

ALFACELL CORP
Form 424B3
August 28, 2006

Table of Contents

**Filed Pursuant to Rule 424(b)(3)
Registration Statement Number 333-136678**

Prospectus

**ALFACELL CORPORATION
12,914,344 shares of Common Stock**

Investing in our common stock involves a high degree of risk. You should carefully consider the Risk Factors beginning on page 4 in determining whether to purchase our common stock.

Our selling securityholders identified on pages 13 and 14 of this prospectus are offering these shares of common stock. For additional information on the methods of sale, you should refer to the section entitled Plan of Distribution beginning on page 11. We will not receive any portion of the proceeds from the sale of these shares.

Our common stock is quoted on the Nasdaq Capital Market under the symbol ACEL.

On August 21, 2006, the last sale price of our common stock on the Nasdaq Capital Market was \$1.75 per share.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities or passed on the adequacy of accuracy of the disclosures in this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is August 25, 2006

TABLE OF CONTENTS

<u>THE COMPANY</u>	3
<u>RECENT DEVELOPMENTS</u>	3
<u>SPECIAL NOTE REGARDING FORWARDED-LOOKING STATEMENTS</u>	3
<u>RISK FACTORS</u>	4
<u>USE OF PROCEEDS</u>	11
<u>ISSUANCE OF COMMON STOCK AND WARRANTS TO SELLING SECURITYHOLDERS</u>	11
<u>PLAN OF DISTRIBUTION</u>	11
<u>SELLING SECURITYHOLDERS</u>	13
<u>LEGAL MATTERS</u>	16
<u>EXPERTS</u>	16
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	17

Table of Contents

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in this prospectus. You should not rely on any unauthorized information. This prospectus does not offer to sell or buy any shares in any jurisdiction in which it is unlawful. The information in this prospectus is current as of the date on the cover.

THE COMPANY

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

Alfacell Corporation was incorporated in Delaware in 1981. Our principal executive officers are located at 225 Belleville Avenue, Bloomfield, New Jersey 07003 and our telephone number is (973) 748-8082. As used in this prospectus, we, us, our and Alfacell refer to Alfacell Corporation, a Delaware corporation.

RECENT DEVELOPMENTS

The following recent developments have occurred since the filing of Alfacell's last Quarterly Report on Form 10-Q for the quarter ended April 30, 2006, which was filed on June 9, 2006.

On July 19, 2006, Alfacell completed a private placement to selling securityholders pursuant to which it issued an aggregate of 6,457,172 shares of its restricted common stock for a per share purchase price of \$1.75 or an aggregate purchase price of approximately \$11.3 million. The selling securityholders also received warrants to purchase up to an additional 6,457,172 shares of common stock of Alfacell. The warrants have a term of five years and were issued in two separate series. The first series of warrants (to purchase 3,228,590 shares of common stock) are exercisable beginning on January 19, 2007, and the second series of warrants (to purchase 3,228,582 shares of common stock) are also exercisable beginning on January 19, 2007. Both sets of warrants have an exercise price equal to \$2.88 per share. If the Company enters into a strategic corporate collaboration as outlined in the second series of warrants by December 31, 2006, the second series of warrants will be cancelled upon notification by the Company to the holders of the warrants. The securities sold in the financing are being offered by the selling securityholders pursuant to this prospectus.

SPECIAL NOTE REGARDING FORWARDED-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements that are based on current expectations, estimates and projections about our industry, management's beliefs, and assumptions made by management. Words such as anticipates, expects, intends, plans, believes, seeks, and variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any forward-looking statements. The risks and uncertainties include those noted in Risk Factors below and in the documents incorporated by reference.

