

ALFACELL CORP  
Form 10-K  
October 14, 2008

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

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**FORM 10-K**

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

**For the fiscal year ended July 31, 2008**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**0-11088**  
**Commission file number**

**ALFACELL CORPORATION**  
(Exact name of registrant as specified in its charter)

**Delaware**  
**(State or other jurisdiction of  
incorporation or organization)**

**22-2369085**  
**(I.R.S. Employer  
Identification No.)**

**300 Atrium Drive, Somerset, New Jersey**  
(Address of principal executive offices)

**08873**  
(Zip Code)

Registrant's telephone number, including area code (732) 652-4525

Securities registered pursuant to Section 12(b) of the Act:

**Common Stock, \$.001 par value**  
**(Title of Class)**

**Nasdaq Capital Market**  
**(Name of Exchange)**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [ X ]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [ ] No [ X ]

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

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-(\$229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [  ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or non-accelerated filer. See definitions of [ ]accelerated filer[ ] and [ ]large accelerated filer[ ] in Rule 12b-2 the Exchange Act. (Check one): Large Accelerated Filer [  ] Accelerated Filer [ X ] Non accelerated Filer [  ] Smaller Reporting Company [  ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes [  ] No [ X ]

The aggregate market value of the common stock, par value \$.001 per share, held by non-affiliates based upon the reported last sale price of the common stock on January 31, 2008, the end of the registrant's second fiscal quarter, was approximately \$94,601,000. As of October 10, 2008 there were 47,313,880 shares of common stock outstanding.

**Documents Incorporated by Reference**

Certain information required in Part III of this annual report on Form 10-K is incorporated reference to portions of the registrant's definitive proxy statement for its 2009 Annual Meeting Stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year.

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The following trademarks appear in this annual report on Form 10-K: ONCONASE® is the registered trademark of Alfacell Corporation, exclusively for its anti-cancer agent, Alimta® is the registered trademark of Eli Lilly, Zolanza® is the registered trademark of Merck & Co. and Avastin® is the registered trademark of Genentech.

This annual report on Form 10-K includes forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We have based these forward looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward looking statements are subject to a number of risks, uncertainties, and assumptions about us, including, among other things:

- the failure to obtain regulatory approval of our lead product;
- the failure to achieve positive results in clinical trials;
- competitive factors;
- available financial resources and the ability to secure adequate funding for development projects;
- the ability to attract and retain qualified management;
- relationships with pharmaceutical and biotechnology companies;
- the ability to develop safe and efficacious drugs;
- variability of royalty, license, and other revenue;
- the failure to satisfy the performance obligations in our agreements;
- the ability to enter into future collaborative agreements;
- uncertainty regarding our patents and patent rights (including the risk that we may be forced to engage in costly litigation to protect such patent rights and the material harm to us if there were an unfavorable outcome of any such litigation);
- governmental regulation;
- technological change;
- changes in industry practices; and
- one-time events.

In addition, in this annual report on Form 10-K, the words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions, as they relate to us, our business, or our management, are intended to identify forward looking statements. All of our forward looking statements are qualified in their entirety by reference to the factors discussed in this document under the heading ITEM 1A. "RISK FACTORS, and any documents incorporated by reference that describe risks and factors that could cause results to differ materially from those projected in these forward looking statements.

We caution you that the risk factors contained herein are not exhaustive. We operate in a continually changing business climate which can be expected to impact our forward looking statements, whether as a result of new information, future events, or otherwise, after the date of this annual report. In light of these risks and uncertainties, the forward looking events and circumstances discussed in this annual report may not occur and actual results could differ materially from those anticipated or implied in the forward looking statements. Accordingly, you should not rely on forward looking statements as a prediction of actual results.

All information in this Form 10-K is as of October 10, 2008, unless otherwise noted and we undertake no obligation to update this information.

**PART I****ITEM 1. BUSINESS.****BUSINESS OVERVIEW**

Alfacell Corporation is a Delaware corporation incorporated on August 24, 1981. We are a biopharmaceutical company primarily engaged in the discovery and development of a new class of therapeutic drugs for the treatment of cancer and other pathological conditions. Our proprietary drug discovery and development program consists of novel therapeutics which are being developed from amphibian ribonucleases (RNases).

RNases are biologically active enzymes that split RNA molecules. RNases are enzymes which play important roles in nature, including the embryonic development of an organism and regulation of various cell functions. RNA is an essential bio-chemical cellular component necessary to support life. There are various types of RNA, all of which have specific functions in a living cell. They help control several essential biological activities, namely; regulation of cell proliferation, maturation, differentiation and cell death. Therefore, they are ideal candidates for the development of therapeutics for cancer and other life-threatening diseases, including HIV and autoimmune diseases, that require anti-proliferative and apoptotic, or programmed cell death, properties.

ONCONASE<sup>®</sup> (ranpirnase) is a novel amphibian ribonuclease, unique among the superfamily of pancreatic ribonuclease, isolated from the eggs of the *Rana pipiens* (the Northern Leopard frog). Ranpirnase is the smallest known protein belonging to the superfamily of pancreatic ribonuclease and has been shown, on a molecular level, to re-regulate the unregulated growth and proliferation of cancer cells. Unlike most anti-cancer agents that attack all cells regardless of phenotype (malignant versus normal) and cause severe toxicities, ONCONASE<sup>®</sup> is not an indiscriminate cytotoxic drug (cell killing agent). ONCONASE<sup>®</sup> primarily affects exponentially growing malignant cells, with activity controlled through unique and specific molecular mechanisms.

The molecular mechanisms which determine the apoptotic cell death induced by ranpirnase have been identified. tRNA (transfer RNA), rRNA (ribosomal RNA), mRNA (messenger RNA) and miRNA (micro RNA) are all different types of RNA with specific functions in a living cell. Ranpirnase preferentially degrades tRNA and targets miRNA, leaving rRNA and mRNA apparently undamaged. The RNA damage induced by ranpirnase appears to represent a "death signal", or triggers a chain of molecular events culminating in the activation of proteolytic enzyme cascades which, in turn, induces disintegration of the cellular components and finally leads to cell death. It has been shown that there is a protein synthesis inhibition-independent component, which, together with the changes induced by the protein synthesis inhibition, results in tumor cell death.

ONCONASE<sup>®</sup>, our lead drug product candidate, is currently being evaluated in human clinical trials for the treatment of various forms of cancer. Our most advanced clinical trial for ONCONASE<sup>®</sup> is a confirmatory Phase IIIb registration trial designed to evaluate the efficacy, safety and tolerability of the combination of ONCONASE<sup>®</sup> and doxorubicin as compared to doxorubicin alone in the treatment of patients with unresectable (inoperable) malignant mesothelioma ("UMM"), a rare and deadly form of lung cancer. Enrollment in the Phase IIIb trial was completed in September 2007. On May 28, 2008, we announced that the preliminary statistical analysis of data from our ONCONASE<sup>®</sup> confirmatory Phase IIIb clinical trial did not meet statistical significance for the primary endpoint of survival in UMM. However, a statistically significant improvement in survival was seen in the treatment of UMM patients who failed one prior chemotherapy regimen, a predefined primary data set for this sub-group of patients in the trial. Based on the preliminary statistical analysis of the data, we have decided to continue with the planned submission of the remaining components of the ONCONASE<sup>®</sup> rolling New Drug Application or NDA for the treatment of this patient population, which represents a currently unmet medical need. The following table summarizes the current clinical development status of ONCONASE<sup>®</sup>.

<b>Clinical Indications</b>	<b>Clinical Development Status</b>
Unresectable malignant mesothelioma	Completed □ Preparing NDA
Lung cancer and other solid tumors	Phase I/II





We believe that ONCONASE<sup>®</sup>, as well as another group of our amphibian RNases known as Amphinases, may also have applications in a variety of other areas in addition to those being investigated currently in our clinical development program. Amphinase is currently in the pre-clinical research and development stage.

We are a development stage company as defined in the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 7, "Accounting and Reporting by Development Stage Enterprises." We are devoting substantially all of our present efforts to establishing a new business and developing new drug products. Our planned principal operations of marketing and/or licensing new drugs have not commenced and, accordingly, we have not derived any significant revenue from these operations.

## MARKET OVERVIEW

According to the American Cancer Society ("ACS") *2008 Cancer Facts and Figures*, cancer is the second leading cause of death in the United States, accounting for one in every four deaths. The ACS *2008 Cancer Facts and Figures* also estimates that doctors will diagnose over 1.4 million new cases of cancer in the United States in 2008. The National Institutes of Health or NIH estimate that the annual cost of cancer in 2007 was approximately \$219.2 billion, including \$89.0 billion in direct medical costs and \$18.2 billion for morbidity costs, which includes the cost of lost productivity.

Cancer is characterized by uncontrolled cell division resulting in the growth of a mass of cells commonly known as a tumor. Cancerous tumors can arise in almost any tissue or organ and cancer cells, if not eradicated, spread, or metastasize, throughout the body. Cancer is believed to occur as a result of a number of factors, including hereditary and environmental factors.

For the most part, cancer treatment depends on the type of cancer and the stage of disease progression. Generally, staging is based on the size of the tumor and whether the cancer has metastasized or spread. Following diagnosis, solid tumors are typically surgically removed or the patient is given radiation therapy. Chemotherapy is the principal treatment for tumors that are likely to, or have, metastasized. Chemotherapy involves the administration of drugs which are designed to kill cancer cells, affect the growth of tumors, or reduce bloodflow to tumors, in an effort to reduce or eliminate cancerous tumors.

Because in most cases cancer is fatal, cancer specialists attempt to attack the cancer aggressively, with as many therapies as available and with as high a dose as the patient can tolerate. Since traditional chemotherapy attacks both normal and cancerous cells, treatment often tends to result in complicating side effects. Additionally, cells which have been exposed to several rounds of chemotherapy develop a resistance to the cancer drugs that are being administered. This is known as "multi-drug resistance." The side effects of chemotherapy often limit the effectiveness of treatment. Cancers often recur and mortality rates remain high. Despite large sums of money spent on cancer research, current treatments are largely inadequate and improved anti-cancer agents are needed.

The products we currently have under development target a broad range of solid tumors. The table below shows the incidence and mortality estimated for the year 2008 for various types of solid tumor cancers that our products seek to treat:

Cancer Indication	New Cases	Deaths
Lung (including mesothelioma)	232,270	166,280
Breast	184,450	40,930
Brain	21,810	13,070
Esophageal	16,470	14,280

Source: American Cancer Society, 2008 Cancer Facts and Figures

UMM is the planned initial, or "gateway", indication for ONCONASE<sup>®</sup>. Malignant mesothelioma is an aggressive tumor of serosal surfaces (e.g., pleura, peritoneum) that is often caused by exposure to asbestos. The

most common form is pleural mesothelioma, which accounts for 75% of all cases and affects the lungs and the protective lining and cavity of the lungs.

The incidence rate for mesothelioma in the U.S. is estimated at approximately 15 cases per million population (Datamonitor, March 2007), which equates to about 4,500 cases per year. By comparison, the rate is approximately 93 and 566 cases per million for Small Cell Lung Cancer (SCLC) and Non-Small Cell Lung Cancer (NSCLC), respectively, according to recent data from the National Cancer Institute Surveillance, Epidemiology and End Results Program (SEER). The incidence of mesothelioma in the European Union is slightly higher, resulting in approximately 8,000 cases diagnosed annually. However, given the latency period of 20-50 years and an average development time of 35-40 years for mesothelioma, the peak incidence for the disease is yet to be reached in some countries and therefore, it is difficult to estimate its future patient potential.

The prognosis for malignant mesothelioma patients is very poor. The overall survival for mesothelioma is approximately seven months. Only 9% of patients are expected to survive for five years.

It is estimated that only approximately 1-5% of all mesothelioma patients are suitable for radical surgery. Furthermore, radiotherapy has no impact on survival and is mainly used for palliative purposes. As such, most patients are treated with various chemotherapy regimens, including antifolates, platinum agents, anthracyclines and antimetabolites. Most of these regimens yield poor response rates, typically between 15% and 20%, and the disease almost always recurs.

## **Competition**

In February 2004, the Food and Drug Administration or FDA granted Eli Lilly & Company approval to market Alimta® (pemetrexed), in combination with cisplatin as a treatment for malignant pleural mesothelioma (MPM), the most prevalent form of mesothelioma. To date, Alimta is the only approved therapy worldwide for the treatment of MPM or any form of mesothelioma. Alimta is a multi-targeted antifolate that is based upon a different mechanism of action than ONCONASE®. Like ONCONASE®, Alimta received Orphan Drug and Fast Track Status from the FDA.

To our knowledge, only two other drugs are in a Phase III trial for the treatment of mesothelioma. Merck & Co.'s Zolanza (vorinostat) is currently in Phase III clinical trials for refractory advanced malignant pleural mesothelioma. Genentech Inc.'s Avastin® (bevacizumab) is currently in Phase II/III clinical trials for malignant pleural mesothelioma in combination with the approved Alimta regimen.

There may be several companies, universities, research teams or scientists, that are engaged in research similar, or potentially similar to research performed by us. Some of these entities or persons may have far greater financial resources, larger research staffs and more extensive physical facilities. In addition, these entities or persons may develop products that are more effective than ours and may be more successful than us at producing and marketing their products.

We are not aware, however, of any product currently being marketed that has the same mechanism of action as our proposed anti-tumor agent, ONCONASE®. Search of scientific literature reveals no published information that would indicate that others are currently employing this method or producing such an anti-tumor agent. However, we cannot assure you that others may not develop new treatments that are more effective than ONCONASE®.

## **BUSINESS STRATEGY**

Our goal is to become a leading biopharmaceutical company focused on discovering and developing innovative anti-cancer treatments based on our proprietary RNase technology platform. Our strategy consists of the following key elements:

### **Focus on the growing cancer market**

Cancer is the second leading cause of death in the United States, yet there remain unmet needs, and current treatments remain ineffective and inadequate for some populations. Given the life-threatening nature of cancer, the FDA has adopted procedures to accelerate the approval of cancer drugs. We intend to continue to use our expertise in the field of cancer research to target this significant market opportunity for cancer drug development.

### **Develop our existing product portfolio**

We currently have a portfolio of clinical and pre-clinical drug product candidates under development for potential use as anti-cancer, and other therapeutics. We intend to further develop these drug product candidates both by expanding our internal resources and by continuing to collaborate with other companies and leading governmental and academic research institutions.

### **Commercialize pharmaceutical products focused on cancer in selected markets**

Our current strategy is to partner with third parties to market our future products to oncologists and other key specialists involved in the treatment of cancer patients. We may also elect to develop an appropriately-sized internal oncology sales and marketing capability in the United States. This group may function as a standalone operation or in a supportive, co-promotion capacity in collaboration with a partner.

## **RESEARCH AND DEVELOPMENT PROGRAM**

Research and development expenses for the fiscal years ended July 31, 2008, 2007, and 2006 were approximately \$8,503,000, \$5,543,000, and \$5,230,000, respectively. Our research and development programs focus primarily on the clinical and pre-clinical research and development of therapeutics from our pipeline of amphibian RNases.

### **Clinical Development Program**

In January 2007, ONCONASE<sup>®</sup> was granted orphan drug designation by the FDA for malignant mesothelioma. Orphan drug designation permits us to be awarded seven years of marketing exclusivity for ONCONASE<sup>®</sup> for the malignant mesothelioma indication upon FDA approval for this indication. Other benefits for which we are eligible with the orphan drug designation include protocol assistance by the FDA in the preparation of a dossier that will meet regulatory requirements, tax credits, research and development grant funding, and reduced NDA submission fees. Previously, our ONCONASE<sup>®</sup> development program received Fast Track Designation from the FDA for the indication of malignant mesothelioma. We continue to have discussions with the FDA to establish mutually agreed upon parameters for the NDA to obtain marketing approval for ONCONASE<sup>®</sup>, assuming the confirmatory Phase IIIb clinical trial for the treatment of malignant mesothelioma results support such approval.

We also have previously received an Orphan Medicinal Product Designation for ONCONASE<sup>®</sup> from the European Agency for the Evaluation of Medicinal Products, or EMEA, as well as Orphan Drug Designation for ONCONASE<sup>®</sup> for malignant mesothelioma in Australia from the Therapeutics Goods Administration, or TGA. Orphan drug designation from these agencies provides benefits such as potential marketing exclusivity, reduced filing fees and regulatory guidance.

The FDA, EMEA and TGA Orphan Drug Designations for ONCONASE<sup>®</sup> for malignant mesothelioma may serve to expedite its regulatory review upon submission of a marketing application. The efficacy and safety of ONCONASE<sup>®</sup> for malignant mesothelioma will ultimately be determined by these regulatory agencies based on the results of our Phase IIIb registration trial.

ONCONASE<sup>®</sup> is currently being evaluated as a treatment for UMM in an international, centrally randomized, confirmatory Phase IIIb registration trial. Malignant mesothelioma is a rare cancer, primarily affecting

the pleura (lining of the lungs), and is usually associated with asbestos exposure. The first Phase III trial of ONCONASE® in UMM was completed in 2000. The most recent confirmatory Phase IIIb registration trial was closed to patient accrual in September 2007.

The confirmatory Phase IIIb registration trial is a randomized and controlled clinical trial designed to evaluate the efficacy, safety and tolerability of the combination of ONCONASE® and doxorubicin as compared to doxorubicin alone, and powered to reach a statistically significant difference in overall survival between the ONCONASE® + doxorubicin treatment group and the doxorubicin treatment group at 316 evaluable events. Patients were stratified based on Cancer Adult Leukemia Group B (CALGB) Group (1 to 4) and histology and then assigned treatment using a centralized randomization plan. The primary endpoint of the trial is overall patient survival. The following data sets were analyzed for efficacy as per the statistical analysis plan for this clinical trial:

- All patients randomized who received at least one dose of study therapy (evaluable patients),
- Previously treated patients,
- All patients randomized,
- All patients who completed 6 cycles of therapy per protocol, and
- All patients with identical inclusion criteria as used in the Alimta submission.

In addition, secondary endpoints to be analyzed in accordance with the Phase IIIb clinical trial statistical analysis plan include:

- Tumor response rates,
- Progression free survival,
- Patient assessment of symptoms associated with malignant mesothelioma,
- Investigator assessment of malignant mesothelioma symptoms,
- Narcotic pain medication usage,
- Lung function, and
- Performance status.

On May 28, 2008, we announced that the results of the preliminary statistical analysis of data from our ONCONASE® confirmatory Phase IIIb clinical trial did not meet statistical significance for the primary endpoint of survival in UMM. However, a statistically significant improvement in survival was seen in the treatment of UMM patients who failed one prior chemotherapy regimen, one of the predefined primary sub-group data sets for patients in the trial. The full analysis of the data is currently ongoing in support of the planned submission of the remaining components of the ONCONASE® rolling NDA for the treatment of UMM patients that have failed a prior chemotherapy regimen, which represents a currently unmet medical need. We have requested a pre-NDA meeting with the FDA to discuss the planned NDA submission in an effort to submit the final components of the rolling NDA by the end of 2008.

In our previous Phase III trial comparing ONCONASE® as a single agent with doxorubicin, the intent-to-treat population showed median survival of 8.4 months for the ONCONASE® arm and 8.2 months for the doxorubicin arm in the study. While not statistically significant, a subset analysis of the results using the CALGB prognostic groups (published during enrollment in the Phase III trial) revealed a marked excess of poor prognosis patients (groups 5 and 6) in the ONCONASE® arm of the trial (32 patients or 38.1% of the patients treated with ONCONASE®) as compared to the doxorubicin arm of the trial (12 patients or 17% of the patients treated with doxorubicin). By excluding these patients and the 10 patients whose central pathology review did not confirm a diagnosis of malignant mesothelioma (N=5) from the 154 intent-to-treat patients, we defined a target treatment group, or TTG, consisting of 104 patients who met the criteria for CALGB prognostic groups 1-4. Of these patients, 47 were treated with ONCONASE® and 57 were treated with doxorubicin. The single agent Phase III results of the TTG showed a median survival benefit of 2 months for ONCONASE® treated patients, 11.6 months median survival time, or MST, versus 9.6 months MST. This two month median survival difference favoring ONCONASE®, while not statistically significant, represents a 20% advantage over the active agent, doxorubicin. Moreover, the clinical activity of ONCONASE® is also evident from the overall 1-year and 2-year survival rates of ONCONASE® versus doxorubicin in the TTG, 46.8% versus 38.6% and 20.2% versus

12.3%, respectively. Doxorubicin treatment was associated with a 60% higher risk of death compared to ONCONASE® treatment. Finally, tumor assessment by an independent radiologist for evaluable patients (which included a baseline and follow-up radiological assessment) revealed evidence of objective clinical activity in 17 patients in each treatment arm. Four partial responses and 13 stabilization of previously progressive disease were reported in the ONCONASE® treated patients and 7 partial responses and 10 stabilization of previously progressive disease were reported in the doxorubicin treated patients. Despite the small number of patients in this subset, the analysis revealed a statistically significant difference, log rank test,  $p = 0.037$ , in survival of the responders favoring ONCONASE® treated patients with an MST 23.3 versus 14.4 months for doxorubicin treated patients as well as the 2 year survival rates of 40% for ONCONASE® and 9% for doxorubicin.

A Phase I/II program to evaluate a new dose and administration schedule of ONCONASE® was initiated in 2005 to attempt to take advantage of potentially increased efficacy with higher and more frequent doses of ONCONASE®. The Phase I portion of this program is complete and we plan to initiate a Phase II clinical trial in non-small cell lung cancer (NSCLC) patients that exhibit resistance to platinum based chemotherapy regimens in early 2009.

### **Pre-Clinical Research Program**

Our drug discovery and pre-clinical research programs form the basis for the development of specific recombinant RNases for chemically linking drugs and other compounds such as monoclonal antibodies, growth factors, etc., as well as developing gene fusion products with the goal of targeting various molecular functions. These programs provide for joint design and generation of new products with outside collaborators. Through these collaborations, we may own these new products along with, or we may grant an exclusive license to, the collaborating partner(s).

The multiple effects of biological activity of ONCONASE® has led to research in other areas of cancer biology. Two important areas associated with significant market opportunities are radiation therapy and control of tumor angiogenesis, or new tumor blood vessel formation. Many types of cancers undergo radiation therapy at early stages of the disease; however, success of such treatment is often limited. We believe any agent capable of enhancing tumor radiosensitivity has great market potential. Moreover, since the growth of essentially all types of cancer is dependent on new blood vessel formation, any agent that has anti-angiogenic activity, we believe, is most desirable.

#### *Ranpirnase Conjugates and Fusion Proteins*

The concept of targeting potent toxins as effector molecules to kill cancer or other specifically targeted cells has been extensively evaluated over the last two decades. An immunotoxin is an antibody linked to a toxic molecule that is used to destroy specific cells. Several immunotoxins containing bacterial and plant toxins or other biotoxins, have been evaluated in human clinical trials. Efficacy has always been limited due to the high incidence of immunogenicity, or an immune response, and other intolerable toxicities, including death. Conjugation of ranpirnase to targeting ligands, or binding to other molecules, appears to eliminate this safety problem in pre-clinical studies.

A Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute, or NCI, has produced RN321, a conjugate of ranpirnase with a monoclonal antibody, that has demonstrated activity against non-Hodgkin's lymphoma in preclinical studies. The relative benefit of killing targeted tumor cells versus non-targeted healthy cells, or the therapeutic index, is greater than 200,000-fold with this conjugate. This CRADA has been concluded and data published. As a result of these findings we are working with our collaborators on the development of first and second generation huRFB4 - ONCONASE® for targeting CD22+ B cell malignancies.

We have also developed a variety of uniquely designed versions of ONCONASE® and amphinase conjugates. These compounds target the EGF receptors and neo-vascularization (tumor blood vessel formation) which have potential clinical application in a broad spectrum of solid tumors.

Novel Amphibian Ribonucleases (Amphinases)

We have also discovered another series of proteins, collectively named amphinases that may have therapeutic uses. These proteins are bioactive in that they have an effect on living cells and organisms and have both anti-cancer and anti-viral activity. All of the proteins characterized to date are RNases. Preclinical testing of the new candidates collectively called amphinases showed them to be similarly active to ranpirnase. Their chemical structure makes them ideal candidates for genetic engineering of designer products.

These compounds have undergone screening by the National Institute of Allergy and Infectious Diseases (NIAID) against various RNA viruses and by outside collaborators. One of these compounds, AC-03-636 has been determined to be active in yellow fever, Hepatitis C and Dengue fever. The same compound has been evaluated at Johns Hopkins University in a sustained time release formulation for the treatment of brain tumors (gliomas).

Evaluation Of ONCONASE® As A Radiation Enhancer

The p53 gene is a tumor-suppressor gene, which means that if it malfunctions, tumors may be more likely to develop. Published preclinical studies have demonstrated that ONCONASE® causes an increase in both tumor blood flow and in median tumor oxygen partial pressure, causing tumor cells to become less resistant to radiation therapy regardless of the presence or absence of the functional p53 tumor-suppressor gene. In pre-clinical research at the University of Pennsylvania, ONCONASE®, when combined with radiation therapy, enhanced the radiation-sensitivity to treatment in NSCLC tumor cells without causing the common radiation-induced tissue damage to non-tumor cells. ONCONASE® inhibited SLDR (sub-lethal damage repair) and PLDR (potentially lethal damage repair) in these animal models. We believe these findings further expand the profile of ONCONASE® *in vivo* activities and its potential clinical utility and market potential.

ONCONASE® As a Resistance-Overcoming and Apoptosis-Enhancing Agent

The *Fas* (CD95) cell surface receptor (and its *Fas* ligand *FasL*) has been recognized as an important [death] receptor involved in the induction of the [extrinsic] pathway of apoptosis. The apoptotic pathways have been the preferred target for new drug development in cancer, autoimmune, and other therapeutic areas.

The Thoracic Surgery Branch of the NCI confirmed the synergy between ranpirnase and soluble *Fas* ligand (*sFasL*) in inducing significant apoptosis in *sFasL*-resistant *Fas+* tumor cells. These results provided rationale for using ONCONASE® as a potential treatment of *FasL*-resistant tumors and possibly other disorders such as the autoimmune lympho-proliferative syndrome (ALPS). Further research in this area is ongoing.

Evaluation Of ONCONASE® As An Anti-Viral Agent

The ribonucleolytic activity was the basis for testing ONCONASE® as a potential anti-viral agent against HIV. The NIH has performed an independent *in vitro* screen of ONCONASE® against the HIV virus type 1. The results showed ONCONASE® to inhibit replication of HIV by up to 99.9% after a four-day incubation period at concentrations not toxic to uninfected cells. *In vitro* findings by the NIH revealed that ONCONASE® significantly inhibited production of HIV in several persistently infected human cell lines, preferentially breaking down viral RNA while not affecting normal cellular ribosomal RNA and messenger RNAs, which are essential to cell function.

Moreover, the NIAID also screened ONCONASE® for anti-HIV activity. ONCONASE® demonstrated highly significant anti-HIV activity in the monocyte/macrophage, or anti-viral, system. Ranpirnase may inhibit viral replication at several points during the life cycle of HIV, including its early phases. Ranpirnase may inhibit replication of all different HIV-1 subtypes. These properties of ranpirnase are particularly relevant in view of the extremely high and exponentially increasing rate of mutations of HIV that occur during infection, and which are primarily responsible for the development of resistance to several currently available anti-viral drugs. At present, over 50% of clinical isolates of HIV are resistant to both reverse transcriptase, mechanisms which combat viral replication, and protease inhibitors drugs, a class of anti-viral drugs. An additional 25%, while being sensitive to protease inhibitors, are resistant to reverse transcriptase inhibitor drugs.





## COMMERCIAL RELATIONSHIPS

### License Agreements

In January 2008, we entered into a U.S. License Agreement for ONCONASE® with Par Pharmaceutical, Inc. (¶Par¶). Under the terms of the License Agreement, Strativa Pharmaceuticals (¶Strativa¶), the proprietary products division of Par, received exclusive marketing, sales and distribution rights to ONCONASE® for the treatment of cancer in the United States and its territories. We retain all rights and obligations for product manufacturing, clinical development and obtaining regulatory approvals, as well as all rights for those non-U.S. jurisdictions in which we have not currently granted any such rights or obligations to third parties. Joint oversight committees with members from Alfacell and Strativa will manage the alliance. We received a cash payment of \$5 million upon the signing of the License Agreement and will be entitled to an additional minimum cash payment of \$20 million, up to a maximum of \$30 million, upon FDA approval of ONCONASE® for UMM. We will also be entitled to receive up to \$190 million in additional development and sales milestone payments in connection with the development of ONCONASE® for up to three additional cancer indications and achieving certain net sales levels, in addition to receiving double-digit royalties on net sales of ONCONASE®. In the event of approval of ONCONASE® for a cancer indication in addition to UMM, we will have the option to co-promote ONCONASE® in the United States, with support from Strativa. Strativa will provide technical expertise for a future Alfacell oncology sales force, as well as funding for certain associated costs. Under certain circumstances, we will have the right to co-promote ONCONASE®, at our cost, prior to the time ONCONASE® is approved for any such additional cancer indication. We will also supply all of Strativa¶s requirements for ONCONASE® pursuant to a Supply Agreement with Par executed on January 14, 2008.

Strativa has the right to terminate the License Agreement if ONCONASE® does not receive marketing approval by the FDA on or before January 1, 2012 or receives a not approvable communication from the FDA with respect to the primary UMM indication. In the case of termination of the License Agreement for any reason, we will retain all rights to ONCONASE®.

### Marketing and Distribution Agreements

#### Megapharm Ltd.

In May 2008, we entered into an exclusive marketing, sales and distribution agreement with Megapharm Ltd. for the commercialization of ONCONASE® in Israel. Under the agreement, we are eligible to receive 50% of net sales in the territory. We will be responsible for the manufacture and supply of ONCONASE® to Megapharm, while Megapharm will be responsible for all activities and costs related to regulatory filings and commercial activities in the territory.

#### BL&H Co. Ltd.

In January 2008, we entered into a marketing and distribution agreement with BL&H Co. Ltd. for the commercialization of ONCONASE® in Korea, Taiwan and Hong Kong. Under the agreement, we received a \$100,000 up-front fee and are eligible to receive additional cash milestones and 50% of net sales in the territory. We will be responsible for the manufacture and supply of ONCONASE® to BL&H, while BL&H will be responsible for all activities and costs related to regulatory filings and commercial activities in the territory.

