ANIKA THERAPEUTICS INC
Form 8-K
September 02, 2005

UNITED STATES
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 31, 2005**

Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Massachusetts	**000-21326**	**04-3145961**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

160 New Boston Street, Woburn, Massachusetts	**01801**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s Telephone Number, Including Area Code: **(781) 932-6616**

No Change Since Last Report

(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 obligations of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.02: Termination of a Material Definitive Agreement

On July 23, 2004, Anika Therapeutics, Inc. entered into an exclusive worldwide development and commercialization partnership agreement with the Ortho Neutrogena Division of Ortho-McNeil Pharmaceutical, Inc. (Ortho), for its hyaluronic acid based cosmetic tissue augmentation (CTA) therapy, a therapy for correcting dermal defects, including facial wrinkles, scar remediation and lip augmentation. Under the terms of the multi-year agreement, Anika received an initial payment of $1 million with additional milestone payments to be made upon receipt of final marketing approval from the U.S. Food and Drug Administration (FDA), receipt of a European CE Mark, and upon achievement of other sales and development targets. The agreement also provided for royalties and transfer payments for the supply of CTA products

As Anika has previously publicly disclosed, in May 2004 a U.S. pivotal clinical trial for our CTA product was initiated. The trial was designed to evaluate the effectiveness of CTA for correcting nasolabial folds and was being conducted by dermatologists and plastic surgeons at 10 centers throughout the U.S. Patient enrollment was completed during the third quarter of 2004 and in the second quarter of 2005 Anika completed its review of the clinical study primary end point results. Accordingly, Anika publicly indicated its intention to file a pre-market approval application (PMA) by the end of the third quarter of 2005, even though Ortho had instructed it not to file that PMA.

Following discussions with OrthoNeutrogena regarding this issue, on September 1, 2005, Anika announced that it had reached a mutual agreement with Ortho for the termination of the agreement, effective August 31, 2005. Pursuant to this termination agreement, Anika will receive a cash amount plus reimbursement of certain development expenses. In addition, in accordance with the provisions of the original agreement and the termination agreement, all worldwide development and commercialization rights related to Anika s CTA product reverted to Anika.

A copy of the press release announcing the termination of the agreement is filed as Exhibit 99.1 hereto.

Item 8.01: Other Events

On September 1, 2005, Anika announced that it had filed a pre-market approval application (PMA) with the U.S. Food and Drug Administration for its CTA product and is currently exploring options for its worldwide commercialization.

A copy of the press release announcing the filing of the PMA is filed as Exhibit 99.1 hereto.

Item 9.01: Financial Statements and Exhibits.

(c) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Anika Therapeutics, Inc. on September 1, 2005

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.

ANIKA THERAPEUTICS, INC.

September 2, 2005

By: /s/ Kevin W. Quinlan
Kevin W. Quinlan
Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release issued by Anika Therapeutics, Inc. on September 1, 2005