancer	Preclinical
LPE /PLP*Paclitaxel* (**L**ipid **P**olymer **E**mulsions/ **P**olymer **L**ipid **P**articles)	Breast, ovarian and lung cancer	Preclinical

orBec

Our lead product, orBec , is an oral formulation of beclomethasone dipropionate, or BDP, a site-active corticosteroid drug originally synthesized in the 1960s. It has been approved by the FDA and sold by Glaxo Wellcome ("Glaxo"), as Beconase®, as an inhaled formulation for the treatment of asthma, allergic rhinitis, and nasal polyposis.

The development of orBec focuses on a novel oral formulation of BDP to treat a series of gastrointestinal disorders, the first of which is Graft vs. Host Disease ("GVHD"). Dr. George McDonald, Head of Gastroenterology and Hepatology at the Fred Hutchinson Cancer Research Center and a Professor of Internal Medicine and Gastroenterology at the University of Washington Medical Center, developed this novel use and formulation of orBec . DOR has obtained an exclusive worldwide license to develop and commercialize Dr. McDonald's patents covering aspects of treating and preventing intestinal GVHD, and other gastrointestinal disorders such as Crohn's disease, ulcerative colitis, and inflammatory bowel disease.

Glaxo's original composition-of-matter patent covering BDP has expired. To our knowledge, there are no issued method patents regarding the use of BDP to treat GVHD or gastrointestinal diseases.

DOR BioPharma is currently testing orBec in a multicenter, pivotal phase III clinical trial for the treatment of intestinal GVHD, a life-threatening disorder that can arise following a bone marrow transplant. Bone marrow transplants represent a successful treatment modality for different types of cancer, particularly leukemias and myeloma. GVHD affects the gastrointestinal tract, skin, and liver of patients who have received bone marrow transplants; it is thought to start in the gastrointestinal tract and spread to the skin and liver. GVHD is a disease in which the donor cells of the donated bone marrow transplant (the "graft") attack the host's cells (the person receiving the transplant), and is part of an immune rejection process. The symptoms of intestinal GVHD typically include severe diarrhea, anorexia, vomiting, and death of the cells that line the intestinal tract.

According to the National Marrow Donor Program, 12,748 allogenic bone-marrow transplants (transplants of blood or bone marrow cells from another person) were performed worldwide from

January 1, 2001, through July 31, 2001. Despite improved preventive measures, acute GVHD still occurs in 50% to 70% of transplants where the donor was HLA-mismatched and in 30% to 40% of transplants where the donor was HLA-matched. Special blood tests, called human leukocyte antigen, or HLA, typing, determine whether a patient has a suitable donor for bone-marrow-cell transplant. These same studies indicate that intestinal GVHD accounts for 15% to 30% of all cases of GVHD.

Intestinal GVHD is typically treated by high doses of prednisone, a potent corticosteroid, along with cyclosporin and other immunosuppressive agents. The systemic immunosuppression resulting from immunosuppressive therapy and the systemic side effects of corticosteroids can result in infection and even death. orBec allows for larger doses of BDP to be delivered to the affected gastrointestinal area without the significant side effects associated with other steroids, resulting from rapid conversion and deactivation of BDP and incomplete absorption of BDP and its metabolites. Availability of a safe and effective treatment for GVHD should increase the number of patients who could benefit from bone marrow transplantation by improving the risk-to-benefit ratio of the treatment.

orBec completed a phase I/II clinical trial and a randomized phase II/III clinical trial in intestinal GVHD, achieving statistical significance compared to those treated with a placebo for its primary endpoint increasing the caloric intake of patients. This study has been published in the scientific literature. During 2000, the FDA granted "fast track" status of the Company's application for use of orBec for the treatment of intestinal GVHD. Under special circumstances, the FDA grants a company's product fast track review, in which case the FDA must review the related NDA within 6 months. Fast-track designation is typically granted when a product treats unmet medical needs. orBec has also been designated as an "orphan drug" by the U.S. FDA and the European equivalent regulatory agency, EMEA, for treatment of intestinal GVHD; additionally, the FDA has further designated orBec as a orphan drug for the prevention of GVHD. We initiated a phase III clinical trial in the third quarter of 2001 in the U.S. The multicenter phase III clinical trial consists of a total of 130 patients. The results of this phase III trial will form the basis for a New Drug Application, or "NDA", that we plan to file with the FDA. DOR intends to extend these trials into Europe and Canada, so as to seek regulatory development and approval in these markets as well.

Concurrently with the phase III clinical trial, we have initiated a phase II clinical trial of orBec for another gastrointestinal disorder, Crohn's disease. *Crohn's disease* is a serious inflammatory disease of the gastrointestinal tract. It primarily affects, or is confined, to the small and large intestine, but may occur in other sections of the gastrointestinal tract. The disease can be localized in patches of bowel. Crohn's disease usually causes diarrhea and painful abdominal cramps, often results in fever, and at times causes rectal bleeding. Loss of appetite and subsequent weight loss may also occur. Crohn's disease is chronic and its cause is not known. Medication currently available for the treatment of this disease decreases inflammation and usually controls the symptoms, but does not provide a cure for the disease, and has a high level of side effects for the patient.

DOR is also evaluating the initiation of additional clinical trials for orBec in two other gastrointestinal disorders: ulcerative colitis and prevention of Graft vs. Host Disease.

Ulcerative colitis is an inflammatory disease of the large intestine and is characterized by inflammation and ulceration of the innermost lining of the colon. Symptoms characteristically include diarrhea, with or without rectal bleeding, and often abdominal pain. Ulcerative colitis differs from Crohn's disease: it affects only the colon, wherein the inflammation is maximal in the rectum and extends up the colon in a continuous manner without any "skip" areas of normal intestine. Only the innermost lining of the colon is affected in ulcerative colitis, whereas in Crohn's disease the entire thickness of the bowel wall may be affected.

Because Crohn's disease and ulcerative colitis behave similarly, it is difficult to differentiate between the two disorders, which are grouped together as inflammatory bowel disease, or IBD. According to the Crohn's and Colitis Foundation, currently in the United States approximately

1,000,000 persons suffer from IBD (roughly half of those patients have Crohn's disease, while the other half have ulcerative colitis). Each year, approximately 20,000 new cases of IBD are reported in the United States.

We plan to conduct further clinical trials of the effectiveness of orBec in treating ulcerative colitis and in preventing GVHD. If there are positive results from these clinical trials, we will continue product development towards filing NDAs for the above-mentioned indications.

Oraprine

DOR BioPharma is also developing Oraprine , an oral suspension of the immunosupressant drug azathioprine (AZA). The composition-of-matter patent covering AZA has expired. DOR has licensed a United States patent application covering the use of Oraprine to treat oral autoimmune diseases in a novel liquid formulation.

AZA is a widely used immunosuppressive medication commonly prescribed in injectable and tablet form to organ transplant patients to suppress rejection of the transplanted organ. AZA is also prescribed as a "second-line" treatment for severe, active rheumatoid arthritis in patients who are refractory to initial arthritis medications. According to IMS Health market research data, in 2000 approximately one million units of AZA were sold in the United States for total revenues of approximately $65 million.

A phase I bioequivalency clinical trial has been completed in the United States for Oraprine . This phase I trial demonstrated that Oraprine is equivalent to the currently marketed FARO Pharmaceutical's product, Imuran®. Although DOR's initial liquid formulation of Oraprine has been demonstrated to be bioequivalent to the marketed product, this formulation has some stability issues which are being evaluated by DOR's drug delivery group. Further clinical trials will be initiated when this stability issue has been resolved.

DOR's initial commercialization plans for Oraprine include filing an Abbreviated New Drug Application, or ANDA, for Oraprine . We propose to position Oraprine as a specialty generic product to be used by patients with autoimmune disorders who cannot swallow medicines in tablet form. In particular, children, the elderly, and cancer patients are prone to this difficulty. If we receive approval, we plan to conduct studies in patients who are afflicted with chronic oral ulcerations, such as oral GVHD and other autoimmune diseases of the mouth and upper esophagus. We have completed a pilot phase I/II clinical efficacy trial using Oraprine to treat oral GVHD. We are currently evaluating additional clinical trials in this area and for other diseases, pending the outcome of our formulation work. We have filed patent applications for the use of Oraprine to treat oral autoimmune disorders. In addition, the FDA has granted orphan drug status for our application for use of Oraprine for the treatment of oral GVHD.

Oral Drug Delivery Platforms: Peptides and Water-Insoluble Drugs

LPM Leuprolide

Utilizing our core competency in lipids and polymers, we have been developing the Lipid Polymer Micelles (LPM) system for enhancing the intestinal absorption of water-soluble drugs/peptides. This 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 macromolecules can be incorporated into LPM , there is a molecular size cutoff for a commercially viable oral bioavailability enhancement, and this system is most effective with drugs/peptides having molecular weight of about 500 to 5000 daltons. Using a simple and scaleable manufacturing process, aqueous solutions of peptides can be incorporated into lipid-polymer mixtures forming stable micelles. Further coating of these micelles by biocompatible polymers and/or by encapsulation in enteric-coated gelatin capsules renders these particles stable in the harsh environment of the GI.

The Company is currently utilizing the LPM system to develop 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. According to IMS data, leuprolide, a potent agonist of the Luteinizing Hormone Releasing Hormone (LHRH) generated more than $800 million in U.S. sales, and is presently administered solely by depot injection. In preclinical studies, DOR scientists using LPM have been able to demonstrate promising intestinal absorption enhancement of both LHRH and Leuprolide in comparison to solution formulations of the peptides. Based on our promising preclinical data, we plan further development of LPM -leuprolide, 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 (endometrium) 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. It has been proposed that a conservative figure for the number of cases worldwide is 90 million. This number is based on estimates and could only be confirmed by diagnosis via laparoscopy. Annual sales of leuprolide in the U. S. endometriosis market are estimated at over $300 million (IMS, Year 2000).

Our preclinical studies in a rat model have demonstrated consistent bioavailability in both LHRH and leuprolide. During 2002, we plan to confirm these results in a dog model, in addition to appropriate toxicology and scale up studies to complete a filing for an Investigational New Drug Application (IND) with the FDA by year-end so as to initiate human clinical trials.

In addition to LHRH and agonists, we plan to evaluate other classes of water-soluble drugs/peptides with the LPM system. Two initial patent applications covering broadly LPM for oral water-soluble drug/peptide delivery have been filed in 2001, with more filings planned for 2002.

LPE and LPP Systems for Water-Insoluble Drugs

The Company is developing two lipid-based systems, LPE (Lipid Polymer Emulsions) and PLP (Polymer Lipid Particles), to support the oral delivery of small molecules (those with a molecular weight of up to 2000 daltons) of water insoluble drugs. Such drugs include most kinds of cancer chemotherapeutics currently delivered intravenously. The LPE system is in the form of an emulsion or an emulsion pre-concentrate incorporating lipids, polymers and co-solvents, particularly perillyl alcohol (POH) and derivatives. The Company is building IP on the use of POH as a solvent, surfactant and absorption enhancer for lipophilic compounds (paclitaxel). LPP is in the form of a suspension where drug particles are coated with lipids and polymers. The polymers used in these formulations can either be commercially available or proprietary polymerized lipids and lipid analogs. These formulations can further incorporate non-volatile gelatin compatible proprietary solvents, such as POH and POH analogs. Avoidance of volatile solvents, such as alcohol, can be very beneficial from manufacturing processing and storage perspectives. The Company has filed patents on this new proprietary use of POH.

The Company is utilizing both LPE and PLP systems to initially develop an oral dosage form of paclitaxel. Both systems are aimed at increasing the solubility and intestinal absorption of paclitaxel and other water insoluble cancer drugs to allow them to be delivered orally. High drug solubilization has been demonstrated with paclitaxel, and initial preclinical data looks promising. Three initial patent applications covering broadly LPE and PLP for oral water-insoluble drug/peptide delivery have been filed in 2001, with more filings planned for 2002 and beyond.

The Company's committed to identifying the right delivery technologies and drug molecules and timely developing orally active dosage forms of cancer therapies and other injectable-only drugs that will not only match the therapeutic efficacy of the injectable format but also alleviate the unnecessary pain and cost associated with needle-based drug delivery. The Company believes that one or more of

these novel oral formulations of these important cancer drugs could be taken into human clinical trials during 2002.

Oral-Suspension Drug Delivery Technology

DOR has acquired an exclusive option to evaluate and license a novel oral drug delivery technology from University Pharmaceutics of Maryland, Inc. This technology allows a pharmaceutical tablet to rapidly break apart in water into a suspension that can be easily swallowed by patients, and can also be used with controlled-release drugs. DOR is evaluating this technology as applied to a well-known drug used to treat a chronic disease in children. Should the results of this evaluation be encouraging, DOR plans to license this technology exclusively and on a worldwide basis.