We do not intend to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent that we are required to do so by law. We also may

Table of Contents

make additional disclosures in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K that we may file from time to time with the Securities and Exchange Commission, or SEC. Please also note that we provide a cautionary discussion of risks and uncertainties under the section entitled "Risk Factors" in our Annual Report on Form 10-K. These descriptions and statements are based on management's current expectations. Our actual results may differ significantly from the results discussed in these forward-looking statements as a result of certain factors, including those set forth in the "Risk Factors" section and elsewhere in this prospectus.

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 S-3 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.

Risks Related to Our Company

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

We are a development stage company and since our inception one of the principal sources of our working capital has been private sales of our common stock. We incurred a net loss of approximately \$5,323,000 for the nine months ended April 30, 2006 and net losses of approximately \$6,462,000, \$5,070,000 and \$2,411,000 for the fiscal years ended July 31, 2005, 2004 and 2003, respectively. We have continued to incur losses since April 30, 2006. We may never achieve revenue sufficient for us to attain profitability.

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

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

The occurrence of manufacturing or distribution disruptions.

We 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.

Table of Contents

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

We may need additional financing in order to continue operations, including completion of our current clinical trials and filing marketing registrations for ONCONASE® with the FDA in the United States, with the EMEA in Europe and with the TGA in Australia. If the results from our current clinical trial do not demonstrate the efficacy and safety of ONCONASE® for malignant mesothelioma, our ability to raise additional capital will be adversely affected. Even if regulatory applications for marketing approvals are filed and approved, we may need additional financing to continue operations if we are unable to generate sufficient cash flow to support our operations prior to the time our current cash reserves are depleted. In July 2006, we consummated a private placement of common stock and warrants pursuant to which we received approximately \$10.4 million in net proceeds. We expect that such net proceeds, together with our cash reserves prior to the closing of such transaction, will be sufficient to fund our operations through July 31, 2008 based on our expected level of expenditures. However, to assure our ability to continue our operations beyond this date, we may continue to seek additional financing through equity or debt financings but we cannot be sure that we will be able to raise capital on favorable terms or at all. We may also obtain additional capital through the exercise of outstanding options and warrants, although we cannot provide any assurance of such exercises or estimate the amount of capital we will receive, if any. If we are required to raise additional capital to fund further operations and are unable to do so, our operations will be severely curtailed and our business and financial condition will be materially adversely affected.

We cannot predict how long it will take us nor how much it will cost us to complete part two of our Phase III trial because it is a survival study.

We currently have ongoing a two-part Phase III trial of ONCONASE® 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 we have exceeded the full enrollment target of 316 patients. The first interim analysis results based on the 105 events (deaths) showed a two-month survival advantage of ONCONASE® + doxorubicin (12 months) vs. doxorubicin (10 months). These results were consistent with the results from the first part of the trial and were the basis for our decision to continue the trial. 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® in patients with unresectable (inoperable) malignant mesothelioma. Since it is impossible to predict with certainty when these patient deaths 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, EMEA and TGA.

In addition, clinical trials are very costly and time consuming. The length of time required to complete a clinical trial depends on several factors including the size of the patient population, the ability of patients to get to the site of the clinical study, and the criteria for determining which patients are eligible to join the study. 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® 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.

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. We cannot apply for FDA, EMEA or TGA approval to market ONCONASE® until the clinical trials and all other registration requirements have been met. 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

Table of Contents

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, EMEA or TGA approval to market ONCONASE® 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, EMEA and TGA could stop our trials before completion.

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 you that the FDA or other regulatory agencies will ever approve the use of our products that are under development. Even if we receive regulatory approval, such approval may involve limitations on the indicated uses for which we may market our products. Further, even after approval, discovery of previously unknown problems could result in additional restrictions, including withdrawal of our products from the market.

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

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

We do not have the required manufacturing facilities to manufacture our product. We presently rely on third parties to perform certain of the manufacturing processes for the production of ONCONASE® for use in clinical trials. Currently, we contract with Scientific Protein Laboratories, LLC 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^â and with Cardinal Health and Aptuit for the labeling, storage and shipping of ONCONASE® for clinical trial use. We utilize the services of these third party manufacturers solely on an as needed basis with terms and prices customary for our industry.