#### US Pharmacia

In July 2007, we entered into a Distribution and Marketing Agreement (the ¶Distribution Agreement¶), with USP Pharma Spolka Z.O.O. (the ¶Distributor¶), an affiliate of US Pharmacia, pursuant to which the Distributor was granted exclusive rights for the marketing, sales, and distribution of ONCONASE® for use in oncology in Poland, Belarus, Ukraine, Estonia, Latvia, and Lithuania (the ¶Territory¶) for an initial term that ends upon the earlier of (i) 10 years from the first commercial sale in the Territory and (ii) the date all of the patents covering the

product in the Territory expire. We received an upfront payment of \$100,000 and will also be entitled to receive milestone payments based on the achievement of certain regulatory approvals and certain sales goals. In addition, we will receive a royalty on net sales as well as a transfer price for product sold by us to the Distributor. We will be responsible for making regulatory filings with and seeking marketing approval of ONCONASE® in the Territory and manufacturing and supplying ONCONASE® to the Distributor. The Distributor will be responsible for all commercial activities and related costs in the Territory.

In connection with the Distribution Agreement, we also entered into a Securities Purchase Agreement, with Unilab LP, an affiliate of US Pharmacia, pursuant to which we issued a total of 553,360 shares of restricted common stock for approximately \$1.4 million, or \$2.53 per share.

#### GENESIS Pharma S.A.

In December 2006, we entered into a Distribution and Marketing Agreement with GENESIS Pharma S.A. (["GENESIS"]), pursuant to which GENESIS was granted exclusive rights for the marketing, sales, and distribution of ONCONASE® for use in oncology in Greece, Cyprus, Bulgaria, Romania, Slovenia, Croatia, Serbia, and the Former Yugoslavian Republic of Macedonia (the ["Region"]) for an initial term that ends upon the earlier of (i) 10 years from the first commercial sale in the Region and (ii) the date all of the patents covering the product in the Region expire. We will retain ownership of all intellectual property relating to ONCONASE® and responsibility for all regulatory filings with EMEA in the European Union (EU), with GENESIS providing assistance with regard to regulatory filings in the non-EU countries included in this agreement. We will also be responsible for manufacturing and supplying the product to GENESIS, which will distribute the product. GENESIS will have lead responsibility for all ONCONASE® commercialization activities and will manage all operational aspects of the marketing, sales and distribution of the product in the Region. We are entitled to receive milestone payments based on the achievement of certain regulatory approvals and certain sales goals. In addition, we will receive a royalty on net sales as well as a transfer price for product sold by us to GENESIS.

#### **Manufacturing**

In January 2008, we entered into a Purchase and Supply Agreement (the ["Supply Agreement"]) with Scientific Protein Laboratories LLC (["SPL"]). Under the Supply Agreement, SPL will manufacture and be our exclusive supplier for the bulk drug substance used to make ONCONASE®. The term of the Supply Agreement shall be ten years and we have the right to terminate the Supply Agreement at any time without cause on two years prior notice to SPL.

Additionally, we contract with Ben Venue Laboratories Inc. (["Ben Venue"]) for vial filling and with Bilcare Global Clinical Supplies, Americas (["Bilcare"]), Aptuit, Inc. (["Aptuit"]) and Catalent Pharma Solutions, Inc. (["Catalent"]) for the labeling, storage and shipping of ONCONASE® for use in clinical trials. Other than these arrangements we do not have specific arrangements for the manufacture of ONCONASE®.

Products manufactured for use in clinical trials and for commercial sale must be manufactured in compliance with Current Good Manufacturing Practices (["CGMP"]). SPL, Ben Venue, Aptuit and Catalent are all licensed or approved by the appropriate regulatory agencies and all work is performed in accordance with CGMP. For the foreseeable future, we intend to rely on these manufacturers and related service providers, or substitute vendors, if necessary, to manufacture our product. We believe, however, that there are substantial alternative providers for the services for which we contract. For those relationships where we have not entered into formal agreements, we utilize the services of these third party contractors solely on an as needed basis with prices and terms customary for companies in businesses that are similarly situated. In order to replace an existing manufacturer, we must amend our Investigational New Drug application to notify the appropriate regulatory agencies of the change. We are dependent upon our contract manufacturers to comply with CGMP and to meet our production requirements. It is possible that our contract manufacturers may not comply with CGMP or deliver sufficient quantities of our products on schedule, or that we may be unable to find suitable and cost effective alternative providers if necessary.

## Raw Materials

The major active ingredient derived from leopard frog eggs is the protein ranpirnase. We have sufficient egg inventory on hand to produce enough ONCONASE® for at least two years after commercialization. In addition, we have successfully produced ranpirnase in small proof-of-concept size batches using recombinant technology. However, this technology requires additional testing and FDA approval and it may be determined to not be more cost effective than current methods of production.

## Patents and Proprietary Technology

We have sought to protect our technology by applying for, and obtaining, patents and trademark registrations. We have also relied on trade secrets and know-how to protect our proprietary technology. We continue to develop our portfolio of patents, trade secrets, and know how. We have obtained, and continue to apply for, patents concerning our RNase-based technology.

In addition, we have filed (and we intend to continue to file) foreign counterparts to certain U.S. patent applications. Generally, we apply for patent protection in the United States, Europe, Japan, and certain other foreign countries.

We own the following U.S. patents:

Patent No.	Issue Date	Subject Matter	Expiration **
5,529,775	June 1996	covers combinations of ONCONASE® with certain other pharmaceuticals	June 2013
5,728,805	Mar. 1998	covers a family of variants of ONCONASE®	June 2013
5,540,925	July 1996	covers combinations of ONCONASE® with certain other pharmaceuticals	July 2013
5,559,212	Sept. 1996	covers the amino acid sequence of ONCONASE®	Sept. 2013
5,595,734	Jan. 1997	covers combinations of ONCONASE® with certain other pharmaceuticals	Jan. 2014
6,649,392B1*	Nov. 2003	covers a family of recombinant variants of ONCONASE®	Apr. 2016
6,649,393B1*	Nov. 2003	covers nucleic acids encoding recombinant variants of ONCONASE® and methodology for producing such variants	Apr. 2016
6,290,951B1	Sept. 2001	covers alteration of the cell cycle <i>in vivo</i> , particularly for inducing apoptosis of tumor cells	Aug. 2018
6,239,257B1	May 2001	covers a family of variants of ONCONASE®	Dec. 2018
6,175,003B1	Jan. 2001	covers the genes of ONCONASE® and a variant of ONCONASE®	Sept. 2019
6,423,515B1	July 2002	covers methodology for synthesizing gene sequences of ranpirnase and a genetically engineered variant of ranpirnase	Sept. 2019
7,229,824B1***	June 2007	covers a vector containing DNA encoding a genetically engineered variant of ONCONASE®	May 2024

\*We own this patent jointly with the U.S. Government. We do not pay maintenance fees to keep this patent in force.

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We own the following foreign patents in Europe (European patents are validated in selected European nations), Japan and Singapore:

Patent No.	Subject Matter	Expiration **
EP 0 440 633	covers ONCONASE® and process technology for making it	Mar. 2009
EP 0 500 589	cover combinations of ONCONASE® with certain other pharmaceuticals	Oct. 2010
JP 2972334		
EP 0 656 783	covers combinations of ONCONASE® with certain other	July 2013
JP 3655628	pharmaceuticals	
EP 0 837 878	covers a variant of ONCONASE®	June 2016
JP 3779999		
SG 118886	covers variants of ONCONASE® and methods of making them	May 2024

\*\*Assumes timely payment of all applicable maintenance fees and annuities; excludes term extensions that do or may apply.

\*\*\*Includes a term extension of 312 days under 35 U.S.C. §154(b).

We also have patent applications pending in the United States, Europe, Japan, and other foreign countries.

The scope of protection afforded by patents for biotechnological inventions can be uncertain, and such uncertainty may apply to our patents as well. The patent applications we have filed, or that we may file in the future, may not result in patents. Our patents may not give us a competitive advantage, may be wholly or partially invalidated or held unenforceable, or may be held not to have been infringed by products that compete with our products. Patents owned by others may adversely affect our ability to do business. Furthermore, others may independently develop products that are similar to our products or that duplicate our products, and may design around the claims of our patents. Although we believe that our patents and patent applications are of substantial value to us, we cannot assure you that such patents and patent applications will be of commercial benefit to us, will adequately protect us from competing products or will not be challenged, declared invalid, or found not to have been infringed by competing products. We also rely on proprietary know-how and on trade secrets to develop and maintain our competitive position. Others may independently develop or obtain access to such know-how or trade secrets. Although our employees and consultants having access to proprietary information are required to sign agreements that require them to keep such information confidential, our employees or consultants may breach these agreements or these agreements may be held to be unenforceable.

### Government Regulation

The manufacturing and marketing of pharmaceutical products in the United States require the approval of the FDA under the Federal Food, Drug and Cosmetic Act. Similar approvals by comparable regulatory agencies are required in most foreign countries. The FDA has established mandatory procedures and safety standards that apply to the clinical testing, manufacturing and marketing of pharmaceutical products in the United States. Obtaining FDA approval for a new therapeutic may take many years and involve substantial expenditures. State, local and other authorities also regulate pharmaceutical manufacturing facilities.

As the initial step in the FDA regulatory approval process, preclinical studies are conducted in laboratory dishes and animal models to assess the drug's efficacy and to identify potential safety problems. Moreover manufacturing processes and controls for the product are required. The manufacturing information along with the results of these studies is submitted to the FDA as a part of the Investigational New Drug Application, or IND, which is filed to obtain approval to begin human clinical testing. The human clinical testing program typically involves up to three phases. Data from human trials as well as other regulatory requirements such as chemistry, manufacturing and controls, pharmacology and toxicology sections, are submitted to the FDA in an NDA or Biologics License Application, or BLA. Preparing an NDA or BLA involves considerable data collection, verification and analysis. A



similar process in accordance with EMEA regulations in Europe and with TGA regulations in Australia is required to gain marketing approval. Moreover, a commercial entity must be established and approved by the EMEA in a member state of the EU at least three months prior to filing the Marketing Authorization Application, or MAA.

We have not received United States or other marketing approval for any of our product candidates and may not receive any approvals. We may encounter difficulties or unanticipated costs in our effort to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

With respect to patented products, delays imposed by the governmental approval process may materially reduce the period during which we may have the exclusive right to exploit them.

### **Environmental Matters**

Our operations are subject to comprehensive regulation with respect to environmental, safety and similar matters by the United States Environmental Protection Agency and similar state and local agencies. Failure to comply with applicable laws, regulations and permits can result in injunctive actions, damages and civil and criminal penalties. If we expand or change our existing operations or propose any new operations, we may need to obtain additional or amend existing permits or authorizations. We spend time, effort and funds in operating our facilities to ensure compliance with environmental and other regulatory requirements.

Such efforts and expenditures are common throughout the biotechnology industry and generally should have no material adverse effect on our financial condition. The principal environmental regulatory requirements and matters known to us requiring or potentially requiring capital expenditures by us do not appear likely, individually or in the aggregate, to have a material adverse effect on our financial condition. We believe that we are in compliance with all current laws and regulations.

### **Employees**

As of July 31, 2008, we had fifteen full time employees, of whom ten were engaged in clinical and pre-clinical research and development activities and five were engaged in administration and management. Five employees hold Ph.D. degrees. All of our employees are covered by confidentiality agreements. We consider relations with our employees to be good. None of our employees is covered by a collective bargaining agreement.

### **Available Information**

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through our website ([www.alfacell.com](http://www.alfacell.com)) as soon as reasonably practicable after we electronically file the material with, or furnish it to, the Securities and Exchange Commission (the "SEC"). You may read and copy any document we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.W., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our SEC filings are also available to the public at the SEC's website at <http://www.sec.gov>. Additionally, we have also adopted a Code of Business Conduct and Ethics applicable to all officers, directors, and employees, which is also available on our website.

**ITEM 1A. RISK FACTORS.**

*An investment in our common stock is speculative and involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information in this Form 10-K and our other SEC filings before deciding whether to purchase shares of our common stock. If any of the following risks actually occur, our business and operating results could be harmed. This could cause the trading price of our common stock to decline, and you may lose all or part of your investment.*

**We are highly dependent on achieving success in the clinical testing, regulatory approval, and commercialization of ONCONASE® and our other compounds currently under development. If we fail to obtain the necessary regulatory approvals, we will not be allowed to commercialize ONCONASE® and our business will be harmed.**

The FDA in the United States and comparable regulatory agencies in foreign countries impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve the completion of lengthy and detailed pre-clinical and clinical testing and other costly and time consuming procedures. Satisfaction of these requirements typically takes several years depending on the level of complexity and novelty of the product. The length of time required to complete a clinical trial depends on several factors including the size of the patient population, the ability of patients to get to the site of the clinical study, and the criteria for determining which patients are eligible to join the study. A significant portion of our expenditures have been devoted, and in the future will be devoted, to the clinical trials for our lead product candidate, ONCONASE® and activities related to the preparation and filing of the NDA for ONCONASE® for the treatment of malignant mesothelioma. A delay in the commercial sale of ONCONASE® or sales of ONCONASE® which did not result in significant revenue to us, would increase the time frame during which our cash flow would be negative, which, in turn, might require us to seek additional financing. Such financing may not be available, and even if it is available, it may not be available on terms favorable or acceptable to us.

We have conducted the preliminary statistical analysis from our confirmatory Phase IIIb clinical trial of ONCONASE® and that analysis indicated that ONCONASE® did not meet statistical significance for the primary endpoint of survival in UMM. However, a statistically significant improvement in survival was seen in the treatment of UMM patients who failed one prior chemotherapy regimen. We plan to submit an NDA to the FDA for the treatment of this patient population, which represents a currently unmet medical need. While we believe that the statistical analysis of the data from the confirmatory Phase IIIb clinical trial of ONCONASE® have produced results that support the filing of an NDA with the FDA, we cannot be certain that the FDA will allow us to file an NDA or approve our NDA, if it is filed. Also if safety concerns develop, the FDA, EMEA and TGA could take actions that negatively affect our NDA submission. We or 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.

All statutes and regulations governing the conduct of clinical trials are subject to future changes by various regulatory agencies, including the FDA, which could affect the cost and duration of our clinical trials. Any unanticipated costs or delays in our clinical studies would delay our ability to generate product revenues and to raise additional capital and could cause us to be unable to fund the completion of the studies.

We may not market or sell any product for which we have not obtained regulatory approval. We cannot assure you that the FDA or other regulatory agencies will ever approve the use of our products that are under development. Even if we receive regulatory approval, such approval may involve limitations on the indicated uses for which we may market our products. Further, even after approval, discovery of previously unknown problems could result in additional restrictions, including withdrawal of our products from the market.

If we fail to obtain the necessary regulatory approvals, we cannot market or sell our products in the United States or in other countries and our long-term viability would be threatened. If we fail to achieve regulatory approval or foreign marketing authorizations for ONCONASE® we will not have a product suitable for sale or product revenues for quite some time, if at all, and may not be able to continue operations.

Our profitability will depend on our ability to develop, obtain regulatory approvals for, and effectively market ONCONASE® as well as entering into strategic alliances for the development of new drug candidates from the out-licensing of our proprietary RNase technology. The commercialization of our pharmaceutical products involves a number of significant challenges. In particular, our ability to commercialize ONCONASE® depends on the success of our clinical development programs, our efforts to obtain regulatory approval and our sales and marketing efforts or those of our marketing partners, directed at physicians, patients and third-party payors. A number of factors could affect these efforts including:

- our ability to demonstrate clinically that our products have utility and are safe;
- delays or refusals by regulatory authorities in granting marketing approvals;
- our limited financial resources relative to our competitors;
- our ability to obtain and maintain relationships with current and additional marketing partners;
- the availability and level of reimbursement for our products by third party payors;
- incidents of adverse reactions to our products;
- misuse of our products and unfavorable publicity that could result; and
- the occurrence of manufacturing or distribution disruptions.

**We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future. We do not have a current source of product revenue and may never be profitable.**

We are a development stage company and since our inception one of the principal sources of our working capital has been private sales of our common stock. Over the past three fiscal years, we have incurred aggregate net losses of approximately \$28.9 million and since our inception we have incurred aggregate net losses of approximately \$104.4 million. We expect to incur additional losses and, as our development efforts, efforts to file an NDA for ONCONASE® and clinical testing activities continue, our rate of losses may increase. We also expect to experience negative cash flows for the foreseeable future as we fund our losses and capital expenditures. Our losses have adversely impacted, and will continue to adversely impact, our working capital, total assets and stockholders' equity. To date, we have not sold or received approval to sell any drug product candidates, and it is possible that revenues from drug product sales will never be achieved. We cannot at this time predict when or if we will be able to develop other sources of revenue or when or if our operations will become profitable, even if we are able to commercialize some of our drug product candidates.

We will seek to generate revenue through licensing, marketing and development arrangements prior to receiving revenue from the sale of our products. To date we have entered into one US license agreement and four non-US regional marketing and distribution agreements and we may not be able to successfully negotiate any additional agreements. In the past, we have entered into several development arrangements which have resulted in limited revenues for us. We cannot assure investors that these arrangements or future arrangements, if any, will result in significant amounts of revenue for us in the future. We, therefore, are unable to predict the extent of any future losses or the time required to achieve profitability, if at all.

**We will need additional financing to continue operations, which may not be available on favorable or acceptable terms, if it is available at all.**

We estimate that as of July 31, 2008, our then existing cash reserves including our expected level of receipts and expenditures should be sufficient to support our activities into the fourth quarter of our fiscal year 2009, which assumes the timely and successful submission of the ONCONASE® NDA. As a result of our continuing losses and lack of capital, the report of our independent registered public accounting firm on our July 31, 2008 financial statements included an explanatory paragraph which states that our recurring losses from operations and negative cash flows from operating activities raise substantial doubt about our ability to continue as a going concern. Our financial statements at July 31, 2008 do not include any adjustments that might result from the outcome of this uncertainty. Regardless of whether we are able to file our NDA or whether our NDA is approved, we will need additional financing to conduct our business after April 30, 2009. If our ONCONASE® NDA is approved by the FDA, we will be eligible to receive significant cash milestone payments from our U.S. marketing partner. If we are



delayed in submitting the NDA, the receipt of milestone payments would be delayed and if the results of our Phase IIIb clinical trial do not support the filing of an NDA, or if our NDA is not approved, we would not receive such milestone payment and our ability to raise additional capital would be adversely affected. Additional factors that would affect the amount and timing of additional capital required include, but are not limited to, the following:

- the progress and cost of completing and filing marketing registrations for ONCONASE<sup>®</sup> with the FDA in the United States, with the EMEA in Europe and with the TGA in Australia;
- our degree of success in commercializing our drug product candidates, including entering into additional marketing and distribution agreements;
- the progress and cost of research and development and clinical trial activities relating to our drug product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our patent claims and other intellectual property rights and investigating and defending against infringement claims asserted against us by others;
- the emergence of competing technologies and other adverse market developments;
- changes in or terminations of our existing licensing, marketing and distribution arrangements;
- the amount of milestone payments we may receive from current and future collaborators, if any; and
- the cost of manufacturing scale-up and development of marketing operations, if we undertake those activities.

Additional financing may not be available when we need it or be on terms acceptable to us. If adequate financing is not available, we may be required to delay, scale-back, or eliminate certain of our research and development programs, to relinquish rights to some of our technologies or products, or to grant licenses to third parties to commercialize products or technologies that we would otherwise seek to develop ourselves. We could also be required to cease operations. If additional capital is raised through the sale of equity, our stockholders' ownership interest could be diluted and such newly-issued securities may have rights, preferences, or privileges superior to those of our other stockholders. The terms of any debt securities we may sell to raise additional capital may place restrictions on our operating activities.

**Budget constraints may force us to delay our efforts to develop certain drug product candidates in favor of developing others, which may prevent us from commercializing all drug product candidates as quickly as possible.**

Because we are an emerging company with limited resources, and because completing and submitting an NDA is an expensive process, we must regularly assess the most efficient allocation of our research and development budget. As a result, we may have to further prioritize development activities and may not be able to fully realize the value of some of our drug product candidates in a timely manner, and they may be delayed in reaching the market, if at all. A reduction in spending on our other drug product candidates could delay our commercialization efforts and negatively impact our ability to diversify our development risk across a broad portfolio of drug product candidates.

**Competition in the biopharmaceutical field is intense and subject to rapid technological change. Our principal competitors have substantially greater resources to develop and market products that may be superior to ours.**

If we obtain regulatory approval for any of our drug product candidates, the extent to which they achieve market acceptance will depend, in part, on competitive factors. Competition in our industry is intense, and it is increased by the rapid pace of technological development. Existing drug products or new drug products developed by our competitors may be more effective or have fewer side effects, or may be more effectively marketed and sold, than any that we may develop. Our principal competitors have substantially greater research and development capabilities and experience and greater manufacturing, marketing, financial, and managerial resources than we do. Competitive drug compounds may render our technology and drug product candidates obsolete or noncompetitive prior to our recovery of research, development, or commercialization expenses incurred through sales of any of our

drug product candidates. The FDA's policy of granting "fast track" approval for cancer therapies may also expedite the regulatory approval of our competitors' drug product candidates.

In February 2004, the FDA granted Eli Lilly & Company approval to sell its Alimta<sup>®</sup> medication as an orphan drug to treat patients with pleural mesothelioma. Alimta<sup>®</sup> is a multi-targeted antifolate that is based upon a different mechanism of action than ONCONASE<sup>®</sup>. To our knowledge, no other company is developing a product with the same mechanism of action as ONCONASE<sup>®</sup>. However, there may be other companies, universities, research teams or scientists who are developing products to treat the same medical conditions our products are intended to treat. To our knowledge, only two other drugs are in a Phase III trial for the treatment of mesothelioma. Merck & Co.'s Zolanza (vorinostat) is currently in Phase III clinical trials for refractory advanced malignant pleural mesothelioma. Genentech Inc.'s Avastin<sup>®</sup> (bevacizumab) is currently in Phase II/III clinical trials for malignant pleural mesothelioma in combination with the approved Alimta regimen.

We also compete with other drug development companies for collaborations with large pharmaceutical and other companies.

**Our stock price has been and is likely to continue to be volatile, and an investment in our common stock could decline in value.**

The market price of our common stock, like that of the securities of many other development stage biotechnology companies, has fluctuated over a wide range and it is likely that the price of our common stock will fluctuate in the future. For example, over the past three fiscal years, the sale price for our common stock, as reported by Nasdaq has fluctuated from a low of \$0.35 to a high of \$4.99. The market price of our common stock could be impacted by a variety of factors, including:

- the success or failure of our clinical trials, including, but not limited to, the Phase IIIb trial involving our lead compound, ONCONASE<sup>®</sup>, or those of our competitors;
- announcements of technological innovations or new drug products by us or our competitors;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain financing, when needed;
- economic conditions in the United States and abroad;
- comments by or changes in our assessments or financial estimates by securities analysts;
- adverse regulatory actions or decisions;
- losses of key management;
- changing governmental regulations;
- our ability to secure adequate third party reimbursement for products developed by us;
- developments or disputes concerning patents or other proprietary rights;
- product or patent litigation; and
- public concern as to the safety of products developed by us.

The stock market continues to experience extreme price and volume fluctuations and these fluctuations have especially affected the market price of many biotechnology companies. Such fluctuations have often been unrelated to the operating performance of these companies. Volatility or a lack of positive performance in our stock price may adversely affect our ability to retain key employees, all of whom have been granted stock options. These factors and fluctuations, as well as political and market conditions, may materially adversely affect the market price of our common stock.

**The trading market for our common stock may be limited if we are unable to continue listing our common stock on the Nasdaq Capital Market.**

From April 1999, when we were delisted from Nasdaq, until September 9, 2004, when we were relisted on the Nasdaq Capital Market, there was no established trading market for our common stock. During that time, our common stock was quoted on the OTC Bulletin Board and was thinly traded. As of July 31, 2008, we did not comply with the \$35 million minimum market value requirement under Marketplace Rule 4310(c)(3)(B) or the \$1

per share minimum bid price requirement under Marketplace Rule 4310(c)(4). We received notification of delisting from Nasdaq and were granted a hearing to appeal the decision. Furthermore, if the bid price of our common stock does not close at \$1.00 per share or more for a minimum of 10 consecutive business days at any time before January 12, 2009, we may be delisted from the Nasdaq Capital Market. In addition, as of July 31, 2008, we also did not meet the \$2.5 million minimum stockholders' equity requirement under Marketplace Rule 4310(c)(3)(A) or the requirement for a minimum net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years under Marketplace Rule 4310(c)(3)(C). For continued listing on the Nasdaq Capital Market, we must comply with, among other requirements, the minimum bid price requirement and at least one of the other three alternative listing standards described above. We have been granted additional time to consider actions that may allow us to regain compliance with the Nasdaq continued listing standards and maintain our Nasdaq listing. There is no assurance, however, that we will be able to take any of these actions or that any of the actions will be sufficient to allow our Nasdaq listing to continue or for how long such listing will continue. In addition, our stock remains thinly traded at times and you may be unable to sell our common stock during times when the trading market is limited.

**We are and will be dependent upon third parties for manufacturing our products. If these third parties do not devote sufficient time and resources to our products our revenues and profits may be adversely affected.**

We do not have the required manufacturing facilities to manufacture our product. We presently rely on third parties to produce ONCONASE® for use in clinical trials. We have entered into a ten year purchase and supply agreement with SPL, for the manufacturing of ranpirnase (protein drug substance) from the oocytes, or the unfertilized eggs, of the *Rana pipiens* frog, which is found in the Northwest United States and is commonly called the leopard frog.

Additionally, we contract with Ben Venue for the manufacturing of ONCONASE® and with Bilcare, Catalent and Aptuit for the storage, labeling and shipping of ONCONASE® for clinical trial use. We utilize the services of these third party manufacturers solely on an as needed basis with terms and prices customary for our industry.

We use FDA CGMP licensed manufacturers for ranpirnase and ONCONASE®. We have identified alternative providers for the manufacturing services for which we may contract. In order to replace an existing service provider we must amend our IND to notify the FDA of the new manufacturer. Although the FDA generally will not suspend or delay a clinical trial as a result of replacing an existing manufacturer, the FDA has the authority to suspend or delay a clinical trial if, among other grounds, human subjects are or would be exposed to an unreasonable and significant risk of illness or injury as a result of the replacement manufacturer.

We intend to rely on third parties to manufacture our products if they are approved for sale by the appropriate regulatory agencies and are commercialized. Third party manufacturers may not be able to meet our needs with respect to the timing, quantity or quality of our products or to supply products on acceptable terms.

**Because we do not have in-house marketing, sales or distribution capabilities, we have contracted with third parties and expect to contract with third parties in the future for these functions and we will therefore be dependent upon such third parties to market, sell and distribute our products in an effort to generate revenues.**

We currently have no in-house sales, marketing or distribution capabilities. In order to commercialize any product candidates for which we receive FDA or non-U.S. approval, we expect to rely on established third parties who have strategic partnerships with us to perform these functions. To date, we have entered into a license agreement with Par Pharmaceutical, Inc. in the United States and four marketing and distribution agreements for ONCONASE® in regions outside the United States. We cannot assure you we will be able to maintain these relationships or establish new relationships with biopharmaceutical or other marketing companies with existing distribution systems and direct sales forces to market any or all of our product candidates on acceptable terms, if at all.

In addition, we may incur significant expenses in determining our commercialization strategy with respect to one or more of our product candidates for regions outside the United States. The determination of our commercialization strategy with respect to a product candidate will depend on a number of factors, including:

- the extent to which we are successful in securing third parties to collaborate with us to offset some or all of the funding obligations with respect to product candidates;
- the extent to which our agreement with our collaborators permits us to exercise marketing or promotion rights with respect to the product candidate;
- how our product candidates compare to competitive products with respect to labeling, pricing, therapeutic effect, and method of delivery; and
- whether we are able to establish agreements with third party collaborators, including large biopharmaceutical or other marketing companies, with respect to any of our product candidates on terms that are acceptable to us.

**Our lack of operating experience may cause us difficulty in managing our growth.**

We have no experience in selling pharmaceutical or other products or in manufacturing or procuring drug products in commercial quantities in compliance with FDA regulations and we have only limited experience in negotiating, establishing and maintaining collaborative relationships and conducting later stage phases of the regulatory approval process. Our ability to manage our growth, if any, will require us to improve and expand our management and our operational and financial systems and controls. If our management is unable to manage growth effectively, our business and financial condition would be adversely affected. In addition, if rapid growth occurs, it may strain our operational, managerial and financial resources, which are limited.

**Our proprietary technology and patents may offer only limited protection against infringement and the development by our competitors of competitive products.**

We own two patents jointly with the United States government. These patents expire in 2016. We also own ten United States patents with expiration dates ranging from 2013 to 2024, four European patents with expiration dates ranging from 2009 to 2016, three Japanese patents with expiration dates ranging from 2010 to 2016 and one Singaporean patent with an expiration date in 2024. We also own patent applications that are pending in the United States, Europe, Japan, and other foreign countries. The scope of protection afforded by patents for biotechnological inventions is uncertain, and such uncertainty applies to our patents as well. Therefore, our patents may not give us competitive advantages or afford us adequate protection from competing products. Furthermore, others may independently develop products that are similar to our products, and may design around the claims of our patents. Patent litigation and intellectual property litigation are expensive and our resources are limited. To date, we have not received any threats of litigation regarding patent issues. However, if we were to become involved in litigation, we might not have the funds or other resources necessary to conduct the litigation effectively. This might prevent us from protecting our patents, from defending against claims of infringement, or both.

**We may be sued for infringing on the intellectual property rights of others.**

Our commercial success also depends in part on ensuring that we do not infringe the patents or proprietary rights of third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. While we have not been sued for infringing the intellectual property rights of others, there can be no assurance that the drug product candidates that we have under development do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing their proprietary technology without authorization. Moreover, United States patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. Further, some applications are kept secret during the entire length of their pendency by request of the applicant in special circumstances. As a result, there may be patents of which we are unaware, and avoiding patent infringement may be difficult. Patent holders sometimes send communications to a number of companies in related

fields, suggesting possible infringement. If we are sued for patent infringement, we would need to demonstrate that we either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, which we may not be able to do. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to further develop, commercialize and sell products, and such claims could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. In that event, we could encounter delays in product introductions while we attempt to develop alternative methods or products or be required to cease commercializing affected products and our operating results would be harmed.

