ALFACELL CORP
Form 10-K
October 14, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

[X] 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	**22-2369085**
(State or other jurisdiction of incorporation or organization)	**(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	**Nasdaq Capital Market**
(Title of Class)	**(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]

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 [ ]

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.

TABLE OF CONTENTS

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, Zolinza® 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,□ □anticip □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® (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® is not an indiscriminate cytotoxic drug (cell killing agent). ONCONASE® 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®, 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® is a confirmatory Phase IIIb registration trial designed to evaluate the efficacy, safety and tolerability of the combination of ONCONASE® 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® 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® 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®.

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

We believe that ONCONASE®, 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®. 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 Zolinza (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® 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® 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® 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®, 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® from the European Agency for the Evaluation of Medicinal Products, or EMEA, as well as Orphan Drug Designation for ONCONASE® 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® for malignant mesothelioma may serve to expedite its regulatory review upon submission of a marketing application. The efficacy and safety of ONCONASE® for malignant mesothelioma will ultimately be determined by these regulatory agencies based on the results of our Phase IIIb registration trial.

ONCONASE® 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 ov erall 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 *in vivo*, 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.

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 JP 2972334	cover combinations of ONCONASE® with certain other pharmaceuticals	Oct. 2010
EP 0 656 783 JP 3655628	covers combinations of ONCONASE® with certain other pharmaceuticals	July 2013
EP 0 837 878 JP 3779999	covers a variant of ONCONASE®	June 2016
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) 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® 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® medication as an orphan drug to treat patients with pleural mesothelioma. Alimta® is a multi-targeted antifolate that is based upon a different mechanism of action than ONCONASE®. To our knowledge, no other company is developing a product with the same mechanism of action as ONCONASE®. 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 Zolinza (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.

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®, 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

23

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

27

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 12Security 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 (1)	(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.

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® NDA.

The primary use of cash over the next 12 months will be to fund our regulatory and commercial efforts for ONCONASE® 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®. 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:

	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	$ 1,496,3
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	$ 1,496,3

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

35

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)	*

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)	*

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 toExhibit 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	*

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	*

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	*

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

^ 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

Index to Financial Statements

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

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

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
ASSETS		
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
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIENCY)		
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

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.

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
Operating expenses:&n				