

ALFACELL CORP
Form 10-K
November 13, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended July 31, 2009

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 (I.R.S.
other Employer
jurisdiction of
incorporation Identification
or No.)
organization)

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:
None

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

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

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No []

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§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, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one): Large Accelerated Filer Accelerated Filer 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

The aggregate market value of the voting and non-voting common equity held by non-affiliates based upon the reported last sale price of the common stock on January 31, 2009, the end of the registrant's second fiscal quarter, was approximately \$4,766,000. As of November 10, 2009 there were 47,313,880 shares of common stock, par value \$.001 per share, outstanding.

Documents Incorporated by Reference

Certain information required in Part III of this annual report on Form 10-K is incorporated by reference to portions of the registrant's definitive proxy statement for its 2010 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year.

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PART IV

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The following trademarks appear in this annual report on Form 10-K: ONCONASE® is the registered trademark of Alfacell Corporation, exclusively for its anti-cancer agent, Alimta® is the registered trademark of Eli Lilly, 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;
- the ability of our senior secured creditors to realize their security interest in all of our assets and to demand repayment of amounts owed to such creditors;
 - certain limitations on our ability to use a portion of the proceeds from our October 2009 private financing;
- uncertainty regarding the outcome of legal proceeding including the risk that we may be forced to engage in lengthy, time-consuming and expensive litigation and the material adverse effect to us of any unfavorable outcome of any such litigation;
 - one-time events.

In addition, in this annual report on Form 10-K, the words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “i 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 annual report 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 annual report is as of November 10, 2009, 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 believed to be good 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, has been evaluated in human clinical trials for the treatment of various forms of cancer. Our most recent clinical trial for ONCONASE® was a confirmatory Phase IIIb registration trial that was 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. In May 2008, we reported 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, which represents a currently unmet medical need. The Food and Drug Administration or the FDA, recommended that an additional clinical trial be conducted in UMM patients that have failed one prior chemotherapy regimen, prior to filing a New Drug Application or NDA. At this time we do not expect to pursue further clinical trials for ONCONASE® for the UMM indication. We are evaluating which indications to pursue, including lung cancer and other solid tumors and currently we expect to use the proceeds we received from the private financing we closed in October 2009 to pursue a

Phase II clinical trial of ONCONASE® for the treatment of non-small cell lung cancer in patients who have reached maximum progression on their current chemotherapy regimens.

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”) 2009 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 2009 Cancer Facts and Figures also estimates that doctors will diagnose over 1.5 million new cases of cancer in the United States in 2009. The National Institutes of Health or NIH estimate that the annual cost of cancer in 2008 was approximately \$228.1 billion, including \$93.2 billion in direct medical costs and \$18.8 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.

We believe that the products we currently have under development could be used to target a broad range of solid tumors. The table below shows the incidence and mortality estimated for the year 2009 for various types of solid tumor cancers that our products could be designed to treat:

Cancer Indication	New Cases	Deaths
Lung	219,440	159,390
Breast	194,280	40,610
Brain	22,070	12,920
Esophageal	16,470	14,530

Source: National Cancer Institute

Competition

There are many companies with resources significantly greater than ours that are currently marketing approved drug products that treat, and are developing new drug products that are designed to treat, several of the cancers that we may seek to treat with our products. The drug products currently marketed or developed by these companies may prove to be more effective than the products we seek to develop.

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 utilizing 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, 2009, 2008 and 2007 were approximately \$3,268,000, \$8,503,000 and \$5,543,000, 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

ONCONASE® was most recently 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.

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The confirmatory Phase IIIb registration trial was 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 was 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 that were analyzed in accordance with the Phase IIIb clinical trial statistical analysis plan included:

- 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.

In May 2008, we reported 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, which represents a currently unmet medical need. At the pre-NDA meeting with the FDA in January 2009, the FDA recommended that an additional clinical trial be conducted in UMM patients that have failed one prior chemotherapy regimen, prior to filing an NDA.

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 currently, we plan to initiate a Phase II clinical trial in non-small cell lung cancer (NSCLC) for patients who have reached maximum progression on their current chemotherapy regimens in 2010.

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.

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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.

