

September 26, 2006

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DOR BioPharma, Inc.
www.dorbiopharma.com

DORB.OB \$0.26

Recommendation: Speculative Buy

Stock Data

52 Week Range	\$0.20-\$0.69
Daily Vol (50 day)	229,574
Market Capitalization	\$18mm
Shares Outstanding	68.5mm
Diluted Shares	111mm
Est Float	42mm

Financials

Sales (ttm)	\$3.07mm
Net Income (ttm)	\$(8.2)
Cash	\$1.9mm

Valuation

Price/Earnings	NM
Price/Book	12x
Price/Sales	5.8x

<u>FY Dec</u>	<u>Rev</u>	<u>EPS</u>
2004A	\$997K	(\$0.16)
2005A	\$3mm	(\$0.09)
2006E	\$2.1m	(\$0.10)

See last 2 pages of report for important disclaimers.

DOR BioPharma, Inc.

Biopharmaceuticals: Therapeutics and Vaccines

DOR BioPharma is a biopharmaceutical company addressing the life-threatening side effects of cancer and cancer treatments, serious gastrointestinal diseases and disorders, and biodefense vaccines. Its lead product orBec® is a potent, locally acting corticosteroid being developed for the treatment of gastrointestinal graft-versus-host disease (GI GVHD). GI GVHD is a common serious complication of bone marrow and stem cell transplantation for cancer. DOR's vaccine program is focused on two potent and weaponizable biological toxins, ricin and botulinum.

- **Recommendation:** We are initiating coverage of DOR BioPharma with a Speculative Buy recommendation.
- On September 22, 2006, DOR announced the filing of an NDA for orBec®. orBec® has been assigned an orphan drug designation in the U.S. and Europe and fast track status in the U.S.
- In response to the U.S. Government's funding program "Project Bioshield", DOR is developing vaccine products that combat the threat of two potentially lethal biological toxins: ricin toxin and botulinum toxin.
- On August 30, 2006, DOR announced that it had appointed Christopher J. Schaber, Ph.D., as its new President and Chief Executive Officer to replace Michael T. Sember.

Business Summary

DOR BioPharma is a biopharmaceutical company addressing life-threatening side effects of cancer and cancer treatments, serious gastrointestinal diseases and disorders, and the development of biodefense vaccines. The Company's lead product, orBec® (oral beclomethasone dipropionate or BDP), is a potent, locally-acting corticosteroid being developed for the treatment of gastrointestinal graft-versus-host disease (GI GVHD). GI GVHD is associated with significant morbidity and mortality. Bone marrow and stem cell transplant procedures are being increasingly utilized to treat leukemia and other cancer patients with the prospect of eliminating residual disease and reducing the likelihood of relapse. The incidence of GI GVHD increases as the number of transplants increase. orBec® represents a first-of-its kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GI GVHD -- the organ system where GI GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressives to treat GI GVHD. Specifically, orBec® allows for patients to be exposed to significantly reduced amounts of systemic steroids after a bone marrow transplant. High doses of systemic steroids such as prednisone can severely suppress the immune system, leading to an increased risk of fatal infection and relapse of leukemia. DOR has completed a 129 patient pivotal Phase III clinical trial for orBec® conducted at sixteen bone marrow / stem cell transplant centers in the U.S. and France. orBec® has been assigned "orphan drug" designation and "fast track" status by the FDA. There are currently no approved oral formulations of BDP in the U.S. and there are no therapies approved by the FDA for the treatment of GI GVHD. On September 22, 2006 DOR announced that it had submitted a New Drug Application ("NDA") for orBec®.

On the biodefense side, DOR is collaborating with two U.S. academic research institutions in the development of vaccine products to combat the threat posed by two potentially lethal biological toxins, ricin toxin and botulinum toxin. Both vaccines are recombinant products in bacterial hosts and both consist of nontoxic subunits of the native toxic agents. These subunits retain the ability to induce antibodies that completely neutralize the toxins from which they are derived. Through exclusive licenses with two universities, DOR has secured intellectual property rights related to these vaccines. Both botulinum toxin and ricin toxin are considered bioterrorism threats by the U.S. Department of Homeland Security (DHS), National Institute of Allergic and Infectious Diseases (NIAID), Department of Defense (DOD) and Centers for Disease Control and Prevention (CDC). DOR is developing its biodefense countermeasures for potential U.S. government procurement pursuant to the Project Bioshield Act of 2004, which provides incentives to industry to expeditiously supply biodefense countermeasures to the Strategic National Stockpile. DOR responded to an RFI (Request for Information) from the DOD for ricin vaccines in August '04. DOR initiated enrollment in a Phase I clinical trial for RiVax™, its vaccine against ricin toxin, in January '05. On January 30, 2006 DOR announced positive results of its Phase I safety and immunogenicity dose-escalation study, demonstrating that the vaccine is well tolerated and induces antibodies in humans that neutralize ricin toxin. On April 7, 2006, DOR announced the first successful evaluation in animal tests of a nasal, bivalent combination of its botulinum toxin vaccine, BT-VACC™. The antigens were made in collaboration with Dowpharma, utilizing their Pfenex Expression Technology.