In the future, others may file patent applications covering technologies that we may wish to utilize with our proprietary technologies, or products that are similar to products developed with the use of our technologies. If these patent applications result in issued patents and we wish to use the claimed technology, we would need to obtain a license from the third party, and this would increase our costs of operations and harm our operating results.

**If we lose key management personnel or are unable to attract and retain the talent required for our business, our business could be materially harmed.**

We are highly dependent on the principal members of our management team, including, but not limited to, Kuslima Shogen, our scientific founder and Chief Executive Officer or CEO, and Lawrence A. Kenyon, our President, Chief Financial Officer or CFO, and Corporate Secretary. Ms. Shogen announced her planned retirement effective no later than March 31, 2009 and entered into a retirement agreement with us that specifies payments to be made to her through March 31, 2011. These payments primarily consist of annual payments to Ms. Shogen representing her current salary and medical benefits. Mr. Kenyon does not have an employment contract with us. We do not have key man insurance on any of our management. If we were to lose the services of Mr. Kenyon or other members of our management team, and were unable to replace them, our product development and the achievement of our strategic objectives could be delayed.

In addition, our success will depend on our ability to attract and retain qualified commercial, scientific, technical, and managerial personnel. While we have not experienced unusual difficulties to date in recruiting and retaining personnel, there is intense competition for qualified staff and there is no assurance that we will be able to retain existing personnel or attract and retain qualified staff in the future.

**If we are unable to obtain favorable reimbursement for our product candidates, their commercial success may be severely hindered.**

Our ability to sell our future products may depend in large part on the extent to which reimbursement for the costs of our products is available from government entities, private health insurers, managed care organizations and others. Third-party payors are increasingly attempting to contain their costs. We cannot predict what actions third-party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. Reduced or partial reimbursement coverage could make our products less attractive to patients, suppliers and prescribing physicians and may not be adequate for us to maintain price levels sufficient to realize an appropriate return on our investment in our product candidates or to compete on price.

In some cases, insurers and other healthcare payment organizations try to encourage the use of less expensive generic brands and over-the-counter, or OTC, products through their prescription benefits coverage and reimbursement policies. These organizations may make the generic alternative more attractive to the patient by providing different amounts of reimbursement so that the net cost of the generic product to the patient is less than the net cost of a prescription brand product. Aggressive pricing policies by our generic product competitors and the prescription benefits policies of insurers could have a negative effect on our product revenues and profitability.

Many managed care organizations negotiate the price of medical services and products and develop formularies for that purpose. Exclusion of a product from a formulary can lead to its sharply reduced usage in the



managed care organization patient population. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic or OTC products, our market share and gross margins could be negatively affected, as could our overall business and financial condition.

The competition among pharmaceutical companies to have their products approved for reimbursement may also result in downward pricing pressure in the industry or in the markets where our products will compete. We may not be successful in any efforts we take to mitigate the effect of a decline in average selling prices for our products. Any decline in our average selling prices would also reduce our gross margins.

In addition, managed care initiatives to control costs may influence primary care physicians to refer fewer patients to oncologists and other specialists. Reductions in these referrals could have a material adverse effect on the size of our potential market and increase costs to effectively promote our products.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

There have been a number of legislative and regulatory proposals aimed at changing the healthcare system and pharmaceutical industry, including reductions in the cost of prescription products and changes in the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products. For example, the Prescription Drug and Medicare Improvement Act of 2003 provides a Medicare prescription drug benefit that began in 2006 and mandates other reforms. Although we cannot predict the full effects on our business of the implementation of this new legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues. It is also possible that other proposals will be adopted. As a result of the new Medicare prescription drug benefit or any other proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could harm our ability to operate our business efficiently, obtain collaborators and raise capital.

**Our product candidates may not be accepted by the market.**

Even if approved by the FDA and other regulatory authorities, our product candidates may not achieve market acceptance, which means we would not receive significant revenues from these products. Approval by the FDA does not necessarily mean that the medical community will be convinced of the relative safety, efficacy and cost-effectiveness of our products as compared to other products. In addition, third party reimbursers such as insurance companies and HMOs may be reluctant to reimburse expenses relating to our products.

**Material weaknesses or deficiencies in our internal control over financial reporting could harm stockholders' and business partners' confidence in our financial reporting, our ability to obtain financing, and other aspects of our business.**

Internal control over financial reporting can provide only reasonable and not absolute assurance that deficiencies or weaknesses are identified. Additionally, potential control deficiencies that are not yet identified could emerge and internal controls that are currently deemed to be in place and operating effectively are subject to the risk that those controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Identification and corrections of these types of potential control deficiencies could have a material impact on our business, financial position, results of operations and disclosures and impact our ability to raise funds.

**Our investments could lose market value and consequently harm our ability to fund continuing operations.**

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash and cash equivalents in a variety of securities, including government and corporate obligations and money market funds. The market values of these investments may fluctuate due to market conditions and other conditions over which we have no control. Fluctuations in the market price and valuations of these securities may require us to record losses due to impairment in the value of the securities underlying our investment. This could result in future charges to our earnings. All of our investment securities are denominated in US dollars.

Investments in both fixed-rate and floating-rate interest earning instruments carry varying degrees of interest rate risk. Fixed-rate securities may have their fair market value adversely impacted due to a rise in interest rates. In general, securities with longer maturities are subject to greater interest rate risk than those with shorter maturities. While floating-rate securities generally are subject to less interest rate risk than fixed-rate securities, floating-rate securities may produce less income than expected if interest rates decrease. Due in part to these factors, our investment income may fall short of expectations or we may suffer losses in principal if securities are sold that have declined in market value due to changes in interest rates.

**We handle hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business. We could also be liable for damages, penalties, or other forms of censure if we are involved in a hazardous waste spill or other accident.**

Our research and development processes involve the controlled storage, use, and disposal of hazardous materials and biological hazardous materials. We are subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of hazardous materials and certain waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, even by a third party, we could be held liable for any damages that result, and such liability could exceed the \$2,000,000 limit of our current general liability insurance coverage and our financial resources. In the future, we may not be able to maintain insurance on acceptable terms, or at all. We could also be required to incur significant costs to comply with current or future environmental laws and regulations.

**We may be sued for product liability.**

Our business exposes us to potential product liability that may have a negative effect on our financial performance and our business generally. The administration of drugs to humans, whether in clinical trials or commercially, exposes us to potential product and professional liability risks which are inherent in the testing, production, marketing and sale of new drugs for humans. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a negative effect on our financial performance and materially adversely affect our business. We maintain product liability insurance to protect our products and product candidates in amounts customary for companies in businesses that are similarly situated, but our insurance coverage may not be sufficient to cover claims. Furthermore, liability insurance coverage is becoming increasingly expensive and we cannot be certain that we will always be able to maintain or increase our insurance coverage at an affordable price or in sufficient amounts to protect against potential losses. A product liability claim, product recall or other claim, as well as any claim for uninsured liabilities or claim in excess of insured liabilities, may significantly harm our business and results of operations. Even if a product liability claim is not successful, adverse publicity and time and expense of defending such a claim may significantly interfere with our business.

**Our incorporation documents may delay or prevent the removal of our current management or a change of control that a stockholder may consider favorable.**

We are currently authorized to issue 1,000,000 shares of preferred stock. Our Board of Directors is authorized, without any approval of the stockholders, to issue the preferred stock and determine the terms of the





preferred stock. This provision allows the board of directors to affect the rights of stockholders, since the board of directors can make it more difficult for common stockholders to replace members of the board. Because the board of directors is responsible for appointing the members of our management, these provisions could in turn affect any attempt to replace current management by the common stockholders. Furthermore, the existence of authorized shares of preferred stock might have the effect of discouraging any attempt by a person, through the acquisition of a substantial number of shares of common stock, to acquire control of our company. Accordingly, the accomplishment of a tender offer may be more difficult. This may be beneficial to management in a hostile tender offer, but have an adverse impact on stockholders who may want to participate in the tender offer or inhibit a stockholder's ability to receive an acquisition premium for his or her shares.

**Events with respect to our share capital could cause the price of our common stock to decline.**

Sales of substantial amounts of our common stock in the open market, or the availability of such shares for sale, could adversely affect the price of our common stock. We had 47,276,880 shares of common stock outstanding as of July 31, 2008. The following securities that may be exercised into shares of our common stock were issued and outstanding as of July 31, 2008:

- Options. Stock options to purchase 6,353,067 shares of our common stock at a weighted average exercise price of approximately \$2.69 per share.
- Warrants. Warrants to purchase 14,862,534 shares of our common stock at a weighted average exercise price of approximately \$2.09 per share.

The shares of our common stock that may be issued under the options and warrants are currently registered with the SEC or are eligible for sale without any volume limitations pursuant to Rule 144 under the Securities Act.

**The ability of our stockholders to recover against Armus Harrison & Co., or AHC, may be limited because we have not been able to obtain the reissued reports of AHC with respect to the financial statements included in our Form 10-K, nor have we been able to obtain AHC's consent to the use of such report herein.**

Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") provides that any person acquiring or selling a security in reliance upon statements set forth in a Form 10-K may assert a claim against every accountant who has with its consent been named as having prepared or certified any part of the Form 10-K, or as having prepared or certified any report or valuation that is used in connection with the Form 10-K, if that part of the Form 10-K at the time it is filed contains a false or misleading statement of a material fact, or omits a material fact required to be stated therein or necessary to make the statements therein not misleading (unless it is proved that at the time of such acquisition such acquiring person knew of such untruth or omission).

In June 1996, AHC dissolved and ceased all operations. Therefore, we have not been able to obtain the reissued reports of AHC with respect to the financial statements included in the annual report on Form 10-K for the fiscal year ended July 31, 2008 nor have we been able to obtain AHC's consent to the use of such report herein. As a result, in the event any persons seek to assert a claim against AHC under Section 18 of the Exchange Act for any untrue statement of a material fact contained in these financial statements or any omissions to state a material fact required to be stated therein, such persons will be barred. Accordingly, you may be unable to assert a claim against AHC under Section 18 of the Exchange Act for any purchases of the Company's Common Stock made in reliance upon statements set forth in the Form 10-K for the fiscal year ended July 31, 2008. In addition, the ability of AHC to satisfy any claims properly brought against it may be limited as a practical matter due to AHC's dissolution in 1996.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

In March 2007, we entered into a lease for 15,410 square feet in an industrial office building located in Somerset, New Jersey to replace our facility in Bloomfield, NJ as our principal office. The lease term commenced on July 3, 2007 and is scheduled to terminate on November 30, 2017. The average monthly rental obligation over the full term of the lease is approximately \$25,000. We believe that the facility is sufficient for our needs in the foreseeable future.

**ITEM 3. LEGAL PROCEEDINGS.**

None.

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

None.

**EXECUTIVE OFFICERS OF ALFACELL**

The following persons were our executive officers as of October 10, 2008:

*Kuslima Shogen, 63*, has served as our Chief Executive Officer since September 1986, and as a Director since our inception in 1981. She also served as our Chairman of the Board from August 1996 until January 2008, Acting Chief Financial Officer from June 23, 1999 until March 2004, as our Chief Financial Officer from September 1986 through July 1994 and as our President from September 1986 through July 1996. Ms. Shogen formed the company in 1981 to pursue research that she had initiated while a biology student in the University Honors Program at Fairleigh Dickinson University. Prior to our founding, from 1976 to 1981 she was founder and president of a biomedical research consortium specializing in Good Laboratory Practices and animal toxicology. During that time, she also served as a consultant for the Lever Brothers Research Group. She earned a B.S. degree in 1974, M.S. in 1976 and also completed graduate studies in 1978 in embryology from Fairleigh Dickinson University.

*Lawrence A. Kenyon, 43*, joined us in January 2007, as Executive Vice President, Chief Financial Officer and Corporate Secretary, was named Chief Operating Officer and elected to our Board of Directors in November 2007, and named President in April 2008. Previously, from September 2000 thru August 2006, Mr. Kenyon served as Executive Vice President, Chief Financial Officer and Corporate Secretary with NeoPharm Inc., a publicly traded biopharmaceutical company. From October 1999 until September 2000, he was Senior Vice President of the Gabelli Mathers Fund, a regulated investment company, and from March 1988 until October 1999 he held a variety of positions with Mathers and Company Inc. an investment management firm, most recently serving as Chief Financial Officer for both Mathers and Company Inc. and Mathers Fund Inc. Mr. Kenyon began his career with Arthur Andersen & Co. in 1987 after receiving a bachelor's degree in accounting from the University of Wisconsin --Whitewater.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

Our common stock is listed on the Nasdaq Capital Market, or Nasdaq, and has traded under the symbol "ACEL" since September 9, 2004. Prior to September 9, 2004, our common stock was traded on the OTC Bulletin Board (OTCBB). As of October 10, 2008, there were approximately 986 stockholders of record of our common stock.

As of July 31, 2008, we did not comply with the \$35 million minimum market value requirement under Marketplace Rule 4310(c)(3)(B) or the \$1 per share minimum bid price requirement under Marketplace Rule 4310(c)(4). We received notification of delisting from Nasdaq and were granted a hearing to appeal the decision. Furthermore, if the bid price of our common stock does not close at \$1.00 per share or more for a minimum of 10



consecutive business days at any time before January 12, 2009, we may be delisted from the Nasdaq Capital Market. In addition, as of July 31, 2008, we also did not meet the \$2.5 million minimum stockholders' equity requirement under Marketplace Rule 4310(c)(3)(A) or the requirement for a minimum net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years under Marketplace Rule 4310(c)(3)(C). For continued listing on the Nasdaq Capital Market, we must comply with, among other requirements, the minimum bid price requirement and at least one of the other three alternative listing standards described above. We have been granted additional time to consider actions that may allow us to regain compliance with the Nasdaq continued listing standards and maintain our Nasdaq listing. There is no assurance, however, that we will be able to take any of these actions or that any of the actions will be sufficient to allow our Nasdaq listing to continue or for how long such listing will continue. In addition, our stock remains thinly traded at times and you may be unable to sell our common stock during times when the trading market is limited.

The following table sets forth the range of high and low sale prices of our common stock for the two fiscal years ended July 31, 2008 and 2007. The prices were obtained from Nasdaq and are believed to be representative of inter-dealer quotations, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

	High	Low
Year Ended July 31, 2008:		
First Quarter	\$ 2.70	\$ 1.75
Second Quarter	2.69	1.45
Third Quarter	2.60	1.70
Fourth Quarter	2.20	0.35
Year Ended July 31, 2007:		
First Quarter	2.09	1.17
Second Quarter	1.95	0.73
Third Quarter	3.74	1.05
Fourth Quarter	2.99	2.05

**STOCKHOLDER RETURN PERFORMANCE GRAPH**

The following graph summarizes the total cumulative return experienced by Alfacell's stockholders during the five-year period ended July 31, 2008, compared to the Nasdaq Composite Index and the Nasdaq Pharmaceutical Index. The changes for the periods shown in the graph and table are based on the assumption that \$100.00 was invested in Alfacell Corporation Common Stock and in each index below on July 31, 2003 and that all cash dividends were reinvested. The table does not forecast performance of our common stock.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

Among Alfacell Corporation, The NASDAQ Composite Index  
And The NASDAQ Pharmaceutical Index

\*\$100 invested on 7/31/03 in stock & index-including reinvestment of dividends. Fiscal year ending July 31.

**Dividends**

We have not paid dividends on our common stock since inception and we do not plan to pay dividends in the foreseeable future. Any earnings we may realize will be retained to finance our growth.

**Equity Compensation Plan Information**

The information called for by Item 5(a) relating to compensation plan information is incorporated herein by reference to Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stock Matters of this Form 10-K.

**Recent Sales of Unregistered Securities**

None.

**Issuer Purchases of Equity Securities**

We did not repurchase any shares of our common stock during the fiscal year 2008.

**ITEM 6. SELECTED FINANCIAL DATA.**

Set forth below is the selected financial data for our company for the five fiscal years ended July 31, 2008:

	Year Ended July 31,				
	2008	2007	2006	2005	2004
Investment income	\$ 227,591	\$ 370,650	\$ 107,386	\$ 141,708	\$ 42,113
Other income (loss)	--	--	--	9,836	--
Net loss <sup>(1)</sup>	(12,321,101)	(8,755,144)	(7,810,175)	(6,461,920)	(5,070,307)
Dividends	None	None	None	None	None
Total assets	5,320,036	7,820,499	11,826,428	4,901,624	10,421,063
Long-term debt	--	--	--	--	--
Total equity (deficiency)	(3,556,606)	5,778,480	9,233,003	3,221,670	8,881,647
Loss per basic and diluted common share	\$ (0.26)	\$ (0.19)	\$ (0.21)	\$ (0.18)	\$ (0.17)

- (1) Included in the net loss of \$12,321,101, \$8,755,144 and \$7,810,175 for the fiscal years ended July 31, 2008, 2007 and 2006, respectively, are tax benefits of \$1,755,380, \$510,467 and \$317,382, respectively, related to the sale of certain state tax operating loss carryforwards.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION RESULTS OF OPERATIONS.**

*The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and notes to those statements included in Item 8 of Part II of this Form 10-K.*

**Overview**

We are a biopharmaceutical company engaged in the research, development, and commercialization of drugs for life threatening-diseases, such as malignant mesothelioma and other cancers. Our corporate strategy is to become a leader in the discovery, development, and commercialization of novel ribonuclease (RNase) therapeutics for cancer and other life-threatening diseases.

We are a development stage company as defined in the Financial Accounting Standards Board's (the "FASB") Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises" (SFAS 7). We are devoting substantially all of our present efforts to establishing a new business and developing new drug products. Our planned principal operations of marketing and/or licensing new drugs have not commenced and, accordingly, we have not derived any significant revenue from these operations.

Since our inception in 1981, we have devoted the vast majority of our resources to the research and development of ONCONASE®, our lead drug candidate, as well as other related drug candidates. In recent years we have focused our resources towards the completion of the clinical program for ONCONASE® in patients suffering from UMM.

ONCONASE® has received orphan drug designation from the FDA for the treatment of mesothelioma. Orphan drug designation permits us to be awarded seven years of marketing exclusivity for ONCONASE® for the malignant mesothelioma indication upon FDA approval for this indication. Other benefits for which we are eligible with the orphan drug designation include protocol assistance by the FDA in the preparation of a dossier that will meet regulatory requirements, tax credits, research and development grant funding, and reduced filing fees for the marketing application. Previously, our ONCONASE® development program received Fast Track Designation from the FDA for the treatment of malignant mesothelioma patients.

We also have previously received an Orphan Medicinal Product Designation for ONCONASE® from the EMEA, as well as Orphan Drug Designation for ONCONASE® for malignant mesothelioma in Australia from the TGA. Orphan drug designation from these agencies provides benefits such as marketing exclusivity, reduced filing fees and regulatory guidance.

During our fiscal year ended July 31, 2008, management's efforts were primarily focused on the completion of our confirmatory Phase IIIb clinical trial and preparation of the remaining components of our NDA, which are expected to be submitted to the FDA by the end of December 2008. We also continued to enter into commercial agreements with partners in key regions, including Strativa Pharmaceuticals (a division of Par Pharmaceutical, Inc.) in the United States, BL&H Co. Ltd. in Korea, Hong Kong and Taiwan, and Megapharm Ltd. in Israel. Changes to our executive team in 2008 included the appointment of David Sidransky, M.D. as Chairman of the Board of Directors and Lawrence A. Kenyon, our CFO and Secretary, to the additional role of President and Chief Operating Officer. Kuslima Shogen, our scientific founder and CEO, announced that she intends to retire no later than March 31, 2009.

On May 28, 2008, we announced that the results of the preliminary statistical analysis of data from our ONCONASE® confirmatory Phase IIIb clinical trial did not meet statistical significance for the primary endpoint of survival in UMM. However, a statistically significant improvement in survival was seen in the treatment of UMM patients who failed one prior chemotherapy regimen, one of the predefined primary sub-group data sets for patients in the trial. The full analysis of the data is currently ongoing in support of the planned submission



of the remaining components of the ONCONASE® rolling NDA for the treatment of UMM patients that have failed a prior chemotherapy regimen, which represents a currently unmet medical need. We have requested a pre-NDA meeting with the FDA to discuss the planned NDA submission in an effort to submit the final components of the rolling NDA by the end of 2008.

Almost all of the \$69.3 million of research and development expenses we have incurred since our inception has gone toward the development of ONCONASE® and related drug candidates. For the fiscal years 2008, 2007 and 2006, our research and development expenses were approximately \$8.5 million, \$5.5 million, and \$5.2 million, respectively, almost all of which were used for the development of ONCONASE® and related drug candidates.

We have incurred losses since inception and we have not received FDA approval of any of our drug candidates. We expect to continue to incur losses for the foreseeable future as we continue our efforts to receive marketing approval for our drug candidates, which includes the sponsorship of human clinical trials. Until we are able to consistently generate revenue through the sale of drug or non-drug products, we anticipate that we will be required to fund the development of our pre-clinical compounds and drug product candidates primarily by other means, including, but not limited to, licensing the development or marketing rights to some of our drug candidates to third parties, collaborating with third parties to develop our drug candidates, or selling Company issued securities.

We fund the research and development of our products primarily from cash receipts resulting from the sale of our equity securities and convertible debentures in registered offerings and private placements. Additionally, we have raised capital through other debt financings, the sale of our tax benefits and research products, interest income and financing received from our CEO. During the fiscal year ended July 31, 2008, we received net proceeds of approximately \$0.7 million as a result of private placements of common stock and from exercises of stock options and warrants. These proceeds will be used primarily to complete our confirmatory Phase IIIb clinical trial and support our anticipated filing of an NDA of ONCONASE® for malignant mesothelioma. We have incurred losses since inception and, to date, we have generated only small amounts of capital from commercial agreements for ONCONASE®.

## Results of Operations

### *Fiscal Year Ended July 31, 2008, as compared to Fiscal Year Ended July 31, 2007*

We are a development stage company as defined in the FASB's SFAS 7. We are devoting substantially all our present efforts to establishing a new business and developing new drug products. Our planned principal operations of marketing of new drugs have not commenced and, accordingly, we have not derived any significant revenue from these operations. We focus most of our productive and financial resources on the development of ONCONASE®. We did not record any revenue in fiscal years 2008 or 2007.

Research and development expense for fiscal year 2008 was \$8.5 million compared to \$5.5 million for fiscal year 2007, an increase of approximately \$3 million, or 53.4%. The increase in research and development expenses is directly related to increased expenses of approximately \$3.2 million related to our preparations for the completion of the ONCONASE® rolling NDA submission, which included the required statistical analysis of the data from our confirmatory Phase IIIb clinical trial, offset by a decrease of approximately \$0.2 million in expenses incurred from the completion of the Phase I component of our Phase I/II ONCONASE® clinical trials.

General and administrative expense for fiscal year 2008 was approximately \$5.8 million compared to approximately \$4.1 million for fiscal year 2007, an increase of approximately \$1.7 million, or 41.6%. This increase was primarily the result of increased compensation expense of approximately \$1.1 million directly related to the planned retirement of our CEO in 2009. Additionally, professional service fees for consultants and legal advisors increased approximately \$0.5 million as a result of our increased activity in pursuing and negotiating commercial agreements in fiscal 2008. Other general and administrative expenses increased by a total of approximately \$0.1 million in 2008 as a result of increased commercial insurance premiums.

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Investment income for fiscal year 2008 was \$0.2 million compared to \$0.4 million for fiscal year 2007, a decrease of \$0.2 million. The decrease was due to lower balances of cash and cash equivalents on hand during the fiscal year 2008 as compared to the same period in 2007.

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of its state tax loss carryforwards and state research and development credits in order to obtain tax benefits. For the state fiscal year 2008 (July 1, 2007 to June 30, 2008), we had approximately \$2.5 million of total available state tax benefits that qualified for sale, of which New Jersey permitted us to sell approximately \$2.0 million. In December 2007, we received approximately \$1.8 million from the sale of these state tax benefits, which was recognized as state tax benefit in the fiscal year ended July 31, 2008.

We have incurred net losses during each year since our inception. The net loss for fiscal year 2008 was approximately \$12.3 million as compared to \$8.8 million in fiscal year 2007. The increased net loss was primarily related to the increased research and development expenses in 2008. The cumulative loss from the date of inception, August 24, 1981 to July 31, 2008, amounted to \$104.4 million. Such losses are attributable to the fact that we are still in the development stage and, accordingly, have not derived sufficient revenues from operations to offset the development stage expenses.

### *Fiscal Year Ended July 31, 2007, as compared to Fiscal Year Ended July 31, 2006*

We did not record any revenue in fiscal years 2007 and 2006.

Research and development expense for fiscal year 2007 was \$5.5 million compared to \$5.2 million for fiscal year 2006, an increase of approximately \$0.3 million, or 5.7%. The increase primarily resulted from increased compensation expense related to employee salaries and benefits of approximately \$0.5 million mostly due to increased stock-based compensation expenses in 2007, in addition to an increase of approximately \$0.2 million in expenses incurred from our ongoing Phase I/II ONCONASE® clinical trials that initiated in June 2005 and November 2006. These increased expenses were offset by decreased expenses of approximately \$0.4 million related to preparations for the completion of our Phase IIIb ONCONASE® clinical trial and the initiation of the related submissions of various sections of our rolling NDA to the FDA.

General and administrative expense for fiscal year 2007 was approximately \$4.1 million compared to approximately \$3.0 million for fiscal year 2006, an increase of approximately \$1.1 million, or 35.7%. This increase was primarily due to increased compensation expense associated with employee salaries and benefits of approximately \$0.7 million related mostly to increased stock-based compensation expenses, as well as increased investor relations expenses of approximately \$0.2 million resulting from our use of an investor relations firm beginning in fiscal year 2007. Other general and administrative expenses, including legal, audit, consulting, travel and miscellaneous office expenses increased by a total of approximately \$0.1 million in 2007.

Investment income for fiscal year 2007 was \$0.4 million compared to \$0.1 million for fiscal year 2006, an increase of \$0.3 million. The increase was due to higher balances of cash and cash equivalents on hand during the fiscal year 2007 as compared to the same period in 2006.

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of its state tax loss carryforwards and state research and development credits in order to obtain tax benefits. For the state fiscal year 2007 (July 1, 2006 to June 30, 2007), we had approximately \$2.3 million of total available state tax benefits that qualified for sale, of which New Jersey permitted us to sell approximately \$0.6 million. In December 2006, we received approximately \$0.5 million from the sale of these state tax benefits, which was recognized as state tax benefit in the fiscal year ended July 31, 2007.

For the state fiscal year 2006 (July 1, 2005 to June 30, 2006), we had approximately \$1.9 million of total available state tax benefits that were saleable; of which New Jersey permitted us to sell approximately \$0.4 million. In December 2005, we received approximately \$0.3 million from the sale of these state tax benefits, which we recognized as state tax benefits for the fiscal year ended July 31, 2006.

The net loss for fiscal year 2007 was \$8.8 million as compared to \$7.8 million in fiscal year 2006.

### **Liquidity and Capital Resources**

We have reported cumulative net losses of approximately \$28.9 million for the three most recent fiscal years ended July 31, 2008. The net losses from date of inception, August 24, 1981 to July 31, 2008, amounts to approximately \$104.4 million. As of July 31, 2008, we have working capital of approximately \$1.9 million.

We have financed our operations since inception primarily through the sale of our equity securities and convertible debentures in registered offerings and private placements. Additionally, we have raised capital through other debt financings, the sale of our state tax benefits and research products, and investment income and financing received from our CEO. As of July 31, 2008, we had approximately \$4.7 million in cash and cash equivalents and no debt. We currently believe that our cash and cash equivalents on hand at July 31, 2008 including our expected level of receipts and expenditures can support our activities into the fourth quarter of our fiscal year 2009, which assumes timely submission of the ONCONASE<sup>®</sup> NDA.

The primary use of cash over the next 12 months will be to fund our regulatory and commercial efforts for ONCONASE<sup>®</sup> and our clinical and pre-clinical research and development efforts. The most significant expenses will be incurred in relation to completing the work necessary for the planned submission of the final components of our rolling NDA submission for ONCONASE<sup>®</sup>. Additional expenses are also expected to be incurred as we continue to move our drug product candidates towards the next phase of clinical and pre-clinical development.

Our audited financial statements for the fiscal year ended July 31, 2008, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1981 and have a history of losses and negative cash flows from operating activities. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to raise additional capital from various sources such as those described above. Such capital raising opportunities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

We may seek to satisfy future funding requirements through public or private offerings of securities or with collaborative or other arrangements with corporate partners. We have retained an investment bank to pursue strategic alternatives, including strategic partnership transactions or a possible sale of the company. Additional financing or strategic transactions may not be available when needed or on terms acceptable to us, if at all. If adequate financing is not available, we may be required to delay, scale back, or eliminate certain of our research and development programs, relinquish rights to certain of our technologies, drugs or products, or license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves.

### **Off-Balance Sheet Arrangements**

We have no debt, no exposure to off-balance sheet arrangements, no special purpose entities, nor activities that include non-exchange-traded contracts accounted for at fair value as of July 31, 2008.

### **Contractual Obligations and Commercial Commitments**

Our major outstanding contractual obligations relate to our building and equipment operating leases. During the fiscal year ended July 31, 2008, we entered into an equipment capital lease which obligates us to pay \$635 per month for five years and during the fiscal year ended July 31, 2007, we entered into separate building and equipment operating leases, which obligates us to pay an average of \$25,393 per month for the building and \$1,866 per month for the equipment for ten and five years, respectively. Below is a table that presents our contractual obligations and commercial commitments as of July 31, 2008:

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Payments Due in Fiscal Year

	Total	2009	2010	2011	2012	2013	2014 and Thereafter
Building lease	\$ 3,026,130	\$ 275,445	\$ 302,036	\$ 317,446	\$ 317,446	\$ 317,446	\$ 1,496,330
Equipment lease	117,160	33,548	31,024	25,976	25,976	636	
Total contractual cash obligations	\$ 3,143,290	\$ 308,993	\$ 333,060	\$ 343,422	\$ 343,422	\$ 318,082	\$ 1,496,330

**Critical Accounting Policies**

In December 2001, the SEC requested that all registrants discuss their most "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of the company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. The accounting policies set forth below have been considered critical because changes to certain judgments, estimates and assumptions could significantly affect our financial statements.

*Use of Estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reporting period. Actual results could differ from those estimates.

*Cash Equivalents*

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The carrying value of these investments approximates their fair market value due to their short maturity and liquidity.

