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ALFACELL CORP
Form 8-K
March 14, 2005

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 11, 2005

ALFACELL CORPORATION.

(Exact name of registrant as specified in its charter)

| | | |
|---|-----------------------------|----------------------------------|
| Delaware | 0-11088 | 22-2369085 |
| ----- | ----- | ----- |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification) |

225 BELLEVILLE AVENUE, BLOOMFIELD, NEW JERSEY 07003

(Address of principal executive offices) (Zip Code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

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On March 11, 2005, Alfacell Corporation issued a press release to report its results of operations and financial condition for the quarter ended January 31, 2005. A copy of the press release is attached hereto as Exhibit 99.1, which is incorporated into this Item 2.02 by reference.

ITEM 8.01 OTHER EVENTS.

On March 11, 2005, Alfacell Corporation reported an extension in the expected time frame for the completion of patient accrual in its malignant mesothelioma Phase IIIb trial. Recent regulatory changes in several large, non-EU countries which have contracted to participate in the trial have occurred. Specifically, local government approvals must now be obtained prior to the initiation of trials in those countries. As a result, patient accrual has been delayed.

The Company continues to enroll patients in those countries for which it has government approvals to conduct trials, including the United States, Canada, Poland, Italy, Germany and most recently Australia and New Zealand. The Company has been successful in accelerating patient accrual in these countries and will continue to use its best efforts to accelerate accruals at all sites. The Company expects to achieve projected patient accruals once the local government approvals are granted. The Company continues to focus on rapid patient enrollment in order to accelerate the completion of the Phase IIIb trial in parallel with the completion of all the required sections of the NDA.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(C) EXHIBITS.

99.1 Press release dated March 11, 2005.

THIS FORM 8-K INCLUDES STATEMENTS THAT MAY CONSTITUTE "FORWARD-LOOKING" STATEMENTS, USUALLY CONTAINING THE WORDS "BELIEVE", "ESTIMATE", "PROJECT", "EXPECT" OR SIMILAR EXPRESSIONS. ANY SUCH FORWARD-LOOKING STATEMENTS ARE BASED ON ASSUMPTIONS THAT THE COMPANY BELIEVES ARE REASONABLE, BUT ARE SUBJECT TO A WIDE RANGE OF RISKS AND UNCERTAINTIES AND, THEREFORE, THERE CAN BE NO ASSURANCE THAT ACTUAL RESULTS MAY NOT DIFFER MATERIALLY FROM THOSE EXPRESSED OR IMPLIED BY SUCH FORWARD-LOOKING STATEMENTS. FACTORS THAT WOULD CAUSE OR CONTRIBUTE TO SUCH DIFFERENCES INCLUDE, BUT ARE NOT LIMITED TO, UNCERTAINTIES INVOLVED IN TRANSITIONING FROM CONCEPT TO PRODUCT, UNCERTAINTIES INVOLVING THE ABILITY OF THE COMPANY TO FINANCE RESEARCH AND DEVELOPMENT ACTIVITIES, POTENTIAL CHALLENGES TO OR VIOLATIONS OF PATENTS, UNCERTAINTIES REGARDING THE OUTCOME OF CLINICAL TRIALS, THE COMPANY'S ABILITY TO SECURE NECESSARY APPROVALS FROM REGULATORY AGENCIES, DEPENDENCE UPON THIRD-PARTY VENDORS, AND OTHER RISKS DISCUSSED IN THE COMPANY'S PERIODIC FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION. BY MAKING THESE FORWARD-LOOKING STATEMENTS, THE COMPANY UNDERTAKES NO OBLIGATION TO UPDATE THESE STATEMENTS FOR REVISIONS OR CHANGES AFTER THE DATE OF THIS FORM 8-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 11, 2005

By: /s/ Andrew Savadelis

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Andrew Savadelis
Chief Financial Officer