Investment Thesis

DOR has just recently filed its NDA for the use of orBec® to treat GI GVHD. GI GVHD is a devastating, costly, often fatal disease and an unmet medical need. An effective treatment for GI GVHD is long overdue. While GI GVHD is not a huge market, FDA approval to market orBec® would almost certainly leave DOR with a substantially higher market capitalization than its current \$18 million level. It's easy to dismiss the likelihood of orBec® receiving regulatory approval given the fact that the primary endpoint for its Phase III trial was missed. Our view is that the missed endpoint in its pivotal Phase III clinical trial has created a potentially very interesting investment opportunity. Although orBec® did not achieve statistical significance it demonstrated positive trends in its primary endpoint of time to treatment failure through day 50 (p-value 0.1177). orBec® did achieve statistical significance in a secondary endpoint of time to treatment failure through Day 80 (p-value 0.0226). Other secondary endpoints included: cumulative treatment failure rate at study day 50, which was 30 in the placebo group compared to only 18 in the orBec® group (p-value 0.0515); and the risk of treatment failure at study day 50 which was reduced by 37% for patients in the orBec® group relative to the placebo group. Additionally, the cumulative treatment failure rate at study day 80 (also prospectively defined) was 39 in the placebo group versus 22 in the orBec® group and was statistically significant (p-value 0.0048). Most importantly, orBec demonstrated a 67% reduction in mortality at 200 days post-transplant, registering only 5 deaths or 8%, versus 16 deaths or 24% for the placebo group (p-value 0.0139).

We believe that the survival data and the safety profile of orBec®, combined with the fact that there is an enormous unmet medical need in the treatment of GI GVHD, has positioned orBec® with a reasonable chance of receiving FDA approval.

In a November 2005 pre-NDA meeting with the FDA's oncology drug products division, the FDA indicated that given the missed primary endpoint, it would place a very high emphasis on the survival data. As such, the FDA suggested that any further survival data that DOR could provide would be extremely helpful and supportive of an NDA filing. DOR subsequently performed a new survival analysis of patients enrolled in the earlier Phase II trial. The results were very similar to the positive Phase III results. (See pages 8-10 for full discussion of the trial data.) DOR statisticians estimate there is a 3 in 10,000 chance of observing odds ratios of similar magnitudes in both Phase II and Phase III studies if there was no effect of orBec® on day-200 survival. Not insignificantly, the review of orBec was shifted from the gastroenterology division of the FDA to the oncology division during the second half of 2005. While the shift is a little late in the game, and will cause the oncology division to come up to speed fairly quickly – we believe it should have been there to begin with. Oncologists often see GI GVHD in conjunction with the treatment of cancer while employing stem cell or bone marrow transplants. Oncologists are intimately familiar with the perils it poses to their cancer patients. Further, in the past 30 years there has not been a drug approved for any form of GVHD that has demonstrated a mortality benefit.

We believe that the survival data and the safety profile of orBec®, combined with the fact that there is an enormous unmet need in the treatment of GI GVHD, has positioned orBec®

with a reasonable chance of receiving FDA approval to market. There are never any certainties in the FDA approval process, but DOR is not in uncharted territory while endeavoring to gain approval despite missing the primary endpoint. For example, ALIMTA® (marketed by Eli Lilly), for the treatment of metastatic non-small cell lung cancer after prior chemotherapy, received FDA approval despite missing its primary endpoint. Similarly, Remodulin®, (marketed by United Therapeutics), for the treatment pulmonary artery hypertension, received FDA approval despite missing its primary endpoint.

We view the biodefense piece of DOR's business model as something of a wild card; albeit a wild card that could potentially be as valuable or more so than orBec®. DOR is the clear worldwide leader in the development of a vaccine for ricin toxin. The successful RiVax™ pilot Phase I trial marked the first time a ricin toxin vaccine has ever been clinically tested in humans. DOR's BT-VACC™ vaccine for botulinum has been designed to be administered mucosally – offering significant advantages to the end-user in terms of ease of distribution, increased safety, lack of pain from injections, and the ability to induce protective antibodies in the lung and the intestines. Both of these vaccines are being developed with a focus on the BioShield Act of 2004, a \$5.6 billion, 10-year appropriation bill. Several significant contracts have already been awarded under the act. While it is difficult to determine the likelihood of DOR ultimately receiving significant funding under the act – it is clear that the further both vaccines are developed, the more likely funding becomes.

BIOTHERAPEUTICS							
	Research	Pre-Clinical	Phase 1	Phase 2	Phase 3	NDA	FDA Approval/Market
orBec® (Oral beclomethasone Dipropionate)							

Tablet formulation of a topically active corticosteroid that has completed a pivotal Phase III clinical trial for the treatment of gastrointestinal Graft-versus-Host Disease (GI GVHD) and currently has an NDA under review with the FDA

LPM™ Leuprolide							
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Oral formulation of the peptide drug Leuprolide for the treatment of endometriosis and prostate cancer.

BIODEFENSE > Regulatory and Development Pathway							
	Proof of Concept	Animal Efficacy	IND Filing	Phase I	Phase II/III	BLA Filing	BLA Approval
RiVax™ (Ricin Toxin Vaccine)							

Bioengineered vaccine intended to protect against exposure to the deadly ricin toxin.