*Property and Equipment*

Property and equipment is recorded at cost and is depreciated using the straight-line method over the estimated useful lives of the respective assets. Maintenance and repairs that do not extend the life of assets are charged to expense when incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in operations for the period in which the transaction takes place.

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted cash flows expected to be generated by the asset. If the carrying amount exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount exceeds the fair value of the asset.

*Income Taxes*

Income taxes are accounted for under the provisions of SFAS No. 109, "Accounting for Income Taxes". Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be



recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Management provides valuation allowances against the deferred tax assets for amounts which are not considered "more likely than not" to be realized.

#### *Revenue Recognition*

We recognize revenue in accordance with Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition," issued by the staff of the SEC. Under SAB No. 104, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and/or services have been rendered, the sales price is fixed or determinable, and collectibility is reasonably assured.

We enter into marketing and distribution agreements, which contain multiple deliverables. Under the provisions of Emerging Issues Task Force ("EITF") No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables," we evaluate whether these deliverables constitute separate units of accounting to which total arrangement consideration is allocated. A deliverable qualifies as a separate unit of accounting when the item delivered to the customer has standalone value, there is objective and reliable evidence of fair value of items that have not been delivered to the customer, and, if there is a general right of return for the items delivered to the customer, delivery or performance of the undelivered items is considered probable and substantially in the control of the company. Arrangement consideration is allocated to units of accounting on a relative fair-value basis or the residual method if the company is unable to determine the fair value of all deliverables in the arrangement. Consideration allocated to a unit of accounting is limited to the amount that is not contingent upon future performance by the company. Upon determination of separate units of accounting and allocated consideration, the general criteria for revenue recognition are applied to each unit of accounting.

#### *Research and Development*

Research and development costs are expensed as incurred. These costs include, among other things, consulting fees and costs related to the conduct of human clinical trials. We also allocate indirect costs, consisting primarily of operational costs for administering research and development activities, to research and development expenses.

#### *Share-Based Compensation*

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R) (revised 2004), "Share-Based Payment" ("SFAS 123(R)"), which amends SFAS 123. The new standard requires all share-based payments, including stock option grants to employees, to be recognized as an operating expense in the statement of operations. The expense is recognized over the requisite service period based on fair values measured on the date of grant. We adopted SFAS 123(R) effective August 1, 2005 using the modified prospective method and, accordingly, prior period amounts have not been restated. Under the modified prospective method, the fair value of all new stock options issued after July 31, 2005 and the unamortized fair value of unvested outstanding stock options at August 1, 2005 are recognized as expense as services are rendered.

#### *Leases*

With respect to our operating leases, we apply the provisions of FASB SFAS No. 13 "Accounting for Leases" ("SFAS 13") and FASB Technical Bulletin ("FTB") 88-1 "Issues Relating to Accounting for Leases", recognizing rent expense on a straight-line basis over the lease term due to escalating lease payments and landlord incentives.

#### *Contingencies*

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated. Recoveries from other parties are recorded when realized.

*Fair Value of Financial Instruments*

Financial instruments consist of cash, cash equivalents, accounts receivable, and accounts payable. The carrying value of these financial instruments is a reasonable estimate of fair value.

**Recently Issued Accounting Pronouncements**

In May 2008, the FASB issued SFAS No. 162 "Hierarchy of GAAP". This statement identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP in the United States. This statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity with GAAP". We will adopt this pronouncement once it becomes effective and are currently evaluating the impact it will have on our reported financial results, if any.

In February 2008, the FASB issued FASB Staff Position ("FSP") SFAS No. 157-1, "Application of FASB Statement No. 157 to SFAS Statement No. 13 and Other Accounting Pronouncements that Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13", ("FSP 157-1"). FSP 157-1 amends SFAS 157 to exclude SFAS 13 and other accounting pronouncements that address fair value measurements for purposes of lease classifications under SFAS 13. However, this scope exception does not apply to assets acquired and liabilities assumed in a business combination that are required to be measured at fair value under FASB Statement No. 141, "Business Combinations", or SFAS 141(R), regardless of whether those assets and liabilities are related to leases. FSP 157-1 is effective upon initial adoption of SFAS 157. We are required to adopt SFAS 157 as of August 1, 2008, and are currently evaluating the impact that the adoption of FSP 157-1 will have, if any, on our reported financial results.

In February 2008, the FASB issued FSP SFAS No. 157-2, "Effective Date of FASB SFAS No. 157", ("FSP 157-2"). FSP 157-2 delays the effective date of SFAS 157 for non financial assets and non financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis at least annually. This delay is intended to allow the FASB and constituents additional time to consider the effect of various implementation issues that have arisen from the application of SFAS 157. We have reviewed FSP 157-2 and will wait to hear for additional positions taken by the FASB before proceeding further.

In December 2007, the FASB issued SFAS No. 141(R) "Business Combinations" ("SFAS 141(R)"). This Statement establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141(R) also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. The guidance will become effective as of the beginning of a company's fiscal year beginning after December 15, 2008. We believe that this new pronouncement will not have a material impact on our financial statements in future periods.

On December 21, 2007, the SEC issued SAB No. 110 ("SAB 110") to permit entities, under certain circumstances to continue to use the "simplified" method, in developing estimates of the expected term of "plain-vanilla" share options in accordance with Statement No. 123R, "Share-Based Payment". SAB 110 amended SAB 107 to permit the use of the "simplified" method beyond December 31, 2007. The adoption of SAB 110 did not have a material impact on our financial statements.

In June 2007, the FASB issued EITF Issue No. 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities", ("EITF 07-03"). EITF 07-03 addresses the diversity that exists with respect to the accounting for the nonrefundable portion of a payment made by a research and development entity for future research and development activities. The EITF concluded that an entity

must defer and capitalize nonrefundable advance payments made for research and development activities and expense these amounts as the related goods are delivered or the related services are performed. EITF 07-03 will be effective for interim or annual reporting periods in fiscal years beginning after December 15, 2007. We are currently evaluating the impact that the adoption of EITF 07-03 will have, if any, on our financial statements.

In February 2007, the FASB issued SFAS No. 159 "The Fair Value Option for Financial Assets and Financial Liabilities" (SFAS 159). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 will be effective for our company on August 1, 2008, and are currently evaluating the impact that the adoption of SFAS 159 will have, if any, on our financial statements.

In December 2006, the FASB issued FSP EITF Issue No. 00-19-2 "Accounting for Registration Payment Arrangements" ("FSP 00-19-2") which addresses an issuer's accounting for registration payment arrangements. FSP 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with SFAS No.5 "Accounting for Contingencies." The guidance in FSP 00-19-2 amends SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," and No.150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity", and FASB Interpretation No.45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" to include scope exceptions for registration payment arrangements. FSP 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of FSP 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP 00-19-2, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We have analyzed the provisions of FSP 00-19-2 and determined that it will not have an effect on our financial statements.

In September 2006, the FASB issued SFAS No. 157 "Fair Value Measurements" (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 does not require new fair value measurements. We are required to adopt SFAS 157 as of August 1, 2008, and are currently evaluating the impact that the adoption of SFAS 157 will have, if any, on our reported financial results.

In September 2006, the SEC issued SAB No. 108 "Quantifying Misstatements in Financial Statements" (SAB 108). Under SAB 108, we are required to use a combination of the two previously-acceptable approaches for quantifying misstatements, and to adjust our financial statements if this combined approach results in a conclusion that an error is material. We adopted SAB 108 and determined that it did not have a material impact on our reported financial results.

In June 2006, the FASB issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109" (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements in accordance with Statement No. 109, "Accounting for Income Taxes." FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a company's tax return. On August 1, 2007, we adopted FIN 48 and determined that it did not have a material impact on our reported financial results.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

As of July 31, 2008, we were exposed to market risks, primarily changes in U.S. interest rates. As of July 31, 2008, we held total cash and cash equivalents of approximately \$4.7 million. All cash equivalents have a maturity less than 90 days. Declines in interest rates over time would reduce our interest income from our investments. Based upon our balance of cash and cash equivalents as of July 31, 2008, a decrease in interest rates of 1.0% would cause a corresponding decrease in our annual interest income of approximately \$47,000.



**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The response to this Item is submitted as a separate section of this report commencing on Page F-1.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

There have been no changes in or disagreements with accountants on accounting or financial disclosures in the past two fiscal years.

On December 1, 1993, certain stockholders of Armus Harrison & Co., or AHC, terminated their association with AHC, or the AHC termination, and AHC ceased performing accounting and auditing services, except for limited accounting services to be performed on our behalf. In June 1996, AHC dissolved and ceased all operations. The report of J.H. Cohn LLP with respect to our financial statements from inception to July 31, 2008 is based on the report of KPMG LLP from August 1, 1992 to July 31, 2002 and of AHC for the period from inception to July 31, 1992, although AHC has not consented to the use of such report herein and will not be available to perform any subsequent review procedures with respect to such report. Accordingly, investors will be barred from asserting claims against AHC under Section 18 of the Exchange Act on the basis of the use of such report in any Form 10-K into which such report is incorporated by reference. In addition, in the event any persons seek to assert a claim against AHC for false or misleading financial statements and disclosures in documents previously filed by us, such claim will be adversely affected and possibly barred. Furthermore, as a result of the lack of a consent from AHC to the use of its audit report herein, or to its incorporation by reference into a Form 10-K, our officers and directors will be unable to rely on the authority of AHC as experts in auditing and accounting in the event any claim is brought against such persons under Section 18 of the Exchange Act based on alleged false and misleading Financial Statements and disclosures attributable to AHC. The discussion regarding certain effects of the AHC termination is not meant and should not be construed in any way as legal advice to any party and any potential purchaser should consult with his, her or its own counsel with respect to the effect of the AHC termination on a potential investment in our common stock or otherwise.

**ITEM 9A. CONTROLS AND PROCEDURES.**

**EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES**

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act are controls and other procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our CEO, and CFO, as appropriate, to allow timely decisions regarding required disclosure.

It should be noted that there are inherent limitations to the effectiveness of any system of disclosure controls and procedures. These limitations include the possibility of human error, the circumvention or overriding of the controls and procedures and reasonable resource constrains. In addition, the design of any system of control is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. Accordingly, our controls and procedures, by their nature, only provide reasonable assurance regarding achieving the management's control objectives.

As of the end of the period covered by this annual report, we conducted an evaluation, under the supervision and with the participation of our management, including our CEO and CFO, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon the foregoing evaluation, our CEO and CFO have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and was accumulated and

communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding the required disclosures.

#### MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)). Internal control over financial reporting is a process designed by, or under the supervision of our principal executive and principal financial officers, or persons performing similar functions, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with GAAP.

Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with the authorizations of our management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our internal control over financial reporting is designed to provide reasonable, but not absolute, assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. There are inherent limitations to the effectiveness of any system of internal control over financial reporting. These limitations include the possibility of human error, the circumvention or overriding of the system and reasonable resource constraints. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of our annual financial statements, management, including our CEO and CFO, has undertaken an assessment of the effectiveness of our internal control over financial reporting as of July 31, 2008, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal controls over financial reporting were effective as of July 31, 2008, in that they ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (2) accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

J.H. Cohn LLP, the independent registered public accounting firm that audited our financial statements included elsewhere in our annual report on Form 10-K, has issued their report on the effectiveness of internal control over financial reporting, a copy of which is included below.

#### CHANGES IN INTERNAL CONTROLS

There has been no change in the Company's internal control over financial reporting during the quarter ended July 31, 2008 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting subsequent to the date of the evaluation referred to above.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Alfacell Corporation

We have audited Alfacell Corporation's internal control over financial reporting as of July 31, 2008, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Alfacell Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists and testing and evaluating the design and operating effectiveness of internal control, based on the assessed risk. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Alfacell Corporation maintained, in all material respects, effective internal control over financial reporting as of July 31, 2008, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets as of July 31, 2008 and 2007 and related statements of operations, stockholders' equity (deficiency) and cash flows for each of the years in the three-year period ended July 31, 2008 and for the period from August 24, 1981 (date of inception) to July 31, 2008 of Alfacell Corporation and our report dated October 13, 2008 expressed an unqualified opinion on those financial statements which included an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ J.H. Cohn LLP  
Roseland, New Jersey  
October 13, 2008

**ITEM 9B. OTHER INFORMATION.**

None.

**PART III**

The information required by Item 10 ☐ Directors, Executive Officers and Corporate Governance; Item 11 ☐ Executive Compensation; Item 12 ☐ Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters; Item 13 ☐ Certain Relationships and Related Transactions and Director Independence and Item 14 ☐ Principal Accounting Fees and Services is incorporated into Part III of this annual report on Form 10-K by reference to the Proxy Statement for the 2009 Annual Meeting of Stockholders, which is to be filed within 120 days of the Company's fiscal year ended July 31, 2008.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

In addition to the materials to be incorporated into this Item 12 by reference to the Proxy Statement for the 2009 Annual Meeting of Stockholders, the following table provides additional information on the Company's equity based compensation plans as of July 31, 2008:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	6,353,067	\$2.69	3,926,983

**PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.**

(a)(1) and (2) The response to these portions of Item 15 is submitted as a separate section of this report commencing on page F-1.

(a)(3) Exhibits (numbered in accordance with Item 601 of Regulation S-K).

Exhibit No.	Item Title	Filed Herewith or Incorporated by Reference
3.1	Certificate of Incorporation, dated June 12, 1981 (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.2	Amendment to Certificate of Incorporation, dated February 18, 1994 (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*

- 3.3 Amendment to Certificate of Incorporation, dated December 26, 1997 (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004) \*

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Exhibit No.	Item Title	Herewith or Incorporated by Reference
3.4	Amendment to Certificate of Incorporation, dated January 14, 2004 (incorporated by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.5	Certificate of Designation for Series A Preferred Stock, dated September 2, 2003 (incorporated by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.6	Certificate of Elimination of Series A Preferred Stock, dated February 3, 2004 (incorporated by reference to Exhibit 3.6 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.7	By-Laws (incorporated by reference to Exhibit 3.4 to Registration Statement on Form S-1, File No. 333-111101, filed on December 11, 2003)	*
10.1	1993 Stock Option Plan and Form of Option Agreement (incorporated by reference to Exhibit 10.10 to Registration Statement on Form SB-2, File No. 33-76950, filed on August 1, 1994)	*
10.2	1997 Stock Option Plan (incorporated by reference to Exhibit 10.2 to Registration Statement on Form S-1, File No. 333-111101, filed on December 11, 2003)	*
10.2.1	Amendment No. 1 to 1997 Stock Option Plan (incorporated by reference to Exhibit 10.2.1 to the Company's Quarterly Report on Form 10-Q, filed on June 9, 2008)	*
10.3	2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
10.3.1	Amendment No. 1 to 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3.1 to the Company's Quarterly Report on Form 10-Q, filed on June 9, 2008)	*
10.4	Form of Subscription Agreement and Warrant Agreement used in Private Placements completed in February 2000 (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K, filed on October 30, 2000)	*
10.5	Form of Subscription Agreement and Warrant Agreement used in the August and September 2000 Private Placements (incorporated by reference to Exhibit 10.24 to the Company's Quarterly Report on Form 10-Q, filed on December 15, 2000)	*
10.6	Form of Subscription Agreement and Warrant Agreement used in the April 2001 Private Placements (incorporated by reference to Exhibit 10.23 to Registration Statement on Form S-1, File No. 333-38136, filed on July 30, 2001)	*
10.7	Form of Convertible Note entered into in April 2001 (incorporated by reference to Exhibit 10.24 to Registration Statement on Form S-1, File No. 333-38136, filed on July 30, 2001)	*
10.8	Form of Subscription Agreement and Warrant Agreement used in the July 2001 Private Placements (incorporated by reference to Exhibit 10.25 to Registration Statement on Form S-1, File No. 333-38136, filed on July 30, 2001)	*

- 10.9 Form of Subscription Agreement and Warrant Agreement used in the August and October 2001 private placement (incorporated by reference to Exhibit 10.26 to Registration Statement on Form S-1, File No. 333-38136, filed on December 14, 2001) \*

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Exhibit No.	Item Title	Filed Herewith or Incorporated by Reference
10.10	Form of Subscription Agreement and Warrant Agreement used in the September 2001, November 2001 and January 2002 private placements (incorporated by reference to Exhibit 10.27 to Registration Statement on Form S-1, File No. 333-38136, filed on February 21, 2002)	*
10.11	Warrant issued in the February 2002 private placement (incorporated by reference to Exhibit 10.28 to Registration Statement on Form S-1, File No. 333-38136, filed on February 21, 2002)	*
10.12	Form of Subscription Agreement and Warrant Agreement used in the March 2002, April 2002 and May 2002 private placements (incorporated by reference to Exhibit 10.29 to Registration Statement on Form S-1, File No. 333-89166, filed on May 24, 2002)	*
10.13	Form of Subscription Agreement and Warrant Agreement used in the June 2002 and October 2002 private placements (incorporated by reference to Exhibit 10.30 to the Post-Effective Amendment to Registration Statement on Form S-1, File No. 333-38136, filed on March 3, 2003)	*
10.14	Form of Note Payable and Warrant Certificate entered into April, June, July, September, November and December 2002 (incorporated by reference to Exhibit 10.31 to the Post-Effective Amendment to Registration Statement on Form S-1, File No. 333-38136, filed on March 3, 2003)	*
10.15	Form of Note Payable and Warrant Certificate entered into November 2001, January, March and May 2003 (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K, filed on October 29, 2003)	*
10.16	Form of Subscription Agreement and Warrant Agreement used in the February 2003 and April through August 2003 private placements (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed on October 29, 2003)	*
10.17	Form of Amended Notes Payable which amends the November 2001, April 2002, June 2002, July 2002, September 2002, November 2002 December 2002, January 2003, March 2003 and May 2003 notes payable (incorporated by reference to Exhibit 10.27 to The Company's Annual Report on Form 10-K, filed on October 29, 2003)	*
10.18	Securities Purchase Agreement and Warrant Agreement used in September 2003 private placement and Form of Warrant Certificate issued on January 16, 2004 and January 29, 2004 to SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K, filed on October 29, 2003)	*
10.19	Registration Rights Agreement used in September 2003 private placement with SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K, filed on October 29, 2003)	*
10.20	Form of Securities Purchase Agreement used in May 2004 private placement with Knoll Capital Fund II, Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.3 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)	*



10.21 Form of Registration Rights Agreement used in May 2004 private placement with Knoll Capital Fund II, Europa International, Inc. and Clifford and Phyllis Kalista \*

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Exhibit No.	Item Title	Filed Herewith or Incorporated by Reference
	JTWROS (incorporated by reference to Exhibit 4.4 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)	*
10.22	Form of Warrant Certificate issued on May 11, 2004 to Knoll Capital Fund II, Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.5 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)	*
10.23	Form of Stock Option Agreement issued to the Company's Board of Directors under the Company's 1997 Stock Option Plan (incorporated by reference to Exhibit 10.23 to the Company's quarterly report on Form 10-Q filed on June 9, 2005)	*
10.24	Form of Stock Option Agreement issued to the Company's Executive Officers under the Company's 1997 Stock Option Plan (incorporated by reference to Exhibit 10.24 to the Company's quarterly report on Form 10-Q filed on June 9, 2005)	*
10.25	Separation Agreement and General Release with Andrew Savadelis dated May 26, 2005 (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K, filed on October 15, 2005)	*
10.26	Securities Purchase Agreement used in May 2005 private placement with Jeffrey D'Onofrio dated May 1, 2006	*
10.27	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	*
10.28	Registration Rights Agreement dated July 17, 2006 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	*
10.29	Agreement to Amend Knoll Warrant dated July 17, 2006 (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	*
10.30	Form of Amended Knoll Warrant (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	*
10.31	Agreement to Amend SF Capital Warrant dated July 17, 2006 (incorporated by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	*
10.32	Form of Amended Warrant for SF Capital Partners, Ltd. (incorporated by reference to Exhibit 4.6 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	*
10.33	Securities Purchase Agreement dated July 17, 2006 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	*
10.34	Form of Stock Option Agreement for Executive Officers under the Company's 2004 Stock Incentive Plan	*
10.35	Offer letter agreement with Lawrence A. Kenyon dated January 16, 2007	*

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- |       |  |   |
|-------|--|---|
| 10.36 | Summary of the Company's Non-Employee Director Compensation Policy   | * |
| 10.37 | Royalty Agreement between the Company and Kuslima Shogen, dated July 24, 1991 and Amendment to Royalty Agreement, dated April 16, 2001 | * |
| 10.38 | Office Lease Agreement, dated March 14, 2007, between I&G Garden State, LLC and the Company  | * |

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Exhibit No.	Item Title	Filed Herewith or Incorporated by Reference
10.39	Form of Distribution and Marketing Agreement, dated July 25, 2007, between the Company and USP Pharma Spolka Z.O.O.	*^
10.40	Form of Securities Purchase Agreement, dated July 25, 2007, between the Company and Unilab LP.	*
10.41	License Agreement, dated January 14, 2008, between the Company and Par Pharmaceutical, Inc. (incorporated by reference to Exhibit 10.41 to the Company's Quarterly Report on Form 10-Q, filed on March 7, 2008)	*^
10.42	Supply Agreement, dated January 14, 2008, between the Company and Par Pharmaceutical, Inc. (incorporated by reference to Exhibit 10.42 to the Company's Quarterly Report on Form 10-Q, filed on March 7, 2008)	*
10.43	Purchase and Supply Agreement, dated January 14, 2008, between the Company and Scientific Protein Laboratories LLC (incorporated by reference to Exhibit 10.43 to the Company's Quarterly Report on Form 10-Q, filed on March 7, 2008)	*
10.44	Amendment No. 1 to 1993 Stock Option Plan (incorporated by reference to Exhibit 10.44 to the Company's Quarterly Report on Form 10-Q, filed on June 9, 2008)	*
10.45	Retirement Agreement, dated April 25, 2008, between the Company and Kuslima Shogen (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed on April 28, 2008)	*~
21.1	Subsidiaries of Registrant	*
23.1	Consent of J.H. Cohn LLP	+
23.2	Consent of KPMG LLP	+
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	+
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	+
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	+
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	+
*	Previously filed; incorporated herein by reference	
+	Filed herewith	

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Portions of this exhibit have been redacted and filed separately with the SEC pursuant to a  
^ confidential

treatment request.

~ Management contract or compensatory plan or arrangement.

**SIGNATURE**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ALFACELL CORPORATION**

Dated: October 14, 2008

By: /s/ KUSLIMA SHOGEN  
Kuslima Shogen, Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Dated: October 14, 2008

/s/ KUSLIMA SHOGEN  
Kuslima Shogen, Chief Executive Officer (Principal Executive Officer)

Dated: October 14, 2008

/s/ LAWRENCE A. KENYON  
Lawrence A. Kenyon, President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Dated: October 14, 2008

/s/ DAVID SIDRANSKY  
David Sidransky, M.D., Chairman of the Board

Dated: October 14, 2008

/s/ JOHN P. BRANCACCIO  
John P. Brancaccio, Director

Dated:

Stephen K. Carter, M.D., Director

Dated: October 14, 2008

/s/ DONALD R. CONKLIN  
Donald R. Conklin, Director

Dated: October 14, 2008

/s/ JAMES J. LOUGHLIN  
James J. Loughlin, Director

Dated: October 14, 2008

/s/ PAUL M. WEISS  
Paul M. Weiss, Ph.D., Director

Alfacell Corporation

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
Alfacell Corporation

We have audited the accompanying balance sheets of Alfacell Corporation (a development stage company) as of July 31, 2008 and 2007, and the related statements of operations, stockholders' equity (deficiency), and cash flows for each of the years in the three-year period ended July 31, 2008 and for the period from August 24, 1981 (date of inception) to July 31, 2008. 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 of Alfacell Corporation for the period from August 24, 1981 to July 31, 2002 were audited by other auditors whose reports dated November 4, 2002 and December 9, 1992, except for Note 18 which is as of July 19, 1993 and Note 3 which is as of October 28, 1993, expressed unqualified opinions on those statements with explanatory paragraphs relating to the Company's ability to continue as a going concern.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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, and 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 and, for the effect on the period from August 24, 1981 (date of inception) to July 31, 2008 of the amounts for the period from August 24, 1981 (date of inception) to July 31, 2002, on the reports of other auditors, the financial statements referred to above present fairly, in all material respects, the financial position of Alfacell Corporation as of July 31, 2008 and 2007, and the results of its operations and its cash flows for each of the years in the three-year period ended July 31, 2008 and for the period from August 24, 1981 (date of inception) to July 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed on Note 2 to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have also audited, in accordance with the Standards of the Public Company Accounting Oversight Board (United States), Alfacell Corporation's internal control over financial reporting as of July 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organization of the Treadway Commission (COSO) and our report dated October 13, 2008 expressed an unqualified opinion.

/s/ J.H. Cohn LLP  
Roseland, New Jersey  
October 13, 2008



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Report Of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors  
Alfacell Corporation:

We have audited the statements of operations, stockholders' equity (deficiency), and cash flows for the period from August 24, 1981 (date of inception) to July 31, 2002 (not presented herein) of Alfacell Corporation (a development stage company). 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 audit. The financial statements of Alfacell Corporation for the period from August 24, 1981 to July 31, 1992 were audited by other auditors who have ceased operations and whose report dated December 9, 1992, except as to note 18 which is July 19, 1993 and note 3 which is October 28, 1993, expressed an unqualified opinion on those statements with an explanatory paragraph regarding the Company's ability to continue as a going concern.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (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 audit provides a reasonable basis for our opinion.

In our opinion, based on our audit and, for the effect on the period from August 24, 1981 to July 31, 2002 of the amounts for the period from August 24, 1981 to July 31, 1992, on the report of other auditors who have ceased operations, the financial statements referred to above present fairly, in all material respects, the results of operations and cash flows for the period from August 24, 1981 to July 31, 2002 (not presented herein) of Alfacell Corporation in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficit and has limited liquid resources which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Short Hills, New Jersey  
November 4, 2002

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On December 1, 1993, certain shareholders of Armus Harrison & Co. (["AHC"]) terminated their association with AHC (the ["AHC termination"]), and AHC ceased performing accounting and auditing services, except for limited accounting services to be performed on behalf of the Company. In June 1996, AHC dissolved and ceased all operations. The report of AHC with respect to the financial statements of the Company from inception to July 31, 1992 is included herein, although AHC has not consented to the use of such report herein and will not be available to perform any subsequent review procedures with respect to such report. Accordingly, investors will be barred from asserting claims against AHC under Section 11 of the Securities Act of 1933, as amended (the ["Securities Act"]) on the basis of the use of such report in any registration statement of the Company into which such report is incorporated by reference. In addition, in the event any persons seek to assert a claim against AHC for false or misleading financial statements and disclosures in documents previously filed by the Company, such claim will be adversely affected and possibly barred. Furthermore, as a result of the lack of a consent from AHC to the use of its audit report herein, or, to its incorporation by reference into a registration statement or other filings, the officers and directors of the Company will be unable to rely on the authority of AHC as experts in auditing and accounting in the event any claim is brought against such persons under Section 11 of the Securities Act based on alleged false and misleading financial statements and disclosures attributable to AHC. The discussion regarding certain effects of the AHC termination is not meant and should not be construed in any way as legal advice to any party and any potential purchaser should consult with his, her or its own counsel with respect to the effect of the AHC termination on a potential investment in the Common Stock of the Company or otherwise.

Independent Auditors' Report

Board of Directors  
Alfacell Corporation  
Bloomfield, New Jersey

We have audited the balance sheets of Alfacell Corporation (a Development Stage Company) as of July 31, 1992 and 1991, as restated, and the related statements of operations, stockholders' deficiency, and cash flows for the three years ended July 31, 1992, as restated, and for the period from inception August 24, 1981 to July 31, 1992, as restated. In connection with our audit of the 1992 and 1991 financial statements, we have also audited the 1992, 1991 and 1990 financial statement schedules as listed in the accompanying index. These financial statements and financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with generally accepted auditing standards. 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 audit provides a reasonable basis for our opinion.

In our opinion the financial statements referred to above present fairly in all material respects, the financial position of Alfacell Corporation as of July 31, 1992 and 1991, as restated, and for the three years ended July 31, 1992, as restated, and for the period from inception August 24, 1981 to July 31, 1992, as restated, and the results of operations and cash flows for the years then ended in conformity with generally accepted accounting principles.

The accompanying financial statements have been prepared on a going concern basis which contemplates the realization of assets and the satisfaction of liability in the normal course of business. As shown in the statement of operations, the Company has incurred substantial losses in each year since its inception. In addition, the Company is a development stage company and its principal operation for production of income has not commenced. The Company's working capital has been reduced considerably by operating losses, and has a deficit net worth. These factors, among others, as discussed in Note 2 to the Notes of Financial Statements, indicates the uncertainties about the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and the amount or classification of liabilities that might be necessary should the Company be unable to continue its existence.

/s/ Armus, Harrison & Co.

Armus, Harrison & Co.

Mountainside, New Jersey

December 9, 1992

Except as to Note 18 which

is July 19, 1993 and Note 3

which is October 28, 1993

ALFACELL CORPORATION  
(A Development Stage Company)

Balance Sheets

July 31, 2008 and 2007

	2008	2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,661,656	\$ 6,968,172
Prepaid expenses	165,259	150,207
Total current assets	4,826,915	7,118,379
Property and equipment, net of accumulated depreciation and amortization of \$342,031 in 2008 and \$290,581 in 2007	143,121	136,723
Loan receivable, related party	□	180,397
Other assets	350,000	385,000
Total assets	\$ 5,320,036	\$ 7,820,499
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)</b>		
Current liabilities:		
Accounts payable	\$ 1,252,478	\$ 432,786
Accrued clinical trial expenses	882,386	898,134
Accrued professional service fees	511,779	322,051
Accrued compensation expense	227,803	143,369
Current portion of obligations under capital lease	3,453	□
Other accrued expenses	4,135	33,560
Total current liabilities	2,882,034	1,829,900
Other liabilities:		
Obligations under capital lease, net of current portion	16,940	□
Accrued retirement benefits	510,000	□
Deferred rent	267,668	112,119
Deferred revenue	5,200,000	100,000
Total other liabilities	5,994,608	212,119
Total liabilities	8,876,642	2,042,019
Stockholders' equity (deficiency):		
Preferred stock, \$.001 par value. Authorized and unissued, 1,000,000 shares at July 31, 2008 and 2007	□	□
Common stock \$.001 par value. Authorized 100,000,000 shares at July 31, 2008 and 2007; issued and outstanding 47,276,880 shares and 46,280,880 shares at July 31, 2008 and 2007, respectively	47,277	46,281

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Capital in excess of par value	100,788,973	97,803,954
Deficit accumulated during development stage	(104,392,856)	(92,071,755)
Total stockholders' equity (deficiency)	(3,556,606)	5,778,480
Total liabilities and stockholders' equity (deficiency)	\$ 5,320,036	\$ 7,820,499

See accompanying notes to financial statements.