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

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

Because we do not have 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 or non US approval, we expect to rely on established third party strategic partners to perform these functions. To date, we have not entered into any marketing or licensing agreements for

Table of Contents

ONCONASE®. We cannot assure you we will be able to establish or maintain 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, on acceptable terms, if at all.

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:

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;

the extent to which our agreement with our collaborators permits us to exercise marketing or promotion rights with respect to the product candidate;

how our product candidates compare to competitive products with respect to labeling, pricing, therapeutic effect, and method of delivery; and

whether we are able to establish agreements with third party collaborators, including large biopharmaceutical or other marketing companies, with respect to any of our product candidates on terms that are acceptable

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

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.

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 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.

Risks Related to Our Industry

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 three Japanese patents with expiration dates ranging from 2010 to 2016. We also own patent applications that are pending in the United States, Europe and Japan. The scope of

Table of Contents

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 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[®] medication as an orphan drug to treat patients with pleural mesothelioma. Alimta is a multi-targeted antifolate that is based upon a different mechanism of action than ONCONASE[®]. To our knowledge, no other company is developing a product with the same mechanism of action as ONCONASE[®]. However, there may be other companies, universities, research teams or scientists who are developing products to treat the same medical conditions our products are intended to treat. 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 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, 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.

Table of Contents

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

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

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

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

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

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

Risks Related to This Offering

We were relisted on the Nasdaq Capital Market after being delisted in 1999; 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 Capital Market, there was no established trading market for our common stock. During that time, our common stock was quoted on the OTC Bulletin Board and was thinly traded. There is no assurance that we will be able to comply with all of the listing requirements necessary to remain listed on the Nasdaq Capital 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.

Table of Contents

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 \$1.25 to a high of \$10.07. The market price of our common stock could be impacted by a variety of factors, including:

announcements of technological innovations or new commercial products by us or our competitors,

disclosure of the results of pre-clinical testing and clinical trials by us or our competitors,

disclosure of the results of regulatory proceedings,

changes in government regulation,

developments in the patents or other proprietary rights owned or licensed by us or our competitors,

public concern as to the safety and efficacy of products developed by us or others,

litigation, and

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.

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 44,289,161 shares of common stock outstanding as of July 31, 2006. The following securities that may be exercised into shares of our common stock were issued and outstanding as of July 31, 2006:

Options. Stock options to purchase 3,830,350 shares of our common stock at a weighted average exercise price of approximately \$3.10 per share.

Warrants. Warrants to purchase 18,119,598 shares of our common stock at a weighted average exercise price of approximately \$1.91 per share.

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

Table of Contents

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

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

In June 1996, AHC dissolved and ceased all operations. Therefore, we have not been able to obtain the reissued reports of AHC with respect to the financial statements included in the Form 10-K for the fiscal year ended July 31, 2005 nor have we been able to obtain AHC's consent to the use of such report herein. As a result, in the event any persons seek to assert a claim against AHC under Section 18 of the Exchange Act for any untrue statement of a material fact contained in these financial statements or any omissions to state a material fact required to be stated therein, such persons will be barred. Accordingly, you may be unable to assert a claim against AHC under Section 18 of the Exchange Act for any purchases of the Company's Common Stock made in reliance upon statements set forth in the Form 10-K for the fiscal year ended July 31, 2005. 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.

USE OF PROCEEDS

The proceeds from the sale of the common stock offered by this prospectus are solely for the account of the selling securityholders. We will not receive any proceeds from the sale of these shares. Some of the shares of Common Stock to be sold in this offering have not yet been issued and will only be issued upon the exercise of warrants. We will receive estimated net proceeds of approximately \$18.6 million if all such warrants are exercised. However, the warrants may not be exercised, in which event we would not receive any proceeds. We intend to use any proceeds received from the exercise of the warrants for general corporate purposes, including the funding of research and development activities. We expect to incur expenses of approximately \$68,473 in connection with this offering.