BT-VACC™ (Botulinum Toxin Vaccine)							
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Bioengineered vaccine intended to protect against exposure to botulinum toxin, the most poisonous natural substance known to man.

Botulinum Toxin Therapeutics							
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Rational drug design program designed to develop new therapeutic drug candidates to treat exposure to botulinum toxin.

Recent Events

On September 22, 2006 DOR announced that it had submitted a New Drug Application to the U.S. FDA to market orBec® for the treatment of GI GVHD.

On August 30, 2006, DOR announced that it had appointed Christopher J. Schaber, Ph.D., as its new President and Chief Executive Officer to replace Michael T. Sember. Dr. Schaber has over 17 years of pharmaceutical experience with a diverse background in development and commercialization. He previously served as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc. (DSCO: NASDAQ), where he was employed for the last 10 years. His responsibilities included overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, preclinical and clinical research, and medical affairs, as well as the coordination of commercial launch preparation activities.

In July, DOR announced that it had successfully completed its cGMP (current Good Manufacturing Practices) milestone for the production of RiVax™, DOR's vaccine against ricin toxin pursuant to a manufacturing collaboration with Cambrex BioSciences and supported by a \$6.4 million NIAID grant.

In April, DOR announced the first successful evaluation in animal tests of a nasal, bivalent combination of its botulinum toxin vaccine, BT-VACC™, addressing two of the most prevalent serotypes of botulinum toxin, types A and B.

Also in April, DOR announced that the European Commission and the centralized European Agency for the Evaluation of Medicinal Products (EMA) has granted DOR incentives for Small and Medium Sized Enterprises (SME). SME status may accord companies reduced or deferred fees associated with marketing authorization applications, scientific advice and inspections.

Also in April, DOR announced a private equity financing of \$3.65 million to institutional investors (13.2 million shares sold @ \$0.276 per share). Despite the recent financing, we believe it is highly likely that DOR will need to raise additional capital in 2006.

Also in April, DOR began trading on the OTC bulletin board under the symbol DORB.OB – it had previously traded on the AMEX as DOR.

Risk Factors

DOR is subject to all the typical risks that any early stage healthcare company faces. There is a real possibility that any investor could lose their entire investment in DOR. Specific risks would include but are certainly not limited to the following (see 10K for more detailed discussion):

- Drug Development Risk. There are always risks that a drug may fail in getting through clinical trials and / or may not gain regulatory approval from the FDA.
- Financial Risk. DOR had \$1.9 million in cash as of June 30, 2006. **We believe it highly likely that DOR will have to raise additional capital between now and year-end.** There is a chance that this capital may not be available on favorable terms, or may not be available at all.
- Small Size – Limited Personnel. DOR is a small company and the loss of 1 or 2 key employees could have a significant negative impact on the company.
- Fierce Competition. There are multiple companies, universities and government entities, including the U.S. Army, that are working on ricin and botulinum toxin vaccines.
- Political Risk. Government contracts are heavily influenced by political factors. The political environment can change rapidly. The biodefense vaccines are in the spotlight today, but may lose their significance over time.

EARNINGS MODEL

	12 Mos Dec-04 Actual	12 Mos Dec-05 Actual	3 Mos Mar-06 Actual	3 Mos Jun-06 Actual	3 Mos Sep-06 Est	3 Mos Dec-06 Est	12 Mos Dec-06 Est
Revenue	997	3,075	1,387	139	150	500	2,176
Cost of Goods	936	2,067	1,039	89	100	350	1,578
Gross Profit	61	1,008	348	50	50	150	598
Operating Exp							
SG&A	2,321	2,162	833	606	550	750	2,739
R&D	3,657	3,681	1,225	1,834	450	100	3,609
Other	-	-	-	982	-	-	982
Total Operating Exp	5,978	5,843	2,058	3,422	1,000	850	7,330
Operating Profit	(5,917)	(4,835)	(1,710)	(3,372)	(950)	(700)	(6,732)
Net Int, Other Inc	45	115	3	26	20	20	69
Pre-Tax Income	(5,872)	(4,720)	(1,707)	(3,346)	(930)	(680)	(6,663)
Pref Stock Dividends	503						
Taxes	-	-	-	-	-	-	-
Net Income	(6,375)	(4,720)	(1,707)	(3,346)	(930)	(680)	(6,663)
Earnings Per Share	(\$0.16)	(\$0.09)	(\$0.03)	(\$0.05)	(\$0.01)	(\$0.01)	(\$0.10)
Avg Weighted Shares	40,626,621	49,726,249	51,221,889	66,978,207	68,500,000	68,500,000	63,800,024