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ALFACELL CORPORATION  
(A Development Stage Company)

Statements of Operations

Years ended July 31, 2008, 2007 and 2006  
and the Period from August 24, 1981  
(Date of Inception) to July 31, 2008

	2008	2007	2006	August 24, 1981 (date of inception) to July 31, 2008
Sales	\$ □	□	\$ □	\$ 553,489
<b>Operating expenses:</b>				
Cost of sales		□	□	336,495
Research and development	8,503,110	5,543,175	5,229,996	69,313,532
General and administrative	5,797,355	4,092,990	3,004,835	38,532,768
<b>Total operating expenses</b>	<b>14,300,465</b>	<b>9,636,165</b>	<b>8,234,831</b>	<b>108,182,795</b>
Loss from operations	(14,300,465)	(9,636,165)	(8,234,831)	(107,629,306)
Investment income	227,591	370,650	107,386	2,276,448
Other income	□	□	□	99,939
<b>Interest expense:</b>				
Related parties		□	□	(1,147,547)
Others	(3,607)	(96)	(112)	(2,877,779)
Loss before state tax benefit	(14,076,481)	(9,265,611)	(8,127,557)	(109,278,245)
State tax benefit	1,755,380	510,467	317,382	4,885,389
Net loss	\$ (12,321,101)	\$ (8,755,144)	\$ (7,810,175)	\$ (104,392,856)
Loss per basic and diluted common share	\$ (0.26)	\$ (0.19)	\$ (0.21)	
<b>Weighted average number of shares outstanding □ basic and diluted</b>				
	46,919,000	44,958,000	37,308,000	

See accompanying notes to financial statements.

ALFACELL CORPORATION  
(A Development Stage Company)

Statement of Stockholders' Equity (Deficiency)

Period from August 24, 1981  
(Date of Inception) to July 31, 2008

	Common Stock		Capital In
	Number of		Excess of
	Shares	Amount	par Value
Issuance of shares to officers and stockholders for equipment, research and development, and expense reimbursement	712,500	\$ 713	\$ 212,987
Issuance of shares for organizational legal service	50,000	50	4,950
Sale of shares for cash, net	82,143	82	108,418
Adjustment for 3 for 2 stock split declared September 8, 1982	422,321	422	(422)
Net loss	□	□	□
Balance at July 31, 1982	1,266,964	1,267	325,933
Issuance of shares for equipment	15,000	15	13,985
Sale of shares to private investors	44,196	44	41,206
Sale of shares in public offering, net	660,000	660	1,307,786
Issuance of shares under stock grant program	20,000	20	109,980
Exercise of warrants, net	1,165	1	3,494
Net loss	□	□	□
Balance at July 31, 1983	2,007,325	2,007	1,802,384
Exercise of warrants, net	287,566	287	933,696
Issuance of shares under stock grant program	19,750	20	101,199
Issuance of shares under stock bonus plan for directors and consultants	130,250	131	385,786
Net loss	□	□	□
Balance at July 31, 1984	2,444,891	2,445	3,223,065
Issuance of shares under stock grant program	48,332	48	478,057
Issuance of shares under stock bonus plan for directors and consultants	99,163	99	879,379
Shares canceled	(42,500)	(42)	(105,783)
Exercise of warrants, net	334,957	335	1,971,012
Net loss	□	□	□
Balance at July 31, 1985	2,884,843	2,885	6,445,730
Issuance of shares under stock grant program	11,250	12	107,020
Issuance of shares under stock bonus plan for directors and consultants	15,394	15	215,385
Exercise of warrants, net	21,565	21	80,977
Net loss	□	□	□
Balance at July 31, 1986 (carried forward)	2,933,052	2,933	6,849,112





ALFACELL CORPORATION  
(A Development Stage Company)

## Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock		Capital In Excess of par Value	Cor Stoc Iss
	Number of			
	Shares	Amount		
Balance at July 31, 1986 (brought forward)	2,933,052	\$ 2,933	\$ 6,849,112	
Exercise of warrants, net	14,745	15	147,435	
Issuance of shares under stock bonus plan for directors and consultants	5,000	5	74,995	
Issuance of shares for services	250,000	250	499,750	
Sale of shares to private investors, net	5,000	5	24,995	
Net loss	□	□	□	
Balance at July 31, 1987	3,207,797	3,208	7,596,287	
Issuance of shares for legal and consulting services	206,429	207	724,280	
Issuance of shares under employment incentive program	700,000	700	2,449,300	
Issuance of shares under stock grant program	19,000	19	66,481	
Exercise of options, net	170,000	170	509,830	
Issuance of shares for litigation settlement	12,500	12	31,125	
Exercise of warrants, net	63,925	64	451,341	
Sale of shares to private investors	61,073	61	178,072	
Amortization of deferred compensation, restricted stock	□	□	□	
Net loss	□	□	□	
Balance at July 31, 1988	4,440,724	4,441	12,006,716	
Sale of shares for litigation settlement	135,000	135	1,074,703	
Conversion of debentures, net	133,333	133	399,867	
Sale of shares to private investors	105,840	106	419,894	
Exercise of options, net	1,000	1	3,499	
Issuance of shares under employment agreement	750,000	750	3,749,250	
Issuance of shares under the 1989 Stock Plan	30,000	30	149,970	
Amortization of deferred compensation, restricted stock	□	□	□	
Net loss	□	□	□	
Balance at July 31, 1989	5,595,897	5,596	17,803,899	
Issuance of shares for legal and consulting services	52,463	52	258,725	
Issuance of shares under the 1989 Stock Plan	56,000	56	335,944	
Sale of shares for litigation settlement	50,000	50	351,067	
Exercise of options at, net	105,989	106	345,856	

ALFACELL CORPORATION  
(A Development Stage Company)

## Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock			Capital In Excess of par Value	Common Stock to be Issued	Defi Accum Dur Develo Sta
	Number of		Amount			
	Shares					
Sale of shares to private investors	89,480	\$ 90	\$ 354,990	□	\$	
Issuance of shares under employment agreement	750,000	750	3,749,250	□		
Conversion of debentures, net	100,000	100	499,900	□		
Amortization of deferred compensation, restricted stock	□	□		□		
Net loss	□	□		□	(4,8	
Balance at July 31, 1990	6,799,829	6,800	23,699,631	□	(20,8	
Exercise of options, net	16,720	16	108,664	□		
Issuance of shares for legal consulting services	87,000	87	358,627	□		
Issuance of shares under the 1989 Stock Plan	119,000	119	475,881	□		
Amortization of deferred compensation, restricted stock	□	□		□		
Net loss	□	□		□	(5,2	
Balance at July 31, 1991	7,022,549	7,022	24,642,803	□	(26,0	
Exercise of options at, net	1,000	1	3,499	□		
Sale of shares to private investors	70,731	71	219,829	□		
Conversion of debentures, net	94,000	94	469,906	□		
Issuance of shares for services	45,734	46	156,944	□		
Issuance of shares under the 1989 Stock Plan	104,000	104	285,896	□		
Amortization of deferred compensation, restricted stock	□	□		□		
Net loss	□	□		□	(4,7	
Balance at July 31, 1992	7,338,014	7,338	25,778,877	□	(30,8	
Sale of shares to private investors	352,667	353	735,147	□		
Issuance of shares for legal services	49,600	50	132,180	□		
Issuance of shares for services	5,000	5	9,995	□		
Issuance of shares under the 1989 Stock Plan	117,000	117	233,883	□		
Amortization of deferred compensation, restricted stock	□	□		□		
Net loss	□	□		□	(2,3	
Balance at July 31, 1993	7,862,281	7,863	26,890,082	□	(33,2	
Conversion of debentures, net	425,400	425	1,701,575	□		
Sale of shares to private investors, net	743,000	743	1,710,048	□		
Conversion of short-term borrowings	72,800	73	181,927	□		
Issuance of shares for services	16,200	16	43,334	□		

ALFACELL CORPORATION  
(A Development Stage Company)

## Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock			Capital In Excess of par Value	Common Stock to be Issued	Deficit Accumulated During Development Stage
	Number of	Amount	Shares			
	Shares					
Issuance of shares under the 1989 Stock Plan, for services	5,000	\$ 5	\$ 14,995	0	\$	
Issuance of options to related parties upon conversion of accrued interest, payroll and expenses	0	0	3,194,969	0		
Repurchase of stock options from related party	0	0	(198,417)	0		
Issuance of options upon conversion of accrued interest	0	0	142,441	0		
Common stock to be issued	0	0	0	50,000		
Amortization of deferred compensation, restricted stock	0	0	0	0		
Net loss	0	0	0	0	(2,234)	
Balance at July 31, 1994	9,124,681	9,125	33,680,954	50,000	(35,455)	
Sale of shares to private investors, net	961,000	961	2,023,241	(50,000)		
Conversion of short-term borrowings	17,600	17	43,983	0		
Issuance of shares for services	30,906	31	77,234	0		
Exercise of options, net	185,000	185	437,015	0		
Common stock to be issued	0	0	0	339,008		
Common stock to be issued, for services	0	0	0	4,800		
Amortization of deferred compensation, restricted stock	0	0	0	0		
Net loss	0	0	0	0	(1,993)	
Balance at July 31, 1995	10,319,187	10,319	36,262,427	343,808	(37,448)	
Sale of shares to private investors, net	2,953,327	2,953	8,969,655	(339,008)		
Issuance of shares for services	19,995	20	70,858	(4,800)		
Exercise of options, net	566,700	567	1,657,633	0		
Sale of warrants	0	0	12,084	0		
Issuance of options/warrants for services	0	0	50,872	0		
Common stock to be issued	0	0	0	258,335		
Subscription receivable	0	0	0	0		
Net loss	0	0	0	0	(2,942)	
Balance at July 31, 1996	13,859,209	13,859	47,023,529	258,335	(40,390)	
Sale of shares to private investors, net	112,000	112	503,888	0		
Issuance of options for services	0	0	76,504	0		
Exercise of options, net	729,134	729	2,620,359	(258,335)		
Exercise of warrants, net	147,450	148	737,102	0		
Net loss	0	0	0	0	(5,018)	
Balance at July 31, 1997 (carried forward)	14,847,793	14,848	50,961,382	0	(45,410)	



ALFACELL CORPORATION  
(A Development Stage Company)

## Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock			Capital In Common Stock to be Issued	Deficit Accumulated During Development Stage
	Number of		Excess of par Value		
	Shares	Amount			
Balance at July 31, 1997 (brought forward)	14,847,793	\$ 14,848	\$ 50,961,382	□	\$ (45,410,139)
Sale of shares to private investors, net	2,337,150	2,337	4,199,877	□	
Issuance of options for services	□	□	199,954	□	
Exercise of warrants, net	4,950	5	11,080	□	
Issuance of shares for services, net	50,000	50	99,950	□	
Net loss	□	□	□	□	(6,387,506)
Balance at July 31, 1998	17,239,893	17,240	55,472,243	□	(51,797,645)
Issuance of options for services	□	□	205,593	□	
Issuance of shares for services, net	46,701	46	16,359	□	
Net loss	□	□	□	□	(3,156,636)
Balance at July 31, 1999	17,286,594	17,286	55,694,195	□	(54,954,281)
Sale of shares to private investors, net	875,000	875	547,417	□	
Exercise of options, net	95,000	95	45,755	□	
Issuance of shares for services, net	174,965	175	92,009	□	
Vesting of options previously issued for services	□	□	146,912	□	
Net loss	□	□	□	□	(1,722,298)
Balance at July 31, 2000	18,431,559	18,431	56,526,288	□	(56,676,579)
Sale of shares to private investors, net	863,331	863	955,561	□	
Exercise of options, net	165,555	166	83,565	□	
Issuance of shares for services, net	11,800	12	10,018	□	
Exercise of convertible debentures, net	330,000	330	296,670	□	
Issuance of warrants with convertible debt	□	□	178,807	□	
Issuance of options for services	□	□	160,426	□	
Net loss	□	□	□	□	(2,294,936)
Balance at July 31, 2001	19,802,245	19,802	58,211,335	□	(58,971,515)
Sale of shares to private investors, net	2,622,122	2,623	1,047,925	□	
Exercise of stock options and warrants	186,000	186	92,814	□	
Issuance of shares for services, net	78,340	78	64,048	□	
Exercise of convertible debentures, net	72,214	72	64,921	□	
Vesting of options previously issued for services	□	□	173,436	□	
Net loss	□	□	□	□	(2,591,162)
Balance at July 31, 2002 (carried forward)	22,760,921	22,761	59,654,479	□	(61,562,677)

ALFACELL CORPORATION  
(A Development Stage Company)

## Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock		Capital In Excess of par Value	Common Stock to be Issued
	Number of			
	Shares	Amount		
Balance at July 31, 2002 (brought forward)	22,760,921	\$ 22,761	\$ 59,654,479	□
Sale of shares to private investors, net	1,315,000	1,315	652,312	□
Exercise of stock options and warrants	764,000	764	376,896	□
Issuance of shares for payment of accounts payable	186,208	186	94,037	□
Issuance of options for services rendered	□	□	75,521	□
Vesting of options previously issued for services	□	□	10,038	□
Issuance of warrants in connection with debt issuances	□	□	594,219	□
Net loss	□	□	□	□
Balance at July 31, 2003	25,026,129	25,026	61,457,502	□
Sale of shares to private investors, net	3,035,200	3,036	10,732,942	□
Exercise of stock options and warrants	3,100,160	3,100	4,155,397	□
Issuance of shares for payment of accounts payable	14,703	15	52,161	□
Issuance of shares for conversion of subordinated debentures	3,042,817	3,043	924,829	□
Issuance of shares for services rendered	128,876	128	288,372	□
Issuance of options for services rendered	□	□	280,612	□
Net loss	□	□	□	□
Balance at July 31, 2004	34,347,885	34,348	77,891,815	□
Exercise of stock options and warrants, net	438,372	438	306,717	□
Issuance of shares and warrants for conversion of subordinated debentures	1,744,978	1,745	462,754	□
Issuance of shares for services rendered	3,000	3	13,497	□
Issuance of options and warrants for services rendered	□	□	16,789	□
Net loss	□	□	□	□
Balance at July 31, 2005	36,534,235	36,534	78,691,572	□
Sale of shares to private investors, net	6,632,099	6,632	10,977,288	□
Exercise of stock options and warrants, net	1,122,827	1,123	1,347,201	□
Issuance of stock options and warrants for services rendered	□	□	1,489,264	□
Net loss	□	□	□	□
Balance at July 31, 2006 (carried forward)	44,289,161	44,289	92,505,325	□

ALFACELL CORPORATION  
(A Development Stage Company)

Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock		Capital In Excess of par Value	Common Stock to be Issued	Deficit
	Number of				During
	Shares	Amount			Development S
Balance at July 31, 2006 (brought forward)	44,289,161	\$ 44,289	\$ 92,505,325	□	\$ (83,316,611)
Sale of shares to private investors, net	553,360	553	1,368,104	□	□
Exercise of stock options and warrants, net	1,438,359	1,439	1,504,261	□	□
Stock-based compensation expense	□	□	2,426,264	□	□
Net loss	□	□	□	□	(8,755,144)
Balance at July 31, 2007	46,280,880	46,281	97,803,954	□	(92,071,755)
Exercise of stock options and warrants, net	996,000	996	686,044	□	□
Stock-based compensation expense	□	□	2,298,975	□	□
Net loss	□	□	□	□	(12,321,101)
Balance at July 31, 2008	47,276,880	\$ 47,277	\$ 100,788,973	□	\$ (104,392,856)

See accompanying notes to financial statements.

ALFACELL CORPORATION  
(A Development Stage Company)

Statements of Cash Flows

Years ended July 31, 2008, 2007 and 2006  
and the Period from August 24, 1981  
(Date of Inception) to July 31, 2008

	2008	2007	2006
Cash flows from operating activities:			
Net loss	\$ (12,321,101)	\$ (8,755,144)	\$ (7,800,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of marketable equity securities	--	--	--
Depreciation and amortization	51,451	39,063	--
Loss on disposal of property and equipment	--	--	--
Loss on lease termination	--	30,964	--
Stock-based compensation expense	2,298,975	2,426,264	1,400,000
Amortization of deferred rent	155,549	14,155	--
Amortization of debt discount	--	--	--
Amortization of deferred compensation	--	--	--
Changes in assets and liabilities:			
(Increase) decrease in prepaid expenses	(15,052)	(83,117)	1,000,000
Decrease (increase) in loans receivable, related party	180,397	(9,527)	--
Decrease (increase) in other assets	35,000	(385,000)	--
Increase in loans and interest payable, related party	--	--	--
Increase (decrease) in accounts payable	819,692	(853,384)	800,000
Increase in accrued payroll and expenses, related parties	--	--	--
Increase in accrued retirement benefits	612,000	--	--
Increase in accrued expenses	126,988	89,859	--
Increase in deferred revenue	5,100,000	100,000	--
Net cash used in operating activities	(2,956,101)	(7,385,867)	(5,200,000)
Cash flows from investing activities:			
Purchase of marketable equity securities	--	--	--
Purchase of short-term investments	--	--	--
Proceeds from sale of marketable equity securities	--	--	--
Proceeds from sale of short-term investments	--	--	--
Capital expenditures	(34,070)	(38,858)	--
Patent costs	--	--	--
Net cash used in investing activities	(34,070)	(38,858)	--



ALFACELL CORPORATION  
(A Development Stage Company)

Statements of Cash Flows, Continued

	2008	2007	2006
Cash flows from financing activities:			
Proceeds from short-term borrowings	\$ --	\$ --	\$ --
Payment of short-term borrowings	--	--	--
Increase in loans payable, related party, net	--	--	--
Proceeds from bank debt and other long-term debt, net of deferred debt costs	--	--	--
Reduction of bank debt and long-term debt	--	--	--
Payment of capital lease obligation	(3,385)	--	--
Proceeds from issuance of common stock, net	--	1,368,657	10,000,000
Proceeds from exercise of stock options and warrants, net	687,040	1,505,700	1,000,000
Proceeds from issuance of convertible debentures, related party	--	--	--
Proceeds from issuance of convertible debentures, unrelated party	--	--	--
Net cash provided by financing activities	683,655	2,874,357	12,000,000
Net increase (decrease) in cash and cash equivalents	(2,306,516)	(4,550,368)	7,000,000
Cash and cash equivalents at beginning of period	6,968,172	11,518,540	4,518,540
Cash and cash equivalents at end of period	\$ 4,661,656	\$ 6,968,172	\$ 11,518,540
Supplemental disclosure of cash flow information □ interest paid	\$ 3,607	\$ 96	\$ --
Noncash investing and financing activities:			
Issuance of convertible subordinated debenture for loan payable to officer	\$ -	\$ -	\$ -
Issuance of common stock upon the conversion of convertible subordinated debentures, related party	\$ -	\$ -	\$ -
Conversion of short-term borrowings to common stock	\$ -	\$ -	\$ -
Conversion of accrued interest, payroll and expenses by related parties to stock options	\$ -	\$ -	\$ -
Repurchase of stock options from related party	\$ -	\$ -	\$ -
Conversion of accrued interest to stock options	\$ -	\$ -	\$ -
Conversions of accounts payable to common stock	\$ -	\$ -	\$ -

ALFACELL CORPORATION  
(A Development Stage Company)

Statements of Cash Flows, Continued

	2008	2007	2006	August 24, 1981 (date of inception) to July 31, 2006
Conversion of notes payable, bank and accrued interest to long-term debt	\$ -	\$ -	\$ -	\$ 1,699,000
Conversion of loans and interest payable, related party and accrued payroll and expenses, related parties to long-term accrued payroll and other, related party	\$ -	\$ -	\$ -	\$ 1,863,500
Issuance of common stock and warrants upon the conversion of convertible subordinated debentures and accrued interest, other	\$ -	\$ -	\$ -	\$ 1,584,300
Issuance of common stock for services rendered	\$ -	\$ -	\$ -	\$ 2,400
Lease incentive allowance	\$ -	\$ 67,000	\$ -	\$ 67,000
Issuance of warrants with notes payable	\$ -	\$ -	\$ -	\$ 594,200
Acquisition of equipment through capital lease obligation	\$ 23,778	\$ -	\$ -	\$ 23,778

See accompanying notes to financial statements.

Notes to Financial Statements

Years ended July 31, 2008, 2007 and 2006  
and the Period From August 24, 1981  
(Date of Inception) to July 31, 2008

(1) Summary of Significant Accounting Policies

Business Description

Alfacell Corporation (the "Company") was incorporated in Delaware on August 24, 1981 for the purpose of engaging in the discovery, investigation and development of a new class of anti-cancer drugs and anti-viral agents. The Company is a development stage company as defined in Statement of Financial Accounting Standards No. 7. The Company is devoting substantially all of its present efforts to establishing its business. Its planned principal operations have not commenced and, accordingly, no significant revenue has been derived therefrom.

The Company is engaged in the research, development, and commercialization of drugs for the treatment of various forms of cancer and other life threatening diseases. As of July 31, 2008, the Company is currently preparing to submit a New Drug Application (NDA) for marketing approval of its lead drug product candidate.

The Company plans to continue the further development of its drug product candidates, which requires substantial capital for research, product development, and market development activities. The Company has not yet initiated marketing of a commercial drug product. Future product development will require clinical testing, regulatory approval, and substantial additional investment prior to commercialization. The future success of the Company is dependent on its ability to make progress in the development of its drug product candidates and, ultimately, upon its ability to attain future profitable operations through the successful manufacturing and marketing of those drug product candidates. There can be no assurance that the Company will be able to obtain the necessary financing or regulatory approvals to be able to successfully develop, manufacture, and market its products, or attain successful future operations. Accordingly, the Company's future success is uncertain.

In addition, uncertainty exists as to the Company's ability to protect its rights to patents and its proprietary information. There can also be no assurance that research and discoveries by others will not render some or all of the Company's technology or drug product candidates noncompetitive or obsolete. Nor can there be any assurance that unforeseen problems will not develop with the Company's technologies or applications, or that the Company will be able to address successfully technological challenges it encounters in its research and development programs. While the Company maintains insurance to cover the use of its drug product candidates in clinical trials, it does not maintain insurance covering the sale of its products nor is there any assurance that it will be able to obtain or maintain such insurance on acceptable terms or with adequate coverage against potential liabilities.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reporting period. Actual results could differ from those estimates.

Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The carrying value of these investments approximates their fair market value due to their short maturity and liquidity. The Company maintains cash deposits with banks that at times exceed applicable insurance limits.

Property and Equipment

Property and equipment is recorded at cost and is depreciated using the straight-line method over the estimated useful lives of the respective assets. Maintenance and repairs that do not extend the life of assets are charged to expense when incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in operations for the period in which the transaction takes place. Total depreciation and amortization expense for the years ended July 31, 2008, 2007 and 2006, was \$51,451, \$39,063, and \$29,703, respectively.

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted cash flows expected to be generated by the asset. If the carrying amount exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount exceeds the fair value of the asset.

Other Assets

Other assets consist of the following:

	2008	2007
Lease security deposit held by a bank as collateral for a standby letter of credit in favor of the Company. The cash held by the bank is restricted as to use for the term of the standby letter of credit.	\$ 350,000	\$ 350,000
Deferred private placement costs	-	35,000
Totals	\$ 350,000	\$ 385,000

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Management provides valuation allowances against the deferred tax assets for amounts which are not considered "more likely than not" to be realized.

Revenue Recognition

The Company recognizes revenue in accordance with Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition" issued by the staff of the SEC. Under SAB No. 104, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and/or services have been rendered, the sales price is fixed or determinable, and collectibility is reasonably assured.

The Company enters into marketing and distribution agreements, which contain multiple deliverables. Under the provisions of Emerging Issues Task Force ("EITF") No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables", the Company evaluates whether these deliverables constitute separate units of accounting to which total arrangement consideration is allocated. A deliverable qualifies as a separate unit of accounting when the item delivered to the customer has standalone value, there is objective and reliable evidence of fair value of items that have not been delivered to the customer, and, if there is a general right of return for the items delivered to the customer, delivery or performance of the undelivered items is considered probable and substantially in the control of the Company. Arrangement consideration is allocated to units of accounting on a relative fair-value basis or the residual method if the Company is unable to determine the fair value of all deliverables in the arrangement. Consideration allocated to a unit of accounting is limited to the amount that is not contingent upon future performance by the Company. Upon determination of separate units of accounting and allocated consideration, the general criteria for revenue recognition are applied to each unit of accounting.



The Company has entered into an agreement with USP Pharma Spolka Z.O.O. (USP) to market, sell and distribute ONCONASE® in Poland and other countries in Eastern Europe. The Company received a \$0.1 million upfront nonrefundable fee in July 2007 and is entitled to receive future additional fees, milestone payments and royalties. USP is responsible for all commercial costs in the territory. The Company has agreed to provide or arrange for contract manufacture of a commercial supply of ONCONASE® upon receipt of marketing approval in the territory. The up-front nonrefundable fee received by the Company will be recognized ratably as revenue once the general criteria for revenue recognition has been met for the unit of accounting to which the fee has been allocated.

The Company entered into a License Agreement for ONCONASE® with Par Pharmaceutical, Inc. in the U.S. Under the terms of the License Agreement, on January 14, 2008, Strativa Pharmaceuticals (Strativa), the proprietary products division of Par Pharmaceutical, received exclusive marketing, sales and distribution rights to ONCONASE® for the treatment of cancer in the United States and its territories. The Company retains all rights and obligations for product manufacturing, clinical development and obtaining regulatory approvals in the U.S. and its jurisdictions, as well as all rights for those non-U.S. jurisdictions in which it has not currently granted any such rights or obligations to third parties. Joint oversight committees with members from the Company and Strativa will manage the alliance. The Company received a cash payment of \$5 million upon the signing of the License Agreement and will be entitled to a minimum additional cash payment of \$20 million, with a maximum of up to \$30 million, upon FDA approval of ONCONASE® for UMM. The Company will also be entitled to receive up to \$190 million in additional milestone payments in connection with the development of ONCONASE® for up to three additional cancer indications and achieving certain net sales levels, in addition to receiving double-digit royalties on net sales of ONCONASE®. In the event of approval of ONCONASE® for a cancer indication in addition to UMM, the Company will have the option to co-promote ONCONASE® in the United States, with support from Strativa. Strativa will provide technical expertise for a future Alfacell oncology sales force, as well as funding for certain associated costs. Under certain circumstances, the Company will have the right to co-promote ONCONASE®, at the Company's cost, prior to the time ONCONASE® is approved for any such additional cancer indication. The initial non-refundable cash payment received by the Company was allocated to deferred revenue and will be recognized ratably as revenue once the general criteria for revenue recognition have been met for the unit of accounting to which the payment has been allocated. Strativa has the right to terminate the License Agreement if ONCONASE® does not receive marketing approval by the FDA on or before January 1, 2012 or receives a not approvable communication from the FDA with respect to the primary UMM indication. In the case of termination of the License Agreement for any reason, the Company will retain all rights to ONCONASE®.

#### Research and Development

Research and development costs are expensed as incurred. These costs include, among other things, consulting fees and costs related to the conduct of human clinical trials. The Company also allocates indirect costs, consisting primarily of operational costs for administering research and development activities, to research and development expenses.

#### Share-Based Compensation

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 123(R) (revised 2004), Share-Based Payment (SFAS 123(R)), which amends SFAS 123. The new standard requires all share-based payments, including stock option grants to employees, to be recognized as an operating expense in the statement of operations. The expense is recognized over the requisite service period based on fair values measured on the date of grant. The Company adopted SFAS 123(R) effective August 1, 2005 using the modified prospective method and, accordingly, prior period amounts have not been restated. Under the modified prospective method, the fair value of all new stock options issued after July 31, 2005 and the unamortized fair value of unvested outstanding stock options at August 1, 2005 are recognized as expense as services are rendered.

#### Accounting For Warrants Issued With Convertible Debt

The Company accounts for the intrinsic value of beneficial conversion rights arising from the issuance of convertible debt instruments with non-detachable conversion rights that are in-the-money at the commitment date pursuant to the consensus of EITF Issue No. 98-5 and EITF Issue No. 00-27. Such value is allocated to



additional paid-in capital and the resulting debt discount is charged to interest expense over the terms of the notes payable. Such value is determined after first allocating an appropriate portion of the proceeds received to warrants or any other detachable instruments included in the exchange.

#### Leases

With respect to its operating leases, the Company applies the provisions of FASB SFAS No. 13 "Accounting for Leases" and FASB Technical Bulletin ("FTB") 88-1 "Issues Relating to Accounting for Leases", recognizing rent expense on a straight-line basis over the lease term due to escalating lease payments and landlord incentives.

#### Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated. Recoveries from other parties are recorded when realized.

#### Fair Value of Financial Instruments

Financial instruments consist primarily of cash and cash equivalents, accounts receivable, and accounts payable. The carrying value of these financial instruments approximates fair value due to the relative short term nature of these investments.

#### Recent Accounting Pronouncements

In May 2008, the FASB issued SFAS No. 162 "Hierarchy of GAAP". This statement identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP in the United States. This statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity with GAAP". The Company will adopt this pronouncement once it becomes effective and is currently evaluating the impact it will have on reported financial results, if any.

In February 2008, the FASB issued FASB Staff Position ("FSP") SFAS No. 157-1, "Application of FASB Statement No. 157 to SFAS Statement No. 13 and Other Accounting Pronouncements that Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13", ("FSP 157-1"). FSP 157-1 amends SFAS 157 to exclude SFAS 13 and other accounting pronouncements that address fair value measurements for purposes of lease classifications under SFAS 13. However, this scope exception does not apply to assets acquired and liabilities assumed in a business combination that are required to be measured at fair value under FASB Statement No. 141, "Business Combinations", or SFAS 141(R), regardless of whether those assets and liabilities are related to leases. FSP 157-1 is effective upon initial adoption of SFAS 157. The Company is required to adopt SFAS 157 as of August 1, 2008, and is currently evaluating the impact that the adoption of FSP 157-1 will have, if any, on its reported financial results.

