

Edgar Filing: ALFACELL CORP - Form 10-K

ALFACELL CORP  
Form 10-K  
October 14, 2004

U. S. SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

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

July 31, 2004  
For the fiscal year ended

0-11088  
Commission file number

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

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

225 Belleville Avenue, Bloomfield, New Jersey 07003  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (973) 748-8082

Securities registered pursuant to Section 12(b) of the Act: None

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

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

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  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes  No

The aggregate market value of the common stock, par value \$.001 per share, held by non-affiliates based upon the reported last sale price of the Common Stock on January 31, 2004 was approximately \$128,365,000. As of October 8, 2004 there were 34,980,314 shares of common stock, par value \$.001 per share, outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement for the Annual Meeting of the Stockholders scheduled to be held on January 27, 2005, to be filed with the Commission not later than 120 days after the close of the registrant's fiscal year, have been incorporated by reference, in whole or in part, into Part III Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K.

# Edgar Filing: ALFACELL CORP - Form 10-K

## Table of Contents

PART I	Page
	----
Item 1. Business	3
Item 2. Properties	16
Item 3. Legal Proceedings	16
Item 4. Submission of Matters to a Vote of Security Holders	16
PART II	
Item 5. Market for Common Equity and Related Stockholder Matters	16
Item 6. Selected Financial Data	18
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 7A. Quantitative and Qualitative Disclosure About Market Risk	32
Item 8. Financial Statements and Supplementary Data	32
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	32
Item 9A. Controls and Procedures	32
PART III	
Item 10. Directors and Executive Officers of the Registrant	33
Item 11. Executive Compensation	33
Item 12. Security Ownership of Certain Beneficial Owners and Management	33
Item 13. Certain Relationships and Related Transactions	33
Item 14. Principal Accounting Fees and Services	33
PART IV	
Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K	33

The following trademarks appear in this Annual Report: ONCONASE(R) is the registered trademark of Alfacell Corporation, exclusively for the anti-cancer indications; Alimta(R) and Gemzar(R) are registered trademarks of Eli Lilly; Navelbine(R) is a registered trademark of Glaxo Smith Kline.

All information on this Form 10-K is as of October 14, 2004 and we undertake no obligation to update this information.

## Edgar Filing: ALFACELL CORP - Form 10-K

We maintain a website at [www.alfacell.com](http://www.alfacell.com) to provide information to the general public and our stockholders on our products, resources and services along with general information on Alfacell, its management, financial results and press releases. Copies of our most recent Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q or our other reports filed with the Securities and Exchange Commission, or SEC, can be obtained, free of charge as soon as reasonably practicable after such material is electronically filed with, or furnished to the SEC, from our Investor Relations Department by calling 973-748-8082, through an e-mail request from our website at [www.alfacell.com/info.htm](http://www.alfacell.com/info.htm), or through the SEC's website by clicking the direct link from our website at [www.alfacell.com/investinfo.htm](http://www.alfacell.com/investinfo.htm) or directly from the SEC's website at [www.sec.gov](http://www.sec.gov). Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

Our Board of Directors has adopted a Code of Business Conduct that is applicable to all of our directors, officers and employees. Any material changes made to our Code of Business Conduct or any waivers granted to any of our directors and executive officers will be publicly disclosed by filing a current report on Form 8-K within five business days of such material change or waiver. We intend to make the Code of Business Conduct available on our website at [www.alfacell.com](http://www.alfacell.com). Although our Board of Directors has not established a nominating committee, our formal nominating procedures will be described in our definitive proxy statement for the Annual Meeting of Stockholders to be held on January 27, 2005. In addition, copies of such documents are available to our shareholders upon request either by contacting our Investor Relations Department at 973-748-8082 or through an e-mail request from our website at [www.alfacell.com/info.htm](http://www.alfacell.com/info.htm).

Information contained herein contains, in addition to historical information, forward-looking statements that involve risks and uncertainties. All statements, other than statements of historical fact, regarding our financial position, potential, business strategy, plans and objectives for future operations are "forward-looking statements." These statements are commonly identified by the use of forward-looking terms and phrases such as "anticipates," "believes," "estimates," "expects," "intends," "may," "seeks," "should," or "will" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy. Actual future results may vary from expectations set forth in these forward-looking statements. The matters set forth herein under the caption "Risk Factors" constitute cautionary statements identifying important factors with respect to these forward-looking statements, including certain risks and uncertainties, that could cause actual results to vary significantly from the future results indicated in these forward-looking statements. Other factors could also cause actual results to differ significantly from the future results indicated in these forward-looking statements.

### Part I

#### Item 1. BUSINESS.

##### Overview

Alfacell Corporation is 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. Based on our proprietary Ribonuclease, or RNase, which is a type of biological enzyme that splits RNA molecules and is the basis of our technology platform, our drug discovery and development program consists of novel therapeutics developed from amphibian ribonucleases. These are very basic RNA enzymes which play important roles in nature in the development of an organism's cells and in cell functions. RNA is an essential bio-chemical cellular component necessary to support life. There

## Edgar Filing: ALFACELL CORP - Form 10-K

are various types of RNA, all of which have specific functions in a living cell. They help control several essential biological activities, namely, regulation of cell proliferation, maturation, differentiation and cell death. Therefore, they are ideal candidates for the development of therapeutics for cancer and other life-threatening diseases, including HIV and autoimmune diseases, that require anti-proliferative and apoptotic, or programmed cell death, properties. We have co-sponsored and been a key participant in the International Ribonuclease Meetings which are held every three years.

ONCONASE(R), our trademark name for our lead product, is currently in an international, centrally randomized Phase III trial. The first part of the trial has been completed and the second confirmatory part of the trial is ongoing for which patient enrollment is expected to be completed in the first quarter of 2005. The primary endpoint of the trial is survival, and as such, a sufficient number of deaths must occur in order to perform the

3

required statistical analyses to determine the efficacy of ONCONASE(R) in patients with unresectable (inoperable) malignant mesothelioma. If the results of the clinical trials are positive, we expect to file for marketing registrations (NDA and MAA) for ONCONASE(R) within six months of completion of the statistical analyses. However, at this time, we cannot predict with certainty when a sufficient number of deaths will occur to achieve statistical significance. Hence, the timing of when we will be able to file for marketing registrations in the US and EU is data driven. Therefore, we cannot predict with certainty what our total cost associated with obtaining marketing approvals will be, or when and if such approvals will be granted, or when actual sales will occur. We have also conducted other randomized and non-randomized trials with patients with advanced stages of solid tumors in other types of cancers.

ONCONASE(R), unlike most cancer drugs that attack all cells regardless of their phenotype, malignant versus normal, and produce a variety of severe toxicities, is not an indiscriminate cytotoxic, or cell killing agent, but rather, its activity is controlled through unique and specific molecular mechanisms. ONCONASE(R) affects primarily exponentially growing malignant cells. ONCONASE(R) is a novel amphibian ribonuclease, unique among the superfamily of pancreatic ribonuclease that has been isolated from the eggs of the *Rana pipiens* frog, commonly called the leopard frog. We have determined that, thus far, ranpirinase, the generic name of ONCONASE(R), 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.

In December 2002, we received Fast Track Designation from the FDA for ONCONASE(R) for the treatment of malignant mesothelioma. Fast Track Designation is an FDA program designed to expedite the review of new drugs that are intended to treat serious or life threatening conditions and that demonstrate the potential to address unmet medical needs. In February 2001, we received an Orphan Medicinal Product Designation for ONCONASE(R) from the European Agency for the Evaluation of Medicinal Products, or the EMEA. Orphan Medicinal Product Designation is a program designed to provide marketing, protocol and other incentives for pharmaceutical companies to develop and market products in the European Community that address life threatening or very serious conditions that affect not more than 5 in 10,000 persons in the European Community. Orphan designation in Europe entitles the Company to 10 years of marketing exclusivity, reduced filing fees and regulatory guidance from the EMEA.

These FDA and EMEA designations for ONCONASE(R) may serve to expedite its regulatory review, assuming the clinical trials yield a positive result. Future

## Edgar Filing: ALFACELL CORP - Form 10-K

clinical trials, however, may not demonstrate that ONCONASE(R) is effective. Thus, our applications for FDA or EMEA approval to market ONCONASE(R), which are dependent upon the success of our clinical trials, may be affected. The efficacy and safety of ONCONASE(R) for malignant mesothelioma will ultimately be determined by the FDA. In the interim, our Fast Track Designation allows us to continue to have meetings and discussions with the FDA to establish mutually agreed upon parameters for the NDA to obtain marketing approval for ONCONASE(R), based on the assumption that the clinical trials will continue to yield favorable results.

Our drug discovery program forms the basis for the development of specific recombinant RNases for chemically linking drugs and other compounds such as monoclonal antibodies, growth factors, etc. and gene fusion products with the goal of targeting various molecular functions. This program provides for joint design and generation of new products with outside partners. We may own these new products along with a partner(s), or we may grant an exclusive license to the collaborating partner(s).

We have established a number of scientific collaborations with academic and research institutions including the National Cancer Institute, or NCI that are designed to develop new therapeutic applications for ONCONASE(R). One collaboration has produced RN321, a conjugate of ranpirnase, with a monoclonal antibody that demonstrated activity in treating non-Hodgkin's lymphoma in preclinical studies. These results were presented by the NCI investigators at the 2002 Ribonuclease Meeting in Bath, England. The NCI has undertaken the manufacturing of RN321 (the conjugate) according to Good Manufacturing Practices, or GMP regulations in preparation for commencing clinical trials for the treatment of patients with non-Hodgkin's lymphoma with RN321. Currently, the NIH has produced RN321 clinical grade like material. Clinical grade production of RN321 and Investigational New Drug Application, or IND, directed toxicology studies will require further approval from the Drug Development Group of the NIH prior to commencing human clinical trials.

4

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. These products are currently undergoing preclinical testing. We are currently in discussions with potential pharmaceutical partners for the development of these new compounds as conjugates and fusion proteins.

We have entered into a research and development collaboration with a major US privately held stent and drug delivery company. ONCONASE(R) is being evaluated in stents and other delivery platforms to treat cardiovascular disease and cancer via direct site delivery. This collaboration may result in licensing agreement between the companies, however; there is no assurance that such agreement will be reached.

We have entered into a collaborative agreement (anti-viral screening, non-SARS) with the National Institute of Allergy and Infectious Diseases, or NIAID in which five potential drug candidates (natural and genetically engineered) are under evaluation against various RNA viruses.

Our research and development collaboration with Wyeth Pharmaceuticals is ongoing to develop a number of designer drugs such as conjugates and fusion proteins for a variety of indications using our technology. This collaboration may result in a licensing agreement between the companies, however; there is no assurance that such an agreement will be reached.

## Edgar Filing: ALFACELL CORP - Form 10-K

We have signed confidentiality agreements and have entered into discussions and due diligence with a number of companies for US or non-US marketing rights for ONCONASE(R) and for out-licensing some of our early drug candidates.

We are engaged in the research, development and clinical trials of our products both independently and through research collaborations. We have financed our operations since inception through the sale of our equity securities and convertible debentures in registered offerings and private placements. Additionally, we have raised capital through debt financings, the sale of our tax benefits and research products, interest income and financing received from our Chief Executive Officer. These funds provide us with the resources to acquire staff, facilities, capital equipment, finance our technology, product development, manufacturing and clinical trials. We have incurred losses since inception and to date we have not consummated any licensing, marketing or development arrangements. Presently, our cash balance is sufficient to fund our expanded operations through October 31, 2005 based on our expected level of expenditures in relation to activities in preparing ONCONASE(R) for an NDA filing and other ongoing operations of the company. However, we continue to seek additional capital financing through the sale of equity in private placements, sale of our tax benefits and exercise of stock options and warrants but cannot be sure that we will be able to raise capital on favorable terms or at all.

### Research and Development Programs

Research and development expenses for the fiscal years ended July 31, 2004, 2003, and 2002 were \$3,353,000, \$1,700,000, and \$2,033,000, respectively. Our research and development programs focus primarily on the development of therapeutics from amphibian ribonucleases. Because ribonucleases have been shown to be involved in the regulation of cell proliferation, maturation, differentiation and programmed cell death, known as apoptosis, ribonucleases may be ideal candidates for the development of therapeutics for the treatment of cancer and other life-threatening diseases, including viral and autoimmune diseases that require anti-proliferative and pro-apoptotic properties.

### Technology Platform and Pipeline

Using ribonucleases as therapeutics is a relatively new approach to drug development. The use of these proteins to re-regulate the unregulated growth and proliferation of cancer cells is unlike most cancer drugs that attack all cells regardless of their phenotype, malignant versus normal, and produce a variety of severe toxicities.

ONCONASE(R) and related drug candidates are not indiscriminate cytotoxic, or cell killing, agents, but rather, their activity is controlled through unique and specific molecular mechanisms. They affect primarily exponentially growing malignant cells.

Cancer is associated with the over or under production of many types of proteins in tumor cells. We believe that the ability to selectively halt the production of certain proteins via ribonuclease activity in tumor cells without damaging normal cells, may make treatment of cancer more effective. To make cancer therapy more effective and less toxic, we are developing ONCONASE(R) and a related family of regulatory proteins, collectively named amphinases. These novel RNases are being developed as therapeutics as well as effector moieties (payload), or killer molecules for targeted therapies. We believe that selective

## Edgar Filing: ALFACELL CORP - Form 10-K

degradation of intracellular proteins is central to the process of programmed cell death.

We have devoted significant resources towards the development of recombinant designer RNases for chemical conjugation and gene fusion products with various targeting moieties such as monoclonal antibodies, growth factors, cytokines, etc.

### Apoptosis

Apoptosis, or programmed cell death, is essential for the proper development of embryos and of many body systems, including the central nervous system, immune regulation and others. Apoptosis is required to accommodate the billions of new cells produced daily by our bodies and to eliminate aged or damaged cells. Abnormal regulation of the apoptosis process can result in disease. For example, cancer, autoimmune disorders and many viral infections are associated with inhibited apoptosis or programmed death of cells occurring too slowly. Conversely, HIV is associated with increased apoptosis or programmed death of cells occurring too rapidly. The process of programmed cell death is genetically regulated. We believe that we are the first company to discover and develop a novel family of primordial "regulatory" proteins that have been shown to play a fundamental role in this regulatory process.

### ONCONASE(R) (ranpirnase) Pro-Apoptotic Mechanisms

The molecular mechanisms were identified which determine the apoptotic cell death induced by ranpirnase. tRNA, rRNA and mRNA are all different types of RNA with specific functions in a living cell. Ranpirnase preferentially degrades tRNA, 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.

Many cancer cells become resistant to most types of cancer treatment, including chemotherapy, radiation and monoclonal antibodies. Overcoming resistance to chemotherapy remains a major challenge for cancer therapy. ONCONASE(R) has been shown to overcome multiple drug resistance or prevent resistance to cancer therapy, thereby dramatically increasing the sensitivity of certain cancer cells to chemotherapy and radiation therapy.

It remains unknown whether or not ONCONASE(R) targets and binds preferentially to tumor cells, rather than normal cells of the respective tissues. It is possible that there is no differential targeting and/or binding, but that tumor cells are more susceptible to the cytostatic (suppresses cancer cells from further dividing) and cytotoxic (kills cancer cells) effects of ONCONASE(R). The cytostatic effects are manifested by the inhibition of progression in the cell cycle. These effects have been associated with induction of parallel differentiation and apoptosis. The cytostatic and differentiation-inducing effects are reflected in the stabilization of previously progressive tumors observed in our clinical trials.

### Clinical Studies and Preclinical Development of ONCONASE(R)

We have been very selective in our product development strategy, which is focused on the use of ONCONASE(R) alone or in combination with drugs which have shown evidence of preclinical and clinical efficacy on

## Edgar Filing: ALFACELL CORP - Form 10-K

tumor types for which median survivals are typically less than a year and for which there are few or no approved treatments.

ONCONASE(R) has been tested in Phase I, Phase II and Phase III clinical trials in more than 40 cancer centers across the United States since 1991 and in Europe since 2000, including major centers such as Columbia-Presbyterian, University of Chicago, M.D. Anderson and Cedars-Sinai Cancer Centers.

ONCONASE(R) has been tested as a single agent in patients with a variety of solid tumors. It has also been tested in combination with tamoxifen in patients with prostate cancer, advanced pancreatic cancer and renal cell carcinoma as well as with doxorubicin in patients with malignant mesothelioma.

We have collaborated with NIH, NCI and The University of Pennsylvania Medical Center, Metabolic Magnetic Resonance Research and Computing Center, and have developed a considerable body of knowledge in RNase technology and novel RNase-based therapeutics. ONCONASE(R) has demonstrated a broad spectrum of anti-tumor activity in vitro, or studies of tumor cell lines in laboratory vessels, and was determined to kill cancer cells and therefore was judged to be "active" in the NCI Cancer Screen.

In vitro and in vivo studies showed both cytostatic (suppresses cancer cells from further dividing) and cytotoxic (kills cancer cells) antitumor activity when used as a single agent and in combination with other agents.

### In Vitro

ONCONASE(R), in combination with other drugs has been shown to be synergistic, which means that the effect of ONCONASE(R) when given in combination with other drugs is greater than if the drugs were given alone. The combination of ONCONASE(R) and tamoxifen, an anti-cancer drug, resulted in a significant cell kill in pancreatic, prostate, and ovarian tumor cell lines as compared to each drug alone. Similar results were found with respect to the following:

- o ONCONASE(R) + phenothiazine for non-small cell lung cancer;
- o ONCONASE(R) + lovastatin in pancreatic, ovarian, and two types of non-small cell lung cancer;
- o ONCONASE(R) + cisplatin in ovarian cancer;
- o ONCONASE(R) + all-trans-retinoic acid in glioma (brain) cancer;
- o ONCONASE(R) + vincristine in colorectal cancer and ;
- o ONCONASE(R) + doxorubicin in breast cancer including resistant variants, malignant mesothelioma.

### In Vivo Anti-Cancer Activity

#### ONCONASE(R) as a Single Agent

ONCONASE(R), as a single agent has shown in vivo anti-tumor activity in several mouse models of solid tumors. The following are all examples of the effect of ONCONASE(R) on various types of human cancer cells in mouse models:

- o In the human squamous A-253 carcinoma and the NIH-OVCAR-3 ovarian adenocarcinoma models, ONCONASE(R) has produced prolonged survival and delayed time to development of ascites (fluid in the abdomen),



## Edgar Filing: ALFACELL CORP - Form 10-K

respectively.

- o In mice bearing M109 Madison lung carcinoma cells, time to appearance of ascites and survival were significantly prolonged in ONCONASE(R) treated animals as compared to controls. Several histologically (microscopic study of cells) confirmed cures were noted.
- o In nude mice bearing human DU-145 prostate carcinoma and pancreatic ASPC-1 carcinoma, ONCONASE(R) inhibited growth of the subcutaneously transplanted tumor.
- o In several mouse tumor models, ONCONASE(R) not only demonstrated direct anti-tumor activity but also increased the potential for other drugs to penetrate the tumor tissue as well as increased the tumor sensitivity to radiation therapy.

7

### ONCONASE(R) in Combination With Other Agents

Based on in vivo results, ONCONASE(R) in combination with the following known and approved anti-cancer agents has been evaluated by us, in collaboration with the NCI:

- o vincristine
- o doxorubicin
- o tamoxifen

When used in combination with vincristine, ONCONASE(R) prolonged the survival of nude mice bearing vincristine-resistant, HT-29 human colorectal carcinomas, a type of cancer cell, transfected with mdr-1 gene, a multiple drug resistant gene. These NCI results demonstrated that ONCONASE(R) can restore the sensitivity of resistant tumor cells to chemotherapy.

NCI experiments in nude mice transplanted intravenously with human breast carcinoma cells treated with the combination of ONCONASE(R) and doxorubicin have shown significantly prolonged survival. Tumor growth was significantly inhibited as demonstrated by a decrease in the number of pulmonary metastases, or disseminated lesions in the lung, present at the time of sacrifice.