Overview of Graft-Versus-Host-Disease

Graft-versus-host disease often occurs in patients following an allogeneic bone marrow transplant in which tissues of the host, most frequently the gut, liver and skin, are attacked by lymphocytes in the donor (graft) marrow. These procedures are increasingly being utilized to treat leukemia and other cancer patients with the prospect of eliminating residual disease and reducing the likelihood of relapse. Patients with mild to moderate GI GVHD typically experience loss of appetite, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of GVHD persist and can progress to necrosis and exfoliation of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50 to 70% of the estimated 10,000 annual allogeneic transplant patients in the U.S. will develop some form of acute GI GVHD. Primary therapy for the treatment of GI GVHD typically involves high doses of systemic steroids such as prednisone. These systemic immunosuppressives substantially inhibit the highly desirable graft-versus-leukemia ("GVL") effect of bone marrow transplants, leading to high rates of aggressive forms of relapse, as well as substantial rates of mortality due to opportunistic infection. orBec® is a locally acting therapy tailored to treat the gastrointestinal manifestation of GI GVHD, the organ system where GI GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressives to treat gastrointestinal GI GVHD.

orBec®

orBec® is an orally administered corticosteroid that exerts a potent, local anti-inflammatory effect within the mucosal tissue of the gastrointestinal tract. The active ingredient in orBec®, beclomethasone 17, 21-dipropionate ("BDP"), is a mucosally active anti-inflammatory agent, with a potent local effect. BDP is the active ingredient in a variety of currently marketed products including Beconase Aqua (nasal spray for rhinitis), Becloforte (inhalant for asthma), and Propaderm (a topical cream for eczema and psoriasis). There currently is no FDA-approved oral BDP product in the United States. In addition to an issued patent (6,096,731) claiming use of BDP as a method for preventing tissue damage associated with GI GVHD, DOR's intellectual property includes applications covering the following: long-term treatment of GI GVHD and leukemia, treatment of inflammatory bowel diseases (IBD), and treatment of irritable bowel syndrome. The issued patent for prevention of tissue damage encompasses tissue in the intestinal mucosa and small bile ducts in the liver. orBec® is manufactured as a two-pill formulation (1 mg BDP per pill) administered four times daily (total of 8 mg) for the indication of acute GI GVHD. (By definition, GI GVHD is classified as acute if it occurs before day 100 post-transplant.) The two-pill combination is comprised of an immediate-release pill designed to primarily dissolve in the stomach and proximal intestine and an enterically-coated pill designed to dissolve in the more alkaline pH portion of the small intestine.

Pivotal Phase III Study

Previous Phase I and Phase II studies demonstrated that a two-pill combination of oral BDP was effective in treating GI GVHD, allowing patients to be rapidly tapered off the systemic corticosteroid prednisone, without the recurrence of intestinal symptoms and without clinical manifestation of adrenal suppression. Based upon this data, DOR designed a pivotal Phase III clinical protocol that was subject to a Special Protocol Assessment (SPA) by the FDA and was similar in design to the previously completed Phase II trial. The trial was a 129 patient, randomized, double-blind, placebo controlled safety, efficacy, and pharmacokinetic trial. orBec® did not achieve statistical significance but demonstrated positive trends in its primary endpoint of time to treatment failure through day 50 (p-value 0.1177). orBec® did achieve statistical significance in its secondary endpoint of time to treatment failure through Day 80 (p-value 0.0226). The cumulative treatment failure rate at study day 50 (prospectively defined) was 30 in the placebo group compared to only 18 in the orBec® group (p-value 0.0515) and the risk of treatment failure at study day 50 was reduced by 37% for patients in the orBec® group relative to the placebo group. Additionally, the cumulative treatment failure rate at study day 80 (also prospectively defined) was 39 in the placebo group versus 22 in the orBec® group and was statistically significant (p-value 0.0048). Most importantly, orBec® demonstrated a 67% reduction in mortality, registering only 5 (8%) deaths during the prospectively defined Day 200 post-transplant period versus 16 (26%) deaths for the placebo group (p-value 0.011). Based upon separate analysis conducted by the Company, there is also a statistically significant correlation between treatment failure and mortality.

The Company believes that the p-value of 0.1177 achieved in the primary endpoint through Day 50 is largely due to the higher than expected rate of treatment failures during days 0-10 of the study. During that period, patients were receiving high dose prednisone (1-2mg/kg/day) plus either orBec® (8mg/day) or placebo. For purposes of the study, patients that did not begin the rapid taper of high doses prednisone on Day 10 as called for by the regimen were deemed treatment failures for all purposes, including the calculation of statistical significance of time to treatment failure at Day 50 .

Current Status of orBec® NDA

The Phase III mortality data for orBec® looks quite strong. The question is whether orBec® can overcome the missed primary endpoint of time to treatment failure. Based on discussions with the FDA and as part of DOR's process to submit its NDA, the Company further analyzed mortality data from the Phase II and Phase III clinical trials. The new survival analysis of patients enrolled in the earlier Phase II trial suggests that the results were very similar to those from the pivotal Phase III multi-center study. In the Phase II trial, there were reductions in the risk of mortality of 55% and 43% at transplant day-200 and one-year post-randomization among patients randomized to oral BDP, respectively. The comparable survival data for Phase III were 66% and 51% reductions in the risk of mortality at transplant day-200 and one-year post-randomization among patients randomized to orBec®, respectively. In the Phase III trial, a subgroup analysis revealed that among

patients who had received stem cells from unrelated donors, the reduction in the risk of day-200 mortality among patients randomized to orBec® was 94%.

