ANIKA THERAPEUTICS INC
Form 8-K
March 01, 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): **February 23, 2005**

Anika Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts	**000-21326**	**04-314-5961**
(State or other jurisdiction of incorporation or organization)	Commission file number	(I.R.S. Employer Identification No.)

160 New Boston Street, Woburn, MA 01801
(Address of principal executive offices) (Zip code)

Registrant s telephone number, including area code: **781-932-6616**

(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:

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 2.02. Results of Operations and Financial Condition.

On February 23, 2005, Anika Therapeutics, Inc. issued a press release (Press Release) announcing its financial results for the fourth quarter of and fiscal year ended 2004. A copy of the Press Release is attached as Exhibit 99.1 to this Current Report and is incorporated herein by reference. Additionally, on February 24, 2005, Anika held a teleconference and webcast call to report its financial and operating results for the fourth quarter of and fiscal year ended 2004. A transcript of the call is attached as Exhibit 99.2 to this Current Report and is incorporated herein by reference. The furnishing of the conference call transcript shall not be deemed to be an admission of the Company that any of the material contained in it is material information of a financial or statistical nature relating to the fourth quarter of and fiscal year ended 2004.

Such information, including the exhibits attached hereto, shall not be deemed filed for any purpose, including for purposes of, Section 18 of the Securities and Exchange Act of 1934 (the Exchange Act) or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 of the Exchange Act, regardless of any general incorporation language in such filing.

Safe Harbor

The statements made in this press release and transcript of the conference call which are not statements of historical fact are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements that may be identified by words such as expectations, remains, focus, expected, prospective, expanding, b continue, progress, efforts, hope, believe, objectives, opportunities, will, seek, and other expressions which are predictions of or events and trends and which do not constitute historical matters identify forward-looking statements. These statements also include statements regarding: (i) the Company s efforts and expectations in entering into long-term arrangements to market and distribute ophthalmic and osteoarthritis products, (ii) the level of the Company s revenue or sales in particular geographic areas, for particular products and/or to a particular distributor partner (such as Ortho Biotech), (iii) the market share of any of the Company s products, (iv) expectations regarding future results of operations, including the Company s expectations regarding gross margins, tax rates, Sarbanes-Oxley Act Section 404 costs, cash utilization, (v) the Company s intention to strengthen, expand and grow its ophthalmic franchise and the growth of the Company s ophthalmic business, (vi) the Company s expectations of the size of the United States and European markets, including Germany and France, for osteoarthritis of the knee, (vii) the Company s objectives towards increasing market share for ORTHOVISC® in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee, (viii) the Company s corporate objectives and research and development and collaboration opportunities, including, without limitation, intended preclinical development of potential cosmetic tissue augmentation products and commencement of INCERT® clinical trials, (ix) the results of the U.S. launch for ORTHOVISC® , (x) the Company s plans for augmenting its infrastructure including its research and development department and manufacturing operations and (xi) the Company s intentions on supporting its distributors promotional promotions. These statements are based upon the current beliefs and expectations of the Company s management and are subject to significant risks, uncertainties and other factors. The Company s actual results could differ materially from any anticipated future results, performance or achievements described in the forward-looking statements as a result of a number of factors including: (i) the Company s ability to successfully commence and/or complete clinical trials of its products on a timely basis or at all, obtain clinical data to support a pre-market approval application and/or FDA approval, and/or receive FDA or other regulatory approvals of its products, or that such approvals will not be obtained in a timely manner or without the need for additional clinical trials; (ii) the success of the Company s efforts to improve the financial performance of its core business; (iii) the Company s research and product development efforts and their relative success, including whether the Company has any meaningful sales of any new products resulting from such efforts; (iv) the cost effectiveness and efficiency of our manufacturing operations and production planning; (v) the strength of the Turkish, German, Canadian, Middle Eastern and French economies, in general and other economies in which the Company operates or will be operating, as well as the political stability of any of those geographic areas or (vi) future determinations by the Company to allocate resources to products and in directions not presently contemplated. Any delay in receiving any regulatory approvals may adversely affect the Company s competitive position. Even if regulatory approvals are obtained, there is a risk that meaningful sales of the products may not be achieved. There is also a risk that (i) the Company s existing distributors or customers will not continue to place orders at historical levels or that any of them will seek to modify or terminate existing arrangements, (ii) the Company s efforts to enter into long-term

marketing and distribution arrangements will not be successful, (iii) distribution arrangements, including the agreement with Ortho Biotech Products, L.P. pertaining to ORTHOVISC®, will not result in meaningful sales of the Company s products, (iv) the Company will be unable to achieve performance and sales threshold milestones in its distribution agreements, (v) competitive products will adversely impact the Company s product sales, (vi) the estimated size(s) of the markets which the Company has targeted its products will fail to be achieved, or (vii) increased sales of the Company s products, including HYVISC®, ORTHOVISC®, or its ophthalmic products, will not continue or sales will decrease or not reach historical sales levels, or even if such increases occur that such increases will improve gross margins, any of which may have a material adverse effect on the Company s business and operations (viii) the Company s distribution and supply arrangements will not be conducted in accordance with the contractual requirements. Certain other factors that might cause the Company s actual results to differ materially from those in the forward-looking statements include those set forth under the headings Business, Risk Factors and Certain Factors Affecting Future Operating Results and Management s Discussion and Analysis of Financial Condition and Results of Operations in each of the Company s Annual Report on Form 10-K for the year ended December 31, 2003, and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2004 and Current Reports on Form 8-K, as well as those described in the Company s other press releases and SEC filings.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits.

99.1 Press Release of Anika Therapeutics, Inc. dated February 23, 2005.

99.2 Transcript of fourth quarter of and fiscal year ended 2004 financial results teleconference call held on February 24, 2005.

[Remainder of page left blank intentionally]

SIGNATURE

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

Anika Therapeutics, Inc.

Dated: March 1, 2005

By: /s/ Charles H. Sherwood, Ph.D.
Charles H. Sherwood, Ph.D.
President and Chief Executive Officer

Exhibit Index

99.1	Press Release of Anika Therapeutics, Inc. dated February 23, 2005.
99.2	Transcript of fourth quarter of and fiscal year 2004 financial results teleconference call held on February 24, 2005.