NCI reported the ability of ONCONASE(R) to overcome multiple drug resistance as well as other forms of drug resistance (referring to a drug that no longer kills cancer cells) both in vitro and in vivo. We believe that these in vivo results demonstrate the therapeutic utility of ONCONASE(R) in chemotherapy-resistant tumors, and the findings suggest that ONCONASE(R) in combination with other agents has broad clinical application in cancer treatments.

### Clinical Trials

#### Onconase(R) Phase III Randomized Clinical Trials

We are currently conducting a two-part Phase III clinical trial of ONCONASE(R) as a treatment for malignant mesothelioma. The first part of the Phase III trial compares ONCONASE(R) alone to doxorubicin. Doxorubicin has been considered by opinion leaders to be the most effective drug for the treatment of malignant mesothelioma. The second part of the trial compares the combination of

## Edgar Filing: ALFACELL CORP - Form 10-K

ONCONASE(R) and doxorubicin versus doxorubicin alone. The trial is an open label, centrally randomized, controlled study. The patient enrollment for the first part of the clinical trial has been completed and the trial is on-going. The second part is currently in the enrollment stage and is being conducted in the United States, Europe, Canada and Australia.

Since ONCONASE(R) has Fast Track Designation for the treatment of malignant mesothelioma patients, we continue to have meetings and discussions with the FDA to establish mutually agreed upon parameters for the New Drug Application, or NDA, to obtain marketing approval for ONCONASE(R), assuming the Phase III clinical trial yields favorable results.

### Phase III Single Agent Results

An interim subset analysis of the results of this Phase III clinical trial according to the Cancer Adult Leukemia Group B, or CALGB, prognostic groups revealed a marked excess of poor prognosis patients (groups 5 and 6) in the ONCONASE(R) arm of the trial (32 patients or 38.1% of the patients treated with ONCONASE(R)) as compared to the doxorubicin arm of the trial (12 patients or 17% of the patients treated with doxorubicin). By excluding these patients and the 10 patients whose central pathology review did not confirm a diagnosis of malignant mesothelioma (N=5) from the 154 intent-to-treat patients, we defined a target treatment group, or TTG, consisting of 104 patients who met the criteria for CALGB prognostic groups 1-4. Of these patients, 47 were treated with ONCONASE(R) and 57 were treated with doxorubicin. The single agent Phase III results of the TTG showed a median survival benefit, or MST, of 2 months for ONCONASE(R) treated patients, 11.6 months versus 9.6 months.

8

This two month median survival difference favoring ONCONASE(R) represents a 20% advantage over the active agent, doxorubicin. Moreover, the clinical activity of ONCONASE(R) is also evident from the overall 1-year and 2-year survival rates of ONCONASE(R) versus doxorubicin, 46.8% versus 38.6% and 20.2% versus 12.3%, respectively. Doxorubicin treatment was associated with a 60% higher risk of death compared to ONCONASE(R) treatment. Tumor assessment by an independent radiologist for evaluable patients (had a baseline and follow-up radiological assessment) revealed evidence of objective clinical activity in 17 patients in each treatment arm. Four partial responses and 13 stabilization of previously progressive disease were reported in the ONCONASE(R) treated patients and 7 partial responses and 10 stabilization of previously progressive disease were reported in the doxorubicin treated patients. Despite the small number of patients, the analysis revealed a statistically significant difference, log rank test,  $p = 0.037$ , in survival of the responders favoring ONCONASE(R) treated patients with an MST 23.3 versus 14.4 months for doxorubicin treated patients as well as the 2 year survival rates of 40% for ONCONASE(R) and 9% for doxorubicin. Preliminary results were presented at the 2000 American Society of Clinical Oncologists, or ASCO, meeting.

These survival advantages were recognized as clinically important in this patient population by opinion leaders and the FDA. Therefore, the FDA has requested confirmation of the survival results in the TTG population in the second part of the ongoing trial.

In December 2002, we received Fast Track Designation from the FDA for ONCONASE(R) and doxorubicin for the treatment of malignant mesothelioma. Fast Track is a formal mechanism to interact with the FDA using approaches that are available to all applicants for marketing claims for drugs that are being developed for a serious or life-threatening disease for which there is an unmet medical need. The benefits of Fast Track include scheduled meetings to seek FDA

## Edgar Filing: ALFACELL CORP - Form 10-K

input into development plans, the option of submitting an NDA in sections rather than all components simultaneously, and the option of requesting evaluation of studies using surrogate endpoints. We anticipate to use this designation to reduce the marketing approval timeline for ONCONASE(R).

In February 2001, we received an Orphan Medicinal Product Designation for ONCONASE(R) from the European Agency for the Evaluation of Medicinal Products, or the EMEA. Orphan Medicinal Product Designation is a program designed to provide marketing, protocol and other incentives for pharmaceutical companies to develop and market products in the European Community that address life threatening or very serious conditions that affect not more than 5 in 10,000 persons in the European Community. Orphan designation in Europe entitles the Company to 10 years of marketing exclusivity, reduced filing fees and regulatory guidance from the EMEA. We continue to fulfill the EMEA requirements regarding the Marketing Authorization Application, or MAA registration requirements for ONCONASE(R) for the treatment of malignant mesothelioma.

In part two of the ongoing Phase III trial, interim analyses based on the occurrence of 105 deaths and at 210 deaths are planned. Based upon the results of these analyses, we may be able to file an NDA and an MAA within six months after the completion of the analyses. However, we cannot assure you that marketing approval for ONCONASE(R) as a treatment for malignant mesothelioma will be granted by the FDA or EMEA.

Based on Phase II trial results after meeting with the FDA, we had initiated a Phase III trial in patients with advanced pancreatic cancer in 1995. In the Phase II trial, the median survival time of 5.5 months for 47 patients with stage 4 disease and liver involvement treated with the combination of ONCONASE(R) weekly and tamoxifen daily was more than double the median survival of such patients reported in previously published trials treated with a variety of other systemic therapies (published median survival times ranged from 2.0 to 2.5 months). The Phase III trial was a multicenter randomized trial designed to evaluate an ONCONASE(R) and tamoxifen regimen in untreated patients as well as patients who had failed GEMZAR(R), an approved drug for pancreatic cancer. The primary endpoint of both segments of this Phase III trial was survival, however, early survival analyses of both segments did not reveal a significant survival advantage of ONCONASE(R) over the controls. Thus, due to the negative results of the Phase III trial, despite favorable results produced in Phase II, competitive pressures and our inability to accrue qualified patients in the clinical trials, we made a decision that further evaluation of this end-stage patient population was not warranted at that time and our resources were refocused on the ongoing malignant mesothelioma program.

9

### ONCONASE(R) Phase II Clinical Trials

ONCONASE(R) as a single agent, demonstrated objective clinical activity in 105 patients with unresectable, or inoperable, malignant mesothelioma that included many heavily pretreated patients with refractory tumors, which are tumors that did not readily yield to the treatment. Analysis of the TTG population confirmed the importance of the CALGB prognostic groups and their utility for evaluating systemic therapies in this patient population.

Of the 105 patients treated, 41 patients, or 39%, reported evidence of clinical activity. Of the patients showing evidence of clinical activity, there were four with partial responses, two with minor responses and 35 showed evidence of stabilization of previously progressive disease. The MST of these patients was 18.5 months and the overall 1-year and 2-year survival rates were 61% and 40.8%, respectively. The results of this trial demonstrated a survival

## Edgar Filing: ALFACELL CORP - Form 10-K

benefit for both newly diagnosed patients and patients who failed prior therapies. The presentation of this data to the FDA resulted in the design of our Phase III malignant mesothelioma trial.

A multicenter Phase II Broad Eligibility trial designed to evaluate ONCONASE(R) as a single agent has been conducted and results of the findings for patients with non-small cell lung cancer, or NSCLC, and advanced breast cancer were published.

ONCONASE(R) as a single agent, demonstrated objective clinical activity in patients with advanced NSCLC and breast cancer. The median survival time of 30 patients with advanced NSCLC was greater than that in 19 of 20 regimens when supportive care, a placebo or another single agent was given. Furthermore it was greater than 75% of the reported MSTs in combination chemotherapy trials. The MST and 1 year survival rates of 7.7 months and 27%, respectively, for ONCONASE(R) treated patients compared favorably to 7.2 months and 30% for patients treated with Navelbine(R) (an approved drug for this indication) as a single agent.

Thirty percent of 17 patients with advanced breast cancer demonstrated objective clinical activity, which included, one partial response, two minor responses, the significant reduction in bone pain in one patient, and the control of uncontrollable malignant fluid in the lungs of another patient.

A series of pilot Phase II studies to evaluate ONCONASE(R) as a single agent, and ONCONASE(R) and tamoxifen in previously treated patients with unresectable, or inoperable, renal cell cancer were conducted. The results of both the Phase II single agent and ONCONASE(R) and tamoxifen were published. Although the single agent study did not demonstrate evidence of clinical activity, the regimen of ONCONASE(R) and tamoxifen did demonstrate evidence of clinical activity which indicated further evaluation in untreated patients was warranted.

### Research And Development Pipeline Of Targeted Therapies

Our drug discovery program forms the basis for the development of recombinant designer RNases for chemical conjugation and gene fusion products with various targeting moieties such as monoclonal antibodies, growth factors, cytokines, etc. We believe these products can be produced in a cost effective and controlled manufacturing environment.

This program also provides for joint design and generation of new products with outside partners. We, along with any outside partners, may own these new products jointly, or we may grant an exclusive license to the collaborating partner(s).

### 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.

## Edgar Filing: ALFACELL CORP - Form 10-K

We have established a number of scientific collaborations with academic and research institutions including the NCI. The objective of our collaboration with the NCI is to develop new therapeutic applications for ONCONASE(R). This collaboration has produced RN321, a conjugate of ranpirnase, with a monoclonal antibody that demonstrated activity in treating non-Hodgkin's lymphoma in preclinical studies. The relative benefit in killing targeted tumor cells versus non-targeted healthy cells, or the therapeutic index, is greater than 200,000-fold with this conjugate. These "proof-of-concept" results were presented at the 2002 Ribonuclease Meeting in Bath, England. The NCI has undertaken the manufacturing of RN321 (the conjugate) according to Good Manufacturing Practices, or GMP regulations in preparation for commencing clinical trials for the treatment of patients with non-Hodgkin's lymphoma with RN321. Clinical grade production of RN321 and Investigational New Drug Application, or IND, directed toxicology studies will require further approval from the Drug Development Group of the NIH prior to commencing human clinical trials.

Although ranpirnase is active against a variety of human cancers, its activity is not uniform across different tumor types. However, whether the tumor is more or less sensitive to ranpirnase as a single agent, its anti-tumor activity can be greatly augmented by conjugation to different targeting moieties, or groups. One of these moieties is the epidermal growth factor, or EGF, which is a ligand for the EGF receptor often hyperexpressed on malignant cells. The genetically engineered ranpirnase conjugates with EGF (rRNP-EGF) exerted significant anti-tumor activity in human cell types of the head and neck and pancreatic carcinomas, and human D54MG glioblastoma, a cancerous brain tumor cell. Other constructs target tumor blood vessel formation, which could be potentially used in a broad spectrum of solid tumors. They are in pre-clinical evaluation by our European collaborator.

### Novel Amphibian Ribonucleases

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.

### Research Collaborations

In addition to the above programs, we are pursuing some programs in collaboration with the NIH, NCI and The University of Pennsylvania Medical Center, Metabolic Magnetic Resonance Research and Computing Center.

We have established a number of scientific collaborations with the NIH and NCI. The objective of our collaborations with the NIH and NCI is to develop new therapeutic applications for ONCONASE(R) as well as other drug candidates.

The multiple effects of biological activity of ONCONASE(R) 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.

### Evaluation Of ONCONASE(R) As A Radiation Enhancer

The p53 gene is a tumor-suppressor gene meaning that if it malfunctions, tumors will develop. Published studies have demonstrated that ONCONASE(R) causes

## Edgar Filing: ALFACELL CORP - Form 10-K

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. We believe these findings further expand the profile of ONCONASE(R) in vivo activities and its potential clinical utility and market potential.

The University of Pennsylvania Medical Center, Metabolic Magnetic Resonance Research and Computing Center will further evaluate ONCONASE(R) in combination with radiation and cisplatin, an anti-cancer drug, in human lung adenocarcinoma, a form of lung cancer, in a series of animal models as well as look at the effects of

11

ONCONASE(R) in the inhibition of sub-lethal damage repair (SLDR) and potentially lethal damage repair (PLDR) in human lung carcinoma cells.

ONCONASE(R) As a Resistance-Overcoming and Apoptosis-Enhancing Agent

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

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

Evaluation Of ONCONASE(R) As An Anti-Viral Agent

A collaborative agreement (anti-viral screening, non-SARS) with the National Institute of Allergy and Infectious Diseases, or NIAID, has yielded positive results, which have been confirmed with one of our amphinases. Further evaluation of this potential therapeutic is ongoing.

The ribonucleolytic activity was the basis for testing ONCONASE(R) as a potential anti-viral agent against HIV. The NIH has performed an independent in vitro screen of ONCONASE(R) against the HIV virus type 1. The results showed ONCONASE(R) 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(R) 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 NIH, Division of AIDS also screened ONCONASE(R) for anti-HIV activity. ONCONASE(R) 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

## Edgar Filing: ALFACELL CORP - Form 10-K

class of anti-viral drugs. An additional 25%, while being sensitive to protease inhibitors, are resistant to RT inhibitor(s) drugs, reverse transcriptase drugs. European collaborators continue to investigate the anti-viral properties of ONCONASE(R). The ribonucleolytic activity of ONCONASE(R) suggested that it might be active against a variety of RNA viruses, including HIV and hepatitis C.

### Commercial Collaborations with Pharmaceutical/Drug Delivery Companies

A research and development collaboration with a major US privately held stent and drug delivery company is ongoing. ONCONASE(R) is being evaluated in stents and other delivery platforms to treat cardiovascular disease and cancer via direct site delivery. This collaboration may result in licensing agreement between the companies, however; there is no assurance that such agreement will be reached.

Our research and development collaboration with Wyeth Pharmaceuticals is ongoing to develop a number of designer drugs such as conjugates and fusion proteins for a variety of indications using our proprietary technology. This collaboration may result in a licensing agreement between the companies, however; there is no assurance that such an agreement will be reached.

12

### Raw Materials

The major active ingredient derived from leopard frog eggs is the protein ranpirnase. We have sufficient egg inventory on hand to produce enough ONCONASE(R) to complete the current Phase III clinical trial for malignant mesothelioma and supply ONCONASE(R) for up to two years after commercialization. In addition, we can successfully produce ranpirnase by using recombinant technology; however, it may not be more cost effective.

### Manufacturing

We have signed an agreement with Scientific Protein Laboratories, which will perform the intermediary manufacturing process of purifying ranpirnase. We contract with BenVenue Corporation for vial filling and with Cardinal Health for the labeling, storage and shipping of ONCONASE(R) during the Phase III trial period. Other than these arrangements, we do not have specific arrangements for the manufacture of our product. Products manufactured for use in Phase III clinical trials and for commercial sale must be manufactured in compliance with Current Good Manufacturing Practices. Scientific Protein Laboratories, BenVenue Corporation and Cardinal Health all manufacture in accordance with Current Good Manufacturing Practices. For the foreseeable future, we intend to rely on these manufacturers, or substitute manufacturers, if necessary, to manufacture our product. We believe, however, that there are substantial alternative service providers for the services for which we contract. Because we have not yet received drug approval, we utilize the services of these third party manufacturers 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 FDA of the new manufacturer. We are dependent upon our contract manufacturers to comply with Current Good Manufacturing Practices and to meet our production requirements. It is possible that our contract manufacturers may not comply with Current Good Manufacturing Practices or deliver sufficient quantities of our products on schedule.

### Marketing

We do not plan to market our products at this time. We have entered into a

## Edgar Filing: ALFACELL CORP - Form 10-K

number of Confidential Disclosure Agreements and have been in discussions with several United States and multinational biopharmaceutical companies for the selection of suitable marketing partners for our lead product ONCONASE(R), our proprietary RNA interference technology pipeline, as well as several patented product candidates.

We intend to enter into development and marketing agreements with third parties. We expect that under such arrangements we would grant exclusive marketing rights to our corporate partners in return for assuming further research and development cost, up-front fees, milestone payments and royalties on sales. Under these agreements, our marketing partner may have the responsibility for a significant portion of product development and regulatory approval. In the event that our marketing partner fails to develop a marketable product or fails to market a product successfully, our business may be adversely affected.

### Government Regulation

The manufacturing and marketing of pharmaceutical products in the United States requires 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 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

13

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 is required to gain marketing approval in Europe. 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.

### Patents and Proprietary Technology



## Edgar Filing: ALFACELL CORP - Form 10-K

We have protected our business 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 of certain U.S. patent applications. Generally, we apply for patent protection in the United States, selected European countries, and Japan.

We own the following U.S. patents:

Patent No. -----	Issue Date -----	
6,423,515 B1	July 2002	covers methodology for synthesizing gene sequences of ranpirinase and a genetically engineered variant of ranpirinase
6,290,951 B1	Sept. 2001	covers alteration of the cell cycle in vivo, particularly inducing apoptosis of tumor cells
6,239,257 B1	May 2001	covers a family of variants of ONCONASE(R)
6,175,003 B1	Jan. 2001	covers the genes of ONCONASE(R) and a variant of ONCONASE(R)
5,728,805	Mar. 1998	covers a family of variants of ONCONASE(R)
5,595,734	Jan. 1997	covers combinations of ONCONASE(R) with certain other pharmaceuticals
5,559,212	Sept. 1996	covers the amino acid sequence of ONCONASE(R)
5,540,925	July 1996	covers combinations of ONCONASE(R) with certain other pharmaceuticals
5,529,775	June 1996	covers combinations of ONCONASE(R) with certain other pharmaceuticals
4,888,172	Dec. 1989	covers a pharmaceutical produced from fertilized frog (Rana pipiens) and the methodology for producing it
6,649,392 B1*	Nov. 2003	covers a family of recombinant variants of ONCONASE(R)
6,649,393 B1*	Nov. 2003	covers nucleic acids encoding recombinant variants of ONCONASE(R) and methodology for producing such variants

\*We own this patent jointly with the U.S. Government.

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

## Edgar Filing: ALFACELL CORP - Form 10-K

-----  
Patent No.  
-----

-----  
EP 0 440 633                    covers ONCONASE(R) and process technology for making it  
-----  
EP 0 500 589                    cover combinations of ONCONASE(R) with certain other pharmaceuticals  
JP 2972334  
-----  
EP 0 656 783                    covers combinations of ONCONASE(R) with certain other pharmaceuticals  
-----  
EP 0 837 878                    covers a variant of ONCONASE(R)  
-----

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

These patents cover ONCONASE(R), a variant of ONCONASE(R), process technology for making ONCONASE(R), and combinations of ONCONASE(R) with certain other chemotherapeutics. We also have patent applications pending in the United States, Europe, and Japan.

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 competitive advantages, may be wholly or partially invalidated or held unenforceable, or may be held un 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 un infringed upon. 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.

### Competition

In February 2004, the Food and Drug Administration granted Eli Lilly & Company approval to sell its Alimta(R) medication as an orphan drug to treat patients with pleural mesothelioma. Alimta(R) is a multi-targeted antifolate that is based upon a different mechanism of action than ONCONASE(R). To our knowledge, no other company is developing a product with the same mechanism of action as ONCONASE(R).

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

## Edgar Filing: ALFACELL CORP - Form 10-K

marketing their products.

We are not aware, however, of any product currently being marketed that has the same mechanism of action as our proposed anti-tumor agent, ONCONASE(R). 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(R).

Employees

15

As of September 30, 2004, we have 15 employees, of whom 8 were engaged in research and development activities and 7 were engaged in administration and management. We have 6 employees who hold Ph.D. degrees. All of our employees are covered by confidentiality agreements. We consider relations with our employees to be good. None of our employees are covered by a collective bargaining agreement.

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.

Item 2. PROPERTIES.

We lease a total of approximately 17,000 square feet in an industrial office building located in Bloomfield, New Jersey on a month-to-month basis. The monthly rental obligation is \$11,333. We believe that the facility is sufficient for our needs in the foreseeable future.