DOR statisticians estimate there is a 3 in 10,000 chance of observing odds ratios of similar magnitudes in both the Phase II and Phase III studies if there was no effect of orBec® on day-200 survival. We believe that the mortality data and the safety profile of orBec® combined with the fact that there is an enormous unmet need in the treatment of GI GVHD, has positioned orBec® with a reasonable chance of receiving FDA approval. There has been no drug approved for any form of GVHD in the past 30 years that has shown a mortality benefit. The expansion of stem cell and bone marrow transplants and the associated incidence of GI GVHD only heightens the need for an effective GI GVHD treatment.

DOR has recently filed an NDA for orBec® for the treatment of GI GVHD. The FDA has 60 days from the time of the filing to make sure that the submission is complete and give guidance as to its acceptance. The Fast Track designation is intended for the combination of a product and claim that addresses an unmet medical need, but is independent of Priority Review and Accelerated Approval. While not assured, DOR expects that orBec® will qualify for a six month priority review from the date of the NDA submission.

The European submission should follow shortly thereafter. On April 18, 2006 DOR announced that the European Commission and the centralized European Agency for the Evaluation of Medicinal Products (EMA) has granted DOR incentives for Small and Medium Sized Enterprises (SME). The SME program is a new initiative by the EMA that is dedicated to addressing the particular needs of small and medium sized companies developing medicinal products in Europe. Companies that are granted SME status are able to seek assistance, information and training from dedicated EMA personnel, particularly for Marketing Authorization Applications (MAA). In addition, SME status may accord companies reduced or deferred fees associated with the marketing authorization applications, scientific advisory and inspections.

The Market for orBec®

There are approximately 10,000 bone marrow and stem cell transplants in the U.S. each year. The market potential for orBec for the treatment of GI GVHD is estimated to be between 50 and 70 percent of these procedures. We have assumed \$10,000 per course of treatment for orBec® (actual pricing is obviously still to be determined). This equates to a potential dollar market of between \$50 million and \$70 million. To put this in context, transplant centers are usually reimbursed at a fixed rate of approximately \$250,000 for bone marrow and stem cell transplants. It is estimated that a single readmission to the hospital can cost the institution between \$14,000 and \$50,000. These patients have a high rate of readmission due to relapse of GI GVHD or leukemia. If these patients then become terminal and enter critical care, the costs mount very quickly. In two separate randomized, double-blinded, placebo-controlled trials, orBec has shown an approximately 67% reduction in mortality as well as a significant reduction in GI GVHD relapse rates in the pivotal trial.

Several companies are attempting to develop technologies to treat GVHD by suppressing the immune system. Companies such as Sangstat, Abgenix, and Protein Design Labs are developing monoclonal antibodies to treat GVHD. Novartis, Medimmune and Ariad are developing both gene therapy products and small molecules to treat GVHD. There are no products currently being marketed to selectively treat GI GVHD.

Other Products in BioTherapeutics Pipeline

Due to financial constraints, DOR has focused its R&D efforts on orBec, RiVax™ and BT-VACC™. When the Company is better capitalized, it may re-initiate development on any or all of the additional products it has in its pipeline.

Oral Leuprolide

Leuprolide is a potent analog agonist of the Luteinizing Hormone Releasing Hormone (LHRH), currently used to treat hormone responsive prostate cancer in men, endometriosis in women, and precocious puberty in children. The current injected LHRH analog formulations are depot formulations that are designed to be injected under the skin and release Leuprolide in a controlled fashion over 1 to 4 months (Lupron® marketed by TAP Pharmaceuticals and Zoladex® marketed by Astra Zeneca) and for periods up to 6 months (Eligard®, marketed in the U.S. by Sanofi). Leuprolide is used in treating prostate cancer to slow the growth of the cancer. In children with central precocious puberty, Leuprolide reduces the levels of estrogen and testosterone. Estrogens promote the growth of abnormal uterine tissue that exists outside the uterus and thus Leuprolide is used to reduce the production of estrogen and treat both fibroids and endometriosis.

DOR is developing the Lipid Polymer Micelle (LPM™) system for enhancing the intestinal absorption of water-soluble drugs/peptides that are not ordinarily absorbed or are degraded in the gastrointestinal tract. As the first example of a peptide drug that can be delivered orally, DOR is developing an oral formulation of the peptide drug Leuprolide, The LPM™

system is composed of safe and well characterized ingredients to enhance intestinal absorption.

Based on promising preclinical data and high bioavailability achieved in animals with oral administration of Leuprolide in the LPM™ system, DOR believes that LPM™-Leuprolide may have a competitive role in a segment of the current Leuprolide market and effectively compete with the depot formulations of Leuprolide. Specifically, DOR believes that LPM™-Leuprolide can be developed as a once-a-day oral formulation that can maintain blood levels of Leuprolide resulting in suppression of estrogen production in women suffering from endometriosis. We believe there is a need for a better formulation of a LHRH-like product, such as LPM™-Leuprolide that will increase compliance and efficacy, with fewer side effects.