ISSUANCE OF COMMON STOCK AND WARRANTS TO SELLING SECURITYHOLDERS

On July 19, 2006 we sold 6,457,172 shares of our common stock at a purchase price of \$1.75 per share, and warrants to purchase up to 6,457,172 shares of our common stock at an exercise price of \$2.88 per share, to certain purchasers identified under the heading Selling Securityholders beginning on page 13 of this prospectus. This prospectus covers the resale of the shares of common stock issued in the private placement as well as the shares issuable upon conversion of the warrants.

PLAN OF DISTRIBUTION

Each selling securityholder and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on the principal Trading Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling securityholder may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker dealer solicits purchasers;

block trades in which the broker dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

-11-

Table of Contents

- purchases by a broker dealer as principal and resale by the broker dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker dealers may agree with the selling securityholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling securityholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended (the Securities Act), if available, rather than under this prospectus.

Broker dealers engaged by the selling securityholders may arrange for other brokers dealers to participate in sales. Broker dealers may receive commissions or discounts from the selling securityholders (or, if any broker dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

In connection with the sale of the common stock or interests therein, the selling securityholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling securityholders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling securityholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling securityholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling securityholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling securityholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because selling securityholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under

Table of Contents

the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling securityholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling securityholders without registration and without regard to any volume limitations by reason of Rule 144(k) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling securityholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling securityholders or any other person. We will make copies of this prospectus available to the selling securityholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

SELLING SECURITYHOLDERS

The following table sets forth certain information as of July 31, 2006 with respect to the selling securityholders. The following table assumes that the selling securityholders sell all of the shares offered by this prospectus. We are unable to determine the exact number of shares that actually will be sold.

The number and percentage of shares beneficially owned is based on 44,289,161 shares outstanding at July 31, 2006 determined in accordance with Rule 13d-3 of the Exchange Act. The information is not necessarily indicative of beneficial ownership for any other purpose. Under Rule 13d-3, beneficial ownership includes any shares as to which an individual has sole or shared voting power or investment power, and also includes shares which an individual has the right to acquire within 60 days of July 31, 2006 through the exercise of any stock option or other right. Unless otherwise indicated in the footnotes, each person has sole voting and investment power (or shares such powers with his or her spouse) with respect to the shares shown as beneficially owned.

Except as described in the footnotes below, no selling securityholder has had any material relationship with us or any of our predecessors or affiliates within the last three years.

Selling Securityholder	Shares Beneficially Owned Prior to the Offering		Shares Offered by this Prospectus	Shares Beneficially Owned After the Offering	
	Number	Percent		Number	Percent
Awadalla, Hany S. (1)	228,572	*	228,572		*
C.E. Unterberg, Towbin Capital Partners I, L.P. (2)	314,286	*	314,286		*
Capital Ventures International (3)	1,714,286	3.80%	1,714,286		*
Enable Growth Partners LP (4)	1,285,714	2.86%	1,285,714		*
Enable Opportunity Partners LP (5)	257,144	*	257,144		*
Europa International, Inc. (6)	4,338,574	9.45%	428,572	3,481,430	7.62%
Golomb, Joshua (7)	28,600	*	28,600		*
Hesse, Robert H. (8)	285,714	*	285,714		*
Iroquois Master Fund Ltd. (9)	1,428,570	3.17%	1,428,570		*
Knoll Capital Fund II Master Fund, Ltd. (10)	4,338,574	9.45%	428,572	3,481,430	7.62%