Item 3. LEGAL PROCEEDINGS.

We are presently not involved in any legal proceedings.

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

None.

Part II

Item 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

## Edgar Filing: ALFACELL CORP - Form 10-K

Our common stock is listed on the The Nasdaq SmallCap Market, or Nasdaq, and has traded under the symbol "ACEL" since September 9, 2004. As of October 8, 2004, there were approximately 1,112 stockholders of record of our common stock.

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, 2004 and 2003. The prices were obtained from OTCBB and are believed to be representative of inter-dealer quotations, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

	High ----	Low ---
Year Ended July 31, 2004:		
First Quarter	\$4.51	\$1.25
Second Quarter	5.14	2.65

16

	High ----	Low ---
Third Quarter	9.97	3.70
Fourth Quarter	10.07	5.50
Year Ended July 31, 2003:		
First Quarter	0.36	\$ 0.18
Second Quarter	1.01	0.19
Third Quarter	0.85	0.39
Fourth Quarter	1.45	0.64

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

The following table provides additional information on the Company's equity based compensation plans as of July 31, 2004:

Plan Category -----	Number of securities to be issued upon exercise of outstanding options, warrants and rights -----	Weighted-average exercise price of outstanding options, warrants and rights -----	Numb remai futu equity (exc refle -----
	(a)	(b)	
Equity compensation plans approved by security holders	2,957,445	\$ 2.95	
Equity compensation plans not approved by security holders	55,556 (1)	\$ 1.50	

## Edgar Filing: ALFACELL CORP - Form 10-K

- (1) In August 2001, we converted \$50,000 of our accounts payable into 55,556 shares of common stock. In addition, we issued 55,556 five-year warrants to purchase 55,556 shares of common stock at an exercise price of \$1.50 per share.

### Recent Sales of Unregistered Securities

The following is a summary of transactions involving our securities from May 1, 2004 to July 31, 2004. Each of the following was exempt from registrations under Section 4(2) of the Securities Act of 1933, as amended, based upon the fact that each issuance was to an accredited investor. The net proceeds from these transactions were used for general corporate purposes, including the funding of research and development.

In May 2004, we issued 1,210,654 shares of Common Stock to an existing institutional investor, resulting in gross proceeds of \$10,000,000 to us. In addition, the institutional investor was granted five-year warrants to purchase 1,210,654 shares of Common Stock at an exercise price of \$12.39 per share. We paid a 5% finder's fee and granted a five-year warrant to purchase 60,533 shares of Common Stock at an exercise price of \$12.39 per share to a third party in connection with the private placement.

In May and June 2004, we issued, an aggregate of 785,000 shares of restricted common stock upon the exercise of warrants by unrelated parties, at per share exercise prices ranging from \$0.75 to \$1.50. We realized aggregate gross proceeds of \$1,051,250 from these exercises.

In May 2004, we issued 25,000 shares of restricted common stock as payment for services rendered in the amount of \$198,500.

17

In June 2004, we issued 2,099 restricted shares of common stock as payment of accounts payable in the amount of \$9,447.

From June 2004 through July 15, 2004, we issued an aggregate of 1,574,424 shares of restricted common stock and 1,815,466 shares of common stock underlying five-year warrants with exercise prices ranging from \$1.00 to \$1.10 per share upon the conversion of notes payable by unrelated parties in an aggregate amount of \$413,275.

### Issuer Purchases of Equity Securities

We did not repurchase any shares of our common stock during the fourth quarter of fiscal 2004.

### Item 6. SELECTED FINANCIAL DATA.

Set forth below is the selected financial data for our company for the five fiscal years ended July 31, 2004.

Year Ended July 31,

2004	2003	2002	2001
----	----	----	----

Edgar Filing: ALFACELL CORP - Form 10-K

Investment Income	\$ 42,113	\$ 9,877	\$ 4,838	\$ 13,121	\$
Other Income	--	30,000	--	--	
Net Loss (1)	(5,070,307)	(2,411,532)	(2,591,162)	(2,294,936)	(1,
Net Loss Per Basic and Diluted Share	(.17)	(.10)	(.12)	(.12)	
Dividends	None	None	None	None	
Total Assets	10,421,063	495,322	228,871	201,609	
Long-term Debt	--	242,516	315,929	23,663	
Total Equity (Deficiency)	8,881,647	(2,491,681)	\$(1,885,437)	(740,378)	(

(1) Included in the net loss of \$5,070,307, \$2,411,532 and \$2,591,162 for fiscal years ended July 31, 2004, 2003 and 2002, respectively, are tax benefits of \$221,847, \$231,357 and \$353,732, respectively, related to the sale of certain state tax operating loss carryforwards.

18

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

Overview

Since our inception, we have devoted the vast majority of our resources to the research and development of ONCONASE(R) and related drug candidates. We have focused our resources towards the completion of the clinical program for unresectable, or inoperable, malignant mesothelioma.

Since ONCONASE(R) has Fast Track Designation for the treatment of malignant mesothelioma patients, we continue to have meetings and discussions with the FDA to establish mutually agreed upon parameters for the New Drug Application, or NDA to obtain marketing approval for ONCONASE(R), assuming the Phase III clinical trial for the treatment of malignant mesothelioma yields favorable results.

We received an Orphan Medicinal Product Designation for ONCONASE(R) from the European Agency for the Evaluation of Medicinal Products, or the EMEA. We continue to fulfill the EMEA requirements regarding the Marketing Authorization Application, or MAA registration requirements for ONCONASE(R) for the treatment of malignant mesothelioma.

Almost all of our research and development expenses since our inception of \$44,954,912 has gone toward the development of ONCONASE(R) and related drug candidates. For the fiscal years 2004, 2003 and 2002 our research and development expenses were \$3,353,000, \$1,700,000 and \$2,033,000, respectively, almost all of which was used for the development of ONCONASE(R) and related drug candidates. ONCONASE(R) is currently in an international, centrally randomized Phase III trial. The first part of the trial has been completed and the second confirmatory part of the trial is ongoing for which patient enrollment is expected to be completed in the first quarter of 2005. The primary endpoint of

## Edgar Filing: ALFACELL CORP - Form 10-K

the trial is survival, and as such, a sufficient number of deaths must occur in order to perform the required statistical analyses to determine the efficacy of ONCONASE(R) in patients with unresectable (inoperable) malignant mesothelioma. If the results of the clinical trials are positive, we expect to file for marketing registrations (NDA and MAA) for ONCONASE(R) within six months of completion of the statistical analyses. However, at this time, we cannot predict with certainty when a sufficient number of deaths will occur to achieve statistical significance. Hence, the timing of when we will be able to file for marketing registrations in the US and EU is data driven. Therefore, we cannot predict with certainty what our total cost associated with obtaining marketing approvals will be, or when and if such approvals will be granted, or when actual sales will occur.

We fund the research and development of our products from cash receipts resulting from the sale of our equity securities and convertible debentures in registered offerings and private placements. Additionally, we have raised capital through debt financings, the sale of our tax benefits and research products, interest income and financing received from our Chief Executive Officer. Presently, our cash balance is sufficient to fund our expanded operations at least through October 31, 2005 based on our expected level of expenditures in relation to activities in preparing ONCONASE(R) for marketing registrations and other ongoing operations of the Company. However, we continue to seek additional capital financing through the sale of equity in private placements, sale of our tax benefits and exercise of stock options and warrants but cannot be sure that we will be able to raise capital on favorable terms or at all.

### Results of Operations

Fiscal Years Ended July 31, 2004, 2003 and 2002

#### Revenues

We are a development stage company as defined in the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 7. We are devoting substantially all our present efforts to establishing a new business and developing new drug products. Our planned principal operations of marketing and/or licensing of new drugs have not commenced and, accordingly, we have not derived any significant revenue from these operations. We focus most of our productive and financial resources on the development of ONCONASE(R). We did not have

19

any sales in fiscal 2004, 2003 and 2002. Investment income for fiscal 2004 was \$42,000 compared to \$10,000 for fiscal 2003, an increase of \$32,000. Investment income for fiscal 2003 was \$10,000 compared to \$5,000 for fiscal 2002, an increase of \$5,000. These increases were due to higher balances of cash and cash equivalents. Other income for fiscal 2003 was related to investigational research we performed for a pharmaceutical company.

#### Research and Development

Research and development expense for fiscal 2004 was \$3,353,000 compared to \$1,700,000 for fiscal 2003, an increase of \$1,653,000, or 97%. This increase was primarily due to increases in data management, consulting fees and clinical expenses related to our pivotal Phase III clinical trial for malignant mesothelioma of approximately \$1,302,000, sponsored research and development expenses of approximately \$236,000, regulatory consulting costs of approximately \$142,000, non cash expense related to stock options issued for consulting

## Edgar Filing: ALFACELL CORP - Form 10-K

services of approximately \$94,000, offset by a decrease in personnel and insurance expenses of approximately \$121,000.

Research and development expense for fiscal 2003 was \$1,700,000 compared to \$2,033,000 for fiscal 2002, a decrease of \$333,000, or 16.4%. This decrease was primarily due to decreases in regulatory and clinical costs, personnel costs, and a reduction of non-cash expenses relating to stock options issued for consulting services of approximately \$236,000, \$114,000 and \$23,000, respectively. These decreases were partially offset by increases in costs relating to patent and trademark applications for ONCONASE(R) of approximately \$40,000.

### General and Administrative

General and administrative expense for fiscal 2004 was \$1,578,000 compared to \$624,000 for fiscal 2003, an increase of \$954,000, or 153%. The increase was due primarily to an increase in non-cash expense related to stock and stock options issued for consulting services associated with business development activities of approximately \$402,000, increases in legal, public relations, personnel, insurance, and accounting expenses of approximately \$230,000, \$109,000, \$106,000, \$77,000 and \$30,000, respectively.

General and administrative expense for fiscal 2003 was \$624,000 compared to \$798,000 for fiscal 2002, a decrease of \$174,000, or 21.8%. This decrease was primarily due to decreases in costs related to public relations activities, insurance expenses, reduction in non-cash expense relating to stock options issued for consulting services, legal, personnel costs and other miscellaneous office expenses of approximately \$71,000, \$54,000, \$34,000, \$10,000 and \$5,000, respectively.

### Interest

Interest expense for fiscal 2004 was \$403,000 compared to \$358,000 in fiscal 2003, an increase of \$45,000 or 12.6%. The increase was primarily due to the interest expense on the beneficial conversion feature of the notes payable and its related warrants issued to unrelated parties. The interest expense was based on the value of the warrants using the Black-Scholes options-pricing model, amortized on a straight-line basis over the term of the notes.

Interest expense for fiscal 2003 was \$358,000 compared to \$119,000 in fiscal 2002, an increase of \$239,000. The increase was primarily due to the interest expense on the beneficial conversion feature of the notes payable issued to unrelated parties, the related warrants and the increase in total borrowing levels. The interest expense was based on the value of the warrants using the Black-Scholes options-pricing model, amortized on a straight-line basis over the term of the notes.

### Income Taxes

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or tax benefits. For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), we had approximately \$1,378,000 total available tax benefits that were saleable; of which New Jersey permitted us to sell approximately \$261,000. We received approximately \$222,000 from the sale of the \$261,000 of tax benefits, which we recognized as tax benefits for the fiscal year ended July 31, 2004.



## Edgar Filing: ALFACELL CORP - Form 10-K

For the state fiscal year 2003 (July 1, 2002 to June 30, 2003), we had approximately \$1,373,000 in total available tax benefits that were saleable; of which New Jersey permitted us to sell approximately \$273,000. We received approximately \$231,000 from the sale of the \$273,000 of tax benefits, which we recognized as tax benefits for the fiscal year ended July 31, 2003.

For the state fiscal year 2002 (July 1, 2001 to June 30, 2002), we had approximately \$1,535,000 total available tax benefits that were saleable; of which New Jersey permitted us to sell approximately \$426,000. We received approximately \$354,000 from the sale of the \$426,000 of tax benefits, which we recognized as tax benefits for fiscal 2002.

If still available under New Jersey law, we will attempt to sell the remaining \$1,117,000 of our tax benefits, between July 1, 2004 and June 30, 2005. This amount, which is a carryover of our remaining tax benefits from state fiscal year 2004, may increase if we incur additional tax benefits during state fiscal year 2005. We can not estimate, however, what percentage of our saleable tax benefits New Jersey will permit us to sell, how much money we will receive in connection with the sale, if we will be able to find a buyer for our tax benefits or if such funds will be available in a timely manner.

### Net Loss

We have incurred net losses during each year since our inception. The net loss for fiscal 2004 was \$5,070,000 as compared to \$2,411,000 in fiscal 2003 and \$2,591,000 in fiscal 2002. The cumulative loss from the date of inception, August 24, 1981, to July 31, 2004 amounted to \$69,045,000. Such losses are attributable to the fact that we are still in the development stage and, accordingly, have not derived sufficient revenues from operations to offset the development stage expenses.

### Liquidity and Capital Resources

We have reported net losses of approximately \$5,070,000, \$2,411,000, and \$2,591,000 for the fiscal years ended July 31, 2004, 2003 and 2002, respectively. The loss from date of inception, August 24, 1981, to July 31, 2004 amounts to \$69,045,000.

We have financed our operations since inception through the sale of our equity securities and convertible debentures in registered offerings and private placements. Additionally, we have raised capital through debt financings, the sale of our tax benefits and research products, and interest income and financing received from our Chief Executive Officer. During the fiscal year 2004, we had a net increase in cash and cash equivalents of \$9,818,000, which resulted primarily from net cash provided by financing activities of \$14,886,000, which resulted from \$10,736,000 in net proceeds from private placements of common stock and warrants with several institutional investors, \$4,158,000 in net proceeds from warrants and stock options exercises and a reduction in short term debt of \$9,000, offset by net cash used in operating activities of \$5,015,000, principally for research and development activities, and net cash used in investing activities of \$54,000. Total cash resources as of July 31, 2004 were \$10,148,000 compared to \$330,000 at July 31, 2003.

Our current liabilities as of July 31, 2004 were \$1,539,000 compared to \$2,744,000 at July 31, 2003, a decrease of \$1,205,000. The decrease was primarily due to the payment of accrued payroll of \$644,000 and payroll taxes of \$241,000, maturity of short-term notes payable of approximately \$264,000 and decreased accounts payable and other accrued expenses of approximately \$56,000.

The following transactions occurred after July 31, 2004:

- o In September 2004, we issued 320,157 shares of restricted common stock and an aggregate of 420,157 shares of common stock underlying five year warrants with an exercise price of \$1.00 per share upon the conversion of notes payable in the amount of \$112,055.
- o In September 2004, we issued an aggregate of 292,272 shares of restricted common stock upon the exercise of warrants and stock options by a board member and unrelated parties at exercise prices ranging from \$0.29 to \$1.50 per share. We realized aggregate gross proceeds of \$224,054 from these exercises.

Our continued operations will depend on our ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances, sale of tax benefits, revenues from the commercial sale of ONCONASE(R), licensing of our proprietary RNase technology and our ability to realize revenues from our technology and our drug candidates via out-licensing agreements with other companies. Such additional funds may not become available as we need them or be available on acceptable terms. Through October 14, 2004, a significant portion of our financing has been through the sale of our equity securities and convertible debentures in registered offerings and private placements and exercise of stock options and warrants. Additionally, we have raised capital through debt financings, the sale of our tax benefits and research products, interest income and financing received from our Chief Executive Officer. Until and unless our operations generate significant revenues, we expect to continue to fund operations from the sources of capital previously described. There can be no assurance that we will be able to raise the capital we need on terms which are acceptable, if at all. Presently, our cash balance is sufficient to fund our expanded operations at least through October 31, 2005, based on our expected level of expenditures in relation to activities in preparing ONCONASE(R) for marketing registrations and other ongoing operations of the Company. However, we continue to seek additional capital financing through the sale of equity in private placements, sale of our tax benefits and exercise of stock options and warrants but cannot be sure that we will be able to raise capital on favorable terms or at all.

We will continue to incur costs in conjunction with our U.S. and foreign registrations for marketing approval of ONCONASE(R). We are currently in discussions with potential strategic alliance partners to further the development and marketing of ONCONASE(R) and other related products in our pipeline. However, we cannot be sure that any such alliances will materialize.

The market price of our Common Stock is volatile, and the price of the stock could be dramatically affected one way or another depending on numerous factors. The market price of our Common Stock could also be materially affected by the marketing approval or lack of approval of ONCONASE(R).

#### Off-balance Sheet Arrangements

As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities or SPE, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of July 31, 2004, we are not involved in any material unconsolidated SPE transactions.

#### Critical Accounting Policies

In December 2001, the SEC requested that all registrants discuss their

## Edgar Filing: ALFACELL CORP - Form 10-K

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

### Use of Estimates

22

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures during the reporting period. Since some of those estimates are subjective and complex, actual results could differ from those estimates.

### Research and Development

Research and development costs are expensed as incurred.

### Accounting For Stock-Based Compensation

Statements of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ("SFAS 123"), provides for the use of a fair value based method of accounting for employee stock compensation. However, SFAS 123 also allows an entity to continue to measure compensation cost for stock options granted to employees and directors using the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25"), which only requires charges to compensation expense for the excess, if any, of the fair value of the underlying stock at the date a stock option is granted (or at an appropriate subsequent measurement date) over the amount the employee must pay to acquire the stock, if such amounts differ materially from the historical amounts. We have elected to continue to account for employee stock options using the intrinsic value method under Opinion 25.

Pursuant to SFAS 123, shares, warrants or options issued in connection with debt financing agreements or to non-employees for services are accounted for based on their fair market value determined using the Black-Scholes option pricing model.

### Accounting For Warrants Issued With Convertible Debt

We account for the intrinsic value of beneficial conversion rights arising from the issuance of convertible debt instruments with nondetachable conversion rights that are in-the-money at the commitment date pursuant to the consensus for EITF Issue No. 98-5 and EITF Issue No. 00-27. Such value is allocated to additional paid-in capital and the resulting debt discount is charged to interest expense over the terms of the notes payable. Such value is determined after first allocating an appropriate portion of the proceeds received to warrants or any other detachable instruments included in the exchange.

### Income Taxes

We account for income taxes under the provisions of Statement of Financial

## Edgar Filing: ALFACELL CORP - Form 10-K

Accounting Standards No. 109, "Accounting for Income Taxes" (SFAS No. 109). Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for all years in which the temporary differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized.

### Contractual Obligations and Commercial Commitments

Our major outstanding contractual obligations relate to our equipment operating lease. Below is a table that presents our contractual obligations and commercial commitments as of July 31, 2004:

23

	Total	Payments Due by Fiscal Year	
		2005	2006 and Thereafter
	-----	----	-----
Research and development	\$72,398	\$72,398	\$ -0-
Operating lease	13,100	13,100	-0-
	-----	-----	-----
Total contractual cash obligations	\$85,498	\$85,498	\$ -0-
	=====	=====	=====

### 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 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 our source of working capital has been public and private sales of our stock. We incurred a net loss of approximately \$5,070,000 for the fiscal year ended July 31, 2004. We have continued to incur losses since July 2004. We may never achieve revenue sufficient for us to attain profitability.

We incurred net losses of approximately \$5,070,000, \$2,411,000 and \$2,591,000 for the fiscal years ended July 31, 2004, 2003 and 2002, respectively.

Our profitability will depend on our ability to develop, obtain regulatory approvals for, and effectively market ONCONASE(R) 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(R) 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, if any,

## Edgar Filing: ALFACELL CORP - Form 10-K

directed at physicians, patients and third-party payors. A number of factors could affect these efforts including:

- o Our ability to demonstrate clinically that our products have utility and are safe;
- o Delays or refusals by regulatory authorities in granting marketing approvals;
- o Our limited financial resources relative to our competitors;
- o Our ability to obtain an appropriate marketing partner;
- o The availability and level of reimbursement for our products by third party payors;
- o Incidents of adverse reactions to our products;
- o Side effects or misuse of our products and unfavorable publicity that could result; and
- o The occurrence of manufacturing or distribution disruptions.