In preclinical studies, DOR has demonstrated significant intestinal absorption enhancement of both LPM™-Leuprolide and Leuprolide in comparison to solution formulations of the peptides in rats and dogs. Based on this preclinical data, DOR plans further development of LPM™-Leuprolide when resources permit, which will lead to clinical studies for the treatment of endometriosis. Because of the wide applicability of Leuprolide in other medical conditions, such as in prostate cancer, it is possible that an oral formulation will prove to be useful for other indications. Obtaining marketing approval for further indications will require additional clinical testing in patients. In addition to LHRH and agonists, DOR plans to evaluate other classes of water-soluble drugs/peptides with the LPM™ system when resources permit.

Oraprine™

DOR plans to develop its product called Oraprine™ for a variety of indications and is initiating a strategy to introduce new formulations of the active drug compound initially by an Abbreviated New Drug Application (“ANDA”) regulatory route, and then for other novel medical indications. The active compound in Oraprine™ is azathioprine (AZA), which is a widely used immunosuppressant to inhibit rejection of the transplanted organ, primarily used in kidney transplant patients. AZA is also prescribed as a “second-line” treatment for severe, active rheumatoid arthritis in patients who are refractory to commonly prescribed arthritis medications. There is no formulation of this drug that can be preferentially taken by patients unable to ingest tablets or pills or a formulation that is preferred for juvenile rheumatoid arthritis patients. Therefore DOR plans to develop an oral liquid formulation to occupy this potential market niche.

Based on the outcomes of two Phase I clinical trials of Oraprine™, DOR is planning to reformulate AZA (Oraprine™) as a stable oral liquid suspension with the intent of demonstrating bioequivalence to the branded oral azathioprine tablets currently marketed in the United States (Imuran® and Azasan®). One Phase I bioequivalence trial was conducted with an early formulation and demonstrated bioequivalence to the marketed product. There has also been a small physician’s sponsored clinical study which demonstrated the potential utility of an oral liquid formulation to ameliorate oral lesions arising from graft versus host disease. DOR proposes to position Oraprine™ initially in the market as a specialty generic product to be used by transplant or rheumatoid arthritis

patients who cannot swallow medicines in tablet form. The Company anticipates that the market will include the pediatric transplant populations, the elderly, and cancer patients who have received stem cell transplants.

Project BioShield Overview

In 2001, the United States government began an initiative to stockpile countermeasures and vaccines for over 30 biological threats that could be used in bioterrorist attacks or on the battlefield. The Centers for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Diseases (NIAID) have recognized threats based on several factors: 1) public health impact based on illness and death; 2) ability for an agent to be disseminated, produced, and transmitted from person to person; 3) public perception and fear, and 4) special public health preparedness needs. This prioritization has resulted in classification of three threat categories: A, B, and C – where agents in the Category A have the greatest potential for adverse public health impact, and agents in Category B have potential for large scale risk dissemination, but generally cause less illness and death. Biological agents that are not believed to present a high public health risk but may emerge as future threats, as the scientific understanding of the agents develops, have been placed in Category C. Very few countermeasures or vaccines currently exist for Category A, B, or C agents. Biodefense products can be developed and sold to the U.S. government before the FDA has licensed them for commercial use. The FDA itself has facilitated the approval process, whereby portions of the human clinical development pathway can be truncated. Biodefense products are eligible for priority review in cases where the product is a significant advance for a serious or life threatening condition. Under a \$5.6 billion appropriation bill over 10 years, the BioShield Act 2004 authorizes the government to procure new countermeasures. The bill also allows the NIH to use simplified and accelerated peer-review and contracting procedures for research and development and empowers the FDA to approve distribution of unapproved medical products on an emergency basis.

There is significant competition in the area of biodefense from various companies, universities and governmental agencies, as well as the U.S. Army. The most noteworthy contract to date was awarded to VaxGen, Inc. for the development of an anthrax vaccine. VaxGen was awarded about \$100 million in research and development funds from the NIH. Subsequently it was awarded an \$878 million contract from the Department of Health and Human Services. Earlier this year VaxGen announced that it would not be able to deliver the first of 75 million doses until 2008, nearly 2 years behind the original schedule. Another notable player in this area is Dynport Vaccine Company, LLC. Dynport is a prime contractor to the U.S. Department of Defense. Dynport currently has a \$300 million contract to develop vaccines for the U.S. Military, including anthrax, and botulinum toxin vaccines.

Ricin Vaccine: First Time Ever Tested in Humans

DOR is the worldwide leader in the area of ricin toxin vaccine research and development. Ricin toxin is a heat stable toxin that is easily isolated and purified from the bean of the castor plant. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The Centers for Disease Control and Prevention have classified ricin as a Category B biological agent. Ricin works first by binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin.

In January 2003, DOR executed a worldwide exclusive option to license patent applications with the University of Texas Southwestern (UTSW) Medical Center for nasal, pulmonary and oral uses of non-toxin ricin vaccine. On September 13, 2004, DOR announced that it had been awarded a \$5.17 million "Challenge Grant" from the NIAID for RiVax™. This was increased to \$6.4 million in May 2005. The grants project period is until August 31, 2007 and covers the process development for manufacturing RiVax™.