Table of Contents

Selling Securityholder	Shares Beneficially Owned Prior to the Offering		Shares Offered by this Prospectus	Shares Beneficially Owned After the Offering	
	Number	Percent		Number	Percent
Patry, Richard (11)	360,000	*	200,000	160,000	*
Pierce Diversified Strategy Master Fund LLC, Ena (12)	171,428	*	171,428		*
ProMed Offshore Fund II, Ltd. (13)	2,231,228	4.91%	2,231,228		*
ProMed Offshore Fund, Ltd. (14)	85,460	*	85,460		*
ProMed Partners II, L.P. (15)	24,684	*	24,684		*
ProMed Partners, L.P. (16)	515,800	1.16%	515,800		*
SF Capital Partners Ltd. (17)	2,237,986	4.99%	1,428,572	2,005,296	4.42%
Soto, Eduardo E. and Maria C. (18)	563,125	1.27%	285,714	277,411	*
Southridge Partners LP (19)	1,335,714	2.97%	1,335,714		*
Southshore Capital Fund Ltd. (20)	235,714	*	235,714		*
TOTAL	17,642,599		12,914,344	6,128,189	

* Less than 1%.

(1) Includes 94,286 common shares held by the Hany S. Awadalla IRRA for the benefit of Mr. Awadalla. Also includes an aggregate of 114,286 shares underlying warrants which are not exercisable until January 19, 2007, 94,286 of which are held by the Hany S. Awadalla IRRA and all of which are being offered pursuant to this prospectus.

(2)

Includes an aggregate of 157,143 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

- (3) Includes an aggregate of 857,143 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus. Heights Capital Management, Inc., the authorized agent of Capital Ventures International (CVI), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. CVI is affiliated with one or more registered broker-dealers. CVI purchased the shares being registered

hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares.

(4) Mitch Levine has voting and investment power over the shares held by each of Enable Growth Partners LP and Enable Opportunity Partners LP, and each may be deemed to beneficially own the shares held by the other. Includes an aggregate of 624,857 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

(5) Mitch Levine has voting and investment power over the shares held by each of Enable Growth Partners LP and Enable

Opportunity Partners LP, and each may be deemed to beneficially own the shares held by the other. Includes an aggregate of 128,572 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

- (6) Includes 1,303,916 shares of common stock and 806,786 shares of common stock underlying warrants held by Knoll Capital Fund II Master Fund, Ltd. which are not exercisable until January 19, 2006; 19,350 shares of common stock held by Knoll Special Opp. Fund; and 1,401,736 shares of common stock held by Europa International, Inc., of which 214,286 are being offered pursuant to this

prospectus and
806,786 shares
underlying
warrants held by
Europa
International,
Inc. which are
not exercisable
until January 19,
2007, 214,286
of which are
being offered
pursuant to this
prospectus. Fred
Knoll Knoll
Capital
Management
has voting
power over and
may be the
deemed
beneficial owner
of the shares
held by Knoll
Capital Fund II
Master Fund,
Ltd., Knoll
Special Opp.
Fund and
Europa
International,
Inc.

Table of Contents

- (7) Includes an aggregate of 14,300 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

- (8) Includes an aggregate of 142,857 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

- (9) Includes an aggregate of 714,285 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

- (10) Includes 1,401,736 shares of common stock and 806,786 shares of common stock

underlying warrants held by Europa International, Inc. which are not exercisable until January 19, 2007; 19,350 shares of common stock held by Knoll Special Opp. Fund; and 1,303,916 shares of common stock held by Knoll Capital Fund II Master Fund, Ltd., of which 214,286 are being offered pursuant to this prospectus and 806,786 shares underlying warrants held by Knoll Capital Fund II Master Fund, Ltd. which are not exercisable until January 19, 2007, 214,286 of which are being offered pursuant to this prospectus. Fred Knoll Knoll Capital Management has voting and investment power over, and may be deemed the beneficial owner of, the shares held by Knoll Capital Fund II Master Fund, Ltd.,

Knoll Special
Opp. Fund and
Europa
International,
Inc.