We will seek to generate revenue through licensing, marketing and development arrangements prior to receiving revenue from the sale of our products. To date we have not consummated any licensing or marketing arrangements and we may not be able to successfully consummate any such arrangements. We have entered into several development arrangements, which have resulted in limited revenues for us. However, we cannot ensure that these arrangements or future arrangements, if any, will result in significant amounts of revenue for us. We, therefore, are unable to predict the extent of any future losses or the time required to achieve profitability, if at all.

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

We need additional financing in order to continue operations, including completion of our current clinical trials and filing marketing registrations for ONCONASE(R) in the United States with the FDA and in Europe with the

EMEA. If the results from our current clinical trial do not demonstrate the efficacy and safety of ONCONASE(R) for malignant mesothelioma, our ability to raise additional capital will be adversely affected. Even if regulatory applications for marketing approvals are filed, we will need additional financing to continue operations. In connection with the recent private placement from which we realized \$10.0 million in gross proceeds from an institutional investor, we plan to expand our operations in preparing ONCONASE(R) for marketing registrations in the US and outside the US as well as fund our ongoing operations. Presently, our cash balance is sufficient to fund our expanded operations at least through October 31, 2005, based on our expected level of expenditures. However, taking into consideration all of the uncertainties related to drug development and our industry, we continue to seek additional capital financing through the sale of equity in private placements, sale of our tax benefits and exercise of stock options and warrants but cannot be sure that we will be able to raise capital on favorable terms or at all.

We may be unable to sell certain state tax benefits in the future and if we are unable to do so, it would eliminate a source of financing that we have relied on

## Edgar Filing: ALFACELL CORP - Form 10-K

in the past.

At July 31, 2004, we had federal net operating loss carryforwards of approximately \$47,326,000 that expire from 2005 to 2024. We also had research and experimentation tax credit carryforwards of approximately \$1,426,000 that expire from 2005 to 2024. New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits or tax benefits. The aggregate amount of tax benefits that New Jersey allows corporations to sell each state fiscal year (July 1st through June 30th) is determined annually and if New Jersey reduces such aggregate amount in any fiscal year we may be unable to sell some or all of our available tax benefits as we have in the past. In addition, there is a limited market for these types of sales and we may not be able to find someone to purchase our tax benefits for a reasonable price. Our historical results of operations have been improved by our sale of tax benefits and if we continue to generate a limited amount of revenue and are unable in the future to sell our tax benefits, our results of operations will be negatively impacted.

For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), we had approximately \$1,378,000 total available tax benefits that were saleable; of which New Jersey permitted us to sell approximately \$261,000. We received approximately \$222,000 from the sale of the \$261,000 of tax benefits, which we recognized as tax benefits for the fiscal year ended July 31, 2004. For the state fiscal year 2003 (July 1, 2002 to June 30, 2003), we had approximately \$1,373,000 in total available tax benefits that were saleable; of which New Jersey permitted us to sell approximately \$273,000. We received approximately \$231,000 from the sale of the \$273,000 of tax benefits, which we recognized as tax benefits for the fiscal year ended July 31, 2003.

If still available under New Jersey law, we will attempt to sell the remaining \$1,117,000 of our tax benefits, between July 1, 2004 and June 30, 2005. This amount, which is a carryover of our remaining tax benefits from state fiscal year 2004, may increase if we incur additional tax benefits during state fiscal year 2005. We can not estimate, however, what percentage of our sellable tax benefits New Jersey will permit us to sell, how much money we will receive in connection with the sale, if we will be able to find a buyer for our tax benefits or if such funds will be available in a timely manner.

We cannot predict how long it will take us nor how much it will cost us to complete our Phase III trial because it is a survival study and we are still in patient enrollment in part two of this Phase III trial.

We currently have ongoing a two-part Phase III trial of ONCONASE(R) as a treatment for malignant mesothelioma. The first part of the clinical trial has been completed and the second, confirmatory part is still ongoing for which patient enrollment is expected to be completed in the first quarter of 2005. The primary endpoint of the Phase III clinical trial is survival, which tracks the length of time patients enrolled in the study live. According to the protocol, a sufficient number of patient deaths must occur in order to perform the required statistical analyses to determine the efficacy of ONCONASE(R) in patients with unresectable (inoperable) malignant mesothelioma. Since it is impossible to predict with certainty when these terminal events in the Phase III trial will occur, we do not have the capability of reasonably determining when a sufficient number of deaths will occur, nor when we will be able to file for marketing registrations with the FDA and EMEA.

In addition, clinical trials are very costly and time consuming. The length of time required to complete a clinical trial depends on several factors

## Edgar Filing: ALFACELL CORP - Form 10-K

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. Delays in patient enrollment, could delay achieving a sufficient number of deaths required for statistical analyses, which therefore may delay the marketing registrations. Although we believe we could modify some of our expenditures to reduce our cash outlays in relation to our clinical trials and other NDA related expenditures, we cannot quantify which or the amount such expenditures might be modified. Hence, a delay in the commercial sale of ONCONASE(R) would increase the time frame of our cash expenditure outflows and may require us to seek additional financing. Such capital financing may not be available on favorable terms or at all.

The FDA and comparable regulatory agencies in foreign countries impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve 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 type, complexity and novelty of the product. We cannot apply for FDA or EMEA approval to market ONCONASE(R) until the clinical trials and all other registration requirements have been met.

If we fail to obtain the necessary regulatory approvals, we will not be allowed to commercialize our drugs and will not generate product revenue.

The FDA and comparable regulatory agencies in foreign countries impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve 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. Drugs in late stages of clinical development may fail to show the desired safety and efficacy results despite having progressed through initial clinical testing. While limited trials with our product have produced certain favorable results, we cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of any compound within any specific time period, if at all. Furthermore, the FDA or the company may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition, we cannot apply for FDA or EMEA approval to market ONCONASE(R) until pre-clinical and clinical trials have been completed. Several factors could prevent the successful completion or cause significant delays of these trials including an inability to enroll the required number of patients or failure to demonstrate the product is safe and effective in humans. Also if safety concerns develop, the FDA and EMEA could stop our trials before completion.

In December 2002, we received Fast Track Designation from the Food and Drug Administration, or the FDA for ONCONASE(R) for the treatment of malignant mesothelioma. In February 2001, we received an Orphan Medicinal Product Designation for ONCONASE(R) from the European Agency for the Evaluation of Medicinal Products, or the EMEA.

All statutes and regulations governing the conduct of clinical trials are subject to change by various regulatory agencies, including the FDA, in the future, 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 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

## Edgar Filing: ALFACELL CORP - Form 10-K

indicated uses for which we may market our products. Further, even after approval, discovery of previously unknown problems could result in additional restrictions, including withdrawal of our products from the market.

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

26

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 products. We presently rely on third parties to perform certain of the manufacturing processes for the production of ONCONASE(R) for use in clinical trials. Currently, we contract with Scientific Protein Labs 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. We contract with Ben Venue Corporation for the manufacturing of ONCONASE(R) and with Cardinal Health for the labeling, storage and shipping of ONCONASE(R) 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.

Our use of manufacturers for ranpirnase and ONCONASE(R) have been approved by the FDA. We have identified substantial alternative service providers for the manufacturing services for which we 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 marketing, sales or distribution capabilities, we expect to contract with third parties for these functions and we will therefore be dependent upon such third parties to market, sell and distribute our products in order for us to generate revenues.

We currently have no sales, marketing or distribution capabilities. In order to commercialize any product candidates for which we receive FDA approval, we expect to rely on established third party strategic partners to perform these functions. For example, if we are successful in our Phase III clinical trials with ONCONASE(R), and are granted marketing approval for the commercialization of ONCONASE(R), we will be unable to introduce the product to market without establishing a marketing collaboration with a pharmaceutical company with those resources. If we establish relationships with one or more biopharmaceutical or other marketing companies with existing distribution systems and direct sales forces to market any or all of our product candidates, we cannot assure you that



## Edgar Filing: ALFACELL CORP - Form 10-K

we will be able to enter into or maintain agreements with these companies on acceptable terms, if at all. Further, it is likely that we will have limited or no control over the manner in which product candidates are marketed or the resources devoted to such markets.

In addition, we expect to begin to incur significant expenses in determining our commercialization strategy with respect to one or more of our product candidates. The determination of our commercialization strategy with respect to a product candidate will depend on a number of factors, including:

- o the extent to which we are successful in securing collaborative partners to offset some or all of the funding obligations with respect to product candidates;
- o the extent to which our agreement with our collaborators permits us to exercise marketing or promotion rights with respect to the product candidate;
- o how our product candidates compare to competitive products with respect to labeling, pricing, therapeutic effect, and method of delivery; and
- o 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.

A number of these factors are outside of our control and will be difficult to determine.

27

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.

We depend upon Kuslima Shogen and our other key personnel and may not be able to retain these employees or recruit qualified replacement or additional personnel, which would have a material adverse affect on our business.

We are highly dependent upon our founder, Chairman and Chief Executive Officer, Kuslima Shogen. Kuslima Shogen's talents, efforts, personality, vision and leadership have been, and continue to be, critical to our success. The diminution or loss of the services of Kuslima Shogen, and any negative market or industry perception arising from that diminution or loss, would have a material adverse effect on our business. While our other employees have substantial experience and have made significant contributions to our business, Kuslima Shogen is our senior executive and also our primary supporter because she represents the Company's primary means of accessing the capital markets.

Because of the specialized scientific nature of our business, our continued success also is dependent upon our ability to attract and retain qualified management and scientific personnel. There is intense competition for qualified personnel in the pharmaceutical field. As our company grows our

## Edgar Filing: ALFACELL CORP - Form 10-K

inability to attract qualified management and scientific personnel could materially adversely affect our research and development programs, the commercialization of our products and the potential revenue from product sales.

We do not have employment contracts with Kuslima Shogen or any of our other management and scientific personnel.

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

We own two patents jointly with the United States government. These patents expire in 2016. We also own ten United States patents with expiration dates ranging from 2006 to 2019, four European patents with expiration dates ranging from 2009 to 2016 and one Japanese patent that expires in 2010. We also own patent applications that are pending in the United States, Europe and Japan. 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. 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. To date, we have not received any threats of litigation, legal actions or negotiations regarding patent issues.

Developments by competitors may render our products obsolete or non-competitive.

In February 2004, the Food and Drug Administration granted Eli Lilly & Company approval to sell its Alimta(R) medication as an orphan drug to treat patients with pleural mesothelioma. Alimta is a multi-targeted antifolate that is based upon a different mechanism of action than ONCONASE(R). To our knowledge, no other company is developing a product with the same mechanism of action as ONCONASE(R). 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. Eli Lilly is, and some of these other companies, universities, research teams or scientists may be more experienced and have greater clinical, marketing and regulatory capabilities and managerial and financial resources than we do. This may enable them to develop products to treat the same medical

28

conditions our products are intended to treat before we are able to complete the development of our competing product.

Our business is very competitive and involves rapid changes in the technologies involved in developing new drugs. If others experience rapid technological development, our products may become obsolete before we are able to recover expenses incurred in developing our products. We will probably face new competitors as new technologies develop. Our success depends on our ability to remain competitive in the development of new drugs or we may not be able to compete successfully.

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,

## Edgar Filing: ALFACELL CORP - Form 10-K

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.

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 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 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.

## Edgar Filing: ALFACELL CORP - Form 10-K

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 which was recently enacted. This legislation provides a new Medicare prescription drug benefit beginning 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.

We have only recently been relisted on the Nasdaq SmallCap Market and our stock is thinly traded and you may not be able to sell our stock when you want to do so.

From April 1999, when we were delisted from Nasdaq, until September 9, 2004, when we were relisted on the Nasdaq SmallCap Market, there was no established trading market for our common stock. During that time, our common stock was quoted on the OTC Bulletin Board and was thinly traded. There is no assurance that we will be able to comply with all of the listing requirements necessary to maintain relisted on the Nasdaq SmallCap Market. In addition, our stock remains thinly traded and you may be unable to sell our common stock during times when the trading market is limited.

The price of our common stock has been, and may continue to be, volatile.

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. Over the past three years, the sale price for our common stock, as reported by Nasdaq and the OTC Bulletin Board has fluctuated from a low of \$0.18 to a high of \$10.07. The market price of our common stock could be impacted by a variety of factors, including:

- o announcements of technological innovations or new commercial products by us or our competitors,
- o disclosure of the results of pre-clinical testing and clinical trials by us or our competitors,
- o disclosure of the results of regulatory proceedings,
- o changes in government regulation,

## Edgar Filing: ALFACELL CORP - Form 10-K

- o developments in the patents or other proprietary rights owned or licensed by us or our competitors,
- o public concern as to the safety and efficacy of products developed by us or others,
- o litigation, and
- o general market conditions in our industry.

In addition, the stock market continues to experience extreme price and volume fluctuations. 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. Nonetheless, these broad market fluctuations may negatively affect the market price of our common stock.

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

30

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 34,347,885 shares of common stock outstanding as of July 31, 2004. The following securities that may be exercised for, or are convertible into, shares of our common stock were issued and outstanding as of July 31, 2004:

- o Options. Stock options to purchase 2,957,445 shares of our common stock at a weighted average exercise price of approximately \$2.95 per share.
- o Warrants. Warrants to purchase 11,371,968 shares of our common stock at a weighted average exercise price of approximately \$2.54 per share.
- o Convertible Notes. Notes which will convert into 1,744,978 shares of our common stock at an average conversion price of \$0.27 per share and warrants which are convertible into 2,044,978 shares of our common stock at an exercise price of \$1.00 per share.

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

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

We are currently authorized to issue 1,000,000 shares of preferred stock. Our Board of Directors is authorized, without any approval of the stockholders, to issue the preferred stock and determine the terms of the preferred stock. This provision allows the board of directors to affect the rights of stockholders, since the board of directors can make it more difficult for common stockholders to replace members of the board. Because the board of directors is responsible for appointing the members of our management, these provisions could in turn affect any attempt to replace current management by the common

## Edgar Filing: ALFACELL CORP - Form 10-K

stockholders. Furthermore, the existence of authorized shares of preferred stock might have the effect of discouraging any attempt by a person, through the acquisition of a substantial number of shares of common stock, to acquire control of our company. Accordingly, the accomplishment of a tender offer may be more difficult. This may be beneficial to management in a hostile tender offer, but have an adverse impact on stockholders who may want to participate in the tender offer or inhibit a stockholder's ability to receive an acquisition premium for his or her shares.

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 this Form 10-K, nor have we been able to obtain AHC's consent to the use of such report herein.

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

In June 1996, AHC dissolved and ceased all operations. Therefore, we have not been able to obtain the reissued reports of AHC with respect to the financial statements included in this Form 10-K 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 this Form 10-K. 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.

31

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not Applicable.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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

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

As described in the current report on Form 8-K we filed on December 12, 2002, on December 6, 2002, KPMG LLP resigned as our independent registered public accounting firm and was replaced by J.H. Cohn LLP as our independent registered public accounting firm for fiscal 2003. The engagement of J.H. Cohn LLP was approved by our Audit Committee. The reports of KPMG LLP on the financial statements for the two fiscal years prior to their resignation as our independent registered public accounting firm contained no adverse opinion or

## Edgar Filing: ALFACELL CORP - Form 10-K

disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principle except that the report on our financial statements for the fiscal years ended July 31, 2002 and 2001 contained a separate paragraph stating that "the Company has suffered recurring losses from operations, has a working capital deficit and has limited liquid resources which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty." During our fiscal years ended July 31, 2002 and July 31, 2001 and through December 6, 2002, there were no disagreements between us and KPMG LLP on any matter of accounting principles or practices, financial statement disclosures or auditing scope or procedures, which disagreements if not resolved to the satisfaction of KPMG LLP would have caused them to make reference thereto in their report on the financial statements for such years.

On December 1, 1993, certain stockholders of Armus Harrison & Co., or AHC, terminated their association with AHC, or the AHC termination, and AHC ceased performing accounting and auditing services, except for limited accounting services to be performed on our behalf. In June 1996, AHC dissolved and ceased all operations. The report of J.H. Cohn LLP with respect to our financial statements from inception to July 31, 2004 is based on the report of KPMG LLP from August 1, 1992 to July 31, 2002 and of AHC for the period from inception to July 31, 1992, although AHC has not consented to the use of such report herein and will not be available to perform any subsequent review procedures with respect to such report. Accordingly, investors will be barred from asserting claims against AHC under Section 18 of the Exchange Act on the basis of the use of such report in any Form 10-K into which such report is incorporated by reference. In addition, in the event any persons seek to assert a claim against AHC for false or misleading financial statements and disclosures in documents previously filed by us, such claim will be adversely affected and possibly barred. Furthermore, as a result of the lack of a consent from AHC to the use of its audit report herein, or to its incorporation by reference into a Form 10-K, our officers and directors will be unable to rely on the authority of AHC as experts in auditing and accounting in the event any claim is brought against such persons under Section 18 of the Exchange Act based on alleged false and misleading Financial Statements and disclosures attributable to AHC. The discussion regarding certain effects of the AHC termination is not meant and should not be construed in any way as legal advice to any party and any potential purchaser should consult with his, her or its own counsel with respect to the effect of the AHC termination on a potential investment in our Common Stock or otherwise.

### Item 9A. CONTROLS AND PROCEDURES.

#### (a) Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of July 31, 2004, the evaluation date. Based upon the evaluation, the Chief Executive Officer and

32

Chief Financial Officer concluded that, as of the evaluation date, our disclosure controls and procedures are effective in timely alerting them to the material information relating to us required to be included in our periodic SEC filings.

#### (b) Changes in internal controls.

## Edgar Filing: ALFACELL CORP - Form 10-K

There were no significant changes made in our internal controls during the three months ended July 31, 2004 or, to our knowledge, in other factors that could significantly affect these controls subsequent to the date of their evaluation.

### Part III

The information required by Item 10 - Directors and Executive Officers of the Registrant; Item 11 - Executive Compensation; Item 12 - Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters; Item 13 - Certain Relationships and Related Transactions and Item 14 - Principal Accountant Fees and Services is incorporated into Part III of this Annual Report on Form 10-K by reference to the Proxy Statement for our Annual Meeting of Stockholders scheduled to be held on January 27, 2005.

### Part IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K.

- (a) (1) and (2) The response to these portions of Item 15 is submitted as a separate section of this report commencing on page F-1.
- (a) (3) Exhibits (numbered in accordance with Item 601 of Regulation S-K).

#### Exhibit

Exhibit No.	Item Title
3.1	Certificate of Incorporation, dated June 12, 1981 (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)
3.2	Amendment to Certificate of Incorporation, dated February 18, 1994 (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)
3.3	Amendment to Certificate of Incorporation, dated December 26, 1997 (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)
3.4	Amendment to Certificate of Incorporation, dated January 14, 2004 (incorporated by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)
3.5	Certificate of Designation for Series A Preferred Stock, dated September 2, 2003 (incorporated by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)
3.6	Certificate of Elimination of Series A Preferred Stock, dated February 3, 2004 (incorporated by reference to Exhibit 3.6 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)
3.7	By-Laws (incorporated by reference to Exhibit 3.4 to Registration Statement on Form S-1, File No. 333-111101, filed on December 11, 2003)



## Edgar Filing: ALFACELL CORP - Form 10-K

Exhibit No.	Item Title
---	-----
10.1	1993 Stock Option Plan and Form of Option Agreement (incorporated by reference to Exhibit 10.10 to Registration Statement on Form SB-2, File No. 33-76950, filed on August 1, 1994)
10.2	1997 Stock Option Plan (incorporated by reference to Exhibit 10.2 to Registration Statement on Form S-1, File No. 333-111101, filed on December 11, 2003)
10.3	2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)
10.4	Form of Subscription Agreement and Warrant Agreement used in Private Placements completed in February 2000 (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K, filed on October 30, 2000)
10.5	Form of Subscription Agreement and Warrant Agreement used in the August and September 2000 Private Placements (incorporated by reference to Exhibit 10.24 to the Company's Quarterly Report on Form 10-Q, filed on December 15, 2000)
10.6	Form of Subscription Agreement and Warrant Agreement used in the April 2001 Private Placements (incorporated by reference to Exhibit 10.23 to Registration Statement on Form S-1, File No. 333-38136, filed on July 30, 2001)
10.7	Form of Convertible Note entered into in April 2001 (incorporated by reference to Exhibit 10.24 to Registration Statement on Form S-1, File No. 333-38136, filed on July 30, 2001)
10.8	Form of Subscription Agreement and Warrant Agreement used in the July 2001 Private Placements (incorporated by reference to Exhibit 10.25 to Registration Statement on Form S-1, File No. 333-38136, filed on July 30, 2001)
10.9	Form of Subscription Agreement and Warrant Agreement used in the August and October 2001 private placement (incorporated by reference to Exhibit 10.26 to Registration Statement on Form S-1, File No. 333-38136, filed on December 14, 2001)
10.10	Form of Subscription Agreement and Warrant Agreement used in the September 2001, November 2001 and January 2002 private placements (incorporated by reference to Exhibit 10.27 to Registration Statement on Form S-1, File No. 333-38136, filed on February 21, 2002)
10.11	Warrant issued in the February 2002 private placement (incorporated by reference to Exhibit 10.28 to Registration Statement on Form S-1, File No. 333-38136, filed on February 21, 2002)
10.12	Form of Subscription Agreement and Warrant Agreement used in the March 2002, April 2002 and May 2002 private placements (incorporated by reference to Exhibit 10.29 to Registration Statement on Form S-1, File No. 333-89166, filed on May 24, 2002)
10.13	Form of Subscription Agreement and Warrant Agreement used in the June 2002 and October 2002 private placements (incorporated by reference to Exhibit 10.30 to the Post-Effective Amendment to Registration Statement on Form S-1, File No.