In February 2008, the FASB issued FSP SFAS No. 157-2, "Effective Date of FASB SFAS No. 157", ("FSP 157-2"). FSP 157-2 delays the effective date of SFAS 157 for non financial assets and non financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis at least annually. This delay is intended to allow the FASB and constituents additional time to consider the effect of various implementation issues that have arisen from the application of SFAS 157. The Company has reviewed FSP 157-2 and will wait to hear for additional positions taken by the FASB before proceeding further.

In December 2007, the FASB issued SFAS No. 141(R) "Business Combinations" ("SFAS 141(R)"). This Statement establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141(R) also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. The guidance will



become effective as of the beginning of a company's fiscal year beginning after December 15, 2008. The Company believes that this new pronouncement will not have a material impact on its financial statements in future periods.

On December 21, 2007, the SEC issued SAB No. 110 ("SAB 110") to permit entities, under certain circumstances to continue to use the "simplified" method, in developing estimates of the expected term of "plain-vanilla" share options in accordance with Statement No. 123R, [Share-Based Payment]. SAB 110 amended SAB 107 to permit the use of the "simplified" method beyond December 31, 2007. The adoption of SAB 110 did not have a material impact on the Company's financial statements.

In June 2007, the FASB issued EITF Issue No. 07-03, [Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities,] ([EITF 07-03]). EITF 07-03 addresses the diversity that exists with respect to the accounting for the nonrefundable portion of a payment made by a research and development entity for future research and development activities. The EITF concluded that an entity must defer and capitalize nonrefundable advance payments made for research and development activities and expense these amounts as the related goods are delivered or the related services are performed. EITF 07-03 will be effective for interim or annual reporting periods in fiscal years beginning after December 15, 2007. The Company is currently evaluating the impact that the adoption of EITF 07-03 will have, if any, on its financial statements.

In February 2007, the FASB issued SFAS No. 159 [The Fair Value Option for Financial Assets and Financial Liabilities] ([SFAS 159]). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 will be effective for the Company on August 1, 2008 and is currently evaluating the impact that the adoption of SFAS 159 will have, if any, on its financial statements.

In December 2006, the FASB issued FSP EITF Issue No. 00-19-2 "Accounting for Registration Payment Arrangements" ("FSP 00-19-2") which addresses an issuer's accounting for registration payment arrangements. FSP 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with SFAS No.5 "Accounting for Contingencies." The guidance in FSP 00-19-2 amends SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," and No.150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity", and FASB Interpretation No.45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" to include scope exceptions for registration payment arrangements. FSP 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of FSP 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP 00-19-2, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The Company has analyzed the provisions of FSP 00-19-2 and determined that it will not have an effect on its financial statements.

In September 2006, the FASB issued SFAS No. 157 [Fair Value Measurements] ([SFAS 157]). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 does not require new fair value measurements. The Company is required to adopt SFAS 157 as of August 1, 2008, and is currently evaluating the impact that the adoption of SFAS 157 will have, if any, on its reported financial results.

In September 2006, the SEC issued SAB No. 108 [Quantifying Misstatements in Financial Statements] ([SAB 108]). Under SAB 108, the Company is required to use a combination of the two previously-acceptable approaches for quantifying misstatements, and to adjust its financial statements if this combined approach results in a conclusion that an error is material. The Company has adopted SAB 108 and determined that it did not have a material impact on our reported financial results.

In June 2006, the FASB issued Interpretation No. 48, [Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109] ([FIN 48]). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements in accordance with Statement No. 109,



□Accounting for Income Taxes.□ FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a company□s tax return. On August 1, 2007, the Company adopted FIN 48 and determined that it did not have a material impact on its reported financial results.

(2) Liquidity

The Company has reported net losses of \$12,321,000, \$8,755,000, and \$7,810,000 and negative cash flows from operating activities of \$2,956,000, \$7,386,000 and \$5,257,000 for the fiscal years ended July 31, 2008, 2007 and 2006, respectively. As of July 31, 2008, the Company had working capital of \$1,945,000, and cash and cash equivalents of \$4,662,000. The loss from date of inception, August 24, 1981, to July 31, 2008 amounts to \$104,393,000. Until and unless the Company□s operations generate significant revenues and cash flow, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital described below. The Company□s long-term continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances, sale of tax benefits, revenues from the commercial sale of ONCONASE®, licensing of its proprietary RNase technology and its ability to realize revenues from its technology and its drug candidates via out-licensing agreements with other companies. The Company has engaged a financial advisor to assist in the pursuit of available strategic alternatives. These alternatives will focus on, but not be limited to, strategic partnership transactions, and could include a possible sale of the Company. Such additional funds and various alternatives may not become available as the Company may need them or be available on terms acceptable to the Company. Insufficient funds could require the Company to delay, scale back, or eliminate one or more of its research and development programs or to license third parties to commercialize drug product candidates or technologies that the Company would otherwise seek to develop without relinquishing its rights thereto. The Company expects that its cash balances as of July 31, 2008, including its expected level of receipts and expenditures, will be sufficient to support its activities into the fourth quarter of its fiscal year 2009 which assumes timely and successful submission of the ONCONASE® NDA. There can be no assurance that the Company will be able to raise the capital it needs on terms which are acceptable, if at all. The Company may also obtain additional capital through the exercise of outstanding options and warrants and the sale of its tax benefits, although it cannot provide any assurance of such exercises or sale or the amount of capital it will receive, if any.

The Company□s audited financial statements for the fiscal year ended July 31, 2008, were prepared under the assumption that the Company will continue its operations as a going concern. Continued operations are dependent on the Company□s ability to raise various sources of capital described above. Such capital formation activities may not be available or may not be available on reasonable terms. The Company□s financial statements do not include any adjustments that may result from the outcome of this uncertainty.

(3) Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per common share:

	Year Ended July 31,		
	2008	2007	2006
<b>Numerator:</b>			
Net loss	\$ (12,321,101)	\$ (8,755,144)	\$ (7,810,175)
<b>Denominator:</b>			
Weighted average number of common shares outstanding	46,919,000	44,958,000	37,308,000
Loss per common share - basic and diluted	\$ (0.26)	\$ (0.19)	\$ (0.21)

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	Year Ended July 31,		
	2008	2007	2006
Potentially dilutive securities:			
Warrants	14,862,534	16,070,748	18,119,598
Stock options	6,353,067	4,867,039	3,830,350
Total potentially dilutive securities	21,215,601	20,937,787	21,949,948

As the Company has incurred a net loss for all periods presented, basic and diluted per common share amounts are the same, since the inclusion of all potentially dilutive securities would be anti-dilutive.

(4) Property and Equipment

Property and equipment, at cost, consists of the following at July 31:

	2008	2007
Laboratory equipment	\$ 276,202	\$ 276,202
Office equipment	118,172	84,102
Leasehold improvements	90,778	67,000
Less accumulated depreciation and amortization	(342,031)	(290,581)
Property and equipment, net	\$ 143,121	\$ 136,723

During the fiscal year ended July 31, 2008, the Company's laboratory equipment was not used since the Company did not maintain a laboratory in its principal office. The book value of laboratory equipment as of July 31, 2008 is \$17,930.

During the fiscal year ended July 31, 2007, the Company wrote off the following fully depreciated and unusable property and equipment:

	Amount	Accumulated Depreciation
Laboratory equipment	\$ 505,869	\$ 505,869
Office equipment	235,495	235,495
Leasehold improvements	97,833	97,833
Total	\$ 839,197	\$ 839,197

(5) Loan Receivable, related party

Amounts due from the Company's CEO totaling \$180,397 was paid in full in April 2008. The Company earned 8% interest on the unpaid principal balance in the amount of approximately \$7,000 for fiscal year ended July 31, 2008 and \$9,500 in each of the fiscal years ended July 31, 2007 and 2006.

(6) Stockholders' Equity

On September 1, 1981, the Company issued 712,500 shares of common stock (1,068,750 shares adjusted for the stock split on September 8, 1982) to officers and stockholders in exchange for equipment, research and development services, stock registration costs, reimbursement of expenses and other miscellaneous services. The common stock issued for services was recorded at the estimated fair value of services rendered based upon the Board of Directors' determination and ratification of the value of services. Equipment received in exchange for common stock was recorded at the transferor's cost. Common stock issued for reimbursement of expenses was recorded based upon expenses incurred. All values assigned for expenses and services rendered were charged to operations except for stock registration costs, which were charged against proceeds.

On July 30, 1982, the Company sold 82,143 shares of common stock (123,214 shares adjusted to reflect the stock split on September 8, 1982) to a private investor at a price of \$1.40 per share, resulting in net proceeds to the Company of approximately \$108,500.



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On September 8, 1982, the Company declared a 3-for-2 stock split. Shares previously issued by the Company were restated in accordance with the stock split.

On September 8, 1982, the Company issued 15,000 shares of common stock to an officer and stockholder in exchange for equipment. The equipment received in exchange for the common stock was recorded at the transferor's cost.

On November 1, 1982 and January 3, 1983, the Company sold 28,125 and 16,071 shares of common stock, respectively, to private investors at \$.93 per share, resulting in net proceeds to the Company of approximately \$41,250.

On January 17, 1983, the Company sold 660,000 shares of its common stock and 330,000 common stock purchase warrants in a public offering at a price of \$2.50 per share, resulting in net proceeds to the Company of approximately \$1,308,446. The warrants were to expire 12 months after issuance; however, the Company extended the expiration date to July 16, 1984. During the fiscal years ended July 31, 1983 and 1984, the net proceeds to the Company from the exercise of the warrants amounted to \$934,000. Each common stock purchase warrant was not detachable from its common stock or exercisable until six months after the issuance date of January 17, 1983. Each warrant entitled the holder to purchase one share of common stock at an exercise price of \$3.00 after six months and prior to nine months after issuance. The exercise price increased to \$3.50 after nine months and prior to 12 months after issuance.

In connection with the public offering, the Company sold 60,000 five-year purchase warrants to the underwriters at a price of \$.001 per warrant. Each warrant entitled the holder to purchase one share of common stock at an exercise price of \$3.00. Pursuant to the antidilution provisions of the warrants, the underwriters received warrants to purchase 67,415 shares at an exercise price of \$2.67 per share. By July 31, 1986, all such warrants were exercised and the Company received proceeds of approximately \$180,000.

On February 22, 1984, the Company filed a registration statement with the Securities and Exchange Commission for the issuance of two series of new warrants, each to purchase an aggregate of 330,000 shares (hereinafter referred to as one-year warrants and two-year warrants). The one-year warrants had an exercise price of \$6.50 per share and expired July 17, 1985. The two-year warrants had an exercise price of \$10.00 per share and were to expire July 17, 1986. However, the Company extended the expiration date to August 31, 1987. The one-year warrants and two-year warrants were issued as of July 17, 1984 on a one-for-one basis to those public offering warrant holders who exercised their original warrants, with the right to oversubscribe to any of the warrants not exercised. During the fiscal years ended July 31, 1985, 1986, 1987 and 1988, the Company received net proceeds of approximately \$2,471,000 as a result of the exercise of the warrants.

On January 2, 1987, the Company issued 250,000 shares of common stock to officers and stockholders, including the President and Chief Executive Officer, in recognition of services performed for the Company. The fair value of such shares was recorded as compensation expense.

On February 3, 1987, the Company sold 5,000 shares of common stock to a private investor for \$5.00 per share, resulting in net proceeds to the Company of approximately \$25,000.

On September 1, 1987, the Board of Directors approved new wage contracts for three officers. The contracts provided for the issuance of 700,000 shares of common stock as an inducement for signing. The fair value of these shares was recorded as deferred compensation and was amortized over the term of the employment agreements. The contracts also provided for the issuance of 1,500,000 shares of common stock in 750,000 increments upon the occurrence of certain events. These shares were issued during the fiscal years ended July 31, 1989 and 1990 and the fair value of such shares was recorded as deferred compensation and was amortized over the remaining term of the employment agreements. The contracts also provided for five-year options to purchase 750,000 shares of common stock at \$3.00 per share; options for the purchase of 170,000 shares were exercised on June 16, 1988 and the remaining options for the purchase of 580,000 shares expired on September 2, 1992.

During the fiscal year ended July 31, 1988, the Company issued 206,429 shares of common stock for payment of legal and consulting services. The Company also issued 12,500 shares of common stock in connection with the settlement of certain litigation. The fair value of such shares was charged to operations.



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During the fiscal year ended July 31, 1988, the Company sold 61,073 shares of common stock to private investors at \$2.92 per share resulting in net proceeds to the Company of approximately \$178,133.

On September 21, 1988, the Company entered into a stipulation of settlement arising from a lawsuit wherein it agreed to pay a total of \$250,000 in 12 monthly installments. Under the agreement, the Company authorized the issuance on September 7, 1988 and October 18, 1988 of 85,000 and 50,000 shares, respectively, to an escrow account to secure payment of the \$250,000 due under the stipulation of settlement. During the fiscal year ended July 31, 1989, the Company issued and sold the 135,000 shares of common stock for \$1,074,838. On February 14, 1989, the Board of Directors authorized the issuance of an additional 50,000 shares. During the year ended July 31, 1990, the shares were sold for \$351,117. The proceeds from the above transactions were used to pay the settlement and related legal costs, reduce loans from and interest due to the Company's Chief Executive Officer, and for working capital.

During the fiscal year ended July 31, 1989, the Company sold 105,840 shares of common stock to private investors at \$3.97 per share resulting in net proceeds to the Company of approximately \$420,000.

During the fiscal year ended July 31, 1990, the Company issued 52,463 shares of common stock for payment of legal and consulting services and 50,000 shares of common stock in connection with the settlement of certain litigation. The fair value of the common stock was charged to operations.

During the fiscal year ended July 31, 1990, the Company sold 89,480 shares of common stock to private investors at \$3.97 per share resulting in net proceeds to the Company of approximately \$355,080.

During the fiscal year ended July 31, 1991, the Company issued 87,000 shares of common stock for payment of legal and consulting services. The fair value of the common stock was charged to operations.

During the fiscal year ended July 31, 1992, the Company sold 70,731 shares of common stock to private investors at \$2.75 to \$3.50 per share resulting in net proceeds to the Company of approximately \$219,900.

During the fiscal year ended July 31, 1992, the Company issued 45,734 shares of common stock as payment for services rendered to the Company. The fair value of the common stock was charged to operations.

During the fiscal years ended July 31, 1992 and 1990, 94,000 and 50,000 shares of common stock, respectively, were issued to the Company's Chief Executive Officer upon the conversion of outstanding debentures.

During the fiscal year ended July 31, 1993, the Company sold 352,667 shares of common stock to private investors at prices ranging from \$2.00 to \$3.00 per share resulting in net proceeds to the Company of approximately \$735,500. In addition, the private investors were granted options to purchase common stock totaling 587,167 shares at prices ranging from \$3.00 to \$7.00. During the fiscal years ended July 31, 1995 and 1996, 322,500 and 228,833 options expired, respectively. A total of 42,167 options due to expire on July 31, 1995 were extended to July 31, 1996 and their exercise price was reduced to \$2.50. During the fiscal year ended July 31, 1996, 35,834 options were exercised resulting in net proceeds to the Company of approximately \$89,600.

During the fiscal year ended July 31, 1993, the Company issued 54,600 shares of common stock as payment for legal and other services performed for the Company. The fair value of 49,600 shares was charged to operations. The remaining 5,000 shares were recorded as deferred compensation and were amortized over a one-year period, beginning in February 1993, in accordance with the agreement entered into with the recipient.

During the fiscal year ended July 31, 1994, the Company issued 7,000 shares of common stock as payment for services performed for the Company. The fair value of the common stock was charged to operations.

During the fiscal year ended July 31, 1994, the Company sold 25,000 shares of common stock to a private investor at \$2.00 per share resulting in net proceeds to the Company of \$50,000. In addition, the private investor was granted options to purchase common stock totaling 25,000 shares at \$4.00 per common share. These options were exercised in September 1996 resulting in net proceeds to the Company of \$100,000.



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During the fiscal year ended July 31, 1994, the Company sold 800,000 shares of common stock to private investors at \$2.50 per share resulting in net proceeds to the Company of \$1,865,791. In addition, the private investors were granted warrants to purchase common stock totaling 800,000 shares at \$5.00 per common share. Warrants for the purchase of 147,450 shares were exercised during fiscal 1997 resulting in net proceeds to the Company of \$737,250. The remaining 652,550 warrants expired during fiscal 1997.

During the fiscal year ended July 31, 1994, 400,000 shares of common stock were issued to the Company's Chief Executive Officer upon the conversion of outstanding debentures.

During the fiscal year ended July 31, 1994, 25,400 shares of common stock were issued upon the conversion of other outstanding debentures.

In September 1994, the Company completed a private placement resulting in the issuance of 288,506 shares of common stock and three-year warrants to purchase 288,506 shares of common stock at an exercise price of \$5.50 per share. The warrants expired during fiscal 1998. The common stock and warrants were sold in units consisting of 20,000 shares of common stock and warrants to purchase 20,000 shares of common stock. The price per unit was \$50,000. The Company received proceeds of approximately \$545,000, net of costs associated with the placement of approximately \$55,000 and the conversion of certain debt by creditors of \$121,265 into equivalent private placement units of 17,600 shares for conversion of short-term borrowings and 30,906 shares issued for services rendered. In October 1994, an additional two units at \$50,000 per unit were sold to a private investor under the same terms as the September 1994 private placement resulting in the issuance of 40,000 shares of common stock and warrants to purchase 40,000 shares of common stock. The warrants expired during fiscal 1998.

During the fiscal year ended July 31, 1995, 185,000 shares of common stock were issued upon the exercise of stock options by unrelated parties, resulting in net proceeds to the Company of \$437,200. The exercise prices of the options ranged from \$2.27 to \$2.50, which had been reduced from \$3.50 and \$5.00, respectively, during fiscal 1995.

During the fiscal year ended July 31, 1995, the Company sold 681,000 shares of common stock to private investors resulting in net proceeds to the Company of approximately \$1,379,000. The shares were sold at prices ranging from \$2.00 to \$2.25.

During the fiscal year ended July 31, 1995, the Company sold 139,080 shares of common stock and 47,405 three-year warrants to purchase shares of common stock at an exercise price of \$4.00 per share to private investors. The stock and warrants were sold at prices ranging from \$2.25 to \$2.73 per share and resulted in net proceeds to the Company of \$343,808, of which \$4,800 was for services rendered. The common shares were issued to the investors subsequent to July 31, 1995.

On August 4, 1995, the Company issued 6,060 shares of common stock as payment for services rendered to the Company. The fair value of the common stock was charged to operations.

On September 29, 1995, the Company completed a private placement resulting in the issuance of 1,925,616 shares of common stock and three-year warrants to purchase an aggregate of 55,945 shares of common stock at an exercise price of \$4.00 per share. Of these shares 1,935 were issued for services rendered to the Company. The common stock was sold alone at per share prices ranging from \$2.00 to \$3.70, and in combination with warrants at per unit prices ranging from \$4.96 to \$10.92, which related to the number of warrants contained in the unit. The Company received proceeds of approximately \$4.1 million, including \$1,723,000 for approximately 820,000 shares received during the fiscal year ended July 31, 1995. The warrants expired in October 1998.

As consideration for the extension of the Company's term loan agreement with its bank, the Company granted the bank a warrant to purchase 10,000 shares of common stock at an exercise price of \$4.19. The warrants were issued as of October 1, 1995 and expired on August 31, 1997.

In June 1996, the Company sold in a private placement 1,515,330 shares of common stock and three-year warrants to purchase 313,800 shares of common stock at an exercise price of \$7.50 per share. Of these shares,

12,000 were issued for services rendered to the Company. The common stock was sold alone at a per share price of \$3.70, in combination with warrants at a per unit price of \$12.52 and warrants were sold alone at a per warrant price of \$1.42. Each unit consisted of three shares of common stock and one warrant. The Company received proceeds of approximately \$5.7 million. The warrants expired during the fiscal year 2000.

In June 1996, the Company issued 10,000 five-year stock options as payment for services rendered. The options vested immediately and had an exercise price of \$4.95 per share. The Company recorded research and development expense of \$28,260, which was the fair value of the stock options on the date of issuance. The options expired during the fiscal year ended July 31, 2001.

During the fiscal year ended July 31, 1996, 207,316 shares of common stock were sold from October 1995 to April 1996 at per share prices ranging from \$3.60 to \$4.24 resulting in proceeds of approximately \$808,000.

During the fiscal year ended July 31, 1996, 656,334 stock options were exercised by both related and unrelated parties resulting in net proceeds of approximately \$1.9 million to the Company. Of these shares, 89,634 were issued subsequent to July 31, 1996. The exercise prices of the options ranged from \$2.50 to \$3.87 per share.

In August 1996, the Company issued 10,000 stock options with an exercise price of \$4.69 per share exercisable for five years as payment for services to be rendered. An equal portion of these options vested monthly for one year commencing September 1, 1996. The Company recorded general and administrative expense of \$27,900, which was the fair value of the stock options on the date of issuance. The options expired during the fiscal year ended July 31, 2002.

In March 1997, the Company issued 112,000 shares of common stock at \$4.50 per share in a private placement to an investor resulting in net proceeds of \$504,000 to the Company.

In May 1997, the Company issued 100,000 stock options to Dr. Stephen Carter, a director, with an exercise price of \$5.20 per share as payment for serving as Chairman of the Scientific Advisory Board (the [SAB]). These options vested as follows: 10,000 vested immediately, 10,000 after one full calendar year, 10,000 annually for each of the following three years and 50,000 on May 13, 2002. The Company recorded a total research and development expense of \$353,400, which was the fair value on the date of issuance of that portion of the stock options that had vested as of July 31, 2002. Of these options, 40,000 expired as of the fiscal year ended July 31, 2005.

During the fiscal year ended July 31, 1997, 639,500 stock options were exercised by both related and unrelated parties resulting in net proceeds of approximately \$2.6 million to the Company. The exercise prices of the options ranged from \$2.45 to \$4.00 per share.

During the fiscal year ended July 31, 1997, 147,450 warrants were exercised by both related and unrelated parties resulting in net proceeds of approximately \$737,250 to the Company. The exercise price of the warrants was \$5.00 per share.

In October 1997, the Company issued 75,000 stock options to a director with an exercise price of \$3.66 per share as payment for non-board related services to be rendered. These options vested as follows: 10,000 vested immediately; 10,000 after one full calendar year; 10,000 annually for each of the following three years; and 25,000 on October 31, 2002. A total general and administrative expense of \$185,600 was amortized on a straight line basis over a five-year period, which commenced in October 1997. Of these options, 30,000 expired as of the fiscal year ended July 31, 2005.

In October 1997, the Company issued 12,000 five-year stock options to a consultant with an exercise price of \$3.91 per share as payment for services to be rendered. An equal portion of these options vested monthly and were amortized over a one-year period which commenced in October 1997. In May 1998, the Company terminated the services of the consultant, which resulted in the cancellation of 5,000 options. The Company recorded a total research and development expense for the remaining 7,000 options in the amount of \$15,800, based upon the fair value of such options on the date of issuance, amortized on a straight-line basis over the vesting period of the grant. These options expired during the fiscal year ended July 31, 2003.

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On December 9, 1997, the stockholders authorized the amendment of the Company's Certificate of Incorporation to increase the number of authorized shares of common stock, par value \$.001 from 25,000,000 shares to 40,000,000 shares.

On December 9, 1997, the stockholders approved the 1997 Stock Option Plan (the "1997 Plan"). The total number of shares of common stock authorized for issuance upon exercise of options granted under the 1997 Plan was 2,000,000. Options are granted at fair market value on the date of the grant and generally are exercisable in 20% increments annually over five years starting one year after the date of grant and terminate five years from their initial exercise date.

On January 23, 1998, the SEC declared effective a registration statement on Form S-3 for the offer and sale by certain stockholders of up to 3,734,541 shares of common stock. Of these shares (i) an aggregate of 2,737,480 shares were issued to private placement investors in private placement transactions which were completed during the period from March 1994 through March 1997 (the "Earlier Private Placements"), (ii) an aggregate of 409,745 shares were issuable upon exercise of warrants which were issued to private placement investors in the Earlier Private Placements and (iii) an aggregate of 587,316 shares may be issued, or have been issued, upon exercise of options which were issued to option holders in certain other private transactions. As a result of the delisting of the Company's Common Stock from the Nasdaq SmallCap Market, the Company no longer qualified for the use of a Form S-3 registration statement for this offering when it filed its Annual Report on Form 10-K for the fiscal year ended July 31, 1999 and thus, this registration statement was no longer effective. The Company filed a registration statement on Form S-1 to register these shares, which was declared effective in February 2002.

In February 1998, the Company completed a Private Placement primarily to institutional investors, which resulted in the issuance of 1,168,575 units at a unit price of \$4.00. Each unit consisted of two (2) shares of the Company's common stock, par value \$.001 per share and one (1) three-year warrant to purchase one (1) share of common stock at an exercise price of \$2.50 per share. The Company received net proceeds of approximately \$4,202,000. The placement agent received warrants to purchase an additional 116,858 units comprised of the same securities sold to investors at an exercise price of \$4.40 per unit as part of its compensation. In May 2001, the expiration date of these warrants was extended from May 19, 2001 to August 17, 2001. The warrants expired on August 17, 2001.

In March 1998, the Company converted an outstanding payable into 50,000 shares of the Company's Common Stock. The fair value of the Common Stock approximated the outstanding payable amount of \$100,000.

In March 1998, the Company issued 75,000 stock options to a director with an exercise price of \$2.80 per share as payment for non-board related services rendered. These options vested as follows: 10,000 vested immediately; 10,000 after one full calendar year; 10,000 annually for each of the following three years; and 25,000 on March 24, 2003. A total general and administrative expense of \$138,100 was amortized on a straight-line basis over a five-year period, which commenced in March 1998. As of July 31, 2003, the expense was fully amortized and recorded, based upon the fair value of such 75,000 options on the date of issuance, amortized on a straight-line basis over the vesting period of the grant. Of these options, 10,000 expired during the fiscal year ended July 31, 2003 and 65,000 were exercised during the fiscal year ended July 31, 2004.

On April 20, 1998 the SEC declared effective a registration statement on Form S-3 for the offer and sale by certain stockholders of up to 3,918,299 shares of common stock. Of these shares (i) an aggregate of 2,337,150 shares of common stock were issued to the private placement investors in the February 1998 Private Placement, (ii) an aggregate of 1,168,575 shares may be issued upon exercise of the Warrants which were issued to the private placement investors in the February 1998 Private Placement, (iii) 350,574 shares may be issued upon the exercise of the Placement Agent Warrant which was issued to the placement agent in the February 1998 Private Placement and the Warrants issuable upon exercise of the Placement Agent Warrant, (iv) 50,000 shares of common stock were issued to a Supplier in connection with conversion of an outstanding accounts payable, and (v) 12,000 shares may be issued upon the exercise of options which were issued as payment for services to be rendered. As a result of the delisting of the Company's common stock from the Nasdaq SmallCap Market, the Company no longer qualified for the use of a Form S-3 registration statement for this offering when it filed its Annual Report on Form 10-K for the fiscal year ended July 31, 1999 and thus, this registration statement was no longer effective. The Company filed a registration statement on Form S-1 to register these shares, which was declared effective in February 2002.



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During the fiscal year ended July 31, 1998, the Company issued 833 three-year stock options as payment for services rendered in August 1997. The options vested thirty days from the issuance date and had an exercise price of \$4.47 per share. The total general and administrative expense recorded for these options was \$1,700, based upon the fair value of such options on the date of issuance. These options expired in August 2000.

During the fiscal year ended July 31, 1998, the Company issued 15,000 three-year stock options with an exercise price of \$4.15 per share as payment for services. An equal portion of these options vested monthly and a total general and administrative expense of \$30,000 was amortized over a one-year period which commenced September 1997. The Company also issued 5,000 three-year stock options with an exercise price of \$4.15 per share as payment for services. Of these options, 833 vested monthly for five months commencing September 30, 1997 and 835 vested on the last day of the sixth month. Total general and administrative expense of \$9,700 was amortized over a six-month period which commenced September 1997. As of July 31, 1998, the Company recorded general and administrative expense of \$37,100, based upon the fair value of the 20,000 stock options on the date of the issuance, amortized on a straight-line basis over the vesting periods of the grants. These options expired three years after they vested.

During the fiscal year ended July 31, 1998, 4,950 shares of common stock were issued upon the exercise of warrants by unrelated parties, resulting in net proceeds of approximately \$11,100 to the Company. The exercise prices of the warrants ranged from \$2.20 to \$2.50 per share.

On October 1, 1998 (the "Effective Date"), the Company entered into an agreement with a consultant (the "Agreement"), resulting in the issuance of 200,000 five-year stock options with an exercise price of \$1.00 per share as payment for services to be rendered. These options vested as follows: an aggregate of 20,000 vested on October 1, 1999; an aggregate of 2,500 of such options vested on the last day of each month over the first twelve months after the Effective Date of the Agreement; the remaining 150,000 options vested on the third anniversary of the Effective Date of the Agreement. The Company recorded approximately \$49,300 of general and administrative expense based upon the fair value of the vested options through July 31, 2000. During the fiscal year ended July 31, 2000, the Agreement was terminated which resulted in the cancellation of 150,000 options. The remaining 50,000 options were exercised during the fiscal year ended July 31, 2004, which resulted in gross proceeds of \$50,000 to the Company.

During the fiscal year ended July 31, 1999, the Company issued 5,000 three-year stock options as payment for services rendered. The total general and administrative expense recorded for these options was \$4,200, based upon the fair value of such options on the date of issuance. These options were exercised during the fiscal year ended July 31, 2000, which resulted in gross proceeds of \$7,150 to the Company.

During the fiscal year ended July 31, 1999, the Company issued 40,701 shares of common stock for payment of legal services. The fair value of the common stock in the amount of \$16,631 was charged to operations.

During the fiscal year ended July 31, 1999, the Company issued 6,000 shares of common stock for payment of services rendered. The fair value of the common stock in the amount of \$2,460 was charged to operations.

During the fiscal year ended July 31, 2000, the Company issued 174,965 shares of common stock for payment of services rendered. The fair value of the common stock in the amount of \$92,184 was charged to operations.

During the fiscal year ended July 31, 2000, the Company issued 95,000 shares of common stock upon the exercise of stock options by unrelated parties, which resulted in gross proceeds of \$45,850 to the Company. The exercise prices of the options ranged from \$0.43 to \$1.43.