Metropt

As part of the acquisition of CTD, we acquired licensed rights to two United States patents and certain foreign patent rights relating to certain aspects of using a novel ophthalmic formulation of metronidazole, to treat blepharitis, dry eye, and blepharitis associated dry-eye syndrome. Metronidazole is a broad-spectrum antibiotic that is especially effective against anaerobic infections (infections that grow in the absence of oxygen). In body areas where there is poor central circulation and therefore an inadequate blood supply, only bacteria that can live without oxygen can survive. In such conditions, the metronidazole compound changes so as to inhibit the DNA repair enzymes that normally would repair cells. This kills anaerobic bacteria but has no effect on aerobic tissues. Metronidazole has been approved by the FDA for use in oral, vaginal, dermatological, and intravenous forms for a variety of inflammation-related indications.

We have an FDA-approved investigational new drug application, or IND, for this product, Metropt . As the formulation of Metropt developed by the licensors has formulation and licensing issues, we are evaluating whether we will continue further development of this product.

BOTOX

CTD had previously obtained an exclusive license from Johns Hopkins University to two issued patents and phase II/III clinical data relating to use of endoscopic injections of BOTOXs (botulinum toxin type A) to treat gastrointestinal disorders, including achalasia, morbid obesity, sphincter of oddi dysfunction, constipation, and benign prostatic hyperplasia. *Achalasia* is a rare, life-threatening muscle spasm of the esophageal sphincter. In December 1999, CTD sold to Allergan, Inc. these BOTOX assets, including the two issued patents, the clinical data, and the related IND filed by CTD with the FDA.

As the purchase price for its assets, CTD received a payment of $3.5 million. CTD (now part of the Company) is still entitled to receive milestone payments of $1.5 million from Allergan for each of the first two FDA approvals Allergan is granted utilizing this BOTOXs technology. This asset sale agreement with Allergan however does not specify a deadline for such regulatory submissions, nor are there penalty provisions to Allergan for failure to complete additional clinical development. Although the Company has been in contact with Allergan, Allergan representatives have not been forthcoming on development plans nor are they required to.

Marketing Strategies

The DOR marketing strategy for products and technology is to add value to already FDA approved products 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.

During 2002, we believe we will be able to identify a marketing partner for our lead product orBec® for marketing in the U.S. and Europe for the initial therapeutic indication of this drug, intestinal GVHD. Although this is a niche market, the additional gastrointestinal disorders for which orBec® 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.

Competition

The pharmaceutical industry and specifically the drug 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 drug delivery 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.

orBec Competition

Competition is intense in the gastroenterology and transplant areas being addressed by our company. Companies are attempting to develop technologies to treat GVHD by suppressing, through various mechanisms, the immune system. Some companies, including Sangstat, Abgenix, and Protein Design Labs, Inc., are developing monoclonal antibodies to treat GVHD. Biotransplant, Novartis, Medimmune, and Ariad are developing both gene therapy products and small molecules to treat GVHD. All of these products are in various stages of clinical development.

Competition is also intense in the therapeutic area of IBD, including Crohn's disease and ulcerative colitis. Several companies, including Centocor, Immunex, and Celgene, have products that are currently FDA approved. These products are all in the class of tumor necrosis factor modulating drugs. For example, Centocor, a subsidiary of Johnson & Johnson, markets the drug product Remicade® for Crohn's disease. Other drugs used to treat IBD 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 BDP, the FDA approved this drug for Crohn's disease late in 2001. 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, Inkine 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.

Oral Drug Delivery Competition

Our success as a drug delivery company depends upon establishing and maintaining a competitive position in the oral delivery of peptide-based and water-insoluble based-drugs and obtaining additional

patents. The drug delivery industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Competitors may develop competing technologies and obtain government approval for products before we do. Virtually all of our existing competitors in this field 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. Furthermore, our current and future corporate partners and collaborators may compete against us.

Our competitors in the field of oral delivery of macromolecular drugs include Emisphere Technologies, which has underway phase III trials for oral heparin and phase II trials with oral calcitonin and oral insulin (through its collaborator Novartis); Unigene Laboratories, which has an oral calcitonin product in phase I/II trials; Nobex Corp. (formerly known as Protein Delivery) which has an oral insulin in phase II trials; and Generex which has an oral insulin spray in phase II trials.

Competitors in the lipid and liposomal formulation field include Elan Corporation, Gilead Sciences, Inc.and ALZA Corporation. In addition, there may be other companies which are currently developing competitive technologies and products or which may in the future develop technologies and products that are comparable or superior to our portfolio of technologies and products.

Government Regulation

Prior to 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. Please refer to the risk factors: "*Our product development and commercialization efforts may be reduced or discontinued due to difficulties or delays in clinical trials", "We depend on others for clinical development and regulatory approvals of its product candidates", "We may not receive governmental product approval and may not be able to commercialize our products"* and *"We may be forced to reduce or discontinue product development and commercialization efforts due to delays or failure in obtaining regulatory approvals"*

Patents and Other Proprietary Rights

We rely on patent rights, trade secrets and nondisclosure agreements to establish and protect our proprietary rights to our technologies. Despite these precautions, it may be possible for unauthorized third parties to utilize our technology, to obtain and use information that we regard as proprietary, to design around our proprietary rights, or to create superior competing technologies. The laws of some foreign countries do not protect our proprietary rights in processes and products to the same extent as the laws of the United States.

In February 2002 DOR, the Company expanded its intellectual property portfolio, by filing seven patent applications with the United States Patent and Trademark Office for the three proprietary lipid-based drug delivery systems: LPM , LPE and PLP . These new filings bring the Company's total patent portfolio, either owned directly or licensed exclusively to the Company, to 17 patents issued in the U.S. and over 100 internationally, and 19 patents pending in the U.S. and over 100 internationally. The Company's patents issued in the United States expire between 2015 and 2022.

The Company's patent portfolio also includes drug delivery patents in the United States relating to the Orasome drug delivery system, of which three were original inventions of the Massachusetts Institute of Technology and the fourth was issued to the Company in February 2001. The InnoVaccines joint venture has licensed the rights to a series of vaccine delivery patents from SRI, seven of which were issued in the United States and over 45 of which were issued outside the United States.

Research and Development Expense

Research and development expenditures were approximately $2.5 million for the year ended December 31, 2001 and approximately $1.0 million for the year ended December 31, 2000.

Employees

As of March 1, 2002, DOR BioPharma had 22 employees, 18 of which were full-time employees, including 7 Ph.D.s, 2 M.D.s and 8 masters-level employees. Endorex plans to maintain this level during 2002.

Scientific Advisory Board

From time to time, DOR has assembled a Scientific Advisory Board ("SAB") with leading experts in different scientific fields matching the Company's area of product development. As a result of its acquisition of CTD, and entry into the field of gastrointestinal diseases, the Company will endeavor to assemble a new SAB to provide strategic guidance on the development of its lead drugs, and gastrointestinal-targeted drug delivery systems.

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, as amended (the "Exchange Act"), and Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), that reflect our current expectations about our future results, performance, prospects and opportunities. These forward-looking statements are subject to significant risks and uncertainties, including those identified in the "Risk Factors" section of this Form 10-KSB, 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 are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" and other similar expressions. However, these words are not the exclusive means of identifying such statements. In addition, any statements that refer to expectations, projections, or other characterizations of future events or circumstances are forward-looking statements. 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***.**

If additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts, and reduce the number of employees we currently have.

Until we are able to generate sufficient licensing revenue from our products, we will require additional funding to sustain our research and development efforts, provide for future clinical trials, and continue our operations. We cannot be certain whether we will be able to obtain additional required funding on terms satisfactory to our requirements, if at all. In addition, we have expended, and will continue to expend,

substantial funds developing our product candidates and for our clinical trials. We currently have commitments to spend additional funds in connection with development of our oral delivery systems, licenses, employee agreements and severance arrangements, and consulting agreements. 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 enter into financing arrangements on terms that we would not otherwise accept, or reduce the number of company personnel or take other cost-cutting steps that could adversely affect our ability to achieve our business objectives.

We have had significant losses and anticipate future losses.

We are a development stage company that has experienced significant losses since inception and have a significant accumulated deficit. We expect to incur significant additional operating losses in the future and expect cumulative losses to substantially increase, due to expanded research and development efforts, preclinical studies and clinical trials. All of our products are currently in development, preclinical studies or clinical trials and we have not generated significant revenues from product sales or licensing. There can be no guarantee that we will ever generate product revenues sufficient to become profitable or to sustain profitability.

We may not successfully meet the challenges necessary to realize the potential benefits of our merger with CTD.

We will need to overcome significant issues in order to realize any benefits or synergies from our merger with CTD, including, but not limited to, the following challenges:

developing and commercializing existing product candidates of both companies;

integrating the operations, business models and research and development of both companies;

integrating CTD product candidates and technology with our existing drug delivery technology;

developing or acquiring new product candidates or technology;

successfully commercializing future product candidates or technology;

obtaining FDA approval for the product candidates of both companies;

developing and commercializing products that can successfully compete with similar products; and

raising sufficient funds to develop and commercialize product candidates.

The successful completion of these post-merger events will involve considerable difficulty and there can be no assurance that we will be able to overcome these obstacles, or that there will be a market for existing product candidates or new products developed by us after the merger. Our failure to do so could have a material adverse effect on the combined company's business, financial condition and operating results or could result in the loss of key personnel. In addition, the attention and effort devoted to the integration of the two companies may divert management's attention from other important issues, and could seriously harm the combined company.

Our product development and commercialization efforts may be reduced or discontinued due to difficulties or delays in clinical trials.

To be profitable, our organization must, alone or with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Current technologies and 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. They are also rigorously regulated by the federal government, particularly the FDA, and by comparable agencies in state and local

jurisdictions and in foreign countries. Specifically, each of the following is possible with respect to any one of our technologies or product candidates:

- that we will not be able to maintain our current research and development schedules;
- that we will not be able to enter into human clinical trials because of scientific, governmental or financial reasons, or that we will encounter problems in clinical trials that will cause us to delay or suspend development of the technology or product candidate;
- that the technology or product will be found to be ineffective or unsafe;
- that government regulations will delay or prevent the product's marketing for a considerable period of time and impose costly procedures upon our activities;
- that the FDA or other regulatory agencies will not approve the product or will not do so on a timely basis;
- that the FDA or other regulatory agencies may not approve the process or facilities by which the product is manufactured;
- that our dependence on others to manufacture the product may adversely affect our ability to develop and deliver the product on a timely and competitive basis;
- that, if we are to manufacture the product, we will be subject to similar risks regarding delays or difficulties encountered in manufacturing the product, will require substantial additional capital, and may be unable to manufacture the product in a manner that meets regulatory requirements or in a cost-effective manner;
- that the FDA's policies may change and additional government regulations and policies may be instituted, both of which could prevent or delay regulatory approval of the product; and/or
- that we will be unable to obtain, or will be delayed in obtaining, approval of the product in other countries because the approval process varies from country to country, and the time needed to secure approval may be longer or shorter than that required for FDA approval.

If any of the risks set forth above occurs, we may not be able to successfully develop our technologies and product candidates and our business will be seriously harmed. Similarly, it is possible that, for reasons including, but not limited to those set forth below, we may be unable to commercialize, or receive royalties from the sale of, any given technology, even if it is shown to be effective, if:

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

we are not able to enter into arrangements or collaborations to commercialize the product;

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;

others have superior resources to market similar products or technologies;

government regulation imposes limitations on the indicated uses of the product, or later discovery of previously unknown problems with the product results in added restrictions on the product or results in the product being withdrawn from the market; or

the product has undesirable or unintended side effects that prevent or limit its commercial use.

Our current and future product candidates may not be developed successfully and may not treat medical conditions other than those already being treated by the ACEs.

We are focused on the development of new therapeutic uses and new oral and mucosal formulations of ACEs. However, our product candidates may not effectively treat medical conditions other than those for which the ACE was designed, have new therapeutic uses or utilize new formulations.

Even if orBec is approved, its profitability may be limited.

Our business may not become profitable if and when orBec , our lead product candidate, is approved for commercialization by the FDA or similar foreign regulatory agencies, because the market for the use of orBec for the treatment of intestinal GVHD is relatively small. We have initiated clinical studies to examine whether or not orBec is effective and safe when used to treat disorders other than intestinal GVHD, but we do not know whether these studies will in fact demonstrate safety and efficacy, or if they do, whether we will succeed in receiving regulatory clearance to market orBec for additional indications. If the results of these studies are negative, or if adverse experiences are reported in these clinical studies or otherwise in connection with the use of orBec by patients, this could undermine physician and patient comfort with the product, limit the commercial success of the product, and even impact the acceptance of orBec in the intestinal GVHD market. Furthermore, new technology is being developed for bone marrow transplants that could reduce or eliminate instances of intestinal GVHD resulting from bone marrow transplants, and therapeutic alternatives to bone marrow transplants may become available. Any such developments could significantly decrease the market for orBec .

We are dependent on corporate partnerships.

Our strategy for development and commercialization of our technologies is to rely on licensing agreements with corporate partners. As a result, our ability to commercialize future products is dependent upon the success of third parties in performing clinical trials, obtaining regulatory approvals, manufacturing and successfully marketing our products.