## Edgar Filing: ALFACELL CORP - Form 10-K

333-38136, filed on March 3, 2003)

10.14 Form of Note Payable and Warrant Certificate entered into April, June, July, September, November and December 2002 (incorporated by reference to Exhibit 10.31 to the Post-Effective Amendment to Registration Statement on Form S-1, File No. 333-38136, filed on March 3, 2003)

34

Exhibit  
No.  
---

Item Title  
-----

10.15 Form of Note Payable and Warrant Certificate entered into November 2001, January, March and May 2003 (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K, filed on October 29, 2003)

10.16 Form of Subscription Agreement and Warrant Agreement used in the February 2003 and April through August 2003 private placements (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed on October 29, 2003)

10.17 Form of Amended Notes Payable which amends the November 2001, April 2002, June 2002, July 2002, September 2002, November 2002 December 2002, January 2003, March 2003 and May 2003 notes payable (incorporated by reference to Exhibit 10.27 to The Company's Annual Report on Form 10-K, filed on October 29, 2003)

10.18 Securities Purchase Agreement and Warrant Agreement used in September 2003 private placement and Form of Warrant Certificate issued on January 16, 2004 and January 29, 2004 to SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K, filed on October 29, 2003)

10.19 Registration Rights Agreement used in September 2003 private placement with SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K, filed on October 29, 2003)

10.20 Form of Securities Purchase Agreement used in May 2004 private placement with Knoll Capital Fund II, Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.3 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)

10.21 Form of Registration Rights Agreement used in May 2004 private placement with Knoll Capital Fund II, Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.4 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)

10.22 Form of Warrant Certificate issued on May 11, 2004 to Knoll Capital Fund II, Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.5 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)

21.1 Subsidiaries of Registrant

23.1 Consent of J.H. Cohn LLP

Edgar Filing: ALFACELL CORP - Form 10-K

- 23.2 Consent of KPMG LLP
- 31.1 Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

35

Exhibit

No.	Item Title
---	-----

- |      |  |
|------|--|
| 32.2 | Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
|------|--|

\* Previously filed; incorporated herein by reference

+ Filed herewith

(b) Reports on Form 8-K.

On May 12, 2004, we filed a report on Form 8-K which reported under Item 5 thereof that we completed a private placement to an existing institutional investor resulting in the issuance of 1,210,654 shares of common stock at a price of \$8.26 per share and warrants to purchase an additional 1,210,654 shares of common stock at an exercise price of \$12.39 per share. We received gross proceeds of \$10,000,000 from such private placement.

On June 3, 2004, we filed a report on Form 8-K, which reported under Item 5 thereof the appointment of Dr. David Sidransky to our Board of Directors effective as of May 28, 2004.

36

Signature

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

ALFACELL CORPORATION

Dated: October 14, 2004

By: /s/ KUSLIMA SHOGEN  
Kuslima Shogen, Chief Executive  
Officer and Chairman of the Board

Pursuant to the requirements of the Securities Exchange Act of 1934, this report

Edgar Filing: ALFACELL CORP - Form 10-K

has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Dated: October 14, 2004 /s/ KUSLIMA SHOGEN  
Kuslima Shogen, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)

Dated: October 14, 2004 /s/ JOHN P. BRANCACCIO  
John P. Brancaccio, Director

Dated: October 14, 2004 /s/ STEPHEN K. CARTER  
Stephen K. Carter, M.D., Director

Dated: October 14, 2004 /s/ DONALD R. CONKLIN  
Donald R. Conklin, Director

Dated: October 14, 2004 /s/ JAMES J. LOUGHLIN  
James J. Loughlin, Director

Dated: October 14, 2004 /s/ ANDREW P. SAVADELIS  
Andrew P. Savadelis, Director, Chief Financial Officer (Principal Accounting Officer)

Dated: October 14, 2004 /s/ DAVID SIDRANSKY  
David Sidransky, M.D., Director

Dated: October 14, 2004 /s/ PAUL M. WEISS  
Paul M. Weiss, Ph.D., Director

37

Index

	Page
	----
Audited Financial Statements:	
Report of Independent Registered Public Accounting Firm: J.H. Cohn LLP .	F-2
Report of Independent Registered Public Accounting Firm: KPMG LLP .....	F-3
Independent Auditors' Report of Armus, Harrison & Co. ....	F-4
Balance Sheets - July 31, 2004 and 2003 .....	F-6
Statements of Operations - Years ended July 31, 2004, 2003, and 2002 and the Period from August 24, 1981 (Date of Inception) to July 31, 2004 .....	F-7

Edgar Filing: ALFACELL CORP - Form 10-K

Statement of Stockholders' Equity (Deficiency)  
Period from August 24, 1981  
(Date of Inception) to July 31, 2004 ..... F-8

Statements of Cash Flows - Years ended July 31, 2004, 2003,  
and 2002 and Period from August 24, 1981  
(Date of Inception) to July 31, 2004 ..... F-14

Notes to Financial Statements - Years ended July 31, 2004,  
2003 and 2002 and the Period from August 24, 1981  
(Date of Inception) to July 31, 2004 ..... F-17

F-1

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
Alfacell Corporation

We have audited the accompanying balance sheets of ALFACELL CORPORATION (A Development Stage Company) as of July 31, 2004 and 2003, and the related statements of operations, stockholders' equity (deficiency) and cash flows for the years then ended and for the period from August 24, 1981 (date of inception) to July 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements of Alfacell Corporation for the period from August 24, 1981 to July 31, 2002 were audited by other auditors whose reports dated November 4, 2002 and December 9, 1992, except for Note 18 which is as of July 19, 1993 and Note 3 which is as of October 28, 1993, expressed unqualified opinions on those statements with explanatory paragraphs relating to the Company's ability to continue as a going concern.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and, for the effect on the period from August 24, 1981 to July 31, 2004 of the amounts for the period from August 24, 1981 to July 31, 2002, on the reports of other auditors, the financial statements referred to above present fairly, in all material respects, the financial position of Alfacell Corporation as of July 31, 2004 and 2003, and its results of operations and cash flows for the years then ended and for the period from August 24, 1981 to July 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

/s/ J.H. Cohn LLP

Roseland, New Jersey  
September 17, 2004, except for Note 18,  
which is as of September 23, 2004

F-2

## Edgar Filing: ALFACELL CORP - Form 10-K

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors  
Alfacell Corporation:

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

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

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

/s/ KPMG LLP

Short Hills, New Jersey  
November 4, 2002

F-3

On December 1, 1993, certain shareholders of Armus Harrison & Co. ("AHC") terminated their association with AHC (the "AHC termination"), and AHC ceased performing accounting and auditing services, except for limited accounting services to be performed on behalf of the Company. In June 1996, AHC dissolved and ceased all operations. The report of AHC with respect to the financial statements of the Company from inception to July 31, 1992 is included herein,

## Edgar Filing: ALFACELL CORP - Form 10-K

although AHC has not consented to the use of such report herein and will not be available to perform any subsequent review procedures with respect to such report. Accordingly, investors will be barred from asserting claims against AHC under Section 11 of the Securities Act of 1933, as amended (the "Securities Act") on the basis of the use of such report in any registration statement of the Company into which such report is incorporated by reference. In addition, in the event any persons seek to assert a claim against AHC for false or misleading financial statements and disclosures in documents previously filed by the Company, such claim will be adversely affected and possibly barred. Furthermore, as a result of the lack of a consent from AHC to the use of its audit report herein, or, to its incorporation by reference into a registration statement or other filings, the officers and directors of the Company will be unable to rely on the authority of AHC as experts in auditing and accounting in the event any claim is brought against such persons under Section 11 of the Securities Act based on alleged false and misleading financial statements and disclosures attributable to AHC. The discussion regarding certain effects of the AHC termination is not meant and should not be construed in any way as legal advice to any party and any potential purchaser should consult with his, her or its own counsel with respect to the effect of the AHC termination on a potential investment in the Common Stock of the Company or otherwise.

### Independent Auditors' Report

Board of Directors  
Alfacell Corporation  
Bloomfield, New Jersey

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

We conducted our audit in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

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

F-4

The accompanying financial statements have been prepared on a going concern basis which contemplates the realization of assets and the satisfaction of liability in the normal course of business. As shown in the statement of operations, the Company has incurred substantial losses in each year since its

Edgar Filing: ALFACELL CORP - Form 10-K

inception. In addition, the Company is a development stage company and its principal operation for production of income has not commenced. The Company's working capital has been reduced considerably by operating losses, and has a deficit net worth. These factors, among others, as discussed in Note 2 to the Notes of Financial Statements, indicates the uncertainties about the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and the amount or classification of liabilities that might be necessary should the Company be unable to continue its existence.

/s/ Armus, Harrison & Co.

-----  
Armus, Harrison & Co.

Mountainside, New Jersey  
December 9, 1992  
Except as to Note 18 which  
is July 19, 1993 and Note 3  
which is October 28, 1993

F-5

ALFACELL CORPORATION  
(A Development Stage Company)

Balance Sheets

July 31, 2004 and 2003

	2004	2003
	-----	-----
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,147,694	\$ 330,133
Other assets	64,771	10,100
	-----	-----
Total current assets	10,212,465	340,243
Property and equipment, net of accumulated depreciation and amortization of \$1,095,412 in 2004 and \$1,136,183 in 2003	56,783	12,790
Loan receivable, related party	151,815	142,280
	-----	-----
Total assets	\$ 10,421,063	\$ 495,323
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Current portion of long-term debt, net of debt discount of \$34,120 and \$187,121 at July 31, 2004 and 2003, respectively	\$ 372,611	\$ 637,080
Accounts payable	541,600	699,420



Edgar Filing: ALFACELL CORP - Form 10-K

Accrued expenses	625,205	1,407,97
	-----	-----
Total current liabilities	1,539,416	2,744,48
Long-term debt, less current portion, net of debt discount of \$163,687 at July 31, 2003	--	242,51
	-----	-----
Total liabilities	1,539,416	2,987,00
	-----	-----
Commitments and contingencies		
Stockholders' equity (deficiency):		
Preferred stock, \$.001 par value. Authorized and unissued, 1,000,000 shares at July 31, 2004 and 2003	--	--
Common stock \$.001 par value. Authorized 100,000,000 shares and 40,000,000 shares at July 31, 2004 and 2003, respectively; issued and outstanding 34,347,885 shares and 25,026,129 shares at July 31, 2004 and 2003, respectively..	34,348	25,02
Capital in excess of par value	77,891,815	61,457,50
Deficit accumulated during development stage	(69,044,516)	(63,974,20
	-----	-----
Total stockholders' equity (deficiency)	8,881,647	(2,491,68
	-----	-----
Total liabilities and stockholders' equity (deficiency)	\$ 10,421,063	\$ 495,32
	=====	=====

See accompanying notes to financial statements.

F-6

ALFACELL CORPORATION  
(A Development Stage Company)

Statements of Operations

Years ended July 31, 2004, 2003 and 2002  
and the Period from August 24, 1981  
(Date of Inception) to July 31, 2004

	August 24, 1981 (date of inception) to July 31, 2004	2004	2003
	-----	-----	-----
Revenues:			
Sales	\$ 553,489	\$ --	\$ --
Investment income	1,429,113	42,113	9,877
Other income	90,103	--	30,000
	-----	-----	-----
	2,072,705	42,113	39,877
	-----	-----	-----
Cost and expenses:			

Edgar Filing: ALFACELL CORP - Form 10-K

Cost of sales	336,495	--	--
Research and development	44,954,912	3,352,977	1,699,962
General and administrative	23,866,209	1,578,357	624,406
Interest:			
Related parties	1,147,547	--	--
Others	2,826,243	402,933	358,398
	-----	-----	-----
	73,131,406	5,334,267	2,682,766
	-----	-----	-----
Loss before state tax benefit	(71,058,701)	(5,292,154)	(2,642,889)
State tax benefit	2,014,185	221,847	231,357
	-----	-----	-----
Net loss	\$ (69,044,516)	\$ (5,070,307)	\$ (2,411,532)
	=====	=====	=====
Loss per basic and diluted common share		\$ (0.17)	\$ (0.10)
		=====	=====
Weighted average number of shares outstanding		29,438,000	23,166,000
		=====	=====

See accompanying notes to financial statements.

F-7

ALFACELL CORPORATION  
(A Development Stage Company)

Statement of Stockholders' Equity (Deficiency)

Period from August 24, 1981  
(Date of Inception) to July 31, 2004

	Common Stock		
	Number of Shares	Amount	Ex
	-----	-----	-----
Issuance of shares to officers and stockholders for equipment, research and development, and expense reimbursement	712,500	\$ 713	\$
Issuance of shares for organizational legal service	50,000	50	
Sale of shares for cash, net	82,143	82	
Adjustment for 3 for 2 stock split declared September 8, 1982	422,321	422	
Net loss	--	--	
	-----	-----	-----
Balance at July 31, 1982	1,266,964	1,267	
Issuance of shares for equipment	15,000	15	
Sale of shares to private investors	44,196	44	
Sale of shares in public offering, net	660,000	660	
Issuance of shares under stock grant program	20,000	20	

Edgar Filing: ALFACELL CORP - Form 10-K

Exercise of warrants, net	1,165	1
Net loss	--	--
	-----	-----
Balance at July 31, 1983	2,007,325	2,007
Exercise of warrants, net	287,566	287
Issuance of shares under stock grant program	19,750	20
Issuance of shares under stock bonus plan for directors and consultants	130,250	131
Net loss	--	--
	-----	-----
Balance at July 31, 1984	2,444,891	2,445
Issuance of shares under stock grant program	48,332	48
Issuance of shares under stock bonus plan for directors and consultants	99,163	99
Shares canceled	(42,500)	(42)
Exercise of warrants, net	334,957	335
Net loss	--	--
	-----	-----
Balance at July 31, 1985	2,884,843	2,885
Issuance of shares under stock grant program	11,250	12
Issuance of shares under stock bonus plan for directors and consultants	15,394	15
Exercise of warrants, net	21,565	21
Net loss	--	--
	-----	-----
Balance at July 31, 1986 (carried forward)	2,933,052	2,933
	Deficit Accumulated During Development Stage	Subscription Receivable
	-----	-----
Issuance of shares to officers and stockholders for equipment, research and development, and expense reimbursement	\$ --	\$ --
Issuance of shares for organizational legal service	--	--
Sale of shares for cash, net	--	--
Adjustment for 3 for 2 stock split declared September 8, 1982	--	--
Net loss	(121,486)	--
	-----	-----
Balance at July 31, 1982	(121,486)	--
Issuance of shares for equipment	--	--
Sale of shares to private investors	--	--
Sale of shares in public offering, net	--	--
Issuance of shares under stock grant program	--	--
Exercise of warrants, net	--	--
Net loss	(558,694)	--
	-----	-----
Balance at July 31, 1983	(680,180)	--
Exercise of warrants, net	--	--
Issuance of shares under stock grant program	--	--
Issuance of shares under stock bonus plan for directors and consultants	--	--
Net loss	(1,421,083)	--

Edgar Filing: ALFACELL CORP - Form 10-K

Balance at July 31, 1984	(2,101,263)	--
Issuance of shares under stock grant program	--	--
Issuance of shares under stock bonus plan for directors and consultants	--	--
Shares canceled	--	--
Exercise of warrants, net	--	--
Net loss	(2,958,846)	--
Balance at July 31, 1985	(5,060,109)	--
Issuance of shares under stock grant program	--	--
Issuance of shares under stock bonus plan for directors and consultants	--	--
Exercise of warrants, net	--	--
Net loss	(2,138,605)	--
Balance at July 31, 1986 (carried forward)	(7,198,714)	--

F-8

ALFACELL CORPORATION  
(A Development Stage Company)

Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock		
	Number of Shares	Amount	
Balance at July 31, 1986 (brought forward)	2,933,052	\$ 2,933	\$
Exercise of warrants, net	14,745	15	
Issuance of shares under stock bonus plan for directors and consultants	5,000	5	
Issuance of shares for services	250,000	250	
Sale of shares to private investors, net	5,000	5	
Net loss	--	--	
Balance at July 31, 1987	3,207,797	3,208	
Issuance of shares for legal and consulting services	206,429	207	
Issuance of shares under employment incentive program	700,000	700	
Issuance of shares under stock grant program	19,000	19	
Exercise of options, net	170,000	170	
Issuance of shares for litigation settlement	12,500	12	
Exercise of warrants, net	63,925	64	
Sale of shares to private investors	61,073	61	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	--	--	
Balance at July 31, 1988	4,440,724	4,441	

Edgar Filing: ALFACELL CORP - Form 10-K

Sale of shares for litigation settlement	135,000	135	
Conversion of debentures, net	133,333	133	
Sale of shares to private investors	105,840	106	
Exercise of options, net	1,000	1	
Issuance of shares under employment agreement	750,000	750	
Issuance of shares under the 1989 Stock Plan	30,000	30	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	--	--	
	-----	-----	
Balance at July 31, 1989	5,595,897	5,596	
Issuance of shares for legal and consulting services	52,463	52	
Issuance of shares under the 1989 Stock Plan	56,000	56	
Sale of shares for litigation settlement	50,000	50	
Exercise of options at, net	105,989	\$ 106	\$
	Deficit		
	Accumulated		
	During		
	Development	Subscription	
	Stage	Receivable	
	-----	-----	
Balance at July 31, 1986 (brought forward)	\$ (7,198,714)	\$ --	\$
Exercise of warrants, net	--	--	
Issuance of shares under stock bonus plan for directors and consultants	--	--	
Issuance of shares for services	--	--	
Sale of shares to private investors, net	--	--	
Net loss	(2,604,619)	--	
	-----	-----	
Balance at July 31, 1987	(9,803,333)	--	
Issuance of shares for legal and consulting services	--	--	
Issuance of shares under employment incentive program	--	--	
Issuance of shares under stock grant program	--	--	
Exercise of options, net	--	--	
Issuance of shares for litigation settlement	--	--	
Exercise of warrants, net	--	--	
Sale of shares to private investors	--	--	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	(3,272,773)	--	
	-----	-----	
Balance at July 31, 1988	(13,076,106)	--	
Sale of shares for litigation settlement	--	--	
Conversion of debentures, net	--	--	
Sale of shares to private investors	--	--	
Exercise of options, net	--	--	
Issuance of shares under employment agreement	--	--	
Issuance of shares under the 1989 Stock Plan	--	--	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	(2,952,869)	--	
	-----	-----	
Balance at July 31, 1989	(16,028,975)	--	
Issuance of shares for legal and consulting services	--	--	
Issuance of shares under the 1989 Stock Plan	--	--	