During the fiscal year ended July 31, 2000, the Company sold an aggregate of 875,000 shares of common stock to private investors at prices ranging from \$0.50 to \$1.00 per share resulting in net proceeds of \$548,300 to the Company. In addition, the private investors were granted warrants to purchase an aggregate of 875,000 shares of common stock, inclusive of additional warrants issued so that all investors in the private placements received substantially the same securities, at per share exercise prices ranging from \$1.03 to \$4.55. These warrants expired in May 2003 and May 2005.

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During the fiscal year ended July 31, 2001, the Company issued 11,800 shares of common stock for payment of services rendered. The fair value of the common stock in the amount of \$10,030 was charged to operations.

During the fiscal year ended July 31, 2001, the Company sold an aggregate of 863,331 shares of common stock to private investors at prices ranging from \$0.90 to \$1.50 per share resulting in net proceeds of \$956,000 to the Company. In addition, the private investors were granted warrants to purchase an aggregate of 696,665 shares of common stock at per share exercise prices ranging from \$1.50 to \$3.00. The warrants will expire during the period commencing July 2004 and ending in October 2006. Of these warrants, 418,887 expired and 277,778 were exercised.

During the fiscal year ended July 31, 2001, the Company issued 165,555 shares of common stock upon the exercise of stock options by related parties, which resulted in gross proceeds of \$83,700 to the Company. The per share exercise prices of the options ranged from \$0.29 to \$0.85.

During the fiscal year ended July 31, 2001, the Company issued 50,000 five-year stock options to a director as payment for non-board related services. These options vested immediately and had an exercise price of \$0.90 per share. The Company recorded general and administrative expense of \$31,600, which was the fair market value of the options using the Black-Scholes options-pricing model on the date of issuance. These options were exercised during the fiscal year ended July 31, 2004.

During the fiscal year ended July 31, 2001, the Company issued 330,000 shares of common stock upon the conversion of convertible notes from related parties at \$0.90 per share. In addition, upon conversion, the related parties were granted three-year warrants to purchase an aggregate of 330,000 shares of common stock at an exercise price of \$2.50 per share. The estimated value of these warrants in the amount of \$108,900 was recorded by the Company as interest expense during the fiscal year ended July 31, 2001. In October 2001, the board of directors approved a change of the 330,000 warrants from three-year warrants to five-year warrants and the exercise price from \$2.50 per share to \$1.50 per share to conform with private placements to unrelated parties. These warrants were exercised as of July 31, 2006.

During the fiscal year ended July 31, 2002, the Company issued 72,214 shares of common stock upon the conversion of convertible notes from unrelated parties at \$0.90 per share. In addition, upon conversion, the unrelated parties were granted five-year warrants to purchase an aggregate of 72,214 shares of common stock at an exercise price of \$1.50 per share. The estimated value of these warrants in the amount of \$32,200 was recorded by the Company as interest expense during the fiscal year ended July 31, 2002. These options were exercised during the fiscal years ended July 31, 2007 and 2006.

During the fiscal year ended July 31, 2002, the Company issued 78,340 shares of common stock in settlement of accounts payable in the amount of \$64,126. In addition, one of the vendors was granted five-year warrants to purchase 55,556 shares of common stock at an exercise price of \$1.50 per share. The settled accounts payable amount was credited to equity as the value of the common stock and warrants.

During the fiscal year ended July 31, 2002, the Company issued an aggregate of 85,221 five-year stock options as payment for services rendered. The options vested immediately and had a per share exercise prices of \$0.75 as to 70,000 stock options and \$0.94 as to 15,221 stock options. The Company recorded an aggregate total of \$40,747 non-cash expenses for these options, based upon the fair value on the date of the issuance as estimated by the Black-Scholes options-pricing model. These options were exercised as of July 31, 2005.

During the fiscal year ended July 31, 2002, the Company sold an aggregate of 2,622,122 shares of common stock to private investors at prices ranging from \$0.35 to \$0.90 per share resulting in net proceeds of \$1,050,000 to the Company. In addition, the private investors were granted warrants to purchase an aggregate of 2,673,422 shares of common stock at per share exercise prices ranging from \$0.75 to \$1.50. The warrants will expire during the period commencing August 2006 and ending in September 2007. As of July 31, 2008, 1,733,638 of these warrants were exercised and 939,784 warrants expired.

During the fiscal year ended July 31, 2002, the Company issued warrants to purchase 1,500,000 shares of common stock to Roan Meyers Associates L.P. for an aggregate warrant purchase price of \$1,500 in connection with the engagement of Roan Meyers to render advisory services. Of these warrants, 250,000 were exercisable at \$.50 per share, 650,000 were exercisable at \$1.00 per share and 600,000 were exercisable at



\$1.50 per share. In February 2002, the Company recorded an expense equal to the fair market value of the first 500,000 warrants which vested immediately, based upon the fair value of such warrants as estimated by Black-Scholes pricing model (\$153,300), less the \$1,500 received from the sale of the warrants. The remaining 1,000,000 warrants were to become exercisable if Roan Meyers was successful in helping the Company raise capital. However, Roan Meyers was not successful in raising additional capital from a third party. During the fiscal year ended July 31, 2002, Roan Meyers exercised warrants to purchase an aggregate of 186,000 shares of common stock, at an exercise price of \$0.50 per share, resulting in aggregate gross proceeds of \$93,000 to the Company. During the fiscal year ended July 31, 2003, the vesting of the 600,000 warrants was amended to vest immediately and the exercise price was amended from \$1.50 to \$0.50 per share due to the price change of the Company's common stock. Roan Meyers exercised these warrants and was issued 600,000 shares of common stock. The Company also issued 40,000 shares of common stock upon the exercise of warrants by Roan Meyers at an exercise price of \$.50 per share. The Company realized aggregate gross proceeds of \$320,000 from these capital raising transactions. During the fiscal year ended July 31, 2004, the exercise price of 250,000 warrants was amended from \$1.00 to \$0.50 per share due to the price change of the Company's common stock and the vesting of the 400,000 warrants was amended to vest immediately. Roan Meyers exercised the remaining 674,000 warrants which resulted in the issuance of 674,000 shares of common stock by the Company. The Company realized gross proceeds of \$537,000 in this capital raising transaction.

During the fiscal year ended July 31, 2002, the Company issued an aggregate of 75,000 five-year stock options to unrelated parties as an incentive for lending the Company an aggregate of \$75,000, which was repaid during the quarter. The options vested immediately and have an exercise price of \$1.50 per share. The total non-cash interest expense recorded for these options was \$25,615, based upon the fair value of such option on the date of issuance as estimated by the Black-Scholes options-pricing model. Of these options, 25,000 were exercised and 50,000 expired.

During the fiscal year ended July 31, 2002, the Company issued a note payable to an unrelated party in an aggregate amount of \$300,000. The note was due in thirty days bearing interest at 8% per annum. In addition, the lender received warrants to purchase 300,000 shares of common stock at an exercise price of \$0.60 per share. The total non-cash interest expense recorded for these warrants was \$40,690, based upon the fair value of such option on the date of issuance as estimated by the Black-Scholes options-pricing model. The notes were extended for eighteen months at a conversion price of \$0.40 per share plus a five-year warrant for each share of the Company's common stock issued upon conversion at an exercise price of \$1.00 per share. These notes were converted into shares of the Company's common stock and warrants in fiscal year 2004.

During the fiscal year ended July 31, 2003, the Company issued an aggregate of 764,000 shares of common stock upon the exercise of warrants and stock options by unrelated parties which resulted in gross proceeds of approximately \$378,000 to the Company.

During the fiscal year ended July 31, 2003, the Company issued an aggregate 186,208 shares of common stock in settlement of accounts payable in the aggregate amount of \$94,223. In addition, one of the vendors was granted five-year options to purchase 50,000 shares of common stock at an exercise price of \$1.25 per share. The Company recorded \$17,581 non-cash research and development expenses for these options, based upon the fair value on the date of the issuance as estimated by the Black-Scholes options-pricing model. The settled accounts payable amount was credited to equity as the value of the common stock and options.

During the fiscal year ended July 31, 2003, the Company issued 25,000 five-year stock options to an unrelated party as an incentive for lending the Company an aggregate of \$25,000, which was fully paid as of April 30, 2003. The stock options vested immediately and have an exercise price of \$0.23 per share. The total non-cash interest expense recorded for these stock options was \$2,503. In addition, the Company issued 140,000 five-year stock options for services rendered. These stock options vested immediately and have exercise prices of \$0.84 and \$1.25 per share. The total non-cash charge relating to these options was \$55,437. The total value of these options was based upon the fair value of such options on the date of issuance as estimated by the Black-Scholes options-pricing model. Of these options, 20,000 were exercised during the fiscal year ended July 31, 2004.

During the fiscal year ended July 31, 2003, the Company issued 8% convertible notes payable to unrelated parties with principal balances totaling an aggregate of \$915,000. These notes payable were due to mature on various dates from April 2004 through May 2005 and were convertible into the Company's common stock at



conversion prices ranging from \$0.20 to \$0.50 per share and an equal number of five year warrants with an exercise price of \$1.00 per share. With the issuance of the notes payable, the Company issued to the unrelated parties five year warrants to purchase an aggregate of 665,000 shares of the Company's common stock, at an exercise price of \$0.60 per share. In addition, the Company issued on the due date of the notes payable five year warrants to purchase an aggregate of 915,000 shares of the Company's common stock at per share exercise prices of \$1.00 and \$1.10. The Company valued these warrants at a total of \$219,259 based on the fair value determined by using the Black-Scholes method relative to the fair value of the notes payable. At the issuance dates of the notes payable, the fair market values of the Company's shares exceeded the effective conversion prices. Accordingly, the Company initially increased additional paid-in capital by \$219,259 for the relative fair value of the warrants and reduced the carrying value of the notes payable for the same amount for the debt discount attributable to the fair value of the warrants. The Company also increased its additional paid-in capital and debt discount by \$374,960 for beneficial conversion rights issued in connection with the issuances of these notes.

During the fiscal year ended July 31, 2003, the Company sold an aggregate of 1,315,000 shares of common stock to private investors at prices ranging from \$0.20 to \$0.73 per share resulting in net proceeds of \$653,627 to the Company. In addition, the private investors were granted warrants to purchase an aggregate of 1,315,000 shares of common stock at per share exercise prices ranging from \$1.00 to \$1.50. The warrants will expire during the period commencing January 2008 and ending in October 2008. As of July 31, 2008, 965,000 of these warrants were exercised and 150,000 expired.

On January 14, 2004, at the Company's annual meeting of stockholders, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation, as amended, to increase the number of shares of common stock authorized from 40,000,000 to 100,000,000. Since no notes payable had been converted as of such date, the terms of the Company's notes payable relating to conversion and exercise which were amended to authorize conversion to Series A Preferred Stock because there were an insufficient number of authorized shares of common stock available for issuance upon conversion, reverted to their original terms so that they were again convertible into shares of common stock, rather than shares of Series A Preferred Stock.

On January 14, 2004, at the Company's annual meeting of stockholders, the Company's stockholders approved the 2004 Stock Incentive Plan (the "2004 Plan"). The total number of shares of common stock authorized for issuance under the 2004 Plan is 8,500,000.

During the fiscal year ended July 31, 2004, the Company issued an aggregate of 120,000 shares of common stock to private investors resulting in aggregate gross proceeds of \$60,000 to the Company. In addition, the private investors were granted five-year warrants to purchase 120,000 shares of common stock at an exercise price of \$1.25 per share.

During the fiscal year ended July 31, 2004, the Company issued 3,996 five-year stock options to a consultant as payment for services rendered. The options vested immediately and have a per share exercise price of \$0.60. The Company recorded a total of \$5,235 of non-cash expenses for these options, based upon the fair value on the date of the issuance as estimated by the Black-Scholes options pricing model. These options were exercised during the fiscal year ended July 31, 2004 resulting in gross proceeds of \$2,398 to the Company.

During the fiscal year ended July 31, 2004, the Company entered into a two-part financing agreement with SF Capital Partners, Ltd. for the private placement of 1,704,546 shares of common stock and warrants to purchase 852,273 shares of common stock, at an exercise price of \$1.50 per share. As consideration, the Company received \$1,500,000. In addition, the Company granted SF Capital Partners, Ltd. a warrant to invest an additional \$1,500,000 to purchase the Company's common stock at an exercise price based upon a 20-day trailing average of the closing price per share of the Company's common stock (the "Additional Warrants"). During the fiscal year ended July 31, 2004, SF Capital Partners, Ltd. exercised the Additional Warrants at a 20-day trailing average exercise price of \$3.96 which resulted in gross proceeds of \$1,500,000 and the issuance of 379,170 shares of common stock and an Exercise Warrant to purchase an additional 189,585 shares of common stock at a per share exercise price of \$4.75. The Company also issued an aggregate of 53,876 shares of restricted common stock to a third party as finder's fee. During the fiscal year ended July 31, 2006, the exercise price of the Exercise Warrant to purchase an additional 189,585 shares of common stock was reduced from \$4.75 to \$2.88 per share. As of July 31, 2007, none of these options were exercised.

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During the fiscal year ended July 31, 2004, the Company issued 25,000 five-year stock options to a board member as payment for non-board related services and 110,000 five-year stock options to various consultants for services rendered. The options vested immediately and have a per share exercise price of \$3.46. The Company recorded a total of \$275,377 non-cash expenses for these options, based upon the fair value on the date of the issuance as estimated by the Black-Scholes options pricing model. As of July 31, 2007, 5,000 of these options were exercised.

During the fiscal year ended July 31, 2004, the Company issued an aggregate of 14,703 restricted shares of common stock as payment of accounts payable in the amount of \$52,176.

During the fiscal year ended July 31, 2004, the Company issued an aggregate of 75,000 restricted shares of common stock as payment for services rendered in an aggregate amount of \$288,500.

During the fiscal year ended July 31, 2004, the Company issued 1,210,654 shares of common stock to an existing institutional investor, resulting in gross proceeds of \$10,000,000 to the Company. In addition, the institutional investor was granted five-year warrants to purchase 1,210,654 shares of Common Stock at an exercise price of \$12.39 per share. The Company paid a 5% finder's fee to a third party in connection with the private placement, which included a five-year warrant to purchase 60,533 shares of common stock at an exercise price of \$12.39 per share. During the fiscal year ended July 31, 2006, the exercise price of the warrants to purchase an aggregate of 1,185,000 shares of common stock was reduced from \$12.39 to \$2.88 per share.

During the fiscal year ended July 31, 2004, the Company increased its outstanding shares by 40,000 shares of common stock for replacement of previously issued stock.

During the fiscal year ended July 31, 2004, the Company issued an aggregate of 3,042,817 shares of restricted common stock and five-year warrants to purchase 3,733,839 shares of common stock with exercise prices ranging from \$1.00 to \$1.10 per share upon the conversion of notes payable and accrued interest in the amount of approximately \$927,872.

During the fiscal year ended July 31, 2004, the Company issued an aggregate of 2,676,994 shares of common stock upon the exercise of warrants by unrelated parties and stock options by unrelated parties, employees, a director and former director at per share exercise prices ranging from \$0.26 to \$4.74. The Company realized aggregate gross proceeds of \$2,656,099 from these exercises.

During the fiscal year ended July 31, 2004, the Company incurred an aggregate of \$824,022 of costs relating to various private placements.

During the fiscal year ended July 31, 2005, the Company issued an aggregate of 1,744,978 shares of common stock and five-year warrants to purchase an aggregate of 2,044,978 shares of common stock with an exercise price of \$1.00 per share upon the conversion of notes payable and its accrued interest in an aggregate amount of \$464,499.

During the fiscal year ended July 31, 2005, the Company issued an aggregate of 438,372 shares of common stock upon the exercise of stock options and warrants by unrelated parties, employees and a director at per share exercise prices ranging from \$0.26 to \$1.91. The Company realized aggregate net proceeds of \$307,155 from these exercises.

During the fiscal year ended July 31, 2005, the Company issued 3,000 shares of restricted common stock as payment for services rendered. A non-cash expense of \$13,500 was recorded by the Company for these shares, based upon the fair value of the common stock at the date of issuance.

During the fiscal year ended July 31, 2005, the Company issued 12,500 warrants to a vendor in consideration for services to be rendered. 5,000 of these warrants which vested immediately have an exercise price of \$2.50 per share and 7,500 warrants which vested on the 91st day from the grant date have an exercise price of \$3.50 per share. These warrants will expire 24 months from the date the registration statement registering the shares underlying the warrants is declared effective or 36 months from the date of grant, whichever comes first. These warrants expired during the fiscal year ended July 31, 2008. The Company recorded a total of \$13,552 of non-

cash expense for these warrants, based upon the fair value at July 31, 2005 as estimated by the Black-Scholes option pricing model.

During the fiscal year ended July 31, 2005, the Company issued an aggregate of 20,000 ten-year stock options to consultants as payment for continuing services. The options will vest 25% each year starting on the first anniversary of the commencement of the services of the consultants provided they remain as consultants on the relevant vesting dates. The stock options have an exercise price of \$2.05 per share. The Company recorded a total of \$3,237 of non-cash expense for these options, based upon the fair value at July 31, 2005 as estimated by the Black-Scholes option pricing model. During the fiscal year ended July 31, 2006, the Company recorded under EITF 96-18, a total of \$15,066 of non-cash expense for these options.

During the fiscal year ended July 31, 2006, the Company issued an aggregate of 1,122,827 shares of common stock upon the exercise of warrants and stock options by unrelated parties, consultants, employees, directors and an executive officer at per share exercise prices ranging from \$0.26 to \$3.46. The Company realized aggregate gross proceeds of \$1,348,324 from these exercises.

During the fiscal year ended July 31, 2006, the Company issued 25,000 ten-year stock options to a consultant as payment for services rendered. The options vested immediately and have an exercise price of \$1.32 per share. The Company recorded a total of \$23,166 of non-cash expense for these options.

During the fiscal year ended July 31, 2006, the Company issued 25,000 ten-year stock options to a consultant as payment for services rendered. The options vested immediately and have an exercise price of \$3.37 per share. The Company recorded a total of \$58,387 of non-cash expense for these options.

During the fiscal year ended July 31, 2006, the Company issued 50,000 five-year stock options to a consultant as payment for services to be rendered. These options vest over a one year period, 50% of which vested immediately and 12.5% will vest equally for the next four quarters following the grant date. The stock options have an exercise price of \$2.04 per share and are subject to variable accounting under EITF 96-18. The fair value of these options is being expensed over the service period. During the fiscal year ended July 31, 2006, the Company recorded a total of \$74,253 of non-cash expense for these options.

During the fiscal year ended July 31, 2006, the Company issued 174,927 shares of restricted common stock to a private investor resulting in gross proceeds of \$600,000 to the Company for a purchase price of \$3.43 per share.

During the fiscal year ended July 31, 2006, the Company completed a private placement to various institutional investors which resulted in the issuance of an aggregate of 6,457,172 shares of restricted common stock for a purchase price of \$1.75 per share. The institutional investors also received warrants to purchase up to an additional 6,457,172 shares of common stock of the Company. The fair value of the warrants at the grant date was approximately \$12,962,000 as estimated using the Black-Scholes options pricing model. The warrants have a term of five years and were issued in two separate series. The first series of warrants (to purchase 3,228,590 shares of common stock) are exercisable beginning on January 19, 2007, and the second series of warrants (to purchase 3,228,582 shares of common stock) are also exercisable beginning on January 19, 2007. Both sets of warrants have an exercise price equal to \$2.88 per share. If the Company enters into a strategic corporate collaboration as outlined in the second series of warrants by December 31, 2006, the second series of warrants will be cancelled upon notification by the Company to the holders of the warrants that it has entered into such an agreement prior to such date. The Company did not enter in such agreement by the specified time therefore, the second series of warrants were not canceled. The Company received net proceeds of approximately \$10,384,000 from this private placement. The Company filed a registration statement on Form S-3 to register the resale of the shares and the shares issuable upon exercise of the warrants, which was declared effective in August 2006. If the Company had failed to file the registration statement, request effectiveness of the registration statement, respond to comments of the Securities and Exchange Commission, or cause the registration statement to be declared effective in a timely manner in accordance with the provisions of the registration rights agreement between the Company and the investors, or if the registration statement ceases to remain effective, or the investors are otherwise not permitted to utilize the prospectus in the registration statement to resell the securities for more than 15 consecutive calendar days or more than an aggregate of 25 calendar days during any 12-month period (which need not be consecutive calendar days), then the Company must pay to each investor an amount, in cash, as partial liquidated damages and not as a penalty,

equal to 2% of the aggregate purchase price paid by such investor for any securities registered on the registration statement that are then held by such investor monthly until the failure is cured. However, the Company shall not be required to pay partial liquidated damages to the investor in excess of 10% of the purchase price such investor paid for the registered securities. If the Company fails to pay any partial liquidated damages in full within seven days after the date payable, the Company will pay interest thereon to the investor at a rate of 18% per annum (or such lesser maximum amount that is permitted to be paid by applicable law), accruing daily from the date such partial liquidated damages are due until such amounts, plus all such interest thereon, are paid in full.

During the fiscal year ended July 31, 2007, the Company issued an aggregate of 295,800 shares of its common stock upon the exercise of stock options by an officer, employees and unrelated parties at per share exercise prices ranging from \$0.23 to \$2.16. The Company realized aggregate gross proceeds of \$352,256 from these equal to 2% of the aggregate purchase price paid by such investor for any securities registered on the registration statement that are then held by such investor monthly until the failure is cured. However, the Company shall not be required to pay partial liquidated damages to the investor in excess of 10% of the purchase price such investor paid for the registered securities. If the Company fails to pay any partial liquidated damages in full within seven days after the date payable, the Company will pay interest thereon to the investor at a rate of 18% per annum (or such lesser maximum amount that is permitted to be paid by applicable law), accruing daily from the date such partial liquidated damages are due until such amounts, plus all such interest thereon, are paid in full.

During the fiscal year ended July 31, 2007, the Company issued an aggregate of 295,800 shares of its common stock upon the exercise of stock options by an officer, employees and unrelated parties at per share exercise prices ranging from \$0.23 to \$2.16. The Company realized aggregate gross proceeds of \$352,256 from these exercises.

During the fiscal year ended July 31, 2007, the Company issued an aggregate of 1,142,559 shares of its common stock upon the exercise of warrants by related and unrelated parties at per share exercise prices ranging from \$0.60 to \$2.88. The Company realized aggregate gross proceeds of \$1,153,444 from these exercises.

During the fiscal year ended July 31, 2007, the Company issued an aggregate of 130,000 ten-year stock options to various consultants for services rendered. The options vested immediately and have an exercise price of \$1.71 per share. The Company recorded the total fair value of \$176,800 of non-cash expense for these options upon issuance.

During the fiscal year ended July 31, 2007, the Company issued 10,000 ten-year stock options to a consultant for serving in the Scientific Advisory Board. The options vested immediately and have an exercise price of \$1.49 per share. The Company recorded the total fair value of \$11,660 of non-cash expense for these options upon issuance.

In July 2007, the Company and USP Pharma Spolka Z.O.O. ("USP") entered into a Distribution and Marketing Agreement (the "Agreement"). The Agreement appoints USP as the Company's exclusive distributor in Poland, Lithuania, Estonia, Latvia, Belarus and the Ukraine in the field of Oncology. Included in the Agreement is an up-front fee as consideration for the appointment of USP as the Company's distributor in the defined territory. Based upon its review of SAB No. 101, "Revenue Recognition in Financial Statements", and SAB No. 104, "Revenue Recognition", the Company has determined that the up-front fee is to be recognized on a straight line basis over the term of the Agreement. The term of the Agreement is defined as the earlier of ten (10) years after the first commercial sale or the expiration of the patents covering the Company's product in the defined territory. The Agreement also includes multiple milestone payments and the payment of royalties. The milestone payments are to be paid to the Company upon the attainment of those milestones as defined in the Agreement. The royalty payments by USP to the Company are based on a fixed percentage of net sales. No revenue has been recognized for the up-front fee, milestone achievements and royalties in the accompanying financial statements. In connection with the Distribution Agreement, the Company and Unilab LP, an affiliate of US Pharmacia, entered into a Securities Purchase Agreement, (the "Purchase Agreement"), pursuant to which the Company issued an aggregate of 553,360 shares of its restricted common stock for purchase price of \$2.53 per share. The Company realized gross proceeds of \$1,400,000. The securities sold pursuant to the Purchase Agreement have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States in the absence of an effective registration statement or exemption from registration requirements.

During the fiscal year ended July 31, 2008, the Company issued an aggregate of 760,000 shares of its common stock upon the exercise of warrants by unrelated parties at per share exercise prices ranging from \$0.60 to \$1.25. The Company realized aggregate gross proceeds of \$541,500 from these exercises.

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During the fiscal year ended July 31, 2008, the Company issued an aggregate of 236,000 shares of its common stock upon the exercise of stock options by an officer and employees at per share exercise prices ranging from \$0.26 to \$1.58. The Company realized aggregate gross proceeds of \$145,540 from these exercises.

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During the fiscal year ended July 31, 2008, the Company issued an aggregate of 265,000 stock options to the independent members of its board of directors with an exercise price of \$1.72 per share and a six-year exercise term. The aggregate grant date fair market value of these options, \$275,865, is being amortized over the one-year vesting period. The Company recognized an aggregate compensation expense of \$154,705 for the fiscal year ended July 31, 2008.

During the fiscal year ended July 31, 2008, the Company issued an aggregate of 40,000 stock options to various non-employee consultants for services rendered. The options vested immediately, have an exercise price of \$1.75 per share and a ten-year exercise term. The aggregate grant date fair market value of these options, \$52,840, was recognized as an expense by the Company during the fiscal year ended July 31, 2008.

During the fiscal year ended July 31, 2008, the Company issued an aggregate of 330,000 stock options to various non-employee consultants for serving as the Company's scientific advisors and research collaborators and for contributions made on behalf of the Company's pre-clinical and clinical research programs. Of these options, 110,000 vested immediately, 50% of the balance will vest after one year and the remaining 50% of the balance will vest after two years. The options have an exercise price of \$1.75 per share and a ten-year term. Under the variable accounting provisions of EITF 96-18, the aggregate grant date fair market value of these options, \$456,730, is being amortized over the vesting period and is being re-measured as of each reporting period. At July 31, 2008, the aggregate re-measured fair market value of these options was estimated to be \$189,872.

During the fiscal year ended July 31, 2008, the Company issued 250,000 stock options to its CEO, Kuslima Shogen, with an exercise price of \$2.18 per share and a ten-year exercise term. The options, which were granted as a bonus for entering into an agreement for the marketing rights to ONCONASE® in the U.S., vested immediately and have a grant date fair market value of \$405,000 which was recognized as an expense by the Company during the fiscal year ended July 31, 2008.

During the fiscal year ended July 31, 2008, the Company entered into a retirement agreement (see Note 12) with Kuslima Shogen, its CEO. Under the terms of the agreement, the Company issued 1,000,000 stock options with an exercise price of \$2.00 per share. The options have a ten-year contractual term and will become exercisable only upon the approval of an ONCONASE® NDA by the United States Food and Drug Administration (FDA) for the treatment of malignant mesothelioma. The grant date fair market value of these options, \$1,900,000, is being amortized over the estimated vesting period. As of July 31, 2008, the Company recognized compensation expense of \$429,762.

### (7) Common Stock Warrants

During the fiscal years 1988 and 1991, the Board of Directors granted stock purchase warrants to acquire a maximum of 400,000 shares of common stock at \$5.00 per share which were not exercised and have since expired.