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, or 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 sub-lethal damage repair, or SLDR and potentially lethal damage repair, or PLDR 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, or 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).

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 retained 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. We received a cash payment of \$5 million upon the signing of the License Agreement and were entitled to additional development and sales milestone payments and double-digit royalties on net sales of ONCONASE®.

On September 8, 2009, we entered into a Termination and Mutual Release Agreement (the “Termination Agreement”) with Par pursuant to which our License Agreement and Supply Agreement with Par were terminated. The License Agreement was terminated and all rights under the license granted to Par revert back to us under the Termination Agreement. Under the Supply Agreement, we had agreed to supply all of Par’s requirements for ONCONASE®. Pursuant to the Termination Agreement, Par will be entitled to a royalty of 2% of net sales of ONCONASE® or any other ranpirnase product developed by us for use in the treatment of cancer in the United States and its territories commencing with the first sale of such product and terminating upon the later to occur of the 12th anniversary of the first sale and the date of expiration of the last valid claim of a pending application or issued patent owned or controlled by us with respect to such product.

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 up-front 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 ranpirinase. We believe we have sufficient egg inventory on hand to produce enough ONCONASE® for our future clinical trials and early commercialization. In addition, we have successfully produced ranpirinase 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
6,649,392 B1*	Nov. 2003	covers a family of recombinant variants of ONCONASE®	Apr. 2016
6,649,393 B1*	Nov. 2003	covers nucleic acids encoding recombinant variants of ONCONASE® and methodology for producing such variants	Apr. 2016

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Patent No.	Issue Date	Subject Matter	Expiration **
6,290,951 B1	Sept. 2001	covers alteration of the cell cycle in vivo, particularly for inducing apoptosis of tumor cells	Aug. 2018
6,239,257 B1	May 2001	covers a family of variants of ONCONASE®	Dec. 2018
6,175,003 B1	Jan. 2001	covers the genes of ONCONASE® and a variant of ONCONASE®	Sept. 2019
6,423,515 B1	July 2002	covers methodology for synthesizing gene sequences of ranpirnase and a genetically engineered variant of ranpirnase	Sept. 2019
7,229,824 B1***	June 2007	covers a vector containing DNA encoding a genetically engineered variant of ONCONASE®	May 2024
7,556,952 B2	July 2009	covers a gene encoding a genetically engineered variant of ONCONASE®	July 2023
7,556,951 B2	July 2009	covers a gene encoding a genetically engineered variant of ONCONASE®, and a vector containing DNA encoding a genetically engineered variant of ONCONASE®	July 2023
7,556,953 B2	July 2009	covers a gene encoding a genetically engineered variant of ONCONASE®, and a vector containing DNA encoding a genetically engineered variant of ONCONASE®	July 2023
7,442,535 B2	October 2008	covers a fusion protein containing a genetically engineered variant of ONCONASE®	July 2023
7,585,655 B2	September 2009	covers a gene encoding a genetically engineered variant of ONCONASE®, and a vector containing DNA encoding such variant	July 2023
7,442,536 B2	October 2008	covers genetically engineered variants of ONCONASE®	July 2023
7,585,654 B2	September 2009	covers a vector containing DNA encoding a genetically engineered variant of ONCONASE®, and a gene encoding a genetically engineered variant of ONCONASE®	July 2023
7,473,542 B2	January 2009	Covers a fusion protein containing a genetically engineered variant of ONCONASE®	July 2023

*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 0 500 589	cover combinations of ONCONASE® with certain other pharmaceuticals	Oct. 2010
JP 2972334	pharmaceuticals	
EP 0 656 783	covers combinations of ONCONASE® with certain other pharmaceuticals	July 2013
JP 3655628	pharmaceuticals	
EP 0 837 878	covers a variant of ONCONASE®	June 2016
JP 3779999		
EP 1 141 004	covers a family of variants of ONCONASE®	December 2019
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, 2009, we had six full time employees, of whom three were engaged in clinical and pre-clinical research and development activities and three were engaged in administration and management. Two employees hold Ph.D. degrees. All of our employees have entered into confidentiality agreements with us. We consider relations with our employees to be good. None of our employees are 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.E., 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, in the future will be devoted, to the clinical trials for our lead product candidate, ONCONASE®. Although the financing we received in October 2009 will enable us to commence a new clinical trial for ONCONASE®, we will be required to obtain additional financing to complete this trial and pursue the further development of ONCONASE®. Such financing may not be available, and even if it is available, it may not be available on terms favorable or acceptable to us.