Edgar Filing: ALFACELL CORP - Form 10-K

Sale of shares for litigation settlement		--		--
Exercise of options at, net	\$	--	\$	--

F-9

ALFACELL CORPORATION  
(A Development Stage Company)

Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock		Cap Exce
	Number of Shares	Amount	
Sale of shares to private investors	89,480	90	
Issuance of shares under employment agreement	750,000	750	3
Conversion of debentures, net	100,000	100	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	--	--	
Balance at July 31, 1990	6,799,829	6,800	23
Exercise of options, net	16,720	16	
Issuance of shares for legal consulting services	87,000	87	
Issuance of shares under the 1989 Stock Plan	119,000	119	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	--	--	
Balance at July 31, 1991	7,022,549	7,022	24
Exercise of options at, net	1,000	1	
Sale of shares to private investors	70,731	71	
Conversion of debentures, net	94,000	94	
Issuance of shares for services	45,734	46	
Issuance of shares under the 1989 Stock Plan	104,000	104	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	--	--	
Balance at July 31, 1992	7,338,014	7,338	25
Sale of shares to private investors	352,667	353	
Issuance of shares for legal services	49,600	50	
Issuance of shares for services	5,000	5	
Issuance of shares under the 1989 Stock Plan	117,000	117	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	--	--	
Balance at July 31, 1993	7,862,281	7,863	26
Conversion of debentures, net	425,400	425	1
Sale of shares to private investors, net	743,000	743	1
Conversion of short-term borrowings	72,800	73	
Issuance of shares for services	16,200	16	

Edgar Filing: ALFACELL CORP - Form 10-K

	Deficit Accumulated During Development Stage -----	Subscription Receivable -----
Sale of shares to private investors	--	--
Issuance of shares under employment agreement	--	--
Conversion of debentures, net	--	--
Amortization of deferred compensation, restricted stock	--	--
Net loss	(4,860,116)	--
	-----	-----
Balance at July 31, 1990	(20,889,091)	--
Exercise of options, net	--	--
Issuance of shares for legal consulting services	--	--
Issuance of shares under the 1989 Stock Plan	--	--
Amortization of deferred compensation, restricted stock	--	--
Net loss	(5,202,302)	--
	-----	-----
Balance at July 31, 1991	(26,091,393)	--
Exercise of options at, net	--	--
Sale of shares to private investors	--	--
Conversion of debentures, net	--	--
Issuance of shares for services	--	--
Issuance of shares under the 1989 Stock Plan	--	--
Amortization of deferred compensation, restricted stock	--	--
Net loss	(4,772,826)	--
	-----	-----
Balance at July 31, 1992	(30,864,219)	--
Sale of shares to private investors	--	--
Issuance of shares for legal services	--	--
Issuance of shares for services	--	--
Issuance of shares under the 1989 Stock Plan	--	--
Amortization of deferred compensation, restricted stock	--	--
Net loss	(2,357,350)	--
	-----	-----
Balance at July 31, 1993	(33,221,569)	--
Conversion of debentures, net	--	--
Sale of shares to private investors, net	--	--
Conversion of short-term borrowings	--	--
Issuance of shares for services	--	--

F-10

ALFACELL CORPORATION  
(A Development Stage Company)

Statement of Stockholders' Equity (Deficiency), Continued

Edgar Filing: ALFACELL CORP - Form 10-K

	Common Stock		
	Number of Shares	Amount	Capital Excess Value
Issuance of shares under the 1989 Stock Plan, for services	5,000	5	
Issuance of options to related parties upon conversion of accrued interest, payroll and expenses	--	\$ --	\$ 3
Repurchase of stock options from related party	--	--	
Issuance of options upon conversion of accrued interest	--	--	
Common stock to be issued	--	--	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	--	--	
Balance at July 31, 1994	9,124,681	9,125	33
Sale of shares to private investors, net	961,000	961	2
Conversion of short-term borrowings	17,600	17	
Issuance of shares for services	30,906	31	
Exercise of options, net	185,000	185	
Common stock to be issued	--	--	
Common stock to be issued, for services	--	--	
Amortization of deferred compensation, restricted stock	--	--	
Net loss	--	--	
Balance at July 31, 1995	10,319,187	10,319	36
Sale of shares to private investors, net	2,953,327	2,953	8
Issuance of shares for services	19,995	20	
Exercise of options, net	566,700	567	1
Sale of warrants	--	--	
Issuance of options/warrants for services	--	--	
Common stock to be issued	--	--	
Subscription receivable	--	--	
Net loss	--	--	
Balance at July 31, 1996	13,859,209	13,859	47
Sale of shares to private investors, net	112,000	112	
Issuance of options for services	--	--	
Exercise of options, net	729,134	729	2
Exercise of warrants, net	147,450	148	
Net loss	--	--	
Balance at July 31, 1997 (carried forward)	14,847,793	14,848	50
	Deficit Accumulated During Development Stage	Subscription Receivable	
Issuance of shares under the 1989 Stock Plan, for services	--	--	
Issuance of options to related parties upon conversion of accrued interest, payroll and expenses	\$ --	\$ --	
Repurchase of stock options from related party	--	--	



Edgar Filing: ALFACELL CORP - Form 10-K

Issuance of options upon conversion of accrued interest	--	--
Common stock to be issued	--	--
Amortization of deferred compensation, restricted stock	--	--
Net loss	(2,234,428)	--
	-----	-----
Balance at July 31, 1994	(35,455,997)	--
Sale of shares to private investors, net	--	--
Conversion of short-term borrowings	--	--
Issuance of shares for services	--	--
Exercise of options, net	--	--
Common stock to be issued	--	--
Common stock to be issued, for services	--	--
Amortization of deferred compensation, restricted stock	--	--
Net loss	(1,993,123)	--
	-----	-----
Balance at July 31, 1995	(37,449,120)	--
Sale of shares to private investors, net	--	--
Issuance of shares for services	--	--
Exercise of options, net	--	--
Sale of warrants	--	--
Issuance of options/warrants for services	--	--
Common stock to be issued	--	--
Subscription receivable	--	(254,185)
Net loss	(2,942,152)	--
	-----	-----
Balance at July 31, 1996	(40,391,272)	(254,185)
Sale of shares to private investors, net	--	--
Issuance of options for services	--	--
Exercise of options, net	--	254,185
Exercise of warrants, net	--	--
Net loss	(5,018,867)	--
	-----	-----
Balance at July 31, 1997 (carried forward)	(45,410,139)	--

F-11

ALFACELL CORPORATION  
(A Development Stage Company)

Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock		
	Number of	Amount	Capital In
	Shares		Excess of pa
	-----	-----	Value
	-----	-----	-----
Balance at July 31, 1997 (brought forward)	14,847,793	\$ 14,848	\$ 50,961,38
Sale of shares to private investors, net	2,337,150	2,337	4,199,87
Issuance of options for services	--	--	199,95
Exercise of warrants, net	4,950	5	11,08

Edgar Filing: ALFACELL CORP - Form 10-K

Issuance of shares for services, net	50,000	50	99,95
Net loss	--	--	--
	-----	-----	-----
Balance at July 31, 1998	17,239,893	17,240	55,472,24
Issuance of options for services	--	--	205,59
Issuance of shares for services, net	46,701	46	16,35
Net loss	--	--	--
	-----	-----	-----
Balance at July 31, 1999	17,286,594	17,286	55,694,19
Sale of shares to private investors, net	875,000	875	547,41
Exercise of options, net	95,000	95	45,75
Issuance of shares for services, net	174,965	175	92,00
Vesting of options previously issued for services	--	--	146,91
Net loss	--	--	--
	-----	-----	-----
Balance at July 31, 2000	18,431,559	18,431	56,526,28
Sale of shares to private investors, net	863,331	863	955,56
Exercise of options, net	165,555	166	83,56
Issuance of shares for services, net	11,800	12	10,01
Exercise of convertible debentures, net	330,000	330	296,67
Issuance of warrants with convertible debt	--	--	178,80
Issuance of options for services	--	--	160,42
Net loss	--	--	--
	-----	-----	-----
Balance at July 31, 2001	19,802,245	19,802	58,211,33
Sale of shares to private investors, net	2,622,122	2,623	1,047,92
Exercise of stock options and warrants	186,000	186	92,81
Issuance of shares for services, net	78,340	78	64,04
Exercise of convertible debentures, net	72,214	72	64,92
Vesting of options previously issued for services	--	--	173,43
Net loss	--	--	--
	-----	-----	-----
Balance at July 31, 2002 (carried forward)	22,760,921	22,761	59,654,47
	Deficit		
	Accumulated		Deferr
	During		compensa
	Development	Subscription	restric
	Stage	Receivable	stoo
	-----	-----	-----
Balance at July 31, 1997 (brought forward)	\$ (45,410,139)	\$ --	\$
Sale of shares to private investors, net	--	--	--
Issuance of options for services	--	--	--
Exercise of warrants, net	--	--	--
Issuance of shares for services, net	--	--	--
Net loss	(6,387,506)	--	--
	-----	-----	-----
Balance at July 31, 1998	(51,797,645)	--	--
Issuance of options for services	--	--	--
Issuance of shares for services, net	--	--	--
Net loss	(3,156,636)	--	--
	-----	-----	-----
Balance at July 31, 1999	(54,954,281)	--	--

Edgar Filing: ALFACELL CORP - Form 10-K

Sale of shares to private investors, net	--	--
Exercise of options, net	--	--
Issuance of shares for services, net	--	--
Vesting of options previously issued for services	--	--
Net loss	(1,722,298)	--
	-----	-----
Balance at July 31, 2000	(56,676,579)	--
Sale of shares to private investors, net	--	--
Exercise of options, net	--	--
Issuance of shares for services, net	--	--
Exercise of convertible debentures, net	--	--
Issuance of warrants with convertible debt	--	--
Issuance of options for services	--	--
Net loss	(2,294,936)	--
	-----	-----
Balance at July 31, 2001	(58,971,515)	--
Sale of shares to private investors, net	--	--
Exercise of stock options and warrants	--	--
Issuance of shares for services, net	--	--
Exercise of convertible debentures, net	--	--
Vesting of options previously issued for services	--	--
Net loss	(2,591,162)	--
	-----	-----
Balance at July 31, 2002 (carried forward)	(61,562,677)	--

F-12

ALFACELL CORPORATION  
(A Development Stage Company)

Statement of Stockholders' Equity (Deficiency), Continued

	Common Stock		
	Number of Shares	Amount	Capital In Excess of p Value
	-----	-----	-----
Balance at July 31, 2002 (brought forward)	22,760,921	\$ 22,761	\$ 59,654,4
Sale of shares to private investors, net	1,315,000	1,315	652,3
Exercise of stock options and warrants	764,000	764	376,8
Issuance of shares for payment of accounts payable	186,208	186	94,0
Issuance of options for services rendered	--	--	75,5
Vesting of options previously issued for services	--	--	10,0
Issuance of warrants in connection with debt issuances	--	--	594,2
Net loss	--	--	--
	-----	-----	-----
Balance at July 31, 2003	25,026,129	25,026	61,457,5
Sale of shares to private investors, net	3,035,200	3,036	10,732,9
Exercise of stock options and warrants	3,100,160	3,100	4,155,3

Edgar Filing: ALFACELL CORP - Form 10-K

Issuance of shares for payment of accounts payable	14,703	15	52,1
Issuance of shares for conversion of subordinated debentures, other	3,042,817	3,043	924,8
Issuance of shares for services rendered	128,876	128	288,3
Issuance of options for services rendered	--	--	280,6
Net loss	--	--	
Balance at July 31, 2004	34,347,885	\$ 34,348	\$ 77,891,8

	Deficit Accumulated During Development Stage	Subscription Receivable	Deferr compensa restric stoc
Balance at July 31, 2002 (brought forward)	\$ (61,562,677)	\$ --	\$
Sale of shares to private investors, net	--	--	
Exercise of stock options and warrants	--	--	
Issuance of shares for payment of accounts payable	--	--	
Issuance of options for services rendered	--	--	
Vesting of options previously issued for services	--	--	
Issuance of warrants in connection with debt issuances	--	--	
Net loss	(2,411,532)	--	
Balance at July 31, 2003	(63,974,209)	--	
Sale of shares to private investors, net	--	--	
Exercise of stock options and warrants	--	--	
Issuance of shares for payment of accounts payable	--	--	
Issuance of shares for conversion of subordinated debentures, other	--	--	
Issuance of shares for services rendered	--	--	
Issuance of options for services rendered	--	--	
Net loss	(5,070,307)	--	
Balance at July 31, 2004	\$ (69,044,516)	\$ --	\$

See accompanying notes to financial statements.

F-13

ALFACELL CORPORATION  
(A Development Stage Company)

Statements of Cash Flows

Years ended July 31, 2004, 2003 and 2002  
and the Period from August 24, 1981  
(Date of Inception) to July 31, 2004

August 24, 1981

Edgar Filing: ALFACELL CORP - Form 10-K

	(date of inception) to July 31, 2004	2004
	-----	-----
Cash flows from operating activities:		
Net loss	\$ (69,044,516)	\$ (5,070,307)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of marketable securities	(25,963)	--
Depreciation and amortization	1,556,767	9,549
Loss on disposal of property and equipment	18,926	--
Noncash operating expenses	6,686,724	569,112
Amortization of debt discount	560,099	316,688
Amortization of deferred compensation	11,442,000	--
Amortization of organization costs	4,590	--
Changes in assets and liabilities:		
(Increase) decrease in other current assets	(124,638)	(54,668)
Increase in other assets	(55,764)	(9,528)
Increase in loans and interest payable, related party	744,539	--
(Decrease) increase in accounts payable	1,048,235	(105,653)
Increase in accrued payroll and expenses, related parties	2,348,145	--
(Decrease) increase in accrued expenses	1,279,590	(669,901)
	-----	-----
Net cash used in operating activities	(43,561,266)	(5,014,708)
	-----	-----
Cash flows from investing activities:		
Purchase of marketable securities	(290,420)	--
Proceeds from sale of marketable equity securities	316,383	--
Purchase of property and equipment	(1,460,373)	(53,537)
Patent costs	(97,841)	--
	-----	-----
Net cash used in investing activities	(1,532,251)	(53,537)
	-----	-----

F-14

ALFACELL CORPORATION  
(A Development Stage Company)

Statements of Cash Flows, Continued

	August 24, 1981 (date of inception) to July 31, 2004	2004
	-----	-----
Cash flows from financing activities:		
Proceeds from short-term borrowings	\$ 874,500	\$
Payment of short-term borrowings	(653,500)	
Increase (decrease) in loans payable, related party, net	2,628,868	
Proceeds from bank debt and other long-term debt, net of deferred debt costs		

Edgar Filing: ALFACELL CORP - Form 10-K

	3,667,460	
Reduction of bank debt and long-term debt	(2,959,837)	(8,
Proceeds from issuance of common stock, net	40,750,316	10,735,
Proceeds from exercise of stock options and warrants, net	10,219,411	4,158,
Proceeds from issuance of convertible debentures, related party	297,000	
Proceeds from issuance of convertible debentures, unrelated party	416,993	
	-----	-----
Net cash provided by financing activities	55,241,211	14,885,
	-----	-----
Net increase in cash and cash equivalents	10,147,694	9,817,
Cash and cash equivalents at beginning of period	--	330,
	-----	-----
Cash and cash equivalents at end of period	\$ 10,147,694	\$ 10,147,
	=====	=====
Supplemental disclosure of cash flow information - interest paid	\$ 1,713,713	\$ 6,
	=====	=====
Noncash financing activities:		
Issuance of convertible subordinated debenture for loan payable to officer	\$ 2,725,000	\$
	=====	=====
Issuance of common stock upon the conversion of convertible subordinated debentures, related party	\$ 3,242,000	\$
	=====	=====
Conversion of short-term borrowings to common stock	\$ 226,000	\$
	=====	=====
Conversion of accrued interest, payroll and expenses by related parties to stock options	\$ 3,194,969	\$
	=====	=====
Repurchase of stock options from related party	\$ (198,417)	\$
	=====	=====
Conversion of accrued interest to stock options	\$ 142,441	\$
	=====	=====

F-15

ALFACELL CORPORATION  
(A Development Stage Company)

Statements of Cash Flows, Continued

	August 24, 1981 (date of inception) to July 31, 2004	2004
	-----	-----
Conversions of accounts payable to common stock	\$ 506,725	\$ 52,176
	=====	=====

## Edgar Filing: ALFACELL CORP - Form 10-K

Conversion of notes payable, bank and accrued interest to long-term debt	\$ 1,699,072 =====	\$ -- =====
Conversion of loans and interest payable, related party and accrued payroll and expenses, related parties to long-term accrued payroll and other, related party	\$ 1,863,514 =====	\$ -- =====
Issuance of common stock upon the conversion of convertible subordinated debentures and accrued interest, other	\$ 1,119,865 =====	\$ 927,872 =====
Issuance of common stock for services rendered	\$ 2,460 =====	\$ -- =====
Issuance of warrants with notes payable	\$ 594,219 =====	\$ -- =====

See accompanying notes to financial statements.

F-16

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements

Years ended July 31, 2004, 2003 and 2002  
and the Period From August 24, 1981  
(Date of Inception) to July 31, 2004

(1) Summary of Significant Accounting Policies

Business Description

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

The Company's current operations encompass all the risks inherent in discovering and developing a new drug, including: an uncertainty regarding the timing and amount of future revenues to be derived from the Company's technology; obtaining future capital as needed; attracting and retaining key personnel; and a business environment with heightened competition, rapid technological change and strict government regulations.

Use of Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect reported amounts and disclosures in these financial statements. Actual results could differ from those estimates.

## Edgar Filing: ALFACELL CORP - Form 10-K

### Property and Equipment

Property and equipment is stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets ranging from three to seven years. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in operations for the period.

The cost of repairs and maintenance is charged to operations as incurred; significant renewals and betterments are capitalized.

### Cash Equivalents

The Company considers all highly-liquid investments with maturities of three months or less, at the time of purchase, to be cash equivalents.

### Research and Development

Research and development costs are expensed as incurred.

### Fair Value of Financial Instruments

For all financial instruments, their carrying value approximates fair value due to the short maturity of those instruments. Debt instruments have been issued at rates which represent prevailing market rates for similar financings.

F-17

## ALFACELL CORPORATION (A Development Stage Company)

### Notes to Financial Statements, Continued

#### (1) Summary of Significant Accounting Policies, (Continued)

##### Comprehensive Income (Loss)

The net loss of \$5,070,000, \$2,411,000 and \$2,591,000 recorded for the years ended July 31, 2004, 2003 and 2002, respectively, is equal to the comprehensive loss for those periods in accordance with Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income".

##### Earnings (Loss) Per Common Share

"Basic" earnings (loss) per common share equals net income (loss) divided by weighted average common shares outstanding during the period. "Diluted" earnings per common share equals net income divided by the sum of weighted average common shares outstanding during the period, adjusted for the effects of potentially dilutive securities. The Company's Basic and Diluted per share amounts are the same since the Company is in a loss position and the assumed exercise of stock options, warrants and conversion of convertible notes would be all anti-dilutive. The number of outstanding options and warrants that could dilute earnings per share in future periods was 14,329,413, 9,663,023 and 9,040,881 at July 31, 2004, 2003 and 2002, respectively. This excludes the potential dilution that could occur upon the conversion of convertible notes into 1,744,978 common stock and warrants to purchase 2,044,978 shares of common stock.



## Edgar Filing: ALFACELL CORP - Form 10-K

### Long-Lived Assets

The Company reviews long-lived assets for impairment annually or whenever events or changes in business circumstances occur that indicate that the carrying amount of the assets may not be recoverable. The Company assesses the recoverability of long-lived assets held and to be used based on undiscounted cash flows, and measures the impairment, if any, using discounted cash flows. SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, has not had a material impact on the Company's financial position, operating results or cash flows.