We cannot assure you that corporate collaborations or corporate partnerships will be successful. We have been in discussions with Elan regarding terminating the two joint ventures, InnoVaccines and Newco, although no definitive agreements have been reached with respect to such terminations. We cannot assure you that the results of these discussions will be favorable or if there will be a negative financial impact to us. We have included a liability in on our balance sheet for potential expenses owed to Elan by the joint ventures, but have not allocated specific cash reserves for payment. Should the termination discussions be unfavorable, we may have to make payments to Elan which could impact our financial position. Additionally, if Elan discontinues its collaborations with us, we may not be able to continue to license or have access to certain proprietary technology from Elan.

Newco is our joint venture with Elan to develop a product to deliver iron chelation compounds using Elan's MEDIPAD® delivery device. During 2000, Newco licensed Elan's MEDIPAD® device on a worldwide basis to Schein Pharmaceutical, (Bermuda) Ltd., or Schein, which became a subsidiary of Watson Pharmaceuticals, Inc., or Watson, for use with Schein's iron chelation compound. Schein agreed to develop and market the MEDIPAD® iron chelation product in the United States, and Newco and Schein agreed to jointly seek partners for marketing the product outside the United States. In May 2001, Schein indicated to us that it was not going to continue to meet the obligations originally agreed to in connection with the license. In March, 2002, Schein and Newco signed an agreement which terminated the license agreement and reimbursed Newco for certain development expenses related to the project in the amount of $300,000. Based on this activity, it is unlikely that we will continue with our MEDIPAD® iron chelator joint venture, Newco with Elan.

We intend to pursue new corporate partnerships and collaborations; however, the terms available may not be acceptable to us, and any corporate partnerships or collaborations that we establish may not be successful. In addition, the amount and timing of resources that our collaborators devote to these activities are not within our control. If any of our current corporate partnerships, such as those discussed above, are discontinued, we may not be able to find others to develop and commercialize our current product candidates. Furthermore, if any of our corporate partnerships and collaborations for our current product candidates are discontinued, we may not be able to continue the development of such product candidates due to the loss of technology, intellectual property or expertise or due to contractual restrictions. The successful development and commercialization of our drug delivery technology depends upon entering into corporate partnerships, collaborations or license agreements that are compatible with our drug delivery technology and that are safe and proven effective for medical conditions. We may not be able to enter into such new corporate partnerships, collaborations or license agreements to develop and commercialize any future product candidates using our drug delivery technology.

Problems in product development may increase and vary the rate at which we spend our funds.

Our organization has limited experience with preclinical development, clinical trials and regulatory affairs, and if we encounter unexpected difficulties with our operations or clinical trials, we may have to spend additional funds, which would increase our cash depletion rate. Our cash depletion rate will vary substantially from quarter to quarter as we fund non-recurring items associated with clinical trials, product development, patent expenses, legal fees and consulting fees.

Our product development and commercialization efforts may not be successful.

Our proprietary product candidates, which have not received regulatory approval, are in various stages of development. If the initial results from any of the evaluations for these product candidates are poor, those results could seriously harm our business and our ability to raise additional capital which may be necessary to continue research and development for our oral delivery technology. In addition, product candidates resulting from our research and development efforts, if any, are not expected to be available commercially for several years, if at all.

Although we are involved in developing oral versions of injectable drugs that have already been approved by the FDA, the products we are currently developing will require significant additional laboratory and clinical testing and investment for the foreseeable future. Our product candidates may not show sufficient efficacy in animal models to justify continuing research into clinical testing stages or may not prove to be effective in clinical trials or may cause serious harmful side effects. In addition, our product candidates, if approved, may prove impracticable to manufacture in commercial quantities at a reasonable cost and/or with acceptable quality. Any of these results could seriously harm our business.

Our products, if approved, may not be immediately used by doctors unfamiliar with our product applications. Either the Company or our commercialization partner may be required to implement an aggressive education and promotion plan with doctors in order to gain market recognition, understanding and acceptance of our products. Any such effort may be time consuming and costly and might not be successful.

We lack manufacturing experience and will rely on third-party manufacturers, which could adversely affect our ability to meet customers' demands.

We have no manufacturing capabilities. Accordingly, we will need to rely on third-party manufacturers or suppliers of our products. We may not be able to identify any such manufacturers or suppliers, and, even if we are able to do so, we may not be able to enter into manufacturing or supply agreement on terms that are favorable to us, if at all. We will be required to rely on contract

manufacturers and suppliers for the foreseeable future to produce quantities of products and substances necessary for research and development, pre-clinical trials, human clinical trials and product commercialization. Such products may not be able to be manufactured or supplied at a cost or in quantities necessary to make them commercially viable. Third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products. If we are unable to contract for a sufficient supply of required products and substances on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our research and development, pre-clinical and clinical testing would be delayed, thereby delaying the submission of products for regulatory approval or the market introduction and subsequent sales of such products. Any such delays may have a material adverse effect on our business, financial condition and results of operations. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices regulations enforced by the FDA through its facilities inspection program. If the facilities of such manufacturers cannot pass a pre-approval plant inspection, the FDA pre-market approval of our products will not be granted.

Our research and development contractors may not be complying with United States Good Laboratory Practice.

We do not have, and some third party contractors performing research and development for us may not have, Good Laboratory Practice, or GLP, designation from the United States regulatory authorities, and we and they may fail to qualify for GLP designation. Failure of ourselves or any of our third party contractors to qualify for GLP designation may impair our ability to use the results of such party's research, which may seriously harm our product development efforts.

Future inability to obtain raw materials or products from contract manufacturers could seriously affect our operations.

We currently obtain raw materials and other products from single domestic or foreign suppliers. Although to date we have not experienced difficulty in obtaining these products, the supply could be interrupted in the future or we may have to obtain substitute materials and products. Changes in our raw material suppliers, including the lack of suitable alternative FDA certified suppliers, could result in delays in production, higher raw material costs, and loss of sales and customers because regulatory authorities must generally approve raw material sources for pharmaceutical products.

We depend on others for clinical development and regulatory approvals of our product candidates.

In order for us to successfully develop and commercialize our product candidates, we may need to enter into collaboration agreements with partners to help research and develop our product candidates and to fund all or part of the costs thereof. We may not be able to enter into such collaboration agreements or the terms of the collaboration agreements may not be favorable to us. Our inability to enter into collaboration agreements could delay or 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 collaborative partners, if any, rights to license and commercialize pharmaceutical and related products developed under these collaborative agreements, and such rights would limit our flexibility in considering alternatives for the commercialization of such products. Under such agreements, we may rely on our collaborative partners to conduct research efforts and clinical trials on, obtain regulatory approvals for, and manufacture market and commercialize certain of our product candidates. Although we believe that our collaborative partners will have an economic motivation to commercialize the pharmaceutical and related products which they may license, the amount and timing of resources devoted to these activities generally will be controlled by each such individual partner.

We do not have agreements with third parties or a sales force to market our products.

If we receive approval from the FDA for our initial product candidates, the commercialization of these products will depend upon our ability to enter into marketing agreements with companies that have sales and marketing capabilities or to recruit, develop, train and deploy our own sales force. We currently intend to sell our products in the United States and internationally in collaboration with one or more marketing partners. We cannot assure you that we will be able to enter into any such collaboration to commercialize products in a timely manner or on commercially reasonable terms, if at all. Additionally, we do not currently have a sales force, or possess the resources or experience necessary to market any of our product candidates, if they are approved. Development of an effective sales force requires significant financial resources, time and expertise. We cannot assure you that we will be able to obtain the financing necessary to establish such a sales force in a timely or cost effective manner, if at all, or that such a sales force will be capable of generating demand for our product candidates, if they are approved.

We maintain limited product liability insurance and may be exposed to claims if our insurance coverage is insufficient.

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. We currently have clinical trial and product liability insurance with limits of liability of $10 million. Because liability insurance is expensive and difficult to obtain, we cannot assure you that it will be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage on acceptable terms or to otherwise protect against potential liability claims in excess of our insurance coverage could seriously harm our business.

We use hazardous materials in our business. Any claims relating to improper handling, storage, or disposal of these materials could be costly.

Our research and development processes involve the controlled use of hazardous materials, including hazardous chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We cannot fully eliminate the risk of accidental contamination or discharge of such materials and any resulting injury. We could be subject to civil damages in the event of improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, we could be sued for injury or contamination that results from our use of hazardous materials or their use by third parties or our collaborators, and our liability may exceed our assets. Federal, state, and local laws and regulations govern the use, manufacture, storage, handling, and disposal of these materials. Compliance with these laws and regulations may be expensive, and current or future laws and regulations relating to hazardous materials may impair our research, development, or commercialization efforts.

We may not be able to compete 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. Numerous companies are attempting to develop technologies to treat GVHD, including Sangstat, Abgenix, and Protein Design Labs, Inc. (monoclonal antibodies). Biotransplant, Novartis, Medimmune, and Ariad are developing gene therapy products or small molecules to treat GVHD.

Competition is also intense in the therapeutic area of inflammatory bowel disease, or IBD, including Crohn's disease and ulcerative colitis. Companies, including Centocor, Immunex, and Celgene, have products that are currently FDA approved. Other drugs used to treat IBD include another orally-active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada under the tradename of Entocort®. 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, Inkine Pharmaceutical Corporation, and Elan Pharmaceuticals, Inc. Isis Pharmaceuticals, Inc. is in the process of developing an antisense therapy to treat Crohn's disease.

Our competitors in the field of oral delivery of peptide-based drugs include Emisphere Technologies, which has started phase III trials for oral heparin and phase I trials for oral calcitonin (through its collaborator Novartis) and oral insulin; Unigene Laboratories, which has an oral calcitonin product in phase I/II trials; Nobex Corp. (formerly known as Protein Delivery), which has an oral insulin in phase II trials, and Generex, which has an oral insulin spray in phase II trials. Our competitors in the lipid and liposomal formulation field include Elan Corporation, Gilead Sciences, Inc. and ALZA Corporation, and NeoPharm, which are developing these technologies with cancer drugs; however these products are injectable. In addition, there may be other companies which are currently developing competitive technologies and products or which may in the future develop technologies and products that are comparable or superior to our technologies and products. Accordingly, we cannot assure you that we will be able to compete successfully with our existing and future competitors or that competition will not negatively affect our financial position or results of operations in the future.

We may not be able to qualify our product candidates for certain governmental programs and obtain the market exclusivity provided under such programs.

Our business strategy relies significantly on the product and use exclusivity provided by various government programs, including programs under the Orphan Drug Act of 1983 and Waxman-Hatch Amendments of 1984, as well as the three year market exclusivity period for approved new drug applications and supplemental new drug applications. Currently, the FDA has granted orphan drug status to orBec , for treatment of intestinal GVHD and prevention of GVHD, and to Oraprine , for the treatment of oral auto-immune diseases. Additionally, EMEA has granted orphan drug status to orBec for treatment of intestinal GVHD for the European Community. However, we may not be able to maintain the orphan drug designations or qualify our future product candidates for such governmental programs and obtain the exclusivity provided under

those programs, or obtain the market exclusivity provided for new drug applications and supplemental new drug applications. Without such exclusivity, we may not be able to successfully commercialize our product candidates

We may not receive required governmental approvals for our products

Our proposed products offerings will be subject to very stringent United States, federal, foreign, state and local government regulations, including, without limitation, the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to such acts. Similar regulatory frameworks exist in other countries where we may seek to market our products. Prior to marketing any proposed product we may develop, such product must undergo an extensive regulatory approval process.

The regulatory process includes 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. Delays or denials of marketing approval are regularly encountered due to the submission of data deemed unacceptable or incomplete by the FDA or other similar regulatory

agencies, or due to regulatory policy for product approvals. These delays may be encountered both domestically and abroad. Other problems that may arise during clinical trials include:

results of clinical trials may not be consistent with earlier clinical or pre-clinical study results; and

products may not be shown to be safe and efficacious.

There is no assurance that, even after clinical testing, regulatory approval will ever be obtained. If obtained, regulatory approval entails limitations on the indicated uses for which any products may be marketed. Following regulatory approval, if any, 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. Moreover, 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 criminal prosecution.

We may be liable for significant damages and be unable to commercialize our products if we are unable to protect our proprietary rights

If we fail to adequately protect our intellectual property rights or face a claim of intellectual property infringement by a third party, then we could lose valuable intellectual property rights, be liable for significant damages or be prevented from commercializing products.

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. 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 technology, possibly at lower prices. It is also possible that we could 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.

We have filed various patent applications covering certain uses of our product candidates. However, 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 ("PTO") regarding the breadth of claims allowed in biotechnology patents.

In addition, since patent applications in the United States are maintained in secrecy until patents issue, and since 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 they are the first to file. Moreover, the PTO may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, there can be no assurance that patents owned by us or patents licensed to us in the future will be valid or will afford it protection against competitors with similar technology or that patent applications licensed to us will result in the issuance of patents. Any challenge to, or invalidation or circumvention of,

our patents or patent applications could have a material adverse effect on our business.

Any issued patents may not provide competitive advantages for the proposed products or may be successfully challenged or circumvented by competitors. In addition, others may independently develop similar products or duplicate any of our products. 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 may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

We rely upon unpatented proprietary technology.

We rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to such unpatented proprietary technology. Furthermore, competitors may duplicate or independently develop substantially equivalent technology. A failure by us to protect our rights could seriously harm our business. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. Third parties, typically drug companies, hold patents or patent applications covering the composition-of-matter for most of the ACEs for which we have use patents or patent applications. In each of these cases, unless we have or obtain a license agreement, we generally may not commercialize the ACE until these third-party patents expire. Because pharmaceutical patents typically provide valuable rights that take many years to develop, the United States has laws that allow the term of such patents to be extended. This has led to complex and costly litigation between large pharmaceutical companies and others seeking to sell products based on compositions of matter covered by expiring patents. Licenses may not be available to us for these patents on acceptable terms, if at all. In addition, we would incur substantial cost, expense and delay, as well as expand considerable management and operational resources, if we need to contest the validity of a third-party patent or defend ourselves against claims that we infringed a third-party patent. Moreover, litigation involving third party patents may not be resolved in our favor.

The application of patent law to the field of biotechnology is relatively new and has resulted in considerable litigation. Since patent applications in the United States are maintained in secrecy until patents issue, and since 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 they are the first to file. Moreover, the PTO may commence interference proceedings involving our patents or patent applications, in which the question of first inventorship is contested. There is a substantial risk in the rapidly developing biotechnology industry that patents and other intellectual property rights held by us could be infringed by others or that products developed by us or our method of manufacture could be covered by patents owned by other companies. Although we believe that our products and services do not infringe on any third party's patents or other intellectual property rights, we cannot be certain that we can avoid litigation involving such proprietary rights. Intellectual property litigation entails substantial legal and other costs and may take years to resolve, and we may not have the necessary financial resources to defend or prosecute our rights in connection with any litigation. Responding to, defending or bringing claims related to patents and other intellectual property rights may require our management to redirect our human and monetary resources to address these claims and may take years to resolve.

We depend on licenses from third parties.

We rely on license agreements from several third parties for the rights to commercialize our product candidates. Such agreements require that we meet certain milestones; the failure to meet those milestones allows licensors to terminate the licenses, whereas meeting those milestones triggers payment obligations on our part. We may not be able to retain the rights granted under such agreements or negotiate additional agreements on reasonable terms, or at all. We are currently involved in a dispute with the licensors of our Metropt product candidate regarding the current product formulation, and have received communications from the licensors that they intend to terminate that license agreement unless certain conditions are met. We may not be able to resolve that dispute or resolve the formulation issue on terms that are favorable to us, or at all. In the event that we are not able to settle that dispute and retain the rights under the Metropt license agreement, we would not be able to further develop and commercialize the Metropt product.

Our business also depends, in part, on our license of polymerized liposome technology from the Massachusetts Institute of Technology, or MIT, licenses from Elan in connection with our two joint ventures with Elan, and the technology licensed by InnoVaccines from Southern Research Institute. Our license agreement with MIT provides that we will commence phase I clinical trials with the MIT liposome technology

prior to January 1, 2002. We were able to obtain an extension to this agreement, but we cannot assure you that the technology underlying these licenses will be profitable, or that we will be able to retain or plans to retain licenses for these technologies. If we are unable to retain these licenses and rights to third party technology, or if we are unable to obtain rights to substitute technology on reasonable terms, our development efforts and business may be harmed.

We may be forced to reduce or discontinue product development and commercialization efforts due to delays or failure in obtaining regulatory approvals.

We will need to do substantial additional development and clinical testing prior to seeking any regulatory approval for commercialization of our product candidates. Testing, manufacturing, commercialization, advertising, promotion, exporting and marketing, among other things, of our proposed products are subject to extensive regulation by governmental authorities in the United States and other countries. The testing and approval process requires substantial time, effort and financial resources and we cannot guarantee that any approval will be granted on a timely basis, if at all. At least initially, we intend, to the extent possible, to rely on licensees to obtain regulatory approval for marketing our products. Failure by us or by our licensees to adequately demonstrate the safety and efficacy of any of our product candidates under development could delay, limit or prevent regulatory approval of the product, which may require us to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in conducting advanced human clinical trials, even after obtaining promising results in earlier trials. Furthermore, the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Also, even if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which the product may be marketed. Accordingly, we may be unable to, or experience difficulties and delays in obtaining, necessary governmental clearances and approvals to market a product.

Our products, if approved, may not be commercially 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 such changes 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 such 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, within certain guidelines, can make their own coverage decisions. Accordingly, 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 and other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services. Also, the trend toward managed health care and the growth of health maintenance organizations in the United States may

result in lower prices for our products, if approved and when commercially available, than we currently expect. The cost containment measures that health care payers and providers are instituting and the effect of any health care changes could negatively affect our financial performance, if one or more of our products are approved and available for commercial use.

Our business could be seriously harmed if we cannot attract and retain key personnel.

Our success is dependent, in part, upon Dr. Colin Bier, DOR's Chairman and Chief Executive Officer, Michael S. Rosen, DOR's President and Chief Operating Officer, Panayiotis Constantinides, Ph.D., DOR's Vice President of Research and Development, John McCracken, DOR's Vice President of Business Development, and Steve Koulogeorge, DOR's Controller, Treasurer and Corporate Secretary, and Dr. Franco Quagliata, Medical Director. We also believe that our future success will depend largely upon our ability to attract and retain highly skilled research and development and technical personnel. Although we currently maintain and are the beneficiary of key-man life insurance on Mr. Rosen, we do not believe the proceeds would be adequate to compensate us for the loss. We face intense competition in recruiting activities, including competition from larger companies with greater resources. We cannot assure you that we will be successful in attracting or retaining skilled personnel. The loss of certain key employees or our inability to attract and retain other qualified employees could seriously harm our business.

Our stock price is highly volatile and our stock is thinly traded.

The market price of DOR BioPharma's 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 many factors, including, but not limited to:

- actual or anticipated fluctuations in our results of operations;
- announcements of innovations by us or our competitors;
- introduction of new products by us or our competitors;
- additions or departures of key personnel;
- commencement of litigation;
- developments with respect to intellectual property rights;
- conditions and trends in the pharmaceutical and drug delivery industries;
- changes in estimates of the development, future size and growth rate of our markets;
- general market conditions; and
- future sales of our common stock.

In addition, the stock market has experienced significant price and volume fluctuations that affect the market price for our common stock, as well as for the common stock of other biotechnology companies. These market fluctuations have sometimes been unrelated or disproportionate to the operating performance of these companies. Any significant stock market fluctuations in the future, whether due to our actual performance or prospects or not, could result in a significant decline in the market price of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action has often been instituted against that company. If any securities litigation is initiated against us, we could incur substantial costs and our management's attention and resources could be diverted from our business.

Since it commenced trading on the American Stock Exchange on August 6, 1998, DOR BioPharma's common stock has been thinly traded. We cannot assure you that a more active trading market for our common stock will develop.

We cannot assure you that we will continue to be listed on the American Stock Exchange.

We cannot assure you that we will satisfy the requirements necessary to remain listed on the American Stock Exchange or that the American Stock Exchange will not take actions to delist our common stock. If such events were to occur, we cannot assure you that we will 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, an active trading market may not exist for our common stock.

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 2,014,001 shares of common stock at a current exercise price of $1.8209 per share, subject to adjustment, issued in connection with the October 1997 private placement of the Company's common stock;

- warrants to purchase 230,770 shares of common stock at $10.00 per share, subject to adjustment, held by Elan;

- warrants to purchase 43,334 shares of common stock at a current exercise price of $1.6914 per share, subject to adjustment, held by Aries Select Ltd. and warrants to purchase 23,334 shares of common stock at a current exercise price of $1.6914 per share, subject to adjustment, held by Aries Select I LLC, both issued on May 19, 1997 pursuant to a senior line of credit that has been subsequently retired;

- warrants to purchase 452,383 shares of common stock at $5.91 per share, subject to adjustment, held by certain investors pursuant to the April 2000 private placement of DOR's common stock;

- warrants to purchase 226,190 shares of common stock at $5.25 per share, subject to adjustment, issued to Paramount Capital, Inc., as the finder in connection with the April 2000 private placement of the Company's common stock;

- conversion rights and dividend rights of preferred stock held by Elan, consisting of 108,443 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 and 104,435 shares of Series C preferred stock ($8.4 million original liquidation value) bearing a 7% cumulative payment-in-kind dividend and exchangeable for part of the Company's interest in the Newco joint ventures with Elan or convertible at liquidation value into common stock at $8.86 per share;

- options to purchase approximately 3.4 million shares of common stock issued to participants in the Company's stock option plan with a weighted average exercise price of approximately $1.69;

- warrants to purchase 207,077 shares of the Company's common stock at an exercise price of $8.11 per share, pertaining to the conversion of CTD warrants into Company warrants, held by certain investors pursuant to the plan of merger and reorganization; and

- 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.

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.

Future sales of common stock by existing stockholders could adversely affect our stock price.

The market price of our common stock could decline as a result of sales by existing stockholders of shares of common stock in the market, or the perception that these sales could occur. These sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

We have certain relationships that may present potential conflicts of interest.

Lindsay A. Rosenwald, M.D. is the Chairman and sole stockholder of Paramount Capital Asset Management, Inc., or PCAM, Paramount Capital, Inc., or Paramount, and Paramount Capital Investment LLC, or PCI, a merchant banking and venture capital firm specializing in

biotechnology companies. PCAM is the investment manager of Aries Select, Ltd., and the managing member of Aries Select I LLC and Aries Select II LLC, each of which is an affiliate of PCI, PCAM, Paramount and Lindsay Rosenwald. Aries Select I LLC and Aries Select, Ltd. are principal stockholders, and Aries Select II LLC is also a stockholder, of the Company. Paramount has also acted as a placement agent in connection with private placements of DOR common stock, as a finder in connection with a private placement of the Company's common stock and warrants and as a financial advisor to the Company. In addition, certain officers, employees and associates of Paramount and its affiliates own securities of a subsidiary of the Company. In the regular course of its business, PCI identifies, evaluates and pursues investment opportunities in biomedical and pharmaceutical products, technologies and companies. However, PCI is under no obligation to make any additional products or technologies available to us, and we do not expect, and you should not expect, that any biomedical or pharmaceutical product or technology identified by such affiliates or PCI in the future will be made available to us. In addition, certain of 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 Company's interests.

Certain directors, officers and stockholders have significant influence.

Our directors, executive officers and principal stockholders and certain of their affiliates have the ability to influence the election of directors and most other stockholder actions. This may discourage or prevent any proposed takeover of the Company, including transactions in which stockholders might otherwise receive a premium for their shares over the then current market prices. Such stockholders may also influence corporate actions, including influencing elections of directors and significant corporate events.

Item 2. Facilities

The DOR BioPharma, Inc. 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 needs, but may not be sufficient for the foreseeable future, and that suitable additional laboratory space may not be available if and as needed, but the terms or location may not be favorable to us.

Item 3. Legal Proceedings

We are not currently a party to any legal proceedings that we believe would, individually or in the aggregate, have a material adverse effect on our business, financial condition or operating results.

Item 4. Submission of Matters to a Vote of Security Holders.

(a)

An annual meeting of stockholders of the Company was held on November 29, 2001.

(c)

1. The Company's stockholders voted as follows with respect to a proposal to issue shares of its common stock, options and warrants pursuant to a merger agreement among the Company, Corporate Technology Development, Inc. and Roadrunner, a wholly-owned subsidiary of the Company.

FOR	AGAINST	ABSTENTIONS	BROKER NON-VOTES
9,056,965	100,982	6,809	3,569,402

2. The Company's stockholders voted as follows with respect to a proposal to amend the Company's Amended and Restated Certificate of Incorporation changing the Company's name to DOR BioPharma, Inc.:

FOR	AGAINST	ABSTENTIONS	BROKER NON-VOTES
11,953,925	22,320	757,914	n/a

3. The Company's stockholders voted as follows with respect to a proposal to elect six directors to serve until the next annual meeting of stockholders of the Company or until their successors are duly elected and qualified:

DIRECTORS	FOR	AUTHORITY WITHHELD
Michael S. Rosen	12,652,819	81,339
Richard Dunning	12,652,919	81,239
Steve H. Kanzer	12,652,885	81,273
Paul D. Rubin	12,652,919	81,239
Kenneth Tempero	12,652,919	81,239
Steven Thornton	12,652,919	81,239

4. The Company's stockholders voted as follows with respect to a proposal to approve an amendment of the Company's Amended and Restated 1995 Omnibus Incentive Plan to, among other things, increase the number of shares of common stock of the Company reserved for issuance by an additional 2,165,664 shares:

FOR	AGAINST	ABSTENTIONS	BROKER NON-VOTES
8,126,899	265,130	772,726	3,569,402

5. The Company's stockholders voted as follows with respect to a proposal to approve February 21, 2001 option grants to each non-employee member of the Company's board of directors to purchase 50,000 shares of the Company's common stock:

FOR	AGAINST	ABSTENTIONS	BROKER NON-VOTES
8,191,643	183,159	789,954	3,569,402

6. The Company's stockholders voted as follows with respect to a proposal to ratify the appointment of Ernst & Young LLP as the Company's independent auditors for the fiscal year ended December 31, 2001

FOR	AGAINST	ABSTENTIONS	BROKER NON-VOTES
11,940,323	32,970	760,865	n/a

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, 2000 through March 1, 2002. The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.