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 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 are effective and 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.

Based upon guidance provided by the FDA at a pre-NDA meeting, we decided not to file a new drug application (NDA) for ONCONASE® for unresectable malignant mesothelioma (UMM).

As we have previously reported, the results of the preliminary statistical analysis of the data from the confirmatory Phase IIIb clinical trial for ONCONASE® in patients suffering from UMM did not meet statistical significance for the primary endpoint of survival in UMM. Although a statistically significant improvement in survival was seen in the treatment of UMM patients who failed one prior chemotherapy regimen, a pre-defined primary data set for this sub-group of patients in the trial, at a pre-NDA meeting with the FDA held in January 2009, the FDA recommended that an additional clinical trial be conducted in this sub-group of patients prior to our submitting an NDA for ONCONASE®. Based upon our assessment that it would be difficult to design and conduct a clinical trial that would comply with the FDA's recommendation and allow us to file an NDA, we have determined at this time not to pursue further clinical trials for the treatment of UMM. Based upon our current operations and our plans to conduct a Phase II clinical trial for ONCONASE®, we expect that our current cash reserves will enable us to maintain our reduced operations through July 2010. While we intend to continue to pursue strategic transactions and additional capital, we cannot provide any assurance that we will be successful in our efforts, and if we are not successful in these efforts we will be forced to cease operations.

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 \$25.6 million and since our inception we have incurred aggregate net losses of approximately \$108.9 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. Currently, we are party to 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, 2009, our cash reserves should be sufficient to support our activities into the fourth quarter of our fiscal year 2010, after taking into consideration the cash infusion of \$3.25 million received in October

2009 and based upon our current operations and our plans to conduct a Phase II clinical trial for ONCONASE®. As a result of our continuing losses and lack of capital, the report of our independent registered public accounting firm on our July 31, 2009 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, 2009 do not include any adjustments that might result from the outcome of this uncertainty. We will need additional financing to conduct our business after July 2010. Factors that would affect the amount and timing of additional capital required include, but are not limited to, the following:

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- the condition of the capital markets in general and the willingness of investors to invest in development stage biotech companies, in particular;
- the progress and cost of research and development and clinical trial activities relating to our drug product candidates;
- 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 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 or we are unable to conclude a strategic transaction prior to the time our current cash reserves are exhausted we will 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.

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.

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 and the OTCBB has fluctuated from a low of \$0.06 to a high of \$3.74. 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 since our common stock is no longer listed on the Nasdaq Capital Market.

On January 6, 2009 our common stock was delisted from the Nasdaq Capital Market. Since then our common stock has been quoted on the Pink Sheets and may be thinly traded at times. 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 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 eighteen United States patents with expiration dates ranging from 2013 to 2024, four European patents with expiration dates ranging from 2010 to 2019, three Japanese patents with expiration dates ranging from 2010 to 2016 and one Singaporean patent with an expiration date in 2024. 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 currently have only one executive officer, Charles Muniz, our President, Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”). We are highly dependent on Mr. Muniz, who has an employment contract with us. During the fiscal year ended July 31, 2009, Kuslima Shogen, our scientific founder and former CEO retired, and Lawrence A. Kenyon, our former President, CFO, and Corporate Secretary resigned.

We do not have key man insurance on any of our management. If we were to lose the services of Mr. Muniz or other members of our management team, and were unable to replace them, our product development and the achievement of our strategic objectives could be delayed.

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

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

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

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

Many managed care organizations negotiate the price of medical services and products and develop formularies for that purpose. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization patient population. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic or OTC products, our market share and gross margins could be negatively affected, as could our overall business and financial condition.

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

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

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

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

Our product candidates may not be accepted by the market.

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

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

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

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

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

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

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

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

We may be sued for product liability.