The following table summarizes the activity of common stock warrants issued in connection with the private placements and conversion of notes payable completed in fiscal years 1994 through 2006:

	Warrants	Exercise Price	Expiration
Sold in March 1994 Private Placement	800,000	\$ 5.00	3/21/97 to 6/21/97
Outstanding at July 31, 1994	800,000	5.00	3/21/97 to 6/21/97
Sold in September 1994 Private Placement	288,506	5.50	12/9/97 to 12/14/97
Sold in October 1994 Private Placement	40,000	5.50	1/21/98
Sold in September 1995 Private Placement	47,405	4.00	10/1/98
Outstanding and exercisable at July 31, 1995	1,175,911	4.00 - 5.50	3/21/97 to 10/1/98
Issued to bank in connection with an amendment to the Company's term loan	10,000	4.19	8/31/97
Sold in September 1995 Private Placement	8,540	4.00	10/1/98
Sold in June 1996 Private Placement	313,800	7.50	8/29/99 to 9/10/99
Outstanding and exercisable at July 31, 1996	1,508,251	4.00 - 7.50	3/21/97 to 9/10/99
Exercised	(147,450)	5.00	3/21/97 to 6/21/97

Expired	(652,550)	5.00	3/21/97 to 6/21/97
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	Warrants	Exercise Price	Expiration
Outstanding and exercisable at July 31, 1997	708,251	4.00 - 7.50	12/9/97 to 9/10/99
Sold in February 1998 Private Placement	1,168,575	2.50	8/17/01
Issued to the Placement Agent in connection with the February 1998 Private placement	350,574	2.20 - 2.50	8/17/01
Exercised	(4,950)	2.20 - 2.50	5/19/01
Expired	(338,506)	4.19 - 5.50	8/31/97 to 1/21/98
Outstanding and exercisable at July 31, 1998	1,883,944	2.20 - 7.50	10/1/98 to 8/17/01
Expired	(55,945)	4.00	10/1/98
Sold in February 2000 Private Placement	875,000	1.03 - 4.55	5/28/03 to 5/28/05
Expired	(313,800)	7.50	8/30/99 to 9/11/99
Outstanding and exercisable at July 31, 2000	2,389,199	1.03 - 4.55	5/19/01 to 5/28/05
Sold in various private placements	696,665	1.50 - 3.00	7/07/04 to 10/30/06
Issued to related parties upon conversion of note payable	330,000	1.50	7/07/06
Outstanding and exercisable at July 31, 2001	3,415,864	1.03 - 4.55	8/17/01 to 10/30/06
Expired	(1,514,199)	2.20 - 2.50	8/17/01
Sold in various private placements	2,673,422	0.75 - 1.50	11/03/06 to 9/10/07
Issued to vendor upon settlement of accounts payable	55,556	1.50	8/15/06
Issued to unrelated party for advisory services	1,500,000	0.50 - 1.50	2/6/07
Exercised	(186,000)	0.50	2/6/07
Issued to unrelated parties upon conversion of notes payable	72,214	1.50	10/31/06
Issued to unrelated parties in connection with notes payable	300,000	0.60	11/13/06 to 7/29/07
Outstanding and exercisable at July 31, 2002	6,316,857	0.50 - 4.55	5/28/03 to 9/10/07
Expired	(437,500)	1.03 - 3.25	5/28/03
Sold in various private placements	1,315,000	1.00 - 1.50	1/24/08 to 10/31/08
Exercised	(640,000)	0.50	2/6/07
Issued to unrelated parties in connection with notes payable	665,000	0.60	9/6/07 to 3/14/08
Outstanding and exercisable at July 31, 2003	7,219,357	0.50 - 4.55	5/28/05 to 10/31/08
Sold in various private placements	2,372,512	1.25 - 12.39	9/3/08 to 5/9/09
Exercised	(2,014,273)	0.50 - 1.50	2/6/07 to 10/31/08
Issued to third party as finder's fee	60,533	12.39	5/9/09
Issued to unrelated parties in connection with conversion of notes payable	3,733,839	1.00 - 1.10	12/4/08 to 7/15/09
Outstanding and exercisable at July 31, 2004	11,371,968	0.60 - 12.39	5/28/05 to 7/15/09
Exercised	(247,272)	0.75 - 1.25	7/16/07 to 8/5/08
Expired	(437,500)	2.50 - 4.55	5/28/05
Issued to unrelated parties in connection with conversion of notes payable	2,044,978	1.00	9/14/09 to 5/6/10
Issued to a vendor in connection with services rendered	12,500	2.50 - 3.50	4/25/08
Outstanding and exercisable at July 31, 2005	12,744,674	0.60 - 12.39	11/29/05 to 5/6/10
Exercised	(915,582)	0.75 - 1.50	7/7/06 to 9/2/08
Expired	(166,666)	3.00	11/29/05 - 12/21/05
Sold in a private placement	6,457,172	2.88	7/17/11





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	Warrants	Exercise Price	Expiration
Outstanding at July 31, 2006	18,119,598	0.60 - 12.39	10/7/06 to 7/17/11
Exercised	(1,142,559)	0.60 - 2.88	10/7/06 to 7/17/11
Expired	(906,291)	1.50	10/12/06 - 4/9/07
Outstanding at July 31, 2007	16,070,748	0.60 - 12.39	9/6/07 to 7/17/11
Exercisable at July 31, 2007	16,070,748	0.60 - 12.39	9/6/07 to 7/17/11
Exercised	(760,000)	0.60 - 1.25	9/6/07 to 5/10/08
Expired	(448,214)	1.00 - 3.50	9/10/07 - 7/9/08
Outstanding at July 31, 2008	14,862,534	\$1.00 - \$12.39	8/13/08 to 7/17/11
Exercisable at July 31, 2008	14,862,534	\$1.00 - \$12.39	8/13/08 to 7/17/11

(8) Stock Options

2004 Stock Incentive Plan

The Company's stockholders approved the 2004 Stock Incentive Plan (the "2004 Plan") for the issuance of up to 8,500,000 shares, which provides that common stock and stock options may be granted to employees, directors and consultants. The 2004 Plan provides for the granting of stock options, stock appreciation rights, restricted shares, or other share based awards to eligible employees and directors, as defined in the 2004 Plan. Options granted under the 2004 Plan will have an exercise price equal to the market value of the Company's common stock on the date of the grant. The term, vesting period and time and method of exercise of options granted under the 2004 Plan are fixed by the Board of Directors or a committee thereof.

1997 Stock Option Plan

The Company's stockholders approved the 1997 stock option plan for the issuance of options for up to 2,000,000 shares, which provides that options may be granted to employees, directors and consultants. Options are granted at market value on the date of the grant and generally are exercisable in 20% increments annually over five years starting one year after the date of grant and terminate five years from their initial exercise date. This plan expired in May 2007 except to the extent there are outstanding options.

1993 Stock Option Plan

The Company's stockholders approved the 1993 stock option plan for the issuance of options for up to 3,000,000 shares, which provides that options may be granted to employees, directors and consultants. Options are granted at market value on the date of the grant and generally are exercisable in 20% increments annually over five years starting one year after the date of grant and terminate five years from their initial exercise date. This plan expired in November 2003 except to the extent there are outstanding options. As of July 31, 1994, 1,703,159 options were granted and outstanding under the 1993 stock option plan.

The Company recorded the following stock-based compensation expense for employees under SFAS 123(R) based on the fair value of stock options.

	Year Ended July 31,		
	2008	2007	2006
Research and development	\$ 717,059	\$ 794,262	\$ 444,981
General and administrative	1,346,820	1,427,859	873,230
Total stock-based compensation expense	\$ 2,063,879	\$ 2,222,121	\$ 1,318,211
Basic and diluted loss per common share	\$ 0.04	\$ 0.05	\$ 0.04

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At July 31, 2008, the Company reversed a total of \$1,225,112 compensation expense related to 1,072,489 performance stock options issued to employees in May 2007. The Company assessed that the performance condition tied to these stock options is deemed improbable; therefore, no compensation expense should be recognized in accordance to the guidance of SFAS123R.

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The fair value of the stock options at the grant date was estimated using the Black-Scholes option pricing model based on the weighted-average assumptions as noted in the following table. The risk-free interest rate for periods approximating the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The expected stock price volatility is based on historical volatility of the Company's stock price. For post July 31, 2005 grants, the expected term until exercise is derived using the "simplified" method as allowed under the provisions of the SEC's SAB No. 110, "Disclosures about Fair Value of Financial Instruments" and represents the period of time that options granted are expected to be outstanding.

	2008	2007	2006
Expected dividend yield	0%	0%	0%
Risk-free interest rate	3.45%	4.78%	4.40%
Expected volatility	108.2%	107.7%	95.6%
Expected term (years)	7.53	5.36	5.33
Weighted average fair value of options at grant date	\$ 1.64	\$ 1.46	\$ 1.27
Weighted average fair value exercise price	\$ 1.94	\$ 1.80	\$ 1.69

As of July 31, 2008, there was approximately \$2,242,000 of total unrecognized compensation expense related to unvested options granted to employees that is expected to be recognized over a weighted average period of 0.65 years.

Shares, warrants and options issued to non-employees for services are accounted for in accordance with SFAS 123(R) and EITF Issue No. 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring or In Conjunction with Selling Goods or Services" ("EITF 96-18"). The fair value of such securities is recorded as an expense and additional paid-in capital in stockholders' equity over the applicable service periods using variable accounting through the vesting date based on the fair value of the securities at the end of each period or the vesting date. During the fiscal year ended July 31, 2008, the Company recorded under the variable accounting provisions of EITF 96-18, an aggregate total of \$235,096 of non-cash expense for options issued to non-employees.

Option Activity

The following table summarizes stock option activity for the period August 1, 1994 to July 31, 2008:

	Shares Available for Grant	Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Balance August 1, 1994	1,926,841	5,935,337	\$3.76		
Granted	(818,850)	818,850	2.60		
Exercised	-	(185,000)	2.36		
Canceled/Expired	-	(1,897,500)	4.30		
Balance August 1, 1995	1,107,991	4,671,687	3.39		
Granted	(296,205)	296,205	3.99		
Exercised	-	(656,334)	2.92		
Canceled/Expired	6,500	(235,333)	4.89		
Balance July 31, 1996	818,286	4,076,225	3.43		
Authorized by 1997 Plan	2,000,000	-	-		
Granted	(932,500)	932,500	4.90		
Exercised	-	(639,500)	3.82		
Canceled/Expired	484,845	(484,845)	4.70		

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Balance July 31, 1997	2,370,631	3,884,380	3.56
Granted	(234,333)	234,333	3.31
Canceled/Expired	91,100	(91,100)	3.81

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	Shares Available for Grant	Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Balance July 31, 1998	2,227,398	4,027,613	3.54		
Granted	(595,000)	595,000	0.62		
Canceled/Expired	443,934	(555,737)	3.97		
Balance July 31, 1999	2,076,332	4,066,876	3.05		
Granted	(827,000)	827,000	0.52		
Exercised	-	(95,000)	0.48		
Canceled/Expired	638,395	(1,031,880)	2.73		
Balance July 31, 2000	1,887,727	3,766,996	2.65		
Granted	(447,000)	447,000	0.85		
Exercised	-	(165,555)	0.51		
Canceled/Expired	774,315	(1,018,557)	3.42		
Balance July 31, 2001	2,215,042	3,029,884	2.24		
Granted	(544,221)	544,221	0.69		
Canceled/Expired	655,840	(900,081)	2.31		
Balance July 31, 2002	2,326,661	2,674,024	1.90		
Granted	(630,000)	630,000	0.50		
Exercised	-	(124,000)	0.47		
Canceled/Expired	485,118	(736,358)	3.09		
Balance July 31, 2003	2,181,779	2,443,666	1.26		
Authorized by 2004 Stock Incentive Plan	8,500,000	-	-		
Granted	(1,388,996)	1,388,996	5.03		
Exercised	-	(666,717)	0.98		
Canceled/Expired	(262,783)	(208,500)	3.20		
Balance July 31, 2004	9,030,000	2,957,445	2.95		
Granted	(1,073,000)	1,073,000	4.36		
Exercised	-	(191,100)	0.75		
Canceled/Expired	290,500	(341,500)	4.57		
Balance July 31, 2005	8,247,500	3,497,845	3.35		
Granted	(745,000)	745,000	1.76		
Exercised	-	(207,245)	0.90		
Canceled/Expired	171,250	(205,250)	4.67		
Balance July 31, 2006	7,673,750	3,830,350	3.10		
Granted	(2,187,489)	2,187,489	1.80		
Exercised	-	(295,800)	1.19		332,936
Cancelled/Expired	(26,250)	(125,000)	3.07		
Forfeited	325,000	(730,000)	1.69		
Balance July 31, 2007	5,785,011	4,867,039	2.85	6.28	2,277,048
Granted	(1,885,000)	1,885,000	1.94		
Exercised	-	(236,000)	0.62		392,430
Cancelled/Expired	1,000	(137,000)	1.45		
Forfeited	25,972	(25,972)	2.00		
Balance July 31, 2008	3,926,983	6,353,067	\$2.69	6.72	\$ 84,115
Exercisable at July 31, 2007		2,616,333	\$3.25	4.22	\$1,627,756

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Exercisable at July 31, 2008	3,326,816	\$3.33	4.88	\$ 84,115
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Stock option activity prior to adoption of SFAS 123 (see Note 1) is as follows:

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1981 Non-Qualified Stock Option Plan

In 1981, the Board of Directors adopted a non-qualified stock option plan and had reserved 300,000 shares for issuance to key employees or consultants. Options were nontransferable and expired if not exercised within five years. Option grants of 60,000 shares expired unexercised by July 31, 1991.

Non-Qualified Stock Options

The Board of Directors issued non-qualified stock options which were not part of the 1981 non-qualified stock option plan or the 1989 Stock Plan as follows:

	Shares	Price Range
Granted	1,782,000	\$ 3.00-3.87
Exercised	(276,989)	3.00-3.50
Canceled	(106,000)	3.00-3.50
Expired	(649,011)	3.00-3.50
Granted pursuant to conversion of certain liabilities:		
Related party	1,324,014	3.20
Unrelated party	73,804	3.20
Repurchased stock options	(102,807)	3.20
Balance at July 31, 1994	2,045,011	\$ 3.20-3.87

In connection with certain private placements, the Board of Directors had included in the agreements, options to purchase additional shares of the Company's common stock as follows:

	Shares	Price Range
Granted (42,167 options were repriced and extended)	894,887	\$ 2.50-7.00
Exercised	(81,000)	3.97-6.50
Expired	(201,720)	3.97-6.50
Balance at July 31, 1994	612,167	\$ 2.50-7.00

All of the above options expired as of July 31, 2001.

1989 Stock Plan

On February 14, 1989, the Company adopted the Alfacell Corporation 1989 Stock Plan (the "1989 Stock Plan"), pursuant to which the Board of Directors could issue awards, options and grants.

No more options are being granted pursuant to this plan. The per share option exercise price was determined by the Board of Directors. All options and shares issued upon exercise were nontransferable and forfeitable in the event employment was terminated within two years of the date of hire. In the event the option was exercised and said shares were forfeited, the Company would return to the optionee the lesser of the current market value of the securities or the exercise price paid.

The stock option activity is as follows:

	Shares	Price Range
Granted, February 14, 1989	3,460,000	\$ 3.50-5.00
Options issued in connection with share purchase	36,365	2.75
Expired	(1,911,365)	2.75-5.00



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Canceled	(10,000)	5.00
Balance at July 31, 1994	1,575,000	\$ 3.50-5.00

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(9) Stock Grant and Compensation Plans

The Company had adopted a stock grant program effective September 1, 1981, and pursuant to said program, had reserved 375,000 shares of its common stock for issuance to key employees. The stock grant program was superseded by the 1989 Stock Plan, and no further grants will be given pursuant to the grant plan. The following stock transactions occurred under the Company's stock grant program:

Year ended <u>July 31.</u>	<u>Shares</u>	Fair <u>Value</u>	Amount of <u>Compensation</u>
1983	20,000	\$ 5.50	\$ 110,000
1984	19,750	5.125	101,219
1985	48,332	5.125-15.00	478,105
1986	11,250	5.125-15.00	107,032
1988	19,000	3.50	6,500

On January 26, 1984, the Company adopted a stock bonus plan for directors and consultants. The plan was amended on October 6, 1986 to reserve 500,000 shares for issuance under the plan and to clarify a requirement that stock issued under the Plan could not be transferred until three years after the date of the grant. The stock bonus plan for directors and consultants was superseded by the 1989 Stock Plan and no further grants will be given pursuant to the stock bonus plan for directors and consultants. The following stock transactions occurred under the Company's stock bonus plan:

Year ended <u>July 31.</u>	<u>Shares</u>	Fair <u>Value</u>	Amount of <u>Compensation</u>
1984	130,250	\$ 2.50-3.88	\$ 385,917
1985	99,163	3.50-15.00	879,478
1985	(42,500)	2.50	(105,825)*
1986	15,394	9.65-15.00	215,400
1987	5,000	15.00	75,000

\* Shares granted in 1984 were renegotiated in 1985 and canceled as a result of the recipient's termination.

1989 Stock Plan

Under the 1989 Stock Plan, one million shares of the Company's common stock were reserved for issuance as awards to employees. The 1989 Stock Plan also provided for the granting of options to purchase common stock of the Company. In addition, the 1989 Stock Plan provided for the issuance of 1,000,000 shares of the Company's common stock as grants. To be eligible for a grant, grantees must have made substantial contributions and shown loyal dedication to the Company.

Awards and grants were authorized under the 1989 Stock Plan during the following fiscal years:

Year ended <u>July 31.</u>	<u>Shares</u>	Fair <u>Value</u>	Amount of <u>Compensation</u>
1989	30,000	\$ 5.00	\$ 150,000
1990	56,000	6.00	336,000
1991	119,000	4.00	476,000
1992	104,000	2.75	286,000
1993	117,000	2.00	234,000
1994	5,000	3.00	15,000

Compensation expense was recorded for the fair value of all stock awards and grants over the vesting period. The 1994 stock award was immediately vested. There were no stock awards in fiscal year ended 1999 and the plan expired in 1999.

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(10) Income Taxes

The Company accounts for income taxes under the provisions of SFAS 109. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for all years in which the temporary differences are expected to reverse.

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of its state tax loss carryforwards and state research and development credits in order to obtain state tax benefits. For the state fiscal year 2008 (July 1, 2007 to June 30, 2008), the Company had approximately \$2,496,000 of total available state tax benefits that were saleable, of which New Jersey permitted the Company to sell approximately \$1,969,000. In December 2007, the Company received approximately \$1,755,000 from the sale of the \$1,969,000 of state tax benefits, which was recognized as a state tax benefit for the fiscal year ended July 31, 2008.

For the state fiscal year 2007 (July 1, 2006 to June 30, 2007), the Company had approximately \$2,338,000 of total available state tax benefits that were saleable, of which New Jersey permitted the Company to sell approximately \$574,000. In December 2006, the Company received approximately \$510,000 from the sale of the \$574,000 of state tax benefits, which was recognized as a state tax benefit for the fiscal year ended July 31, 2007.

For the state fiscal year 2006 (July 1, 2005 to June 30, 2006), the Company had approximately \$1,903,000 of total available state tax benefits that were saleable; of which New Jersey permitted the Company to sell approximately \$356,000. In December 2005, the Company received approximately \$317,000 from the sale of the \$356,000 of state tax benefits, which was recognized as a state tax benefit for the fiscal year ended July 31, 2006.

If still available under New Jersey law, the Company will attempt to sell the remaining \$1,274,000 of its state tax benefits between July 1, 2008 and June 30, 2009 (state fiscal year 2009). This amount, which is a carryover of the Company's remaining state tax benefits from the state fiscal year 2008, may increase if the Company incurs additional net losses and research and development credits during the state fiscal year 2009. The Company cannot estimate, however, what percentage of its saleable state tax benefits New Jersey will permit it to sell, how much money will be received in connection with the sale, if any, if the Company will be able to find a buyer for its state tax benefits or if such funds will be available in a timely manner.

At July 31, 2008 and 2007, the tax effects of temporary differences that give rise to the deferred tax assets are as follows:

	2008	2007
Deferred tax assets:		
Excess of book over tax depreciation and amortization	\$ 4,581	\$ 392
Stock options	2,350,272	1,487,565
Deferred revenue	2,080,000	□
Temporary differences	521,403	393,414
Federal and state net operating loss carryforwards	23,033,058*	22,697,884*
Research and experimentation credit carryforwards	3,067,618*	2,600,529*
Total gross deferred tax assets	31,056,932	27,179,784
Valuation allowance	(31,056,932)	(27,179,784)
Net deferred tax assets	\$ □	\$ □

\* Net of amount sold pursuant to New Jersey state tax legislation.

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The tax benefit assumed using the federal statutory tax rate of 34% has been reduced to the actual benefits reflected on the statements of operations due principally to the aforementioned valuation allowance. In 2008, 2007 and 2006 the valuation allowance increased by \$3,877,000, \$3,074,000, and \$2,542,000, respectively.

At July 31, 2008, the Company has federal net operating loss carryforwards of approximately \$65,689,000 that



expire in the years 2009 to 2028 (approximately \$14,677,000 expires in the years 2009 to 2013) and state net operating loss carryforwards of approximately \$11,647,000 that expire in years 2016 to 2017. The Company also has federal research and experimentation tax credit carryforwards of approximately \$2,119,000 that expire in the years 2009 to 2028 (approximately \$260,000 expires in the years 2009 to 2013) and state research and experimentation tax credits of approximately \$948,000 that expire in the years 2018 to 2023. Ultimate utilization/availability of such net operating losses and credits is dependent upon the Company's ability to generate taxable income in future periods and may be significantly curtailed if a significant change in ownership occurs in accordance with the provisions of the Tax Reform Act of 1986.

Effective August 1, 2007, the Company adopted FIN 48 which clarifies the accounting and disclosure for uncertainty in income taxes. The adoption of this interpretation did not have any material impact on the Company's financial statements, as there were no unrecognized tax benefits as of August 1, 2007 or during the fiscal year ended July 31, 2008.

The Company files income tax returns in the U.S. federal jurisdiction and New Jersey. For federal income tax purposes, fiscal 2005 through 2008 tax years generally remain open for examination by the tax authorities under the normal three-year statute of limitations. For New Jersey tax purposes, fiscal 2004 through 2008 tax years generally remain open for examination under a four-year statute of limitations.

(11) Related Party Transactions

In March 2008, the Company engaged Champions Biotechnology, Inc. to provide certain services for approximately \$12,300. The Company's non-executive Chairman of the Board of Directors, Dr. David Sidransky, is also the chairman of the board of directors as well as a principal stockholder of Champions Biotechnology, Inc. As of July 31, 2008, 50% of the agreed amount was paid and the remaining 50% will be paid upon the completion of services.

(12) Commitments

*Employment and Retirement Agreements*

On April 28, 2008, the Company announced that Kuslima Shogen, the Company's CEO and scientific founder, will retire from the Company on or before March 31, 2009. On April 25, 2008, Alfacell entered into a retirement agreement (the "Retirement Agreement") with Ms. Shogen. Under the terms of the Retirement Agreement, Ms. Shogen will be entitled to receive her current annual salary of \$300,000 and participate in all benefit plans available for the Company's executives through her retirement date, which will occur on or before March 31, 2009 (the "Termination Date"). Ms. Shogen will receive retirement payments of \$300,000 for each of the two years after the Termination Date. During the fiscal year ended July 31, 2008, the Company accrued these benefits in the amount of \$612,000.

The options to purchase the Company's common stock currently held by Ms. Shogen will remain exercisable after Ms. Shogen's retirement in accordance with their terms. No change was made to the terms of such existing options under the Retirement Agreement, except the Compensation Committee of the Company's Board of Directors amended the Company's 1993 Stock Option Plan and 1997 Stock Option Plan to allow such options to be transferred by Ms. Shogen to members of her family. The Compensation Committee has agreed to give Ms. Shogen the ability to transfer her existing options granted under the 2004 Plan to members of her family subject to all the terms and restrictions of the Plan.

If Ms. Shogen elects COBRA continuation coverage after the Termination Date, the Company will pay for Ms. Shogen's COBRA insurance continuation premiums until the earliest of the second anniversary of the Termination Date, the date Ms. Shogen is no longer eligible for COBRA insurance coverage under applicable law or the date on which Ms. Shogen becomes eligible for Medicare. In the event Ms. Shogen becomes ineligible for COBRA coverage under the Company's insurance plans for any reason other than her death prior to the second anniversary of the Termination Date, the Company will make a lump sum cash payment to Ms. Shogen equal to the amount of the premiums the Company would have had to pay to maintain Ms. Shogen's coverage under the Company's insurance plans had Ms. Shogen remained eligible for coverage under such plans for the period commencing on the date Ms. Shogen became ineligible for such coverage and ending on the second anniversary of the Termination Date.



Pursuant to the terms of the Retirement Agreement, Ms. Shogen has also agreed to terminate the Royalty Agreement dated July 24, 1991, as amended on April 16, 2001 by and between the Company and Ms. Shogen (the "Royalty Agreement"). In exchange for termination of the Royalty Agreement, the Company will make the following payments and awards to Ms. Shogen: (1) a lump sum payment of \$500,000 to be made within ten business days of the date of the Retirement Agreement, from which Alfacell will be entitled to deduct the amount of the outstanding principal and accrued interest of \$187,410 owed by Ms. Shogen to Alfacell as of the date of the Retirement Agreement; (2) if the NDA for ONCONASE<sup>®</sup> for the treatment of malignant mesothelioma is approved by the FDA, Ms. Shogen will receive a one time payment equal to 5% of the initial milestone payment payable to the Company by Par Pharmaceutical Inc. ("Par") pursuant to the License Agreement dated as of January 14, 2008 by and between the Company and Par (the "License Agreement"); (3) if the NDA is approved by the FDA, Ms. Shogen will also receive a payment of \$350,000 on each of the first and second anniversaries of the date of such approval for a total payment of \$700,000; (4) an option (the "Option") to purchase an aggregate of 1,000,000 shares of the Company's common stock under the Plan at an exercise price equal to the fair market value of the common stock as of the date of the Retirement Agreement as determined under the Plan. The Option has a term of ten years and will become exercisable only upon the approval of the NDA by the FDA. As the result of the option to purchase 250,000 shares of common stock granted under the Plan to Ms. Shogen on March 5, 2008 in connection with the Company's execution of the License Agreement and in order to enable the Company to grant this Option to Ms. Shogen, the Board of Directors amended the annual award limitation for a participant in the Plan for 2008 as it relates to Ms. Shogen from 1,000,000 shares to 1,250,000 shares; (5) payments equal to 15% of any royalties payable with respect to net sales which are received by Alfacell pursuant to any and all license agreements entered into by Alfacell for the marketing and distribution of ONCONASE<sup>®</sup> and any other products derived from amphibian source extract, produced either as a natural, synthesized, and/or genetically engineered drug which are covered by the claims of any issued patent owned or controlled by Alfacell which is issued and valid as of December 31, 2007 (the "Licensed Products") and 5% of net sales of Licensed Products which Alfacell books on its financial statements but only to the extent that the aggregate annual net sales of Licensed Products upon which such royalty payments are received by Alfacell and annual net sales of Licensed Products booked by Alfacell when combined are in excess of \$100 million in a year. In the event either or both of the aggregate annual net sales of Licensed Products upon which Alfacell receives royalties and the annual net sales of Licensed Products which Alfacell books on its financial statements are less than \$100 million, but when combined such aggregate annual net sales exceed \$100 million, the payments to be received by Ms. Shogen in that year will be paid with respect to the amount of such aggregate net sales that exceeds \$100 million and pro rated between the 15% Ms. Shogen is entitled to receive on royalties received by Alfacell and the 5% Ms. Shogen is entitled to receive on net sales booked by Alfacell based upon the percentage of the total net sales of the Licensed Products that year represented by aggregate net sales upon which Alfacell receives a royalty and the net sales booked by Alfacell. Ms. Shogen's rights to receive these payments shall terminate when all claims under the relevant patents which cover the Licensed Products have expired.

#### *Lease Commitments*

In November 2007, the Company entered into a capital lease agreement for its building security system for the term of five years with a payment of \$635 per month. The lease agreement also gives the Company the right to purchase the leased equipment at the end of the lease term for \$1.00 plus applicable taxes.

On March 14, 2007 the Company entered into an operating lease agreement for a period of ten years to lease space to relocate its corporate headquarters and laboratories to a new location in Somerset, New Jersey. This lease expires on the tenth anniversary plus 150 days after the commencement date of the lease which expiration date is expected to be November 2017. The first rental payment occurred on July 3, 2007 which is the lease commencement date. The lease may be renewed at the option of the Company for a period of two additional terms of 60 months each. In addition, the Company has received an incentive allowance of \$205,000 with an option to receive an additional incentive allowance of \$105,000. As of July 31, 2007 the Company has not exercised the additional incentive allowance of \$105,000. Both allowances must be used for the cost of leasehold improvements made to the premises. If all or any portion of the remaining allowance is not used by the end of the original lease term of ten years any remaining balance may not be applied to the balance of any rent due at the conclusion of the initial lease term. As part of the operating lease agreement signed on March 14, 2007 the Company agreed to enter into an irrevocable letter of credit in the amount of \$350,000 as security for such operating lease. This irrevocable letter of credit is collateralized by \$350,000 in cash which is



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recorded in [Other Assets] as of July 31, 2008 and 2007. If no event of default occurs under the operating lease the Company may reduce its security deposit under the operating lease to \$250,000 on July 1, 2011, the fourth anniversary of the lease commencement date. In the event of no default as of July 1, 2012, the fifth anniversary of the lease commencement date, the irrevocable letter of credit may be reduced to \$150,000 until the initial term of the lease expires in 2017. Rent expense charged to operations was approximately \$300,000 for fiscal year ended July 31, 2008.

Prior to July 2007, the Company leased its facility on a month-to-month basis. Rent expense charged to operations was approximately \$160,000, \$136,000 and \$136,000 in each of fiscal years ended July 31, 2007, 2006 and 2005, respectively.

In June 2007, the Company entered into an operating lease agreement for its office equipment for the term of five years with a payment of approximately \$1,600 per month. As part of the lease agreement, the Company agreed to terminate its existing office equipment lease. As a result of the early termination of the existing lease, the Company recognized an expense of approximately \$31,000 which will be amortized using straight-line method over the term of the lease and will be charged as a reduction from the equipment rental expense. The new lease did not commence until August 2007. Rent expense charged to operations was approximately \$12,000 for fiscal year ended July 31, 2008. Under the previous lease agreement, equipment rental expense charged to operations was \$16,000 and \$12,000 in each of fiscal years ended July 31, 2007 and 2006, respectively.

Future minimum lease payments under noncancelable operating leases (with initial or remaining terms in excess of one year) as of July 31, 2008:

	Payments Due in Fiscal Year						2014 and Thereafter
	Total	2009	2010	2011	2012	2013	
Building lease	\$ 3,026,130	\$ 275,445	\$ 302,036	\$ 317,446	\$ 317,446	\$ 317,446	\$ 1,496,311
Equipment lease	117,160	33,548	31,024	25,976	25,976	636	-
Total contractual cash obligations	\$ 3,143,290	\$ 308,993	\$ 333,060	\$ 343,422	\$ 343,422	\$ 318,082	\$ 1,496,311

*Defined Contribution Retirement Plan (401(k) Plan)*

Effective October 1, 1998, the Company adopted a 401(k) Savings Plan (the [Plan]). Qualified employees may participate by contributing to the Plan subject to certain Internal Revenue Service restrictions. The Company will match an amount equal to 50% of the first 6% of each participant's contribution. The Company's contribution is subject to a vesting schedule of 0%, 25%, 50%, 75% and 100% for employment of less than one year, one year, two years, three years and four years, respectively, except for existing employees which vesting schedule was based from the date the Plan was adopted. For the fiscal years ended July 31, 2008, 2007 and 2006, the Company's contributions to the Plan amounted to \$46,921, \$34,080, and \$27,810, respectively.

(13) Contingencies

The Company has product liability insurance coverage for clinical trials in the U.S. and in other countries where it conducts its clinical trials. No product liability claims have been filed against the Company. If a claim arises and the Company is found liable in an amount that significantly exceeds the policy limits, it may have a material adverse effect upon the financial condition and results of operations of the Company.

(14) Unaudited Quarterly Financial Data

The following table is the quarterly data for the two years ended July 31, 2008 and 2007.

(In thousands, except per share amounts)

	2008					2007				
	First	Second	Third	Fourth	Totals	First	Second	Third	Fourth	Totals
Investment income	\$ 61	\$ 66	\$ 67	34	\$ 228	\$ 123	\$ 99	\$ 82	67	\$ 371
Operating loss	(2,787)	(3,507)	(5,092)	(2,915)	(14,301)	(2,496)	(2,534)	(2,110)	(2,496)	(9,636)
Net loss (a)	(2,727)	(1,687)	(5,026)	(2,881)	(12,321)	(2,373)	(1,925)	(2,028)	(2,429)	(8,755)
Loss per share										
□ basic and diluted	\$ (0.06)	\$ (0.04)	\$ (0.11)	\$ (0.06)	\$ (0.26)	\$ (0.05)	\$ (0.04)	\$ (0.04)	\$ (0.05)	\$ (0.19)

(a) The net loss of \$1,687 for the second quarter of 2008 and \$1,925 for the second quarter of 2007 is net of state tax benefits of \$1,755 and \$510, respectively, related to the sale of certain state tax operating loss carryforwards.

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