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ALFACELL CORP
Form 8-K
September 01, 2005

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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): August 30, 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))

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ITEM 8.01 OTHER EVENTS.

On August 30, 2005, Alfacell Corporation reported an update on the status of its international, confirmatory Phase IIIb malignant mesothelioma trial for ONCONASE(R) (ranpirnase), the Company's lead investigational drug candidate:

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- o Nearly 90% of the patients required per the study design for full patient accrual are now enrolled.
- o Active patient enrollment is ongoing at leading cancer centers in the United States, Canada, Germany, Italy, Poland, Australia and New Zealand.
- o Earlier this year, the Company reported that recent regulatory changes in several large, non-EU countries had delayed the opening of new sites for the study. The Company is now pleased to announce that government approvals have been obtained and sites recently opened in Russia, Romania, Mexico and Brazil.

The Company will continue to provide updates on the trial as key developments occur.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(c) EXHIBITS.

99.1 Press release dated August 30, 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: September 1, 2005

By: /s/ Robert Love

Robert Love
Chief Financial Officer