MERIDIAN BIOSCIENCE INC
Form 8-K
June 20, 2001

**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) June 13, 2001

**MERIDIAN BIOSCIENCE, INC.**

(Exact name of registrant as specified in its charter)

| Ohio | 0-14902 | 31-0888197 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| 3471 River Hills Drive, Cincinnati, Ohio | 45244 |
|---|---|
| (Address of principal executive offices) | Zip Code |

Registrant's telephone number, including area code (513) 271-3700

(Former name or former address, if changed since last report.)

**Item 5. Other Events.**

On June 13, 2001, the Company received a Warning Letter from the Food and Drug Administration (FDA) which summarized and reiterated certain of the observations made by the FDA during their inspection completed in January 2001. The Company continues to implement its comprehensive plan submitted to the FDA to address the observations resulting from the inspection and has been proceeding with activities required to comply with the Quality Systems Regulations which govern the manufacture of in vitro diagnostics. A discussion of this matter is included in the Company s Quarterly Reports on Form 10-Q for the quarters ended December 31, 2000 and March 31, 2001.

During the second quarter, the Company incurred plan implementation costs in the amount of $1,019,000, primarily related to consulting fees. The Company expects to incur additional plan implementation costs during the next 6 to 9 months and such charges will be reflected in operating results as they are incurred. Plan implementation costs are expected to be approximately the same in the third quarter ending June 30, 2001, and lower in the fourth quarter ending September 30, 2001 compared to the amount incurred in the second quarter ending March 31, 2001.

Contingent upon the successful restructuring of operations and reduction of operating costs, the Company expects cash flows from operations to be sufficient to fund working capital needs, debt service, cash dividends and the stock buyback program for the remainder of the fiscal year. The Company is communicating with the FDA on a periodic basis to advise it on the progress of the plan implementation. At present, it is uncertain whether the Company s actions will be sufficient so that no further remedial action or enforcement action by the FDA will occur.

*[Remainder of page intentionally left blank; signature page follows.]*

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.

MERIDIAN BIOSCIENCE, INC.

By: /s/ Melissa A. Lueke
Melissa A. Lueke
Vice President, Chief Financial Officer and Secretary

Date: June 20, 2001