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

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

We are currently authorized to issue 1,000,000 shares of preferred stock. Our Board of Directors, or the Board 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 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 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 us. 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 47,313,880 shares of common stock outstanding as of July 31, 2009. The following securities that may be exercised into shares of our common stock were issued and outstanding as of July 31, 2009:

- Options. Stock options to purchase 4,771,650 shares of our common stock at a weighted average exercise price of approximately \$2.64 per share.
 - Warrants. Warrants to purchase 8,495,650 shares of our common stock at a weighted average exercise price of approximately \$2.43 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.

Additionally, in October 2009, we completed a private financing pursuant to which we issued the following securities:

- Senior Secured Convertible Notes. Notes convertible into an aggregate of 21,666,666 shares of our common stock at a conversion price of \$0.15 per share (the “Senior Secured Notes”).
- Series A Warrants. Warrants to purchase an aggregate of 21,666,666 shares of our common stock at a exercise price of \$0.15 per share with a three year term (the “Series A Warrants”).
- Series B Warrants. Warrants to purchase an aggregate of 21,666,666 shares of our common stock at a exercise price of \$0.25 per share with a five year term (the “Series B Warrants,” and together with the Series A Warrants, the “Warrants”).

Pursuant to the terms of an investor rights agreement (the “Investor Rights Agreement”) entered into in connection with the financing, we must file a “resale” registration statement covering all of the shares issuable upon conversion of the Senior Secured Notes and the shares issuable upon exercise of the Warrants, up to the maximum number of shares able to be registered pursuant to applicable SEC regulations, by February 16, 2010 and obtain the effectiveness of such registration statement by April 17, 2010. If any securities issuable upon conversion or exercise, respectively, of the Senior Secured Notes and Warrants are unable to be included on the initial “resale” registration statement, we have agreed to file subsequent registration statements until all of the securities have been registered. We are obligated to maintain the effectiveness of the “resale” registration statement until all securities therein are sold or otherwise can be sold pursuant to Rule 144 under the Securities Act, without any restrictions. A cash penalty at the rate of 1% per month will be triggered in the event the Company fails to file or obtain the effectiveness of a registration statement prior to the deadlines set forth in the Investor Rights Agreement or if the Company ceases to be current in filing its periodic reports with the SEC. The aggregate penalty accrued with respect to each investor may not exceed 6% of the original purchase price paid by that investor, or 12% if the only effectiveness failure is the Company’s failure to be current in its periodic reports with the SEC.

We have significant secured indebtedness as a result of a private financing, which we closed in October 2009, pursuant to which we issued the Senior Secured Notes. If we are unable to perform our obligations under such notes, the holders of such notes would be entitled to realize upon their security interest by taking control of all or a portion of our assets.

We substantially increased our debt when we issued the Senior Secured Notes in the aggregate principal amount of \$3.25 million pursuant to a private financing in October 2009. The Senior Secured Notes mature on the earliest of (i) October 19, 2012; (ii) the closing of a public or private offering of the Company’s debt or equity securities subsequent to the date of issuance of the Senior Secured Notes resulting in gross proceeds of at least \$8,125,000, other than a transaction involving a stockholder who holds 5% or more of the Company’s outstanding capital stock as of the date of issuance of the Senior Secured Notes; or (iii) on the demand of the holder of a Senior Secured Note upon the Company’s consummation of a merger, sale of substantially all of its assets, or the acquisition by any entity, person or group of 50% or more of the voting power of the Company. Interest accrues on the principal amount outstanding under the Senior Secured Notes at a rate of 5% per annum, and is due upon maturity. Upon an event of default under the Senior Secured Notes, the interest rate shall increase to 7%, provided that if the Company is unable to obtain stockholder approval by April 1, 2010 to amend its certificate of incorporation to increase its authorized capital stock to provide for sufficient authorized shares of common stock to allow for the issuance of all shares of common stock required upon conversion of all of the Senior Secured Notes and exercise of all of the Warrants issued with the Senior

Secured Notes, the interest rate shall increase to 15% and such failure will be an event of default under the Senior Secured Notes. The Senior Secured Notes are convertible into shares of the Company's common stock at the option of the holder of such note at a price of \$0.15 per share at any time prior to the date on which the Company makes payment in full of all amounts outstanding under such note. The Senior Secured Notes are not prepayable for a period of one year following the issuance thereof.

