

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

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FILER

**BIO TECHNOLOGY GENERAL CORP**

CIK: **722104** | IRS No.: **133033811** | State of Incorporation: **DE** | Fiscal Year End: **1231**  
Type: **8-K** | Act: **34** | File No.: **000-15313** | Film No.: **95546760**  
SIC: **2833** Medicinal chemicals & botanical products

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 8-K  
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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

BIO-TECHNOLOGY GENERAL CORP.  
(Exact name of registrant as specified in its charter)

|   |  |  |
|---|--|--|
| Delaware<br>(State or other jurisdiction<br>of incorporation) | 0-15313<br>(Commission<br>File Number) | 13-3033811<br>(IRS Employer<br>Identification No.) |
|---|--|--|

|  |                     |
|--|---------------------|
| 70 Wood Avenue South, Iselin, New Jersey<br>(Address of principal executive offices) | 08830<br>(Zip Code) |
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Registrant's telephone number, including area code: (908) 632-8800

Not Applicable  
(Former name or former address, if changed since last report)

Item 5. Other Events

A. Closing of Bio-Cardia Exchange Offer

On December 31, 1993, Bio-Technology General Corp. ("BTG") and Bio-Cardia Corporation ("Bio-Cardia") completed a private placement (the "Private Placement") of 375 units, each unit ("Unit") consisting of four shares of common stock of Bio-Cardia and warrants to purchase 15,000 shares of BTG's common stock (the "Warrants"). All of the cash proceeds of the financing were received by Bio-Cardia. In consideration of the Warrants included in the Units, BTG received from each purchaser of Units an option (the "Stock Purchase Option"), exercisable at any time on or prior to December 31, 1997, to purchase the

Bio-Cardia stock at a purchase price beginning at 125% and increasing over time to 200% of the cash portion of the price paid for such stock. Such purchase price may be paid in cash, shares of BTG's common stock or both, at BTG's discretion. In connection with the closing of the financing, BTG and Bio-Cardia entered into an agreement whereby BTG licensed to Bio-Cardia the right to pursue the development and commercialization of certain of BTG's products (the "Technology License Agreement"). BTG and Bio-Cardia have entered into a research and development agreement pursuant to which BTG will conduct research, development and clinical testing of these products.

Bio-Cardia and BTG had originally budgeted approximately \$32 million of the net proceeds of the Private Placement (less if the Stock Purchase Option was exercised prior to January 1, 1997) to fund development and commercialization of the products licensed to Bio-Cardia over a period of four years and to reimburse BTG for previously incurred research and development expenses. However, holders of 218 Units failed to make the required July 1, 1994 payment of \$10,000 per Unit, which resulted in Bio-Cardia being unable to pay certain amounts due BTG in respect of research and development conducted by BTG on behalf of Bio-Cardia and in reimbursement of previously incurred research and development expenses. In October 1994 Bio-Cardia reached settlements with certain of the defaulting stockholders, holding an aggregate of 178 Units, who surrendered to Bio-Cardia their Bio-Cardia stock and Warrants to purchase an aggregate of 2,670,000 shares of BTG common stock (the "Surrendered Warrants") in exchange for a release from their future funding obligations to Bio-Cardia. The net effect of this settlement was to reduce the funding expected by Bio-Cardia by approximately \$14,240,000. In addition, Bio-Cardia commenced legal action against the remaining defaulting stockholders, holding an aggregate of 40 Units, who owe an aggregate of \$3,200,000. Accordingly, Bio-Cardia will not be in a position to fund the up to \$32 million research and development program originally contemplated by Bio-Cardia and BTG. As a result, BTG has the right to terminate the Technology License Agreement and repossess all rights to the technology licensed or sublicensed to Bio-Cardia without the payment of any amounts to Bio-Cardia other than a royalty on all Improvements (as defined in the Technology License Agreement) to the Products developed pursuant to the development program conducted by BTG on behalf of Bio-Cardia. At March 31, 1995, Bio-Cardia owed BTG approximately \$3,660,000 for research and development performed by BTG on behalf of Bio-Cardia during 1994 and

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the three months ended March 31, 1995, as well as \$1,330,000 in reimbursement of previously incurred research and development expenses.

BTG agreed not to terminate the Technology License Agreement in the fiscal year ended December 31, 1995 as a result of the Bio-Cardia defaults in the fiscal year ended December 31, 1994 and has further agreed to fund a revised research and development budget for the fiscal year ended December 31, 1995 aggregating approximately \$6.2 million to the extent Bio-Cardia does not have