In collaboration with UTSW, DOR manufactured the vaccine in small batches in their cGMP facility, developed a stable formulation, filed an IND and completed a pilot Phase I safety and immunogenicity trial. The trial was a dose escalation study. This marks the first time a ricin toxin vaccine has ever been clinically tested in humans. The trial enrolled 15 volunteers in groups of 5 who were vaccinated with three successive monthly injections of the same dose level of RiVax™. Three dose levels were evaluated. The vaccine was prepared without an adjuvant to determine whether the subunit itself was immunogenic and safe. Even without the adjuvant, RiVax™ induced antibodies in all five of the individuals who received the highest doses, four out of five who received the intermediate dose, and one out of five who received the lowest dose levels. The vaccine was well tolerated in all individuals with only mild side effects that are typical of reactions to vaccines injected intramuscularly. Despite the absence of an adjuvant, antibodies were present in the blood of several volunteers for as long as 127 days after their last vaccination. The functional activity of the antibodies was confirmed by transferring serum globulins from the vaccinated individuals along with the active ricin toxin to sensitive mice, which then survived subsequent exposure to ricin toxin. Based on these results, DOR is planning additional human clinical trials with an adjuvant formulation of RiVax™, which is now being evaluated in stability and toxicology studies.

In January 2005, DOR entered into an agreement with a subsidiary of Cambrex Corporation (NYSE: CBM), under which Cambrex will provide process development and cGMP (current Good Manufacturing Processes) production services for the development and manufacture of clinical quantities of RiVax™. This is being done under the auspices of the \$6.4 million NIAID challenge grant awarded to foster development and manufacturing. DOR and Cambrex have extensively characterized the different stages in the process and have performed the process under cGMP in anticipation of Phase II clinical trials with the vaccine. They have also developed a formulation of the vaccine using aluminum salts as

an adjuvant to prolong and enhance the protective immune response in humans. In conjunction with Phase II safety trials, the Company is planning to conduct pivotal efficacy trials with the RiVax™ vaccine to elaborate on the FDA “two animal” rule, which permits licensure of vaccines based on results of safety tests in humans and efficacy results in animals in situations where the evaluation in humans is ethically not permitted. The goal of these studies is to determine the level of antibodies in humans that is correlated to protection against exposure in animals. This must be done to determine the correct dose and dosing regimen for humans. In the case of ricin, it is not ethical to expose humans to ricin post vaccination, so “correlates of immunity” must be established in animal models. DOR’s goal is to make ricin available for the United States government’s Strategic National Stockpile.

Status of Botulinum Vaccine

Botulinum toxin is the product of the bacteria *Clostridium botulinum*. Botulinum toxin is the most poisonous natural substance known to mankind. It causes paralysis, typically within 12 to 72 hours after exposure. Death results from paralysis of the respiratory muscles. Current treatments include respiratory support and passive immunization with antibodies which must be administered before symptoms occur, which leaves little time post-exposure for effective treatment. Botulinum toxin is categorized as a Category A bioterror agent by the CDC. It can be aerosolized and is 100,000 times more toxic than sarin gas. There is currently no FDA-approved vaccine or therapeutic. The toxin is known to exist in seven different serotypes, designated A to G, but three (A, B, and E) account for almost all human cases of the disease.

DOR's botulinum toxin vaccine, called BT-VACC™, was developed through the research of Dr. Lance Simpson at Thomas Jefferson University. (DOR has an exclusive license agreement with Thomas Jefferson University for the oral and intranasal use of their botulinum toxin vaccine technology.) On April 7, 2006, DOR announced the first successful evaluation in animal tests of a nasal, bivalent combination of BT-VACC™, addressing two of the most prevalent serotypes of botulinum toxin, types A and B. DOR is designing BT-VACC™ to be administered by the mucosal route which offers significant advantages to the end-user in terms of increased safety, lack of pain from injections, and the ability to induce protective antibodies in the lung and the intestines. These types of antibodies are associated with inactivation of botulinum toxins before they enter the body. *These results are the first ever report of a combination of botulinum vaccine serotypes given by the mucosal route.*

In these experiments, the botulinum toxin vaccine serotypes A and B were mixed together and given to mice and rats by vaccinating the nasal passages through inhalation of the vaccine. The animals were given a small quantity of the bivalent combination vaccination containing each of the type A and type B antigens (10 micrograms) three times, two weeks apart. All of the animals developed equivalent immune responses to A and B serotypes in the serum. Importantly, they were then protected against exposure to each of the native toxin molecules given at 1000 fold the dose that causes lethality. The immune responses were also comparable to the same vaccines when given by intramuscular injection. Typically, vaccines given by mucosal routes are not immunogenic because they do not attach to immune inductive sites. In the case of the combination BT-VACC, both the A and B antigens were capable of attaching to cells in the mucosal epithelium and inducing an immune response with similar magnitude to the injected vaccine.

The next step is to add the botulinum toxin E serotype vaccine to the mucosal cocktail. DOR is moving the mucosal vaccine as rapidly as possible towards clinical studies. The hope is to compete successfully in supplying the government and the Department of Defense needs for mucosally administered botulinum vaccines that are effective, safe and easier to use than traditional injected vaccines.