The Senior Secured Notes are secured by a senior security interest and lien on all of the Company's rights, title and interest to all of the assets owned by the Company as of the issuance of the Senior Secured Notes or thereafter acquired pursuant to the terms of a security agreement (the "Security Agreement") entered into by the Company with each of the investors. In the case of an event of default under the Senior Secured Notes, the holders of the notes would be entitled to realize their security interests and foreclose on our assets. In addition, the holders of the notes would be entitled to declare the principal and accrued interest thereunder to be due and payable. Our assets may not be sufficient to fully repay amounts outstanding under the Senior Secured Notes in the event of any such acceleration upon an event of default.

We have a limited number of authorized shares of common stock available for issuance, and if our stockholders do not approve an increase in the authorized number of shares of our common stock to at least 130,593,678 shares by April 1, 2010, we will be in violation of the covenants of the Senior Secured Notes and in default of our obligations under the Senior Secured Notes.

Pursuant to the terms of the Senior Secured Notes, we are obligated (i) to issue a proxy statement soliciting an affirmative vote from each of our stockholders at the next meeting of stockholders of the Company, which meeting must occur on or before April 1, 2010, for approval of an increase in the number of authorized shares of common stock of the Company to at least 130,593,678, (ii) to use our best efforts to obtain such stockholder approval no later than April 1, 2010, and (iii) within 2 business days following receipt of such stockholder approval, to cause an amendment to our certificate of incorporation reflecting the approved increase in the authorized shares of our common stock to be filed with the Secretary of State of the State of Delaware. These obligations are subject to a requirement that each holder of the Senior Secured Notes shall take all reasonable actions and use its best efforts to cause the Company to hold such a meeting of its stockholders and to recommend that the Company's stockholders approve such amendment to its certificate of incorporation. Additionally, each holder must cause all shares owned by such holders, including shares owned by such holder's affiliates, representatives and family members, to be voted in favor of such amendment.

If we are unable to obtain stockholder approval to amend our certificate of incorporation as required by the Senior Secured Notes, we will be in violation of the covenants of the Senior Secured Notes and in default of our obligations under the Senior Secured Notes. Upon an event of default under the Senior Secured Notes, the holders of such notes would be entitled to realize upon their security interests and foreclose on our assets. In addition, the holders of the notes would be entitled to declare the principal and accrued interest thereunder to be due and payable.

We will need additional capital in the future and the Senior Secured Notes may make it more difficult for us to obtain the needed capital.

We will need to obtain additional financing over time to fund our operations. The security interest in all of our assets which secures our obligations under the Senior Secured Notes, the covenants in the Senior Secured Notes, the conversion terms of the Senior Secured Notes and the exercise terms of the Warrants issued with the Senior Secured Notes could make it difficult for us to obtain needed financing or could result in our obtaining financing with unfavorable terms. Our failure to obtain financing or obtaining financing on unattractive terms could have a material adverse effect on our business.

A portion of the proceeds received pursuant to our October 2009 private financing were placed in an escrow account, and pursuant to the terms of an escrow agreement governing the escrow account may only be used for certain limited purposes.

In connection with our October 2009 private financing, we entered into an escrow agreement whereby certain investors placed \$1.6 million of the proceeds paid for their units purchased in the financing in an escrow account. The escrow agreement shall terminate on the earlier of the date that all funds have been disbursed from the escrow account and April 19, 2011, at which time any remaining funds will be disbursed to us. Such amounts can be disbursed from

the escrow account only to satisfy obligations of ours owed to clinical research organizations, hospitals, doctors and other vendors and service providers associated with the clinical trials which we intend to conduct for our ONCONASE® product. Until such time that the escrow agreement terminates, we are not permitted to use the funds in the escrow account for any other purposes.

We face certain litigation risks, and unfavorable results of legal proceedings could have a material adverse effect on us.