	High	Low
2000		
1st Quarter	$ 9.94	$ 2.50
2nd Quarter	$ 5.75	$ 1.75
3rd Quarter	$ 3.81	$ 1.81
4th Quarter	$ 2.81	$ 0.81
2001		

	High	Low
1st Quarter	$ 1.75	$ 0.75
2nd Quarter	$ 1.30	$ 0.75
3rd Quarter	$ 1.40	$ 0.80
4th Quarter	$ 1.15	$ 0.80
1st Quarter through March 1, 2002	$ 2.10	$ 0.95

As of March 1, 2002, we had 1,615 registered stockholders of record. We currently intend to retain any earnings for use in our business and do not anticipate paying any cash dividends in the foreseeable future.

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 analysis in conjunction with our audited consolidated financial statements and notes thereto. 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 Form 10-KSB. See "Item 1. Business Cautionary Note Regarding Forward-Looking Statements."

Plan of Operation

DOR BioPharma, Inc. began the year 2001 as Endorex Corporation, which was developing oral drug delivery platforms for protein and peptide-based drugs only available in an injectable format, and its two drug delivery joint ventures with Elan. During the year, the Company shifted its drug delivery efforts away from protein delivery due to the significant challenges with these types of drugs because of their great molecular weight. Representative of this shift away from such delivery was the agreement with Elan to terminate vaccine joint venture R&D activities, and later in the year, the mutual decision with Novo to terminate the oral human growth hormone research and option agreement. Additionally, due to Schein's decision to terminate its license agreement on the Medipad® iron chelator project, Elan and Endorex have been in discussion to also terminate Newco (MEDIPAD®).

During 2001, DOR focused its scientific delivery activities and core competencies to manipulate lipids and polymers so as to develop new delivery platforms for two classes of drugs: 1) peptides (large molecule drugs ranging from 500 to 5000 daltons, a standard molecular weight unit), and 2) water-

insoluble drugs (both peptides and small molecules). These types of drugs present delivery problems as they are poorly absorbed by the gastrointestinal tract. The Company believes its expertise in lipids and polymers as well as the initial promising pre-clinical studies in rodent and non-rodent models with selected drugs representing each class of drugs, will allow for the utilization of its new lipid- based delivery platforms to enhance the stability and preservation of these drugs. Specifically, utilizing its new proprietary lipid-based drug delivery systems, DOR is developing oral versions of two of the leading cancer drugs; leuprolide, a peptide drug (TAP Pharmaceuticals' Lupron®) and paclitaxel a water-insoluble drug (Bristol-Myers Squibb's Taxol®). During 2002, DOR has already completed initial dog studies with leuprolide confirming the consistency of results obtained in the rodent model; these results appear promising. Should these results be further validated, DOR will complete toxicology and other studies in preparation to file an IND so as to initiate human clinical trials. The Company filed a number of new patents at the end of 2001 and in the beginning of 2002 to protect these new delivery platforms. The initial results of the work done on these new technologies were presented in two scientific meetings during the last 3 months: the 6th U.S.-Japan Symposium on Drug Delivery Systems, and the Gordon Conference on Drug Delivery Systems. Additional presentations and abstracts for other scientific meetings are planned during 2002.

During 2001, the Company sought to acquire clinical product candidates, leading to merger discussions with CTD and a letter of intent in February, 2001 and completion of due diligence on CTD's products and patents and a final merger agreement culminating in August, 2001. In November 2001, Endorex Corporation acquired CTD and became DOR BioPharma, Inc. The new company name is an acronym for the company's business: (D)elivery of (Or)al (BioPharma)ceuticals.

DOR BioPharma now has greater critical mass in product portfolio with both a clinical and preclinical pipeline, featuring a lead drug, orBec in a multicentered phase III trial in the U.S. for intestinal Graft-versus Host disease. This same drug orBec , has also initiated a phase II trial for the treatment of Crohn's disease in the U.S. A second drug, Oraprine , has completed 2 clinical trials: a phase I bioequivalency trial and a

phaseI/II trial in oral autoimmune diseases. The strategic fit of CTD to DOR is optimal, as CTD's expertise has been in the development of novel oral versions of small molecule drugs, which have already been approved by the FDA and are marketed), and their development for new proprietary therapeutic uses.

During 2002, DOR will focus on the development of its lead clinical products orBec and Oraprine and on the oral delivery of peptide-based and small molecule water insoluble drugs using its platform drug delivery systems to convert needle-based therapy into the "patient-preferred" oral/mucosal technology. DOR is endeavoring to create proprietary technology positions through novel delivery patents and therapeutics use patents. As these products may target niche diseases, the Company is supplementing such coverage with orphan drug designations where possible from the U.S. FDA and its European and Japanese equivalents. DOR will commercialize its products through corporate partners to physicians and patients until such time as the Company's financial resources and product flow allow it to pursue a direct commercialization strategy. During 2002, DOR expects to complete patient enrollment of the orBec phase III trial for the treatment of intestinal GVHD and for the phase II Crohn's disease trial. DOR also believes that it will complete preclinical development of oral leuprolide and file an IND on this drug formulation paving the way for a phase I trial. DOR should also complete formulation efforts on Oraprine and make a decision on further clinical development. It will also conclude evaluation of the University Pharmaceutics of Maryland "fast-dissolve" technology and reach a decision on licensing such technology, and resolve a decision to further maintain its license and develop Metropt .

During 2002, DOR BioPharma has already enhanced its regulatory and clinical skills by hiring Franco Quagliata, M.D. as its medical director and may further enhance its manufacturing skills by hiring additional expertise to assist the company in the coming months. Also during 2002, the Company expects to resolve the future of its two joint ventures with Elan, for which there is a reasonable expectation that these will be terminated. The Company has already resolved during 2002 the termination of the Schein license agreement resulting in a payment by Schein to Newco of certain development expenses.

Material Changes in Results of Operations

DOR BioPharma, Inc. is a development stage company and to date, has not generated any material revenues from operating activities. Although its product portfolio includes a phase III drug which may be attractive to potential pharmaceutical partners, the Company has no active discussions under way with any such potential partners.

For the twelve months ended December 31, 2001, we had a net loss applicable to common stockholders of $16,117,676 as compared to a $6,177,893 net loss applicable to common stockholders for the twelve months ended December 31, 2000, an increase of $9,939,783, or 161%. Net loss applicable to common stockholders included the impact of preferred stock dividends, which totaled $1,486,501 in 2001, as compared to $1,382,200 in 2000 an 8% increase.

Results for 2001 include a $10,181,000 non-recurring expense for the write-off of acquired in-process research and development (IPR&D) costs associated with the merger with CTD in November 2001.

The 2001 results also reflect a shifting of research and development activities from joint venture R&D, to in-house proprietary R&D activities. Our increased investment in proprietary R&D pre-clinical drug delivery activities during 2001 of $2,470,801 versus $956,742 in 2000, an increase of $1,514,059 or 158%, reflects our new focus on peptides and small molecule drugs. Conversely in 2001, equity in losses from our two joint ventures with Elan was $401,699 as compared to $2,682,368 for 2000, a significant decrease of $2,280,669 or 85%. The reduction of R&D spending from our two joint ventures offset the increased proprietary research and development work performed.

Another contributing factor in 2001 was a decrease of approximately $323,041 or 43% in interest income, from $747,073 in 2000 to $424,032 in 2001, reflecting the reduction in interest rates as well as a reduction in the available cash investment balance for investment.

Research and development expenditures for the twelve months ended December 31, 2001 were $2,470,801 as compared to $956,742 for the twelve months ended December 31, 2000, an increase of $1,514,059 or 158%. This increase in R&D expenditures represents the development of three new proprietary delivery platforms during 2001.

General and administrative expenses for the twelve months ended December 31, 2001 were $1,973,455 as compared to $2,101,767 for the twelve months ended December 31, 2000, a decrease of $128,312 or 6% due to the expiration of the amortization of the financial advisory warrants in 2000.

The write-off of acquired in-process research and development represents a one time adjustment for IPR&D costs of $10,181,000 associated with the acquisition of CTD in November of 2001, which was recorded as expense. Further description of this transaction and the related write-off is available in Note 5 of the Company's financial statements.

Equity in losses from joint ventures, representing our two joint venture operations with Elan, for the twelve months ended December 31, 2001 were $401,699 as compared to $2,682,368 for the same period in 2000, a reduction of approximately $2,280,669 or 85%. This reduction was mostly a result of our shifting to in-house proprietary R&D work, but was also impacted by a $300,000 settlement to

Endorex/Newco from Schein. Our portion of the settlement, $240,000 was a reduction of joint venture related expenses.

Other income decreased in 2001 by $242,412 or 35% due to the sale of an option to purchase some of our oncology business assets in 2000. The option lapsed pursuant to its terms and is no longer exercisable. Interest income (net) for the twelve months December 31, 2001 was $388,192 as compared to $695,184, for the twelve months ended December 31, 2000, a decrease of $306,992 or 44%. This decrease was primarily due to the reduction in the available cash and investment balance generated by the April 2000 equity financing and the sharp reduction in investment rates during 2001.

Financial Condition

As of December 31, 2001 DOR BioPharma had cash, cash equivalents and marketable securities of $9,942,053 as compared to $12,846,250 as of December 31, 2000 and working capital of $6,766,704 as compared to $10,112,440 as of December 31, 2000. For the twelve months ended December 31, 2001, DOR BioPharma's (on a pro forma basis, giving effect to the Company's acquisition of CTD, as if it occurred January 1, 2001) operating cash expenditures, or net cash burn were approximately $7.4 million, a rate we believe will be similar in 2002 due to costs related to on-going and anticipated clinical trials. To maximize its operational efficiency in 2002, DOR will integrate the operations of Endorex and CTD, to achieve cost reduction through the elimination of duplicate administrative expenses, simplification of the organizational structure, and prioritization of its product portfolio, on those opportunities with the highest profit potential.

At December 31, 2001, we have recorded a total of $2,042,833 as a current liability (payable) under the account "Due to joint ventures". Funding obligations, ownership and current funding status for each of the two joint ventures with Elan are disclosed in Note 4 of the Company's financial statement. The InnoVaccines joint venture has a payable due to Elan of approximately $1.8 million of this liability, an amount that is currently in dispute.

The Company believes it has sufficient financial resources to fund its operations for at least the next twelve to fifteen months. In the event that the Company is unable to raise additional capital or obtain funds through licensing arrangements of its products and technology, it has a contingency plan to concentrate on core programs and products, and reduce overall spending. In the longer term, the Company's activities may require the expenditure of additional funds. We may seek to obtain such funds from public or private sales of our securities or other sources. See "Risk Factors *If additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts, and reduce the number of employees we currently have.*"

Critical Accounting Policies

DOR BioPharma's discussion and analysis of its financial condition and results of operations are based upon DOR BioPharma's 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 DOR BioPharma 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, DOR BioPharma evaluates these estimates. DOR BioPharma bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The results of these estimates for making judgments about the carrying value of assets and liabilities are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

DOR BioPharma's critical accounting policies are as follows:

Accounting for the Merger

Treatment of Preferred Series C Stock

Accounting for the Merger

An independent valuation of the acquired company's technology and assets was made for the purposes of determining the value of the intangible assets including in-process research and development. Based on this assessment, the Company recorded a non-recurring expense in 2001 of $10,181,000 which is reflected on the statement of operations. Additionally, the Company recorded identifiable intangibles of $364,151 which are being amortized over a three year period.

Treatment of Preferred Series C Stock

As of December 31, 2001 the Company has recorded $10,348,733 between the debt and stockholders equity section of its balance sheet, relating to 104,435 shares of Series C Preferred Stock held by Elan Corporation plc. Pursuant to the Subscription and Stockholders Agreement ("SSA") of October 21, 1998 between Elan and Endorex Corporation, Elan has the option, at its discretion to either convert such preferred into shares of Endorex common stock at a fixed pre-determined rate, or exchange into an additional 30.1% ownership of Endorex Newco, Ltd. It is this exchange element, at Elan's discretion, that requires the Series C Preferred Stock be excluded from the stockholders equity section of the balance sheet, producing a negative stockholders' equity position for the company.

On October 21, 2002, pursuant to the terms of the SSA, the Series C Preferred Stock automatically converts into DOR BioPharma common stock, which would cause a reclassification of the obligation into the Stockholders Equity section. As a result, the Company's Stockholders Equity would increase by a minimum of $10,348,733.

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.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2002 annual meeting of stockholders, to be filed with the Securities and Exchange Commission (the "Commission") within 120 days after December 31, 2001.

Item 10. Executive Compensation.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2002 annual meeting of stockholders, to be filed with the Commission within 120 days after December 31, 2001.

Item 11. Security Ownership of Certain Beneficial Owners and Management.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2002 annual meeting of stockholders, to be filed with the Commission within 120 days after December 31, 2001.

Item 12. Certain Relationships and Related Transactions.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2002 annual meeting of stockholders, to be filed with the Commission within 120 days after December 31, 2001.

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:

(i) Independent Accountants' Report.