### Stock Option Plans

Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ("SFAS 123"), provides for the use of a fair value based method of accounting for employee stock compensation. However, SFAS 123 also allows an entity to continue to measure compensation cost for stock options granted to employees and directors using the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25"), which only requires charges to compensation expense for the excess, if any, of the fair value of the underlying stock at the date a stock option is granted (or at an appropriate subsequent measurement date) over the amount the employee must pay to acquire the stock, if such amounts differ materially from the historical amounts. The Company has elected to continue to account for employee stock options using the intrinsic value method under Opinion 25.

Pursuant to SFAS 123, shares, warrants or options issued in connection with debt financing agreements or to non-employees for services are accounted for based on their fair market value determined using the Black-Scholes option pricing model.

In accordance with Statement of Financial Accounting Standards No. 148 ("SFAS 148") and SFAS 123, the Company's pro forma option expense is computed using the Black-Scholes option pricing model. To comply with SFAS 148, the Company is presenting the following table to illustrate the effect on the net loss and loss per share if it had applied the fair value recognition provisions of SFAS 123, as amended, to options granted under the stock-based employee compensation plans. For purposes of this pro forma disclosure, the estimated value of the options is amortized ratably to expense over the options' vesting periods.

F-18

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(1) Summary of Significant Accounting Policies, (Continued)

	2004	2003	2002
	-----	-----	-----
Net Loss:			
As reported	\$ (5,070,307)	\$ (2,411,532)	\$ (2,591,162)
Less total stock-based employee			

## Edgar Filing: ALFACELL CORP - Form 10-K

compensation expense determined under a fair value based method for all awards, net of related tax effects	(1,489,721)	(152,598)	(169,708)
	-----	-----	-----
Pro forma	\$ (6,560,028)	\$ (2,564,130)	\$ (2,760,870)
	=====	=====	=====
Basic and diluted loss per common share:			
As reported	\$ (0.17)	\$ (0.10)	\$ (0.12)
Pro forma	(0.22)	(0.11)	(0.13)

### Accounting For Warrants Issued With Convertible Debt

The Company accounts for the intrinsic value of beneficial conversion rights arising from the issuance of convertible debt instruments with non-detachable conversion rights that are in-the-money at the commitment date pursuant to the consensuses of EITF Issue No. 98-5 and EITF Issue No. 00-27. Such value is allocated to additional paid-in capital and the resulting debt discount is charged to interest expense over the terms of the notes payable. Such value is determined after first allocating an appropriate portion of the proceeds received to warrants or any other detachable instruments included in the exchange.

### Income Taxes

The Company accounts for income taxes under the provisions of Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" (SFAS No. 109). Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for all years in which the temporary differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized.

### (2) Liquidity

The Company has reported net losses of approximately \$5,070,000, \$2,411,000, and \$2,591,000 for the fiscal years ended July 31, 2004, 2003 and 2002, respectively. The loss from date of inception, August 24, 1981, to July 31, 2004 amounts to \$69,044,000.

The Company's long-term continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances, sale of tax benefits, revenues from the commercial sale of ONCONASE(R), licensing of its proprietary RNase technology and its ability to realize revenues from its technology and its drug candidates via out-licensing agreements with other companies. Such additional funds may not become available as the Company may need them or be available on acceptable terms. Through September 17, 2004, a significant portion of the Company's financing has been through the sale of its equity securities and convertible debentures in registered offerings and private placements and the exercise of stock options and warrants. Additionally, the Company has raised capital through debt financings, the sale of tax benefits and research

# Edgar Filing: ALFACELL CORP - Form 10-K

## Notes to Financial Statements, Continued

(2) Liquidity, (Continued)

products, interest income and financing received from its Chief Executive Officer. Until and unless the Company's operations generate significant revenues, the Company expects to continue to fund operations from the sources of capital previously described. There can be no assurance that the Company will be able to raise the capital it needs on terms which are acceptable, if at all. Presently, the Company's cash balance is sufficient to fund its expanded operations at least through October 31, 2005, based on its expected level of expenditures in relation to activities in preparing ONCONASE(R) for marketing registrations and other ongoing operations of the Company. However, the Company continues to seek additional capital financing through the sale of equity in private placements, sale of its tax benefits and exercise of stock options and warrants but cannot be sure that it will be able to raise capital on favorable terms or at all.

The Company will continue to incur costs in conjunction with its U.S. and foreign registrations for marketing approval of ONCONASE(R). The Company is currently in discussions with potential strategic alliance partners to further the development and marketing of ONCONASE(R) and other related products in its pipeline. However, it cannot be sure that any such alliances will materialize.

(3) Property and Equipment

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

	2004 ----	2003 ----
Laboratory equipment	\$ 794,123	\$ 755,040
Office equipment	260,239	296,105
Leasehold improvements	97,833	97,833
	-----	-----
Total	1,152,195	1,148,978
Less accumulated depreciation and amortization	1,095,412	1,136,183
	-----	-----
Property and equipment, net	\$ 56,783	\$ 12,795
	=====	=====

(4) Long-term Debt

Long-term debt consists of the following at July 31:

	2004 ----
Convertible notes payable, unsecured, unrelated party at 8% and 8.5% interest, net of debt discount of \$34,120 at July 31, 2004 and \$350,808 at July 31, 2003, with maturity dates during fiscal years July 31, 2004 and 2005	\$365,880
Notes payable, unsecured, unrelated party at 8% interest and due as follows: \$100,000 due December 4, 2003, \$100,000 due February 17, 2004 and \$100,000 due March 29, 2004	--

## Edgar Filing: ALFACELL CORP - Form 10-K

Note payable, in monthly installments of \$1,459, including principal and interest commencing April 2000 and each month thereafter until March 2005, collateralized by equipment

Less current portion

6,731
-----
372,611
-----
372,611
-----
\$     --
=====

F-20

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(4) Long-term Debt, (Continued)

During the fiscal year ended July 31, 2003, the Company issued 8% convertible notes payable to unrelated parties with principal balances totaling an aggregate of \$915,000. These notes payable mature on various dates from April 2004 through May 2005 and are convertible into the Company's common stock at conversion prices ranging from \$0.20 to \$0.50 per share and an equal number of five year warrants at an exercise price of \$1.00 per share. With the issuance of the notes payable, the Company issued to the unrelated parties five year warrants to purchase an aggregate of 665,000 shares of the Company's common stock at an exercise price of \$0.60 per share. In addition, the Company has issued or will issue on the due date of the notes payable five year warrants to purchase an aggregate of 915,000 shares of the Company's common stock at per share exercise prices of \$1.00 and \$1.10. The Company valued these warrants at a total of \$219,259 based on the fair value determined by using the Black-Scholes method. At the issuance dates of the notes payable, the fair market values of the Company's shares exceeded the effective conversion prices.

Accordingly, the Company initially increased additional paid-in capital by \$219,259 for the fair value of the warrants and reduced the carrying value of the notes payable for the same amount for the debt discount attributable to the fair value of the warrants. The Company is amortizing the debt discount over the terms of the notes payable.

Pursuant to the applicable guidance in the consensus for EITF Issue No. 00-27, the Company valued the beneficial conversion feature using the effective conversion price. Accordingly, the Company first allocated \$219,259 to the detachable warrants and decreased the carrying value of the notes payable.

Based on the effective conversion prices, the Company recorded a beneficial conversion charge of \$374,960 which was allocated to additional paid-in capital and debt discount which is being amortized as interest expense over the terms of the notes payable.

During the fiscal year ended July 31, 2004, the principal and accrued interest of the notes payable in an aggregate amount of \$927,872 were converted resulting in the issuance of 3,042,817 shares of common stock and 3,733,839 five year warrants with exercise prices ranging from \$1.00 to \$1.10 per share.

## Edgar Filing: ALFACELL CORP - Form 10-K

The notes require principal payments in each of the years subsequent to July 31, 2004 as follows:

Year Ending July 31, -----	Amount -----
2005	\$ 400,000

(5) Related Party

Amounts due from the Company's CEO totaling \$151,815 and \$142,287 at July 31, 2004 and 2003, respectively, are classified as a long-term asset in Loan receivable, related party as the Company does not expect repayment of these amounts within one year. In each of the fiscal years ended July 31, 2003 and 2004 the Company earned 8% interest in the amount of approximately \$9,500 on the unpaid principal balance.

(6) Note Payable - Convertible Note

In April 2001, the Company entered into convertible notes payable with certain related and unrelated parties in the aggregate amount of \$366,993. The notes were due within ninety (90) days unless the lenders elect to exercise an option to convert the note into the Company's common stock, par value \$.001

F-21

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(6) Note Payable - Convertible Note, (Continued)

per share at a conversion price of \$0.90 per share (the estimated fair market value of the stock based on the average of the high and low trade prices of the Company's common stock for the ten (10) trading days preceding the loan date). In addition, upon conversion, the lender would receive a three-year warrant for each share of converted common stock at an exercise price of \$2.50 per share that will expire on July 7, 2004. The estimated value of the warrants of \$133,793, using the Black-Scholes options-pricing model, was recorded as interest expense over the original ninety day note term. In July 2001, an aggregate of \$297,000 note payables were converted which resulted in the issuance of 330,000 shares of the Company's common stock. In addition, upon conversion, the Company issued the agreed three-year warrants to purchase an aggregate of 330,000 shares of common stock at an exercise price of \$2.50 per share. An aggregate balance of the convertible notes in the amount of \$69,993 was renewed for one hundred twenty (120) days for the same conversion price of \$0.90 per share. In addition, upon conversion, the lender would receive a five-year warrant for each share of converted common stock at an exercise price of \$1.50 per share. The estimated value of the warrants of \$45,000, using the Black-Scholes options-pricing model, was treated as a debt discount which accreted as interest expense over the one hundred twenty day note term through October 31, 2001. In October 2001, an aggregate of \$64,993 notes payable were converted which resulted in the issuance of 72,214 shares of the Company's common stock. In addition, upon conversion, the Company issued the agreed five-year warrants to purchase an aggregate of 72,214 shares of common stock at an exercise price of \$1.50 per share. Also, in

## Edgar Filing: ALFACELL CORP - Form 10-K

October 2001, the Company's Board of Directors approved the change in the exercise price of the 330,000 warrants issued to related parties upon conversion of notes from \$2.50 per share to \$1.50 per share and changed the expiration date to July 7, 2006, to conform with the private placements to unrelated parties.

(7) Leases

The Company leases its facility on a month-to-month basis. Rent expense charged to operations was \$136,000 in each of 2004, 2003 and 2002.

(8) Stockholders' Equity

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

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

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

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

F-22

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(8) Stockholders' Equity, (Continued)

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

On January 17, 1983, the Company sold 660,000 shares of its common stock and 330,000 common stock purchase warrants in a public offering at a price of \$2.50 per share, resulting in net proceeds to the Company of approximately \$1,308,446. The warrants were to expire 12 months after issuance; however, the Company extended the expiration date to July 16, 1984. During the fiscal years ended July 31, 1983 and 1984, the net

## Edgar Filing: ALFACELL CORP - Form 10-K

proceeds to the Company from the exercise of the warrants amounted to \$934,000. Each common stock purchase warrant was not detachable from its common stock or exercisable until six months after the issuance date of January 17, 1983. Each warrant entitled the holder to purchase one share of common stock at an exercise price of \$3.00 after six months and prior to nine months after issuance. The exercise price increased to \$3.50 after nine months and prior to 12 months after issuance.

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

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

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

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

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

## Edgar Filing: ALFACELL CORP - Form 10-K

### Notes to Financial Statements, Continued

#### (8) Stockholders' Equity, (Continued)

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

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

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

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

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

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

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

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

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

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

During the fiscal year ended July 31, 1993, the Company sold 352,667 shares of common stock to private investors at prices ranging from \$2.00 to \$3.00 per share resulting in net proceeds to the Company of approximately \$735,500. In addition, the private investors were granted



## Edgar Filing: ALFACELL CORP - Form 10-K

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

F-24

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(8) Stockholders' Equity, (Continued)

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

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

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

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

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

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

In September 1994, the Company completed a private placement resulting in the issuance of 288,506 shares of common stock and three-year warrants to purchase 288,506 shares of common stock at an exercise price of \$5.50 per share. The warrants expired during fiscal 1998. The common stock and warrants were sold in units consisting of 20,000 shares of common stock and warrants to purchase 20,000 shares of common stock. The price per unit was \$50,000. The Company received proceeds of approximately \$545,000, net of costs associated with the placement of approximately \$55,000 and the

## Edgar Filing: ALFACELL CORP - Form 10-K

conversion of certain debt by creditors of \$121,265 into equivalent private placement units of 17,600 shares for conversion of short-term borrowings and 30,906 shares issued for services rendered. In October 1994, an additional two units at \$50,000 per unit were sold to a private investor under the same terms as the September 1994 private placement resulting in the issuance of 40,000 shares of common stock and warrants to purchase 40,000 shares of common stock. The warrants expired during fiscal 1998.

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

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

F-25

### ALFACELL CORPORATION (A Development Stage Company)

#### Notes to Financial Statements, Continued

#### (8) Stockholders' Equity, (Continued)

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

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

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

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

In June 1996, the Company sold in a private placement 1,515,330 shares of common stock and three-year warrants to purchase 313,800 shares of common

## Edgar Filing: ALFACELL CORP - Form 10-K

stock at an exercise price of \$7.50 per share. Of these shares, 12,000 were issued for services rendered to the Company. The common stock was sold alone at a per share price of \$3.70, in combination with warrants at a per unit price of \$12.52 and warrants were sold alone at a per warrant price of \$1.42. Each unit consisted of three shares of common stock and one warrant. The Company received proceeds of approximately \$5.7 million. The warrants expired during the fiscal 2000.

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

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

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

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

F-26

### ALFACELL CORPORATION (A Development Stage Company)

#### Notes to Financial Statements, Continued

#### (8) Stockholders' Equity, (Continued)

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

In May 1997, the Company issued 100,000 stock options to Dr. Stephen Carter, a director, with an exercise price of \$5.20 per share as payment for serving as Chairman of the Scientific Advisory Board (the "SAB"). These options vested as follows: 10,000 vested immediately, 10,000 after one full calendar year, 10,000 annually for each of the following three years and 50,000 on May 13, 2002. The Company recorded a total research and development expense of \$353,400, which was the fair value on the date of issuance of that portion of the stock options that had vested as of July 31, 2002. Of these options, 30,000 expired as of the fiscal year ended July 31, 2004.

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

## Edgar Filing: ALFACELL CORP - Form 10-K

options ranged from \$2.45 to \$4.00 per share.

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

In October 1997, the Company issued 75,000 stock options to a director with an exercise price of \$3.66 per share as payment for non-board related services to be rendered. These options vested as follows: 10,000 vested immediately; 10,000 after one full calendar year; 10,000 annually for each of the following three years; and 25,000 on October 31, 2002. A total general and administrative expense of \$185,600 was amortized on a straight-line basis over a five-year period, which commenced in October 1997. Of these options, 20,000 expired as of the fiscal year ended July 31, 2004.

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

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

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

On January 23, 1998, the Securities and Exchange Commission (the "SEC") declared effective a registration statement on Form S-3 for the offer and sale by certain stockholders of up to 3,734,541 shares of common stock. Of these shares (i) an aggregate of 2,737,480 shares were issued to private placement

F-27

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(8) Stockholders' Equity, (Continued)

investors in private placement transactions which were completed during the period from March 1994 through March 1997 (the "Earlier Private Placements"), (ii) an aggregate of 409,745 shares were issuable upon exercise of warrants which were issued to private placement investors in

## Edgar Filing: ALFACELL CORP - Form 10-K

the Earlier Private Placements and (iii) an aggregate of 587,316 shares may be issued, or have been issued, upon exercise of options which were issued to option holders in certain other private transactions. As a result of the delisting of the Company's Common Stock from the Nasdaq SmallCap Market, the Company no longer qualified for the use of a Form S-3 registration statement for this offering when it filed its Annual Report on Form 10-K for the fiscal year ended July 31, 1999 and thus, this registration statement was no longer effective. The Company filed a registration statement on Form S-1 to register these shares, which was declared effective in February 2002.

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

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

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

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

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(8) Stockholders' Equity, (Continued)

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

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

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

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

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

During the fiscal year ended July 31, 1999, the Company issued 40,701

## Edgar Filing: ALFACELL CORP - Form 10-K

shares of common stock for payment of legal services. The fair value of the common stock in the amount of \$16,631 was charged to operations.

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

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

F-29

### ALFACELL CORPORATION (A Development Stage Company)

#### Notes to Financial Statements, Continued

#### (8) Stockholders' Equity, (Continued)

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

During the fiscal year ended July 31, 2000, the Company sold an aggregate of 875,000 shares of common stock to private investors at prices ranging from \$0.50 to \$1.00 per share resulting in net proceeds of \$548,300 to the Company. In addition, the private investors were granted warrants to purchase an aggregate of 875,000 shares of common stock, inclusive of additional warrants issued so that all investors in the private placements received substantially the same securities, at per share exercise prices ranging from \$1.03 to \$4.55. Of these warrants, 437,500 expired in May 2003 and the balance have an expiration date of May 2005.

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

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

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

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

## Edgar Filing: ALFACELL CORP - Form 10-K

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

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

F-30

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(8) Stockholders' Equity, (Continued)

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

During the fiscal year ended July 31, 2002, the Company issued an aggregate of 85,221 five-year stock options as payment for services rendered. The options vested immediately and had a per share exercise prices of \$0.75 as to 70,000 stock options and \$0.94 as to 15,221 stock options. The Company recorded an aggregate total of \$40,747 non-cash expenses for these options, based upon the fair value on the date of the issuance as estimated by the Black-Scholes options-pricing model. Of these options, 65,000 were exercised during the fiscal year ended July 31, 2004.

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

During the fiscal year ended July 31, 2002, the Company issued warrants to purchase 1,500,000 shares of common stock to Roan Meyers Associates L.P. for an aggregate warrant purchase price of \$1,500 in connection with the engagement of Roan Meyers to render advisory services. Of these warrants, 250,000 were exercisable at \$.50 per share, 650,000 were exercisable at \$1.00 per share and 600,000 were exercisable at \$1.50 per share. In



## Edgar Filing: ALFACELL CORP - Form 10-K

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

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

F-31

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(8) Stockholders' Equity, (Continued)

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

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

## Edgar Filing: ALFACELL CORP - Form 10-K

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

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

During the fiscal year ended July 31, 2003, the Company issued 8% convertible notes payable to unrelated parties with principal balances totaling an aggregate of \$915,000. These notes payable mature on various dates from April 2004 through May 2005 and are convertible into the Company's common stock at conversion prices ranging from \$0.20 to \$0.50 per share and an equal number of five year warrants with an exercise price of \$1.00 per share. With the issuance of the notes payable, the Company issued to the unrelated parties five year warrants to purchase an aggregate of 665,000 shares of the Company's common stock, at an exercise price of \$0.60 per share. In addition, the Company has issued or will issue on the due date of the notes payable five year warrants to purchase an aggregate of 915,000 shares of the Company's common stock at per share exercise prices of \$1.00 and \$1.10. The Company valued these warrants at a total of \$219,259 based on the fair value determined by using the Black-Scholes method. At the issuance dates of the notes payable, the fair market values of the Company's shares exceeded the effective conversion prices. Accordingly, the Company initially increased additional paid-in capital by \$219,259 for the fair value of the warrants and reduced the carrying value of the notes payable for the same amount for the debt discount attributable to the fair value of the warrants. The Company also increased its additional paid-in capital and debt discount by \$374,960 for beneficial conversion rights issued in connection with the issuances of these notes (see note 4).

F-32

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(8) Stockholders' Equity, (Continued)

During the fiscal year ended July 31, 2003, the Company sold an aggregate of 1,315,000 shares of common stock to private investors at prices ranging

## Edgar Filing: ALFACELL CORP - Form 10-K

from \$0.20 to \$0.73 per share resulting in net proceeds of \$653,627 to the Company. In addition, the private investors were granted warrants to purchase an aggregate of 1,315,000 shares of common stock at per share exercise prices ranging from \$1.00 to \$1.50. The warrants will expire during the period commencing January 2008 and ending in October 2008.