DOR Biodefense Products

Select Agent	Currently Available Countermeasure	DOR Product
Ricin Toxin	No vaccine or antidote currently FDA approved	Injectable Ricin Vaccine Phase I Clinical trial successfully completed
Ricin Toxin	No vaccine or antidote currently FDA approved	Nasal Ricin Vaccine
Botulinum Toxin	No vaccine or antidote currently FDA approved	Oral/Nasal Botulinum Vaccine
Botulinum Toxin	No vaccine or antidote currently FDA approved	Oral Botulinum Therapeutic

Comparables

Company	Symbol	Recent Price	Market Cap Mill	TTM Rev Mill	Rev Mult	TTM Inc Mill	PE Mult
DOR BioPharma	DORB.OB	\$0.26	\$18	\$3	6.0	(\$8.2)	NM
Genex Biotechnology	GNBT	\$1.53	\$150	NM	NA	(\$61.5)	NM
Lorus Therapeutics	LRP	\$0.28	\$49	NM	NA	(\$16.0)	NM
Novadel Pharma	NVD	\$1.18	\$58	\$2	29.0	(\$9.5)	NM
VaxGen	VXGN.PK	\$3.73	\$93	\$14.3	6.5	(\$28.7)	NM

Valuation Discussion

There are no perfect comparables for DOR. There is no universal method to determine a fair valuation for early stage healthcare companies such as those in the above table. Theoretically you could generate projected cash flows for the next five years after estimating: market size, market penetration, average cost per treatment, gross margins, etc. -- and discount them back at some high rate. This would mainly be an academic exercise since there are so many unknowns and assumptions that would go into such a cash flow model. The most important driver of valuation for these stocks in the near-term is going to be an event such as FDA approval, a big pharma partner, or in the case of DOR and VaxGen – a significant procurement award pursuant to Project Bioshield.

We believe that the current valuation of DOR does not reflect a high likelihood that the Company successfully navigates the FDA process with orBec® or that one of its vaccines receives a significant award. We believe that either event would result in a valuation for DOR that is significantly higher than the current level. While we are hesitant to handicap the likelihood of an award on the vaccine front; our belief is that the data from the orBec® trial is sufficiently strong to make the case for FDA approval.

We recommend that non risk-averse investors consider purchasing DOR at its current levels.

Balance Sheet (000s)

ASSETS	JUNE 30, 2006
CASH & EQUIVALENTS	1,903,219*
GRANTS RECEIVABLE	779,239
PREPAID EXPENSES	119,905
TOTAL CURRENT ASSETS	<u>2,802,363</u>
OFFICE AND LABORATORY EQUIPMENT, NET	34,821
INTANGIBLE ASSETS, NET	1,066,721
TOTAL ASSETS	<u>3,903,905</u>
LIABILITIES	
ACCOUNTS PAYABLE	2,316,628
ACCRUED COMPENSATION	89,276
TOTAL LIABILITIES	2,405,904
STOCKHOLDERS' EQUITY	
COMMON STOCK	68,463
ADDITIONAL PAID-IN CAPITAL	91,051,258
DEFICIT ACCUMULATED	(89,621,720)
TOTAL STOCKHOLDERS' EQUITY	1,498,001
TOTAL LIABILITIES & STOCKHOLDERS' EQUITY	<u>\$3,903,905</u>

Capitalization Summary

68.4 million shares outstanding

32.2 million warrants (20 million of which are priced between \$0.45 and \$0.50 – and 10 million of which are priced at \$0.81 or higher)

10.9 million stock options (weighted avg strike price \$0.546)

111.5 million shares if all exercised

If all the warrants are exercised, proceeds to DOR would be approximately \$19 million.

Rating System

Wall Street Advisor does not make a judgment on the prospects for the broad market indices. Our investment ratings have a time horizon of 12-18 months. Relative to the market over that time, we compare a stock's expected performance to that of a broader market, relevant index, which is typically either the S&P 600 or the Russell 2000.

BUY / SPECULATIVE BUY (20% or more appreciation)	We believe that the stock will outperform the market by at least 20% over the next 12-months. Speculative buy has a higher associated risk; the Company's future prospects may hinge on critical assumptions such as sufficient financial liquidity, FDA approvals, market acceptance of a new strategy, etc.
OUTPERFORM (10% to 20%)	We believe that the company's business model and prospects are solid, and we expect that over the long-term the stock will outperform the market by 10% to 20
NEUTRAL (-10% to 10%)	We don't have a strong opinion about which way the stock price will move, but expect it to rise or fall less than 10% relative to the market. Our analysis suggests a value reasonably close to the current price.
UNDERPERFORM (-10% to -20%)	We believe the stock may well be ahead of itself or we are sufficiently concerned about results that we cannot justify the current valuation. We believe the stock may underperform the market by as much as 20%.
SELL (-20% or more)	We expect the stock to underperform the market by at least 20% and see no reason to own the stock.

As of 9/25/06, 40% of our coverage universe has a Buy rating and 60% of our coverage universe has a Speculative Buy rating.

Stock Price History



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