sufficient funds and to advance to Bio-Cardia amounts required by Bio-Cardia for general and administrative expenses. Bio-Cardia anticipates that it will receive \$900,000 in the fiscal year ended December 31, 1995 from third parties (of which \$400,000 was received in January 1995). However, because BTG has not at this time committed to fund any research and development for Bio-Cardia in the fiscal years ended December 31, 1996 or 1997 or to exercise the Stock Purchase Option, and, therefore, because there can be no assurance that Bio-Cardia will have the funds needed to fund research and development after December 31, 1995, Bio-Cardia, with BTG's consent, offered to the non-defaulting Bio-Cardia stockholders the ability to avoid having to make any additional payments to Bio-Cardia under their Investor Note (defined below) (the "Exchange Offer"). Under the terms of the Exchange Offer, Bio-Cardia offered to its non-defaulting stockholders the right to exchange each one share of its common stock, \$.01 par value per share (the "Bio-Cardia Common Stock"), and an unconditional release for (i) \$4,250 in cash (plus simple interest at the rate of 8% per annum on \$2,500 from the date the payment due Bio-Cardia on July 1, 1994 was made through May 18, 1995), (ii) a contingent right (a "Right") to receive certain of the Surrendered Warrants currently owned by Bio-Cardia and (iii) forgiveness of \$17,500 principal amount due under that certain promissory note, dated December 31, 1993 (the "Investor Note") delivered by each stockholder of Bio-Cardia to Bio-Cardia in partial payment for their Bio-Cardia Common Stock. On a per Unit basis, the Exchange Offer constituted an offer to exchange \$17,000 in cash (plus simple interest at the rate of 8% per annum on \$10,000 from the date the payment due Bio-Cardia on July 1, 1994 was made through May 18, 1995), four Rights and forgiveness of the remaining \$70,000 due under the Investor Note for each four shares of Bio-Cardia Common Stock and an unconditional release. The Rights provide that if by December 15, 1995 (i) the average daily price of BTG's common stock for any 20 trading days in any 30 consecutive trading day period does not exceed \$3.50, (ii) the best closing bid price of the Warrants does not exceed \$1.10 during any 20 trading days, and (iii) the exercise price of the Warrants was not reduced in connection with the sale of BTG, then Bio-Cardia will distribute to the Bio-Cardia stockholders that accepted the Exchange Offer some or all of the Surrendered Warrants such that, in the aggregate, the Warrants issued in the Private Placement, together with the Surrendered Warrants distributed by Bio-Cardia, have a value of \$16,500 per Unit as determined using the Black Scholes option pricing formula using an assumption of no dividends and a volatility of 70%.

On May 18, 1995 the Exchange Offer was consummated, and all non-defaulting Bio-Cardia stockholders, owning an aggregate of 157 Units, accepted the Exchange Offer. In connection with the Exchange Offer, BTG advanced to Bio-Cardia an aggregate of \$2,725,850, including \$1,920,000 received from Bio-Cardia in 1994 and the

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three months ended March 31, 1995 but not recognized as revenues. As a result, BTG will recognize an expense of approximately \$800,000 in the second quarter of 1995.

Upon consummation of the Exchange Offer, BTG amended the Warrants to provide that if BTG enters into a Sale Transaction (as hereinafter defined) at a price per share of BTG's common stock less than \$6.59 (adjusted for any stock splits, stock dividends or similar actions), the exercise price of the Warrants will be automatically reduced to a price per share of BTG's common stock equal to the difference between the Sale Price (as hereinafter defined) and \$1.10. For purposes hereof, the term "Sale Transaction" shall mean (i) the execution by BTG of a definitive merger agreement pursuant to which the outstanding shares of BTG's common stock will be converted into the right to receive cash, (ii) the execution by BTG of a definitive asset purchase agreement pursuant to which BTG proposes to sell substantially all its assets for cash, securities or a combination thereof and thereafter to distribute such consideration to BTG's stockholders, or (iii) a third party commences a cash tender offer for all of BTG's outstanding common stock. For purposes hereof, the term Sale Price shall mean (i) in the case of a merger, the cash offered per share of BTG's common stock, (ii) in the case of an asset sale, the fair market value of the consideration to be distributed to BTG's stockholders and (iii) in the case of a cash tender offer, the amount of cash offered.

#### B. United States Food and Drug Administration Approval Letter for Bio-Tropin(TM)

On May 25, 1995 BTG received an approval letter from the United States Food and Drug Administration approving the marketing of BTG's genetically engineered humane growth hormone product, Bio-Tropin(TM), for the long-term treatment of children with growth failure due to growth hormone deficiency. Plans to commence national distribution of Bio-Tropin(TM) are already well under way.

On May 30, 1995, Genentech Inc. filed a motion in the United States District Court for the Southern District of New York for a temporary restraining order and preliminary injunction seeking to prevent BTG from marketing and distributing its human growth hormone in the United States pending the outcome of its patent infringement action which it commenced in December 1994. The Court denied the motion for the temporary restraining order, and hearings on the motion for a preliminary injunction are scheduled to commence on June 14, 1995. Although BTG believes that it does not infringe any valid Genentech patent, there can be no assurance that a preliminary injunction will not be issued. If a preliminary injunction is issued and not stayed, BTG will be precluded from marketing and distributing its human growth hormone in the United States pending the final outcome of the patent infringement action.

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#### 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 thereunto duly authorized.

BIO-TECHNOLOGY GENERAL CORP.

Date: June 7, 1995

By /s/ SIM FASS

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Sim Fass  
President and Chief  
Executive Officer