(ii) Balance Sheets as of December 31, 2001 and December 31, 2000.

(iii) Statements of Operations for the periods ended December 31, 2001 and 2000 and cumulative from February 15, 1985 (date of inception) to December 31, 2001.

(iv) Statements of Cash Flows for the periods ended December 31, 2001 and 2000 and cumulative from February 15, 1985 (date of inception) to December 31, 2001.

(v) Statements of Stockholders' Equity (Deficit) for the period from February 15, 1985 (date of inception) to December 31, 2001.

(vi) Notes to Financial Statements.

(2) Exhibits

2.1	Agreement and Plan of Merger and Reorganization dated as of July 31, 2001 by and among the Company, Roadrunner Acquisition, Inc. ("Roadrunner") and Corporate Technology Development, Inc. ("CTD")(1)
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 issued to CTD warrant holders.(12)
10.1	Patent License Agreement dated December 16, 1996 between the Company and Massachusetts Institute of Technology.(7)
10.2	Purchase Agreement among Dominion Resources, Inc., The Aries Fund, a Cayman Island Trust, The Aries Domestic Fund, L.P., and Endorex 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	Termination and Release Agreement, dated March 7, 2002, by and between Schein Pharmaceutical (Bermuda) Ltd., and Endorex Newco.
10.5 *	Amended and Restated 1995 Omnibus Incentive Plan, as approved by shareholders of the Company on November 29, 2001.
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.
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.
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 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.
10.29	Consulting Agreement entered into by and among the Company, CTD and Nicholas Stergiopoulos dated as of November 29, 2001.
10.30*	Noncompetition and Nonsolicitation Agreement entered into by and among the Company, CTD and Steve H. Kanzer dated as of November 29, 2001.
10.31	Master Loan and Security Agreement, dated as of December 23, 1998, between FINOVA Technology Finance, Inc. and the Company.(12)
10.32	Second amendment dated as of October 31, 2001, to the Patent License Agreement dated December 16, 1996 between the Company and Massachusetts Institute of Technology.(14)

21.1	Subsidiaries of DOR BioPharma, Inc.
23.1	Consent of Ernst & Young LLP.
23.2	Consent of PricewaterhouseCoopers LLP.
24.1	Powers of Attorney

* 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, 2001.

(2) Incorporated by reference to our Quarterly Report on Form 10-QSB, for the fiscal quarter ended June 30, 2000.

(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 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.

(14) 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, 2001.

(b) Reports on Form 8-K

On December 14, 2001, we filed a current report on Form 8-K dated November 29, 2001 (pursuant to Items 2 and 7 of Form 8-K), relating to the completion of our acquisition of all of the outstanding capital stock CTD pursuant to an Agreement and Plan of Merger and Reorganization dated as of July 31, 2001, as amended on November 29, 2001, by and among the Company, CTD and Roadrunner Acquisition, Inc., a wholly-owned subsidiary of the Company. This current report incorporated the required financial statements of CTD and pro forma financial information from the Joint Proxy Statement/Prospectus that forms a part of the Company's Registration Statement on Form S-4, as filed with the Securities and Exchange Commission and declared effective on October 23, 2001.

(A Development Stage Enterprise)

CONSOLIDATED BALANCE SHEETS

	December 31, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,942,053	$ 10,831,266
Marketable securities available for sale		2,014,984
Receivable from related party	44,447	126,538
Prepaid expenses	49,941	58,803
Total current assets	10,036,441	13,031,591
Leasehold improvements and equipment, net of accumulated amortization of $975,860 and $800,066.	365,219	384,162
Patent issuance costs, net of accumulated amortization of $15,091 and $10,970	284,419	253,705
Intangible assets, net of accumulated amortization of $8,611	355,540	
Total assets	$ 11,041,619	$ 13,669,458
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$ 856,187	$ 642,440
Accrued compensation	205,969	147,205
Due to joint ventures	2,042,833	2,010,713
Current portion of capital lease obligations	164,748	118,793
Total current liabilities	3,269,737	2,919,151
Long-term portion of capital lease obligations	52,098	204,162
Total liabilities	3,321,835	3,123,313
Series C exchangeable convertible preferred stock, $.05 par value. Authorized 200,000 shares; 104,435 and 97,603 issued and outstanding, at liquidation value	10,348,733	9,665,512
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; 108,443 and 100,410 issued and outstanding, at liquidation value	10,844,280	10,041,000
Common stock, $.001 par value. Authorized 50,000,000 shares; 20,944,384 and 12,860,500 issued, 20,825,742 and 12,741,858 outstanding	20,945	12,861
Additional paid-in capital	48,983,361	40,365,410
Common Stock held in escrow, 1,350,000 shares	1,687,500	
Deferred compensation		(4,853)
Deficit accumulated during the development stage.	(63,721,285)	(49,090,110)
Accumulated other comprehensive income		75
	(2,185,199)	1,324,383
Less: Cost of 118,642 shares of common stock in treasury	(443,750)	(443,750)
Total Stockholders' Equity (Deficit)	(2,628,949)	880,633
Total liabilities and stockholders' equity (deficit)	$ 11,041,619	$ 13,669,458

	December 31, 2001	December 31, 2000

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

DOR BIOPHARMA, INC. (FORMERLY ENDOREX CORPORATION)

(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2001	Year Ended December 31, 2000	Cumulative Period February 15, 1985 (Inception) to December 31, 2001
SBIR contract revenue	$	$	$ 100,000
Expenses:			
SBIR contract research and development			86,168
Proprietary research and development	2,470,801	956,742	17,303,806
General and administrative	1,973,455	2,101,767	15,045,499
Write-off of acquired in-process research and development	10,181,000		10,181,000
Total expenses	14,625,256	3,058,509	42,616,473
Loss from operations	(14,625,256)	(3,058,509)	(42,516,473)
Equity in losses from joint ventures	(401,699)	(2,682,368)	(23,047,950)
Other income	7,588	250,000	262,890
Interest income	424,032	747,073	3,465,620
Interest expense	(35,840)	(51,889)	(349,150)
Net loss	(14,631,175)	(4,795,693)	(62,185,063)
Preferred stock dividends	(1,486,501)	(1,382,200)	(4,867,301)
Net loss applicable to common stockholders	$ (16,117,676)	$ (6,177,893)	$ (67,052,364)
Basic and diluted net loss per share applicable to common stockholders	$ (1.20)	$ (0.51)	
Basic and diluted weighted average common shares outstanding	13,450,579	12,194,260	

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

DOR BIOPHARMA, INC. (FORMERLY ENDOREX CORPORATION)

(A Development Stage Enterprise)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Common Stock Held in Escrow		Preferred Stock								
	Shares	Par Value	Shares	Par Value	Shares	Par Value	Additional Paid-In Capital	(Deficit) Accumulated During the Development Stage	Other Comprehensive Income	Treasury Stock Shares	Treasury Stock Cost	Unearned Compensation	Note Receivable	Total Stockholders' Equity (Deficit)
Common stock issued for cash in February 1985 at $1.50 per share	667	$ 1		$		$	$ 999	$	$		$	$	$	$ 1,000
Net earnings for the period from February 15, 1985 to January 31, 1986								6,512						6,512
Balance at January 31, 1986	667	1					999	6,512						7,512
Common Stock issued for cash in October 1986 at $750 per share	666	1					499,999							500,000
Excess of fair market value over option price of nonqualified stock option granted							13,230							13,230
Net loss for the year								(34,851)						(34,851)
Balance at January 31, 1987	1,333	2					514,228	(28,339)						485,891
Common stock issued in May 1987 at $750 per share for legal services performed for the company	7						5,000							5,000
Net Proceeds from initial public stock offering in June 1987 at $6,000 per share, less issuance costs	333						1,627,833							1,627,833
Nonqualified stock options exercised	48						33,808					(28,188)		5,620
Amortization of unearned compensation												7,425		7,425
Excess of fair market value over option price of nonqualified stock options granted							75,063							75,063
								(627,652)						(627,652)

			Common Stock Held in Escrow				(Deficit) Accumulated During the Development Stage					
Net loss for the year												
Balance at January 31, 1988	1,721	2				2,255,932	(655,991)			(20,763)		1,579,180

DOR BIOPHARMA, INC. (FORMERLY ENDOREX CORPORATION)

(A Development Stage Enterprise)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

	Common Stock		Common Stock Held in Escrow		Preferred Stock			(Deficit) Accumulated During the Development		Treasury Stock				
	Shares	Par Value	Shares	Par Value	Shares	Par Value	Additional Paid-In Capital	Stage	Other Comprehensive Income	Shares	Cost	Unearned Compensation	Note Receivable	Total Stockholders' Equity (Deficit)
Nonqualified stock options exercised	18	$		$		$	$ 256	$	$		$	$	$	$ 256
Stock warrants exercised	1						12,000							12,000
Common stock redeemed and retired	(10)						(150)							(150)
Excess of fair market value over option price of nonqualified stock options granted							36,524							36,524
Amortization of unearned compensation												19,113		19,113
Net loss for the year								(1,092,266)						(1,092,266)
Balance at January 31, 1989	1,730	2					2,304,562	(1,748,257)				(1,650)		554,657
Nonqualified stock options exercised	71						1,060							1,060
Common stock redeemed and retired	(12)						(175)							(175)
Excess of fair market value over option price of nonqualified stock options granted							113,037							113,037
Net proceeds from secondary public stock	2,174	2					980,178							980,180

			Common Stock Held in Escrow				(Deficit) Accumulated During the Development Stage						
offering in April 1989 at $525 per share, less issuance cost													
Amortization of unearned compensation												1,650	1,650
Net loss for the year							(1,129,477)						(1,129,477)
Balance at January 31, 1990	3,963	4				3,398,662	(2,877,734)						520,932
Common stock issued for cash in October 1990 through January 1991 at $9.00 per share	5,694	6				51,244							51,250
Excess of fair market value over option price of nonqualified stock options granted						30,635							30,635
Net loss for the year							(854,202)						(854,202)
Balance at January 31, 1991	9,657	10				3,480,541	(3,731,936)						(251,385)

DOR BIOPHARMA, INC. (FORMERLY ENDOREX CORPORATION)

(A Development Stage Enterprise)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

	Common Stock		Common Stock Held in Escrow		Preferred Stock			(Deficit) Accumulated During the Development Stage		Treasury Stock					
	Shares	Par Value	Shares	Par Value	Shares	Par Value	Additional Paid-In Capital		Other Comprehensive Income	Shares	Cost	Unearned Compensation	Note Receivable		Total Stockholders' Equity (Deficit)
Common stock issued for cash in February 1991 through April 1991 at $9.00 per share	2,772	$ 3		$		$	$ 24,947	$	$		$	$	$		$ 24,950
Common stock issued for cash and services in November 1991 at $1.50 per share	15,333	15					22,985								23,000
Common stock issued for cash and note in	296,949	297					200,018						(50,315)		150,000

			Common Stock Held in Escrow			(Deficit) Accumulated During the Development Stage					
December 1991 at $0.75 per share											
Excess of fair market value over option price of nonqualified stock options granted					16,570						16,570
Nonqualified stock options exercised	1				1						1
Net loss for the year						(410,149)					(410,149)
Balance at January 31, 1992	324,712	325			3,745,062	(4,142,085)				(50,315)	(447,013)
Payment on note receivable										11,300	11,300
Net proceeds from secondary public stock offering in August 1992 at $112.50 per share, less issuance costs	66,666	66			6,230,985						6,231,051
Nonqualified stock options exercised	2,000	2			28						30
Net loss for the year						(564,173)					(564,173)
Balance at January 31, 1993	393,378	393			9,976,075	(4,706,258)				(39,015)	5,231,195
Excess of fair market value over option price of nonqualified stock options granted					126,000				(126,000)		
Amortization of unearned compensation									40,750		40,750
Nonqualified stock options exercised	67				57						57
Collection of note receivable										39,015	39,015
Net loss for the year						(1,012,882)					(1,012,882)
Balance at January 31, 1994	393,445	393			10,102,132	(5,719,140)			(85,250)		4,298,135

(A Development Stage Enterprise)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

	Common Stock		Common Stock Held in Escrow		Preferred Stock					Treasury Stock				
	Shares	Par Value	Shares	Par Value	Shares	Par Value	Additional Paid-In Capital	(Deficit) Accumulated During the Development Stage	Other Comprehensive Income	Shares	Cost	Unearned Compensation	Note Receivable	Total Stockholders' Equity (Deficit)
Acquisition of treasury stock		$		$		$	$	$	$	41,975	$ (300,000)	$	$	$ (300,000)
Forfeiture of nonqualified stock options granted							(22,402)					22,402		
Amortization of unearned compensation												49,348		49,348
Net loss for the year								(1,349,678)						(1,349,678)
Balance at January 31, 1995	393,445	393					10,079,730	(7,068,818)		41,975	(300,000)	(13,500)		2,697,805
Acquisition of treasury stock										76,667	(143,750)			(143,750)
Forfeiture of nonqualified stock options granted							(1,379)					1,379		
Amortization of unearned compensation												12,121		12,121
Net loss for the year								(1,187,985)						(1,187,985)
Balance at January 31, 1996	393,445	393					10,078,351	(8,256,803)		118,642	(443,750)			1,378,191
Common stock issued at $0.975 per share	333,333	333					324,667							325,000
Common stock issued at $3.00 per share	333,333	333					999,667							1,000,000
Nonqualified stock options exercised	145,283	146					379,003							379,149
Net loss for the period								(1,962,877)						(1,962,877)
Balance at December 31, 1996	1,205,394	1,205					11,781,688	(10,219,680)		118,642	(443,750)			1,119,463
Warrants exercised at $1.20 per share	1,173	1					1,407							1,408
Proceeds on exercise of stock options							5,000							5,000
Warrants issued							5,407,546							5,407,546
Net proceeds from private	8,648,718	8,650					15,122,943							15,131,593