- (11) Includes an aggregate of 100,000 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.
- (12) Mitch Levine has voting and investment power over the shares held by Pierce Diversified Strategy Master Fund LLC, Ena. Includes an aggregate of 85,714 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.
- (13) David Musket and Barry Kurokawa have shared voting and investment power over the shares held by each of ProMed

Offshore Fund II, Ltd., ProMed Offshore Fund, Ltd., ProMed Partners, L.P. and ProMed Partners II, L.P. and each may be deemed to beneficially own the shares held by the other. Mr. Kurokawa and Mr. Musket disclaim beneficial ownership of the shares except to the extent of their respective pecuniary interest therein. Includes an aggregate of 1,115,614 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

- (14) David Musket and Barry Kurokawa have shared voting and investment power over the shares held by each of ProMed Offshore Fund II, Ltd., ProMed Offshore Fund, Ltd., ProMed Partners, L.P.

and ProMed Partners II, L.P. and each may be deemed to beneficially own the shares held by the other.

Mr. Kurokawa and Mr. Musket disclaim beneficial ownership of the shares except to the extent of their respective pecuniary interest therein.

Includes an aggregate of 42,730 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

- (15) David Musket and Barry Kurokawa have shared voting and investment power over the shares held by each of ProMed Offshore Fund II, Ltd., ProMed Offshore Fund, Ltd., ProMed Partners, L.P. and ProMed Partners II, L.P. and each may be deemed to beneficially own the shares held

by the other.
Mr.Kurokawa
and Mr. Musket
disclaim
beneficial
ownership of
the shares
except to the
extent of their
respective
pecuniary
interest therein.
Includes an
aggregate of
12,342 shares
underlying
warrants which
are not
exercisable until
January 19,
2007, all of
which are being
offered pursuant
to this
prospectus.

- (16) David Musket
and Barry
Kurokawa have
shared voting
and investment
power over the
shares held by
each of ProMed
Offshore Fund
II, Ltd., ProMed
Offshore Fund,
Ltd., ProMed
Partners, L.P.
and ProMed
Partners II, L.P.
and each may be
deemed to
beneficially own
the shares held
by the other.
Mr.Kurokawa
and Mr. Musket
disclaim
beneficial
ownership of

the shares except to the extent of their respective pecuniary interest therein. Includes an aggregate of 257,900 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

- (17) SF Capital Partners Ltd., a British Virgin Islands company (SF Capital) and an affiliate of a broker-dealer, purchased all shares covered by this prospectus in the ordinary course of business and, at the time of the purchase of the shares to be resold, had no agreements or understandings, directly or indirectly, with any person to distribute such shares. Michael A. Roth and Brian J. Stark have sole voting and investment control over

securities owned
by SF Capital,
but disclaim
beneficial
ownership of
such securities.
SF Capital holds
an aggregate of
1,756,144
shares
underlying
warrants,
852,273 of
which are
currently
exercisable and
903,871 of
which are not
exercisable until
January 19,
2007. 714,286
of the shares
underlying
warrants are
being offered

Table of Contents

pursuant to this prospectus, and the remaining shares underlying warrants were previously registered. Beneficial Ownership prior to the offering excludes an aggregate of 1,195,882 shares of common stock underlying warrants issued to SF Capital, because the terms of such warrants preclude SF Capital from exercising the warrants if, prior to or after such exercise, SF Capital or any of its affiliates beneficially own or will own in excess of 4.99% of the outstanding shares of common stock of the Company.

- (18) Includes an aggregate of 142,857 shares underlying warrants which are not exercisable until January 19, 2007, all of

which are being offered pursuant to this prospectus.

(19) Includes an aggregate of 667,857 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

(20) Includes an aggregate of 117,857 shares underlying warrants which are not exercisable until January 19, 2007, all of which are being offered pursuant to this prospectus.

LEGAL MATTERS

The validity of the issuance of the common stock offered by this prospectus will be passed upon by Heller Ehrman LLP, New York, New York counsel to Alfacell.

