

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) MAY 18, 1995

T CELL SCIENCES, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN CHARTER)

| | | |
|---|-----------------------------|---|
| DELAWARE | 0-15006 | 13-3191702 |
| (STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION) | (COMMISSION FILE NUMBER) | (I.R.S. EMPLOYER IDENTIFICATION NO.) |

| | |
|---|------------|
| 115 FOURTH AVENUE, NEEDHAM, MASSACHUSETTS | 02194-4135 |
| (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) | (ZIP CODE) |

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE (617) 433-0771

ITEM 5: OTHER EVENTS

T Cell Sciences, Inc. (the "Company") announced on May 18, 1995 that its subsidiary, T Cell Diagnostics, Inc., received clearance from the U.S. Food and Drug Administration to market TRAx(R) CD4 test kit. TRAx(R) CD4 test kit is an in vitro diagnostic test kit which provides a method for enumerating CD4 T cells, a type of white blood cell monitored by physicians treating patients infected with HIV. Further details regarding this announcement are contained in the news release dated May 18, 1995 attached as Exhibit 20 hereto and incorporated by reference herein.

ITEM 7: FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS

(c) Exhibits

Exhibit 99.20 T Cell Sciences, Inc. News Release dated
May 18, 1995

SIGNATURES

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

T CELL SCIENCES, INC.

(Registrant)

Dated: May 23, 1995

By:/s/ James L. Levin

James L. Levin
Vice President, Regulatory Affairs
and Pharmaceutical Evaluation

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FOR IMMEDIATE RELEASE/ May 18,1995

| | | |
|-------------------------|-------------------------|-----------------------------|
| Alan W. Tuck | Duff Brace | Susan Primrose |
| President & | President & | Manager, Market Development |
| Chief Executive Officer | Chief Operating Officer | & Communications |
| T Cell Sciences, Inc. | T Cell Diagnostics | T Cell Sciences, Inc. |
| (617) 433-0771 | (617) 937-0890 | (617) 433-0771 |

T Cell Sciences' Subsidiary Receives FDA Clearance to Market TRAx(R) CD4

Needham, MA, May 18,1995 -- T Cell Sciences, Inc., (NASDAQ: TCEL), announced today that its subsidiary T Cell Diagnostics, Inc. has received clearance from the U.S. Food and Drug Administration to market the TRAx(R) CD4Test Kit as a method for enumerating CD4 T cells, a specific type of white blood cell. CD4 T cell enumeration is the single most important clinical parameter used by physicians to monitor disease progression and to determine proper therapy for patients infected with HIV.

"TRAx CD4 allows more laboratories to participate in HIV patient monitoring by providing a rapid, simple and cost-effective method of CD4 T cell enumeration," said Duff Brace, President and COO of T Cell Diagnostics. "Currently CD4 T cell enumeration is provided by approximately 500 large reference laboratories that own an expensive and complex instrument called a flow cytometer. TRAx CD4 will give more than 3000 laboratories without flow cytometry equipment the ability to offer CD4 T cell monitoring directly, saving substantial time and expense."

Mr. Brace noted that as more individuals are diagnosed with the virus, and as additional treatment options become available, the number of patients monitored and the frequency of monitoring CD4 counts are likely to increase. Recent estimates by the World Health Organization indicate over 1.5 million HIV infected individuals in the United States and Europe and as many as 13-15 million worldwide.

Alan Tuck, President and CEO of T Cell Sciences, commented, "TRAx CD4 is expected to become the Company's first major revenue generating product. TRAx CD4 also is the first of a family of immune monitoring products based on the Company's TRAx technology."

T Cell Diagnostics will sell the TRAx CD4 Test Kit as well as other novel immune markers to clinical labs using its own direct sales force. The Company recently hired a Director of Sales and is adding regional salespeople in the major centers where HIV infected patients are treated. The Company expects to have its sales and marketing efforts underway within thirty to ninety days. T Cell Diagnostics will utilize distribution partners for sales in Europe.

"When compared with flow cytometry, new technologies such as TRAx CD4 hold great promise for improving the efficiency, accuracy and reproducibility of CD4 T cell enumeration," said Alan Landay, Ph.D., Associate Professor, Department of Immunology/ Microbiology at Rush-Presbyterian- St.Luke's in Chicago.

CD4 cell counts provide an objective measure of the immune system's effectiveness. As HIV infection progresses CD4 T cell counts decline. The National Institute of Allergy and Infectious Disease (NIAID) has established clinical guidelines for the use of CD4 T cell counts in managing HIV infection and in guiding drug therapy for patients. Among these, the NIAID states that patients with CD4 cell counts greater than 600 cells/microliter should undergo CD4 cell enumeration every six months. Below 600 cells/microliter it is recommended that patients have their CD4 cell counts monitored four times a year. As CD4 counts approach 500 cells/microliter, patients should be considered candidates for antiviral therapy. Patients with CD4 cell counts at or below 200 cells/microliter should be considered for treatment to prevent pneumocystis carinii pneumonia, a common AIDS-associated infection.

The TRAx CD4 Test Kit is an enzyme linked immunoassay for the quantitative measurement of CD4+ T lymphocyte equivalents in human peripheral blood specimens. TRAx CD4 enumerates cells through a proprietary technology that is compatible with standard enzyme linked immunoassay (ELISA) methods, similar to methods already used in most clinical laboratories. The TRAx assay results are read by a microtiter plate reader commonly found in hospitals and clinical laboratories.

T Cell Sciences, Inc. is developing pharmaceutical products to treat diseases of inflammation and autoimmunity utilizing proprietary complement inhibitor and T cell receptor technology. T Cell Diagnostics, a wholly-owned subsidiary of T Cell Sciences, develops, manufactures and markets innovative immune monitoring and research products.