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

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

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

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

During the fiscal year ended July 31, 2004, the Company entered into a two-part financing agreement with SF Capital Partners, Ltd. for the private placement of 1,704,546 shares of common stock and warrants to purchase 852,273 shares of common stock, at an exercise price of \$1.50 per share. As consideration, the Company received \$1,500,000. In addition, the Company granted SF Capital Partners, Ltd. a warrant to invest an additional \$1,500,000 to purchase the Company's common stock at an exercise price based upon a 20-day trailing average of the closing price per share of the Company's common stock (the "Additional Warrants"). During the fiscal year ended July 31, 2004, SF Capital Partners, Ltd. exercised the Additional Warrants at a 20-day trailing average exercise price of \$3.96 which resulted in gross proceeds of \$1,500,000 and the issuance of 379,170 shares of common stock and an Exercise Warrant to purchase an additional 189,585 shares of common stock at a per share exercise price of \$4.75. The Company also issued an aggregate of 53,876 shares of restricted common stock to a third party as finder's fee.

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

## Edgar Filing: ALFACELL CORP - Form 10-K

During the fiscal year ended July 31, 2004, the Company issued an aggregate of 14,703 restricted shares

F-33

### ALFACELL CORPORATION (A Development Stage Company)

#### Notes to Financial Statements, Continued

of common stock as payment of accounts payable in the amount of \$52,176.

#### (8) Stockholders' Equity, (Continued)

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

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

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

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

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

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

#### (9) Common Stock Warrants

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

The following table summarizes the activity of common stock warrants issued in connection with the Private Placements completed in fiscal years 1994 through 2004:

Edgar Filing: ALFACELL CORP - Form 10-K

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

F-34

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(9) Common Stock Warrants, (Continued)

	Warrants -----	Exercise Price -----
Outstanding and exercisable at July 31, 1996	1,508,251	4.00 - 7.50
Exercised	(147,450)	5.00
Expired	(652,550)	5.00
Outstanding and exercisable at July 31, 1997	708,251	4.00 - 7.50
Sold in February 1998 Private Placement	1,168,575	2.50
Issued to the Placement Agent in connection with the February 1998 Private placement (see note 8)	350,574	2.20 - 2.50
Exercised	(4,950)	2.20 - 2.50
Expired	(338,506)	4.19 - 5.50
Outstanding and exercisable at July 31, 1998	1,883,944	2.20 - 7.50
Expired	(55,945)	4.00
Sold in February 2000 Private Placement	875,000	1.03 - 4.55
Expired	(313,800)	7.50
Outstanding and exercisable at July 31, 2000	2,389,199	1.03 - 4.55
Sold in various private placements	696,665	1.50 - 3.00
Issued to related parties upon conversion of note payable	330,000	1.50

Edgar Filing: ALFACELL CORP - Form 10-K

Outstanding and exercisable at July 31, 2001	3,415,864	1.03 - 4.55
Expired	(1,514,199)	2.20 - 2.50
Sold in various private placements	2,673,422	0.75 - 1.50
Issued to vendor upon settlement of accounts payable	55,556	1.50
Issued to unrelated party for advisory services	1,500,000	0.50 - 1.50
Exercised	(186,000)	0.50
Issued to unrelated parties upon conversion of notes payable	72,214	1.50
Issued to unrelated parties in connection with notes payable	300,000	0.60
-----		
Outstanding and exercisable at July 31, 2002	6,316,857	0.50 - 4.55
Expired	(437,500)	1.03 - 3.25
Sold in various private placements	1,315,000	1.00 - 1.50
Exercised	(640,000)	0.50
Issued to unrelated parties in connection with notes payable	665,000	0.60
-----		
Outstanding and exercisable at July 31, 2003	7,219,357	0.50 - 4.55

F-35

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(9) Common Stock Warrants, (Continued)

	Warrants	Exercis
	-----	-----
Sold in various private placements	2,372,512	1.25 -
Exercised	(2,014,273)	0.50 -
Issued to third party as finder's fee	60,533	12.
Issued to unrelated and unrelated parties in connection with conversion of notes payable	3,733,839	1.00 -
-----		
Outstanding and exercisable at July 31, 2004	11,371,968	\$0.50 -
=====		

(10) Stock Options

2004 Stock Incentive Plan

The Company's stockholders approved the 2004 Stock Incentive Plan (the "2004 Plan") totaling 8,500,000 shares, which provides that options may be granted to employees, directors and consultants. The 2004 Plan provides for the granting of stock options, stock appreciation rights, restricted shares, or other share based awards to eligible employees and directors,

## Edgar Filing: ALFACELL CORP - Form 10-K

as defined in the 2004 Plan. Options granted under the 2004 Plan are granted at market value on the date of the grant, the term, time and method of exercise of which are fixed by the Board of Directors or a committee thereof.

### 1997 Stock Option Plan

The Company's stockholders approved the 1997 stock option plan totaling 2,000,000 shares, which provide that options may be granted to employees, directors and consultants. Options are granted at market value on the date of the grant and generally are exercisable in 20% increments annually over five years starting one year after the date of grant and terminate five years from their initial exercise date.

### 1993 Stock Option Plan

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

As of fiscal year ended July 31, 1994, 1,703,159 options were granted under the 1993 stock option plan.

The following table summarizes stock option activity for the period August 1, 1994 to July 31, 2004:

	Shares Available for Grant -----	Options Outstanding -----	Weighted Average Exercise Price Per Share -----
Balance August 1, 1994	1,926,841	5,935,337	\$3.76
Granted	(818,850)	818,850	2.60
Exercised	--	(185,000)	2.36
Canceled	--	(1,897,500)	4.30
	-----	-----	
Balance August 1, 1995	1,107,991	4,671,687	3.39
Granted	(296,205)	296,205	3.99
Exercised	--	(656,334)	2.92
Canceled	6,500	(235,333)	4.89
	-----	-----	

F-36

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(10) Stock Options, (Continued)

Edgar Filing: ALFACELL CORP - Form 10-K

	Shares Available for Grant	Options Outstanding	Weighted Average Exercise Price Per Share
	-----	-----	-----
Balance July 31, 1996	818,286	4,076,225	3.43
1997 Plan	2,000,000	--	--
Granted	(932,500)	932,500	4.90
Exercised	--	(639,500)	3.82
Canceled	484,845	(484,845)	4.70
	-----	-----	
Balance July 31, 1997	2,370,631	3,884,380	3.56
Granted	(234,333)	234,333	3.31
Canceled	91,100	(91,100)	3.81
	-----	-----	
Balance July 31, 1998	2,227,398	4,027,613	3.54
Granted	(595,000)	595,000	0.62
Canceled	443,934	(555,737)	3.97
	-----	-----	
Balance July 31, 1999	2,076,332	4,066,876	3.05
Granted	(827,000)	827,000	0.52
Exercised	--	(95,000)	0.48
Canceled	638,395	(1,031,880)	2.73
	-----	-----	
Balance July 31, 2000	1,887,727	3,766,996	2.65
Granted	(447,000)	447,000	0.85
Exercised	--	(165,555)	0.51
Canceled	774,315	(1,018,557)	3.42
	-----	-----	
Balance July 31, 2001	2,215,042	3,029,884	2.24
Granted	(544,221)	544,221	0.69
Exercised	--	--	--
Canceled	655,840	(900,081)	2.31
	-----	-----	
Balance July 31, 2002	2,326,661	2,674,024	1.90
Granted	(630,000)	630,000	0.50
Exercised	--	(124,000)	0.47
Canceled	485,118	(736,358)	3.09
	-----	-----	
Balance July 31, 2003	2,181,779	2,443,666	1.26
2004 Stock Incentive Plan	8,500,000	--	--
Granted	(1,388,996)	1,388,996	5.03
Exercised	--	(666,717)	0.98
Canceled	(262,783)	(208,500)	3.20
	-----	-----	
Balance July 31, 2004	9,030,000	2,957,445	\$2.95
	=====	=====	=====

The stock options granted in fiscal year ended July 31, 2000 included an aggregate total of 75,000 stock options issued to the Company's outside Board of Directors and an aggregate total of 350,000 stock options issued to the employees of the Company, which will vest and become exercisable upon certain milestones, or these options will terminate, and the employees must be actively employed by the Company through the date of the achievement of the milestones. Compensation expense, if any, will be determined based on the Company's stock price on the vesting date relative to the options exercise price. No compensation expense was recognized in the four fiscal years ended July 31, 2004. An aggregate of 50,000 options issued to the Company's outside Board of Directors were exercised during the fiscal year 2001. The 350,000 stock options issued to the employees



## Edgar Filing: ALFACELL CORP - Form 10-K

expired during the fiscal year ended July 31, 2002. The options outstanding at July 31, 2004 will expire between October 17, 2004 and June 1, 2014.

The weighted-average fair value per option at the date of grant for options granted during the fiscal years 2004, 2003 and 2002 were \$4.36, \$0.21 and \$0.40, respectively. The fair value was estimated using the Black-Scholes options pricing model based on the following assumptions:

F-37

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(10) Stock Options, (Continued)

	2004	2003	2002
	----	----	----
Expected dividend yield	0%	0%	0%
Risk-free interest rate	4.00%	2.00%	5.50%
Expected stock price volatility	78.0%	77.8%	88.7%
Expected term until exercise (years)	6.86	5.50	5.60

The following table summarizes information concerning options outstanding at July 31, 2004:

Options Outstanding				Options Exercised
Range of Exercise Prices	Shares	Weighted Average Remaining Contractual Term (Years)	Weighted Average Exercise Price	Shares
-----	-----	-----	-----	-----
\$ 0.00 - 1.99	1,672,945	4.15	\$ 0.80	1,099,945
2.00 - 2.99	20,000	0.94	2.45	--
3.00 - 3.99	276,250	4.21	3.59	190,000
4.00 - 4.99	437,000	8.88	4.73	87,000
5.00 - 5.99	90,000	2.00	5.18	90,000
8.00 - 8.99	461,250	8.10	8.28	150,000
=====	-----	=====	=====	-----
	2,957,445			1,616,945
	=====			=====

Stock option activity prior to adoption of SFAS No. 123 is as follows:

1981 Non-Qualified Stock Option Plan

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

Non-Qualified Stock Options

Edgar Filing: ALFACELL CORP - Form 10-K

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

	Shares -----	Price Rang -----
Granted	1,782,000	\$ 3.00-3.8
Exercised	(276,989)	3.00-3.5
Canceled	(106,000)	3.00-3.5
Expired	(649,011)	3.00-3.5
Granted pursuant to conversion of certain liabilities:		
Related party	1,324,014	3.2
Unrelated party	73,804	3.2
Repurchased stock options	(102,807)	3.2
	-----	-----
Balance at July 31, 1994	2,045,011	\$ 3.20-3.8
	=====	=====

F-38

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(10) Stock Options, (Continued)

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

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

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

1989 Stock Plan

On February 14, 1989, the Company adopted the Alfacell Corporation 1989 Stock Plan (the "1989 Stock Plan"), pursuant to which the Board of Directors could issue awards, options and grants. The maximum number of shares of common stock that could have been issued pursuant to the option plan was 2,000,000.

No more options are being granted pursuant to this plan. The per share

## Edgar Filing: ALFACELL CORP - Form 10-K

option exercise price was determined by the Board of Directors. All options and shares issued upon exercise were nontransferable and forfeitable in the event employment was terminated within two years of the date of hire. In the event the option was exercised and said shares were forfeited, the Company would return to the optionee the lesser of the current market value of the securities or the exercise price paid.

The stock option activity is as follows:

	Shares	Price Range
	-----	-----
Granted, February 14, 1989	3,460,000	\$ 3.50-5.00
Options issued in connection with share purchase	36,365	2.75
Expired	(1,911,365)	2.75-5.00
Canceled	(10,000)	5.00
	-----	-----
Balance at July 31, 1994	1,575,000	\$ 3.50-5.00
	=====	=====

### (11) Stock Grant and Compensation Plans

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

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

F-39

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

### (11) Stock Grant and Compensation Plans, (Continued)

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

Edgar Filing: ALFACELL CORP - Form 10-K

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

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

1989 Stock Plan

Under the 1989 Stock Plan, one million shares of the Company's common stock were reserved for issuance as awards to employees. The 1989 Stock Plan also provides for the granting of options to purchase common stock of the Company (see note 10). In addition, the 1989 Stock Plan provided for the issuance of 1,000,000 shares of the Company's common stock as grants. To be eligible for a grant, grantees must have made substantial contributions and shown loyal dedication to the Company.

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

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

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

(12) Income Taxes

The Company accounts for income taxes under the provisions of Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" (SFAS No. 109). Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for all years in which the temporary differences are expected to reverse.

# Edgar Filing: ALFACELL CORP - Form 10-K

ALFACELL CORPORATION  
(A Development Stage Company)

## Notes to Financial Statements, Continued

(12) Income Taxes, (Continued)

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or tax benefits. For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), the Company had approximately \$1,378,000 total available tax benefits that were saleable; of which New Jersey permitted the Company to sell approximately \$261,000. The Company received approximately \$222,000 from the sale of the \$261,000 of tax benefits, which the Company recognized as tax benefits for the fiscal year ended July 31, 2004.

For the state fiscal year 2003 (July 1, 2002 to June 30, 2003), the Company had approximately \$1,373,000 total available tax benefits that were saleable, of which New Jersey permitted the Company to sell approximately \$273,000. The Company received approximately \$231,000 from the sale of the \$273,000 of tax benefits, which the Company recognized as tax benefits for fiscal 2003.

For the state fiscal year 2002 (July 1, 2001 to June 30, 2002), the Company had approximately \$1,535,000 total available tax benefits that were saleable, of which New Jersey permitted the Company to sell approximately \$426,000. The Company received approximately \$354,000 from the sale of the \$426,000 of tax benefits, which the Company recognized as tax benefits for fiscal 2002.

If still available under New Jersey law, the Company will attempt to sell the remaining \$1,117,000 of its tax benefits, between July 1, 2004 and June 30, 2005. This amount, which is a carryover of its remaining tax benefits from state fiscal year 2004, may increase if the Company incurs additional tax benefits during state fiscal year 2005. The Company can not estimate, however, what percentage of its saleable tax benefits New Jersey will permit it to sell, how much money it will receive in connection with the sale, if it will be able to find a buyer for its tax benefits or if such funds will be available in a timely manner.

At July 31, 2004 and 2003, the tax effects of temporary differences that give rise to the deferred tax assets are as follows:

	2004
	-----
Deferred tax assets:	
Excess of book over tax depreciation and amortization	\$ 27
Accrued expenses and other	120
Federal and state net operating loss carryforwards	17,322
Research and experimentation and investment tax credit carryforwards	1,425
	-----
Total gross deferred tax assets	18,896
Valuation allowance	(18,896)
	-----
Net deferred tax assets	\$
	=====

## Edgar Filing: ALFACELL CORP - Form 10-K

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The tax benefit assumed using the federal statutory tax rate of 34% has been reduced to the actual benefits reflected on the statements of operations due principally to the aforementioned valuation allowance. In 2004, 2003 and 2002 the valuation allowance increased by \$2,837,000, decreased by \$205,000 and increased by \$178,000, respectively.

At July 31, 2004, the Company has federal net operating loss carryforwards of approximately \$47,326,000 that expire in the years 2005 to 2024. The Company also has research and experimentation tax credit carryforwards of approximately \$1,426,000 that expire in the years 2005 to 2024. Ultimate utilization/availability of such net operating losses and credits may be significantly curtailed if a significant change in ownership occurs in accordance with the provisions of the Tax Reform Act of 1986.

F-41

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(13) Other Financial Information

Accrued expenses as of July 31, consist of the following:

	2004	2003
	----	----
Payroll and payroll taxes	\$ 44,112	\$ 884,808
Professional fees	92,768	38,351
Clinical trial grants	319,338	379,342
Other	168,987	105,477
	-----	-----
	\$ 625,205	\$1,407,978
	=====	=====

(14) Commitments and Contingencies

On July 23, 1991, the Board of Directors authorized the Company to pay Kuslima Shogen, the Company's CEO, an amount equal to 15% of any gross royalties which may be paid to the Company from any license(s) with respect to the Company's principal product, ONCONASE(R), or any other products derived from amphibian source extract, produced either as a natural, synthesized, and/or genetically engineered drug for which the Company is the owner or co-owner of the patents, or acquires such rights in the future, for a period not to exceed the life of the patents. If the Company manufactures and markets its own drugs, then the Company will pay an amount equal to 5% of net sales from any products sold during the life of the patents. On April 16, 2001, this agreement was amended and clarified to provide that Ms. Shogen would receive the 15% royalty payment relating to licensees or the 5% fee relating to sales but not both, unless the Company and the licensee both market the licensed product.

The Company has product liability insurance coverage in the amount of \$3,000,000 for clinical trials in the U.S. Additionally, the Company also maintains product liability insurance in Europe in the amount of DM20,000,000. No product liability claims have been filed against the Company. If a claim arises and the Company is found liable in an amount

## Edgar Filing: ALFACELL CORP - Form 10-K

that significantly exceeds the policy limits, it may have a material adverse effect upon the financial condition of the Company.

Below is a table that presents our contractual obligations and commercial commitments as of July 31, 2004:

	Payments Due by Fiscal Year		
	Total	2005	2006 and Thereafter
	-----	-----	-----
Research and development	\$72,398	\$72,398	\$ -0-
Operating lease	13,100	13,100	-0-
Total contractual cash obligations	\$85,498	\$85,498	\$ -0-
	=====	=====	=====

(15) Research and Development Agreement

In October 2002, the Company entered into a research collaboration with Wyeth Pharmaceuticals to co-develop a number of designer drugs such as conjugates and fusion proteins for a variety of indications using the Company's proprietary technology. This collaboration may result in a licensing agreement between the companies, however, there is no assurance that such agreement will be reached.

F-42

ALFACELL CORPORATION  
(A Development Stage Company)

Notes to Financial Statements, Continued

(16) 401(K) Savings Plan

Effective October 1, 1998, the Company adopted a 401(K) Savings Plan (the "Plan"). Qualified employees may participate by contributing up to 6% of their gross earnings to the Plan subject to certain Internal Revenue Service restrictions. The Company will match an amount equal to 50% of the first 6% of each participant's contribution. The Company's contribution is subject to a vesting schedule of 0%, 25%, 50%, 75% and 100% for employment of less than one year, one year, two years, three years and four years, respectively, except for existing employees which vesting schedule was based from the date the Plan was adopted. For the fiscal years ended July 31, 2004, 2003 and 2002, the Company's contribution to the Plan amounted to \$15,690, \$24,956 and \$25,717, respectively.

(17) Quarterly Financial Data (Unaudited)

(In thousands, except per share amounts)

Edgar Filing: ALFACELL CORP - Form 10-K

2004

	First	Second	Third	Fourth	Totals	First	Second
Investment income	\$ 3.7	\$ 4.5	\$ 3.1	\$ 30.8	\$ 42.1	\$ .1	\$ .1
Other income	--	--	--	--	--	30.0	--
Operating loss	(980.0)	(1,199.6)	(1,350.5)	(1,762.0)	(5,292.1)	(559.4)	(737.4)
Net loss (a)	(758.2)	(1,199.6)	(1,350.5)	(1,762.0)	(5,070.3)	(329.9)	(737.4)
Loss per share - basic and diluted	\$ (0.03)	\$ (0.04)	\$ (0.05)	\$ (0.05)	\$ (0.17)	\$ (0.01)	\$ (0.03)

(a) Included in the net loss of \$758.2 and \$329.9 for first quarter 2004 and 2003, are tax benefits of \$221.8 and \$229.5, respectively, related to the sale of certain state tax operating loss carryforwards.

(18) Subsequent Events

In September 2004, the Company issued 320,157 shares of restricted common stock and an aggregate of 420,157 five year warrants for the purchase of common stock with an exercise price of \$1.00 per share upon the conversion of notes payable in the amount of \$112,055.

In September 2004, the Company issued an aggregate of 292,272 shares of restricted common stock upon the exercise of warrants and stock options by a board member and unrelated parties at exercise prices ranging from \$0.29 to \$1.50 per share and realized gross proceeds of \$224,054 from these exercises.

F-43