			Common Stock Held in Escrow			(Deficit) Accumulated During the Development Stage					
placement at $2.3125 per share, less issuance cost											
Net loss for the year						(3,244,326)					(3,244,326)
Balance at December 31, 1997	9,855,285	9,856			32,318,584	(13,464,006)		118,642	(443,750)		18,420,684

DOR BIOPHARMA, INC. (FORMERLY ENDOREX CORPORATION)

(A Development Stage Enterprise)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

	Common Stock		Common Stock Held in Escrow		Preferred Stock			(Deficit) Accumulated During the Development Stage		Treasury Stock				
	Shares	Par Value	Shares	Par Value	Shares	Par Value	Additional Paid-In Capital		Other Comprehensive Income	Shares	Cost	Unearned Compensation	Note Receivable	Total Stockholders' Equity (Deficit)
Net proceeds from issuance of common stock and warrants	307,692	$ 308	$	$			$ 1,871,537	$	$	$	$	$	$	$ 1,871,845
Proceeds from exercise of stock options	25,000	25					61,725							61,750
Purchase and retirement of common stock	(133,335)	(134)					(129,866)							(130,000)
Net proceeds from issuance of Series B preferred stock at $100 per share					80,100	8,010,000								8,010,000
Accrued preferred stock dividends					5,986	598,666	(713,187)							(114,521)
Net loss for the year								(21,793,170)						(21,793,170)
Balance at December 31, 1998	10,054,642	10,055			86,086	8,608,666	33,408,793	(35,257,176)		118,642	(443,750)			6,326,588
Proceeds from exercise of stock options	334	4					347							351
Common stock dividends issued	819,319	819					1,535,403	(1,536,222)						
Accrued preferred stock dividends					6,887	688,634	(1,285,412)							(596,778)
								(7,501,019)						(7,501,019)

			Common Stock Held in Escrow				(Deficit) Accumulated During the Development Stage				
Net loss for the year											
Balance at December 31, 1999	10,874,295	10,878		92,973	9,297,300	33,659,131	(44,294,417)		118,642	(443,750)	(1,770,858)
Net proceeds from private placement at $4.725 per share, less issuance costs	1,809,520	1,810				7,772,738					7,774,548
Issuance of options issued in exchange for financial advisory services						87,373				(87,373)	
Issuance of options issued in exchange for consulting services						12,787				(12,787)	
Amortization of unearned compensation										95,307	95,307
Proceeds from exercise of stock options	71,722	69				215,685					215,754
Noncash exercise of warrants	104,963	104				(104)					
Accrued preferred stock dividends				7,437	743,700	(1,382,200)					(638,500)
Unrealized gain on marketable securities								75			75
Net loss for the year							(4,795,693)				(4,795,693)
Comprehensive loss											(4,795,618)
Balance at December 31, 2000	12,860,500	12,861		100,410	10,041,000	40,365,410	(49,090,110)	75	118,642	(443,750)	(4,853)	880,633

DOR BIOPHARMA, INC. (FORMERLY ENDOREX CORPORATION)

(A Development Stage Enterprise)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

Common Stock		Common Stock Held in Escrow		Preferred Stock		Additional Paid-In Capital	(Deficit) Accumulated During the Development Stage	Other Comprehensive Income	Treasury Stock		Unearned Compensation	Note Receivable	To Stockh Equ (Def
Shares	Par Value	Shares	Par Value	Shares	Par Value				Shares	Cost			

			Common Stock Held in Escrow				(Deficit) Accumulated During the Development Stage						
Issuance of common stock for the acquisition of CTD	8,083,884	8,084	1,350,000	1,687,500		10,100,771							11,7
Additional costs related to 2000 private placement						(21,871	)						(
Issuance of options issued in exchange for advisory services and consulting fees						25,552					(25,552)		
Amortization of unearned compensation											30,405		
Accrued preferred stock dividends					8,033	803,280	(1,486,501)						(6
Net loss for the year							(14,631,175)						(14,6
Unrealized loss on marketable securities									(75)				
Comprehensive loss													(14,6
Balance at December 31, 2001	20,944,384	$ 20,945	1,350,000	$ 1,687,500	108,443	$ 10,844,280	$ 48,983,361	$ (63,721,285)	$	118,642	$ (443,750)	$	$ (2,6

DOR BIOPHARMA, INC. (FORMERLY ENDOREX CORPORATION)

(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2001	Year Ended December 31, 2000	Cumulative Period February 15, 1985 (Inception) to December 31, 2001
Operating Activities:			
Net Loss	$ (14,631,175)	$ (4,795,693)	$ (62,185,063)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	188,526	156,856	1,563,106
Gain on sale of marketable securities			(110,244)
Noncash stock compensation	30,405	95,307	786,178
Equity in losses of joint ventures	401,699	2,682,368	23,047,950
Amortization of fair value of warrants			3,307,546
Gain on sale of assets			(4,530)

	Year Ended December 31, 2001	Year Ended December 31, 2000	Cumulative Period February 15, 1985 (Inception) to December 31, 2001
Write off patent issuance cost			439,725
Write-off of acquired research and development	10,181,000		10,181,000
Changes in operating assets and liabilities:			
Receivable from related party	82,091	(92,199)	(44,447)
Prepaid expenses	12,884	9,404	(45,919)
Accounts payable and accrued expenses	68,821	145,551	801,231
Accrued compensation	58,764	(37,303)	205,969
Due to joint ventures	(369,579)	(1,613,988)	(1,041,234)
Total adjustments	10,654,611	1,345,996	39,086,331
Net cash used in operating activities	(3,976,564)	(3,449,697)	(23,098,732)
Investing Activities:			
Cash received in acquisition of CTD, net	1,392,108		1,392,108
Patent issuance cost	(34,835)	(82,712)	(794,060)
Investment in joint ventures			(19,963,883)
Organizational costs incurred			(135)
Purchases of leasehold improvements and equipment	(139,656)	(40,564)	(1,787,109)
Proceeds from assets sold			4,790
Purchases of marketable securities		(5,390,981)	(11,004,080)
Proceeds from sale of marketable securities	2,014,909	6,923,919	11,114,324
Net cash provided by (used in) investing activities	3,232,526	1,409,662	(21,038,045)
Financing Activities:			
Net proceeds from issuance (costs incurred related to issuance) of common stock	(21,871)	7,774,548	37,777,399
Net proceeds from issuance of preferred stock			16,325,712
Proceeds from exercise of options		215,754	417,092
Proceeds from borrowings under line of credit			1,150,913
Repayment of amounts due under line of credit and capital lease obligations	(123,304)	(114,907)	(996,883)
Repayment of long-term receivable			50,315
Repayment of note payable issued in exchange for legal service			(71,968)
Purchase and retirement of common stock			(130,000)
Purchase of common stock for treasury			(443,750)
Net cash provided by (used in) financing activities	(145,175)	7,875,395	54,078,830
Net increase (decrease) in cash and cash equivalents	(889,213)	5,835,360	9,942,053
Cash and cash equivalents at beginning of period	10,831,266	4,995,906	
Cash and cash equivalents at end of year	$ 9,942,053	$ 10,831,266	$ 9,942,053
Supplemental disclosure of cash flow:			
Cash paid for interest	$ 35,840	$ 51,889	
Non-cash transactions			
Issuance of preferred stock dividends in kind	$ 1,486,501	$ 1,382,200	
Issuance of common stock, options and warrants in acquisition	12,214,207		
Capital lease acquisitions	17,195	45,621	

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

DOR BIOPHARMA, INC. (FORMERLY ENDOREX CORPORATION)

(A Development Stage Enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Nature of Operations

Basis of Presentation

DOR BioPharma, Inc. (DOR, or the Company) and Subsidiaries was incorporated in January 1987 as ImmunoTherapeutics, Inc., a wholly owned subsidiary of BiologicalTherapeutics, Inc. (BTI). BTI was incorporated on December 19, 1984 and commenced operations on February 15, 1985 (inception date). On March 30, 1987 BTI was merged into DOR. The Company's financial statements include the accounts of the predecessor, BTI, for all periods presented. In October 1996, DOR formed its first subsidiary, Orasomal Technologies, Inc. (Orasomal), and in July 1997, formed a second subsidiary, Wisconsin Genetics, Inc. (WGI). On November 29, 2001, the Company merged with Corporate Technology Development (CTD), and changed its name from Endorex to DOR BioPharma Inc., as discussed further in Note 5.

Nature of Business

DOR is a development stage, drug delivery company. The Company's core drug delivery technology focuses on oral/mucosal delivery of drugs and vaccines previously delivered only by injection. The Company's Orasome(TM) system utilizes technology licensed from MIT to develop the oral/mucosal delivery of vaccines, proteins and peptides.

In 1998 the Company formed two joint ventures with Elan Corporation, plc (Elan), one of the world's leading drug delivery companies. The purpose of the first joint venture, InnoVaccines Corporation (InnoVaccines), is to research, develop, and commercialize novel delivery systems for the human and veterinary vaccine markets. The second joint venture, Endorex Newco, LTD. (Newco), focuses on the utilization of the MEDIPAD® microinfusion pump, developed by Elan, to deliver iron chelators for the treatment of a series of genetic blood disorders known as iron overload disorders. During 2001, DOR and Elan have begun discussing the possible termination of both joint venture agreements.

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, 2001 of $63,721,285. The Company will continue to be a development stage company, as defined in Statement of Financial Accounting Standards No. 7, "Accounting and Reporting by Development Stage Enterprises", until it begins sales of its anticipated products.

3. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include DOR and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Segment and Geographic Information

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

Accounting for Investments in Non-Controlled Entities

The Company accounts for investments in common stock of non-controlled entities (i.e., InnoVaccines and Newco joint ventures) using the equity method. The Company discontinues application of the equity method when the carrying value of the investment is reduced to zero and does not provide for additional losses provided that the Company has not guaranteed the obligations of the investee and is not otherwise committed to provide further financial support for the investee. See Note 4 for a description of the Company's investment in joint ventures.

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.

Marketable Securities

Marketable securities were comprised of high-grade commercial paper and short-term government agency notes that had maturities ranging from three to twelve months from the purchase date. The fair value of marketable securities classified as available for sale approximated the carrying value of these assets at December 31, 2000 due to the short maturity of the instruments.

Research and Development Costs

Expenditures for research and development activities are charged to operations as incurred.

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.

Impairment of Long-Lived Assets

Equipment, leasehold improvements and 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 held in escrow). 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 taxes have been provided through December 31, 2001 because of the net operating losses incurred by the Company since its inception.

Stock Based Compensation

The Company accounts for stock-based compensation for awards to employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and has adopted the disclosure only alternative of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (FAS 123). Stock compensation expense for options granted to nonemployees has been determined in accordance with FAS 123 and 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 underlying value of the securities changes.

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, marketable securities, receivables from related party, current liabilities and capital lease obligations are considered to be representative of their respective fair values.

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

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.

Reclassifications

Certain reclassifications have been made to the 2000 financial statements to conform to the 2001 presentation.

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 DOR and Elan. At closing, the Company issued to Elan 307,692 shares of DOR common stock and a six-year warrant to purchase an additional 230,770 shares of DOR 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 DOR common stock at a price of $7.38 per share, subject to adjustment. The Series B preferred stock automatically converts to common stock at the conversion price upon the earlier of January 2003 or a public offering of InnoVaccines' common stock with gross proceeds of not less than $10 million. The Series B convertible preferred stock pays an 8% annual in-kind dividend, which was $803,280 and $743,700 in 2001 and 2000, respectively.

InnoVaccines is owned 80.1% by DOR and 19.9% by Elan. Although DOR is the majority shareholder, the joint development agreement of InnoVaccines gives management participation to both DOR and Elan equally. Therefore, because the minority shareholder, Elan, has substantive participating veto rights, DOR accounts 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 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. Elan may receive future milestone payments and royalties based on the joint venture's performance. As the technology did not yet represent a commercial product, the joint venture 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.

Orasomal sub-licensed to InnoVaccines oral vaccine rights to its proprietary Orasome polymerized liposome technology exclusively licensed from MIT. In consideration of the license, Orasomal may receive milestone payments and royalties.

InnoVaccines contracts with both DOR and Elan which perform 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 are 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, 2001 and 2000, DOR incurred research and development and general and administrative expenditures aggregating $.4 and $1.7 million, respectively, which were billed to InnoVaccines.