EXPERTS

Our financial statements as of July 31, 2005 and 2004 and for each of the years in the three-year period ended July 31, 2005 and for the period from August 24, 1981 (the date of inception) to July 31, 2005 and the report on our internal control over financial reporting and management's assessment of our internal control over financial reporting, incorporated in this registration statement by reference from the Alfacell Corporation Annual Report on Form 10-K for the year ended July 31, 2005 have been audited by J.H. Cohn LLP, independent registered public accounting firm, as stated in their reports, which are incorporated herein by reference and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing. The report of J.H. Cohn LLP with respect to our financial statements from inception to July 31, 2005 is based on the reports of Armus Harrison & Co. and KPMG LLP, for the period from inception to July 31, 2002. As discussed in the Alfacell Corporation Annual Report on Form 10-K for the year ended July 31, 2005, Armus Harrison & Co. ceased performing accounting and auditing services for Alfacell in 1993 and subsequently dissolved and ceased all operations.

The statements of operations, stockholders' equity (deficiency), and cash flows of Alfacell Corporation for the period from August 24, 1981 (the date of inception) to July 31, 2002, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The report

of KPMG LLP with respect to our financial statements from inception to July 31, 2002 is based on the report of Armus Harrison & Co., incorporated by reference herein, for the period from inception to July 31, 1992. As discussed in the Alfacell Corporation Annual Report on Form 10-K for the year ended July 31, 2005, incorporated by reference herein, Armus Harrison & Co. ceased performing accounting and auditing services for Alfacell in 1993 and subsequently dissolved and ceased all operations.

The report of KPMG LLP covering the July 31, 2002 financial statements contains an explanatory paragraph that states that our recurring losses from operations, working capital deficit and limited liquid resources raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of that uncertainty.

Alfacell Corporation has agreed to indemnify and hold KPMG LLP (KPMG) harmless against and from any and all legal costs and expenses incurred by KPMG in successful defense of any legal action or proceeding that arises as a result of KPMG's consent to the incorporation by reference of its audit report on the Company's financial statements incorporated by reference in this registration statement.

Table of Contents

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commissions. Certain information in the registration statements has been omitted from this prospectus in accordance with the rules of the SEC. We file proxy statements and annual, quarterly and special reports and other information with the SEC. You can inspect and copy the registration statement as well as the reports, proxy statements and other information we have filed with the SEC at the public reference room maintained by the SEC at 100 F Street, N.E., Washington, D.C., 20549. You can call the SEC at 1-800-732-0330 for further information about the Public Reference Room. We are also required to file electronic versions of these documents with the SEC, which may be accessed from the SEC's World Wide Web site at <http://www.sec.gov>. We maintain a website at www.alfacell.com. Our website and the information contained therein or connected thereto are not intended to be incorporated into this registration statement.

The SEC allows us to incorporate by reference certain of our publicly-filed documents into this prospectus, which means that information included in those documents is considered part of this prospectus. Information that we file with the SEC after August 16, 2006 will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, until the selling securityholders have sold all the shares.

The following documents filed with the SEC are incorporated by reference in this prospectus:

1. Our Annual Report on Form 10-K for the year ended July 31, 2005.
2. Our definitive Proxy Statement dated December 16, 2005, filed in connection with our January 19, 2006 Annual Meeting of Securityholders.
3. Our Quarterly Reports on Form 10-Q for the quarters ended October 31, 2005, January 31, 2006 and April 30, 2006.
4. Our Current Reports on Form 8-K, filed with the SEC on December 8, 2005, May 5, 2006 and July 20, 2006.
5. The description of our common stock in our Registration Statement on Form S-1 filed with the SEC (No. 333-112865).

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, other than exhibits to those documents. You should direct any requests for documents to Chief Financial Officer, 225 Belleville Avenue, Bloomfield, New Jersey 07003, telephone: (973) 748-8082.