As described in Item 3 – Legal Proceedings of this annual report on Form 10-K, we are a party to certain lawsuits. Regardless of the merits of any claim, litigation can be lengthy, time-consuming, expensive, and disruptive to normal business operations and may divert management’s time and resources, which may have a material adverse effect on our business, financial condition and results of operations, including our cash flow. The results of complex legal proceedings are difficult to predict. Should we fail to prevail in these matters, or should any of these matters be resolved against us, we may be faced with significant monetary damages, which also could materially adversely affect our business, financial condition and results of operations, including our cash flow. In addition, we may incur higher general and administrative expenses than we have in the past in order to defend and prosecute this litigation, which could adversely affects our operating results.

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 annual report on Form 10-K for the fiscal year ended July 31, 2009, 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 our annual report on Form 10-K for the fiscal year ended July 31, 2009. 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. Currently, we are in default of our lease agreement for non payment of rent and failure to maintain security deposit, although Landlord has been drawing funds from our secured irrevocable letter of credit. Landlord is seeking to have us vacate the facility.

ITEM 3. LEGAL PROCEEDINGS.

On October 9, 2009, Robert Love, a former Chief Financial Officer and alleged shareholder of the Company, filed a complaint, Love v. Alfacell Corp. et al., Case No. 3:09-cv-05199-MLC-LHG (the "Complaint"), against the Company and certain of its current and former directors in the United States District Court, District of New Jersey, asserting violations of federal and state securities laws, direct and derivative common law claims for fraud and breach of fiduciary duty, and a direct claim for negligent misrepresentation in connection with the Company's Phase IIIb clinical trial for ONCONASE®. The Complaint alleges that the Company misled shareholders by issuing allegedly false projections of when the required number of patients deaths would occur in the Phase IIIb trial. The Complaint seeks compensatory damages of no less than \$350,000, punitive damages of no less than \$20 million, and an accounting and constructive trust. The Company believes that the claims are meritless and intends to defend the case vigorously.

Premier Research Group filed and served a lawsuit against the Company in the Superior Court of New Jersey, Law Division, Essex County, on or about July 26, 2009, seeking the recovery of professional fees that arose from clinical trials purportedly performed in Europe by Premier Research Group as assignee of a contract between Alfacell Corporation and IMFORM GmbH dated October 27, 2005. An Answer with Separate Defenses and Counterclaim was filed on or about July 30, 2009. This case remains in the early stages of discovery.

I & G Garden State, LLC ("Landlord") filed and served a complaint against the Company in the Superior Court of New Jersey Law Division, Special Civil Part Landlord-Tenant Section, Somerset County, on or about October 30, 2009, for non-payment of rent and failure to maintain security deposit. The complaint seeks to have us vacate the property. Although Landlord filed this complaint, Landlord has been drawing funds from the Company's secured irrevocable letter of credit which was placed in March 2007 in the amount of \$350,000.

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

None.

EXECUTIVE OFFICERS OF ALFACELL

The following person was our only executive officer as of November 10, 2009:

Charles Muniz, 55, has joined us on April 3, 2009 as our President, Chief Operating Officer ("CEO") and Chief Financial Officer and a member of our Board of Directors. From 2007 to April 2009, Mr. Muniz was a consultant to a wide variety of clients focusing primarily on the strategic use of operations and technology. Prior to consulting, from 1989 to 2007, he was President and Chief Executive Officer of Digital Creations Corp., a company he founded which sold high-end systems, work stations, peripherals, networking and software products. Mr. Muniz attended Pace University in New York and majored in Business Administration.

PART II

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

Our common stock has been quoted on the Pink Sheets since our delisting from the Nasdaq Capital Market, or Nasdaq, on January 6, 2009 for failure to 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). In addition, 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). Our common stock remains thinly traded at times and you may be unable to

sell our common stock during times when the trading market is limited. As of November 10, 2009, there were approximately 975 stockholders of record of our common stock.

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Prior to January 6, 2009, our common stock was listed on Nasdaq and had traded under the symbol "ACEL" since September 9, 2004. Before September 9, 2004, our common stock was traded on the OTC Bulletin Board (OTCBB).

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, 2009 and 2008. The prices were obtained from Pink Sheets and Nasdaq, and are believed to be representative of inter-dealer prices, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

	High	Low
Year Ended July 31, 2009:		
First Quarter	\$0.85	\$0.40
Second Quarter	0.54	0.08
Third Quarter	0.20	0.06
Fourth Quarter	0.52	0.11
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