DOR has a payable due to InnoVaccines of approximately $1.8 million as of December 31, 2001, which consists of DOR's share of the joint venture's net losses to date in excess of DOR's initial investment less amounts billed by the Company to the joint venture. The InnoVaccines joint venture has a payable due to Elan of $1.8 million, representing the amount Elan has contributed to InnoVaccines in excess of its funding obligation.

DOR and Elan also incurred $246,000 and $677,000 of expenditures during the years ended December 31, 2001 and 2000, 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 and $126,538 at December 31, 2001 and 2000, respectively, on the accompanying consolidated balance sheets represents reimbursements not yet received from Elan. The Company's portion of the license costs have been included in equity in losses from joint ventures in the accompanying statements of operations. These amounts were not capitalized, because the technology does not yet represent a commercial product.

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 is exchangeable at Elan's option for an additional 30.1% ownership interest of Newco's common stock, or it may be converted into DOR's common stock at a price of $8.86 per share, which causes the classification of the Series C Preferred Stock to be outside of equity. If not exchanged, the Series C Preferred Stock automatically converts to common stock at the conversion price upon the earlier of October 21, 2002 or a public offering of Newco's common stock with gross proceeds of not less than $10 million. Conversion of the Series C Preferred Stock will cause total stockholders' equity to increase by the liquidation value of the Series C Preferred Stock. As of December 31, 2001 the liquidation value of the Series C Preferred Stock, was $10,348,733. The Series C Preferred Stock pays a 7% annual in-kind dividend, which was $683,221 and $638,500 in 2001 and 2000, respectively.

Newco is owned 80.1% by DOR and 19.9% by ELAN. Although DOR BioPharma Inc. is the majority shareholder, the joint development agreement of Newco gives management participation to both DOR and Elan equally. Therefore, because the minority shareholder, Elan, has substantive participating veto rights, DOR accounts 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 license fee expense. The Company recorded its $8.0 million share of the

license fee in accordance with the equity method. Elan may also receive future milestone payments and royalties based on Newco's performance.

In consideration of the license fee, Newco has obtained an exclusive worldwide license to the MEDIPAD drug delivery system developed by Elan with two drugs. Newco is focusing on development of the first of those drugs, Norditropin, an iron chelator for the treatment of a series of genetic blood disorders known as iron overload disorders. MEDIPAD is a lightweight, microinfusion pump, which combines the simplicity of a patch with the extensive delivery capabilities of an infusion pump.

The Newco joint venture entity contracts with both DOR and Elan, which perform research and development on behalf of the joint venture. During 2001 and 2000, Elan and DOR were required to fund Newco expenditures according to their respective ownership interests. DOR may choose to borrow from a multi-draw convertible note with Elan to fund its portion of Newco's research and development expenses. Through December 31, 2001, no amounts have been borrowed under this note.

During the years ended December 31, 2001 and 2000, DOR incurred research and development and general and administrative expenditures aggregating $45,000 and $42,000, respectively, related to the joint venture and billed to Newco. DOR has a payable due to Newco of $254,000 at December 31, 2001, which consists of DOR's share of the joint venture's net losses to date in excess of DOR's initial investment less amounts billed by the Company to the joint venture.

In 2000, Newco entered into an agreement with Schein Pharmaceutical (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. Schein Pharmaceuticals Ltd. is a subsidiary of Watson Pharmaceuticals, Inc.

Condensed Financial Statements for Joint Ventures

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

	December 31 2001	2000
InnoVaccines net loss	$ (586,828)	$ (3,466,101)
Newco net income (loss)	44,421	(168,945)
Total net loss	$ (542,407)	$ (3,635,046)
Reconciliation of joint venture net losses to equity in losses from joint ventures recorded by DOR:		
Total joint venture net losses	$ (542,407)	$ (3,635,046)
DOR mark-up (a)	155,872	617,925
Elan minority interest	107,939	723,374
InnoVaccines costs incurred by DOR, outside of joint venture	(123,103)	(388,621)
Equity in losses from joint venture DOR	$ (401,699)	$ (2,682,368)

(a) The Company invoices the joint venture at cost, plus mark-up that is agreed to by Elan, which is 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, shareholders 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 are held in escrow to cover any damages for breach of contract by CTD or other specific matters and will be issued incrementally through March 31, 2002. In addition, 566,121 options and warrants to purchase 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 of assets 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 in-process research and development (IPR&D) of $10,181,000. Contractual rights relate to a potential future milestone payment and was 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 one research and development project is highly uncertain.

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 $175,794 and $151,024 for the periods ended December 31, 2001 and 2000, respectively. Leasehold improvements and equipment consisted of the following at December 31:

	December 31 2001	2000
Leasehold improvements	$ 262,985	$ 255,888
Laboratory equipment	857,560	786,902
Office equipment	220,534	141,438
	1,341,079	1,184,228
Accumulated depreciation	(975,860)	(800,066)
	$ 365,219	$ 384,162

7. Stockholders' Equity (Deficit)

Private Placements

In April 2000, the Company sold an aggregate of 1,809,520 shares of common stock in a private placement. Gross proceeds were $8.6 million with net proceeds, after deducting commissions and expenses, of $7.8 million.

In connection with the 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 may be called if the closing bid price

of DOR's common stock equals or exceeds $13.125 per share for at least 20 consecutive trading days.

During 1997, the Company sold an aggregate of 8,648,718 shares of common stock to certain accredited investors. The gross proceeds of these issuances were $20 million with net proceeds, after deducting commissions and expenses, of $15.1 million.

In connection with the 1997 private placement, the Company issued warrants for the purchase of 864,865 shares of DOR common stock at a current exercise price of $1.8209 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 a current exercise price of $1.8209 per share to certain employees of the placement agent. The estimated fair value of the warrants at the grant date was $3.16 million, which was recorded as a deferred cost and amortized to expense over two years, the term of the agreement. The warrants are exercisable and expire on April 16, 2003. Through December 31, 2001, 148,161 warrants have been exercised.

Common Stock Dividend

The terms of the 1997 private placement also included 5% semi-annual dividends payable in additional shares of common stock based on the number of shares held as of the record date, including

previous dividend distributions. The first and second semi-annual common stock dividends were payable to holders of stock with dividend rights as of the record date of April 16, 1999 and October 16, 1999, respectively. The Company distributed the first and second dividends on June 1, 1999 and November 16, 1999, respectively. No dividends were paid during 2000; dividend rights were terminated effective March 20, 2000.

Warrants

In connection with a prior financing, the Company granted warrants to purchase an aggregate of 66,668 shares of common stock at a current exercise price equal to $1.6914 per share. The warrant exercise price and the number of shares that can be purchased are subject to adjustment in certain circumstances. The warrants are exercisable until May 19, 2002.

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 Board of Directors' Compensation Committee determines the terms of the options, including vesting periods. No one person participating in the Plan may receive options and separately exercisable stock appreciation rights for more than 750,000 shares of common stock per calendar year.

Had the Company accounted for its stock option plans based on the fair value at the grant date for options granted under the plan, based on provisions of SFAS 123, the Company's pro forma net loss and pro forma net loss per share would have increased by approximately $0.9 million, or $.07 per share, and $0.1 million, or $0.01 per share, for 2001 and 2000, respectively. Net loss and net loss per share would have increased as follows:

	December 31	
	2001	2000
Net loss applicable to common stockholders:		
As reported	$ (16,117,676)	$ (6,177,893)
Pro forma	(17,023,173)	(6,325,952)

	December 31	
Basic and diluted net loss per share applicable to common stockholders:		
As reported	$ (1.20)	$ (0.51)
Pro forma	(1.27)	(0.52)

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.83 and $0.75 for 2001 and 2000, 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 105% and 102% in 2001 and 2000, respectively and average risk-free interest rates in 2001 and 2000 of 4.5% and 5.5%, respectively.

The rollforward of shares available for grant through December 31, 2001 is as follows:

Shares available for grant at December 31, 2000	708,697
Increase in shares available based upon the annual Evergreen provision	127,419
Amendment to increase shares available in plan	2,165,664
Options granted	(1,629,500)
Options forfeited	88,000
Options assumed in CTD acquisition	(359,042)
Shares available for grant at December 31, 2001	1,101,238

Option activity for the periods ended December 31, 2001 and 2000 was as follows:

	Options	Weighted-Average Options Exercise Price
Balance at December 31, 1999	1,571,502	$ 2.82
Granted	168,500	3.78
Exercised	(71,722)	3.01
Forfeited	(157,155)	4.76
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

The weighted-average exercise price, by price range, for outstanding options as of December 31, 2001 is:

	Weighted-Average Remaining Contractual Life	Outstanding Options	Options Exercisable
Price Range $ .74 - $1.50	9.2	2,039,542	1,265,917
Price Range $1.88 - $2.54	6.0	1,200,125	1,181,719
Price Range $3.25 - $4.88	8.2	87,000	42,100
Price Range $5.50 - $6.75	6.0	85,000	85,000

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:

	December 31	
	2001	2000
Deferred tax assets:		
Net operating loss carryforwards	$ 14,220,000	$ 11,181,000
Research and development credit carryforwards	1,748,000	360,000
Work opportunity credit carryforwards	260,000	260,000
Orphan drug credit carryforwards	936,000	278,000
Licensing fees	3,906,000	3,721,000
Other	65,000	98,000
	21,136,000	15,898,000
Valuation allowance	(21,136,000)	(15,898,000)
Net deferred tax assets	$	$

At December 31, 2001, the Company had net operating loss carryforwards of approximately $36 million for U.S. Federal and state tax purposes, which expire beginning in 2007. In the event of a change 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. Lease Commitments

The Company leases executive offices and research facilities under operating leases, which provide for annual minimum rent and additional rent based on increases in operating costs and real estate taxes. Rental expense was $63,967 during 2001 and $59,318 during 2000.

The Company has three capitalized leases. The aggregate interest rates incurred to date range from 10.09% to 13.82%. The leases are payable in monthly installments over a period of 48 months, with a final payment in December 2004.

Future minimum lease payments under capital leases and non-cancelable operating leases with initial terms of one year or more consisted of the following at December 31, 2001:

	Capital Leases	Operating Leases
2002	$ 186,927	$ 57,300
2003	42,876	59,018
2004	17,660	
Total minimum lease payments	247,463	$ 116,318
Amounts representing interest	(30,617)	

	Capital Leases	Operating Leases
Present value of net minimum lease payments, including current portion	$ 216,846	

At December 31, 2001, the gross amount of equipment and leasehold improvements recorded under capital leases and related accumulated amortization was approximately $520,283 and $312,550, respectively.

11. License Agreements

As part of the acquisition of CTD, 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.

In February 2001, a subsidiary of CTD received a notice of termination of one of the license agreements from the licensor alleging nonpayment of a $200,000 penalty payment. The Company maintains that it is not required to make such payment.

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.

Report of Ernst & Young LLP, Independent Auditors

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

We have audited the accompanying balance sheet of DOR BioPharma, Inc. (the Company, a development stage enterprise) as of December 31, 2001 and 2000, and the related statements of operations, stockholders' equity (deficit), and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements for the period February 15, 1985 (inception) through December 31, 1999 were audited by other auditors whose report dated February 4, 2000 expressed an unqualified opinion on those statements. The financial statements for the period February 15, 1985 (inception) through December 31, 1999 include total revenues and net loss of $100,000 and $(42,758,195), respectively. Our opinion on the statements of operations, stockholders' equity, and cash flows for the period February 15, 1985 (inception) through December 31, 2001, insofar as it relates to amounts for the period from February 15, 1985 through December 31, 1999, is based solely on the report of other auditors.

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.

In our opinion, based on our audits, the financial statements referred to above present fairly, in all material respects, the financial position of the Company at December 31, 2001 and 2000 and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst and Young LLP

Milwaukee, Wisconsin
January 31, 2002

REPORT OF INDEPENDENT ACCOUNTANTS

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

In our opinion, the accompanying consolidated statements of operations, of stockholders' equity (deficit) and of cash flows for the period cumulative from inception (February 15, 1985) to December 31, 1999 present fairly, in all material respects, the results of operations and cash flows of DOR BioPharma, Inc. (formerly Endorex Corporation) and its subsidiaries (a development stage enterprise) for the period cumulative from inception (February 15, 1985) to December 31, 1999, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

Chicago, Illinois
February 4, 2000

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, on April 1, 2002.

DOR BIOPHARMA, INC.

By: /s/ COLIN BIER

Colin Bier
Chairman and Chief Executive Officer

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 April 1, 2002.

Signature	Title
/s/ COLIN BIER Colin Bier	Chairman, Chief Executive Officer (principal executive officer) and Director
/s/ STEVE J. KOULOGEORGE Steve J. Koulogeorge	Controller, Treasurer and Corporate Secretary (principal financial and accounting officer)
* Richard Dunning	Director
* Steve H. Kanzer	Director

Signature	Title
*	Director
Peter Kliem	
*	Director
Guy Rico	
*	President and Chief Operating Officer and Director
Michael S. Rosen	
*	Director
Paul D. Rubin	
*	Director
Steve Thornton	
*	Director
Kenneth Tempero	

*By: /s/ COLIN BIER

Colin Bier
Attorney-in-fact

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