

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K/A

Current report filing [amend]

Filing Date: **1996-01-11** | Period of Report: **1995-08-11**
SEC Accession No. **0000950123-96-000074**

([HTML Version](#) on [secdatabase.com](#))

FILER

NU TECH BIO MED INC

CIK: **716778** | IRS No.: **251411971** | State of Incorpor.: **DE** | Fiscal Year End: **1231**
Type: **8-K/A** | Act: **34** | File No.: **000-11772** | Film No.: **96502692**
SIC: **8071** Medical laboratories

Mailing Address
55 ACCESS RD
WARWICK RI 02886

Business Address
55 ACCESS RD
WARWICK RI 02886
4017326520

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K/A

AMENDMENT NO. 1

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 11, 1995

NU-TECH BIO-MED, INC.

(Exact Name of Registrant as specified in charter)

Delaware	0-11772	25-1411971
----------	---------	------------

(State or other jurisdiction of incorporation) (Commission File Number) (IRS Employer Identification No.)

55 Access Road, Warwick, Rhode Island 02886

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (401) 732-6520

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

ITEM 5. OTHER EVENTS.

Listing of Common Stock on the Boston Stock Exchange

On August 11, 1995, the Common Stock of the Company was listed for trading on the Boston Stock Exchange under the symbol "NTB".

Clinical Trials Agreement

On August 14, 1995, Analytical Biosystems Corporation ("ABC"), a wholly-owned subsidiary of the Company, entered into an agreement (the "Clinical Trials Agreement") with a research institution (the "Institution") and certain individuals (the "Principal Investigators").

The Clinical Trials Agreement relates to the conduct and performance of certain proprietary research and development activities to be performed and/or coordinated on a work for hire basis on behalf of ABC by the Institution. The protocol for which the clinical trials are to be conducted is entitled "A Randomized Trial Comparing Empiric Therapy Versus Chemotherapy Directed by In Vitro Sensitivity Testing in Patients with Carcinoma of Unknown Primary Site". The conduct of the clinical trials is under the exclusive direction and control of the Institution and the Principal Investigators, who will coordinate the protocol with participating physicians, manage the project, collect and correlate data and provide ABC with a final report of the study in form and content generally accepted by medical and scientific publications and journals. The Principal Investigators are to direct the study in accordance with applicable Institution policies and are in accordance with generally accepted standards of good clinical practice, and all applicable local, state and federal laws and regulations governing the performance of clinical investigations.

The total approximate cost to ABC is not to exceed \$568,000. ABC may

terminate the Clinical Trials Agreement with the Institution at any time, in which case it is responsible for a payment to the Institution on the basis of the number of patients evaluated through the date of termination. The clinical trials being conducted are non-mandatory and are part of the Company's objective of obtaining correlated data with respect to evaluated patients with respect to whom treatment has been determined with the aid of the FCA. The cost of the funding of such clinical trials was an anticipated use of proceeds received from the Company's December 20, 1994 public offering. It is anticipated that the clinical trials will commence on or about October 16, 1995 and will be completed approximately one year thereafter.

2

3

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

(c) Exhibits.

<TABLE>
<CAPTION>

Exhibit No. -----	Description of Exhibit -----
<S> 10.1	<C> Redacted copy of Clinical Trials Agreement dated August 14, 1995. Portions of full unredacted copy of this exhibit is the subject of a confidential treatment request.

</TABLE>

SIGNATURE

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.

NU-TECH BIO-MED, INC.

By: /s/ J. Marvin Feigenbaum

J. Marvin Feigenbaum
Chairman of the Board,
President, Chief Executive
and Chief Financial Officer

Dated: January 10, 1996

3

4

EXHIBIT INDEX

Exhibit No. -----	Description -----	Page No. -----
EX-10.1	Redacted copy of Clinical Trials Agreement	

REDACTED COPY

Portions of the full unredacted copy of this agreement is the subject of a request for confidential treatment. Confidential portions have been omitted and have been filed separately with the Securities and Exchange Commission.

CLINICAL TRIALS AGREEMENT

This Agreement is entered into by and among (Information omitted and filed separately subject to a request for confidential treatment) ("Institution"), (Information omitted and filed separately subject to a request for confidential treatment) ("Principal Investigators") and Analytical Biosystems Corporation, a Rhode Island corporation with its principal office and place of business at 55 Access Road, Warwick, RI 02886-9911. ("Analytical Biosystems").

WITNESSETH:

WHEREAS, the research study contemplated by the Agreement (the "Study") is of mutual interest and benefit to the Institution and to Analytical Biosystems.

WHEREAS, the Protocol entitled "A Randomized Trial Comparing Empiric Therapy versus Chemotherapy Directed by In Vitro Sensitivity Testing in Patients with Carcinoma of Unknown Primary Site" dated July 14, 1995, which is attached hereto as Exhibit A and incorporated herein by reference, including any future amendments or revisions thereto ("Protocol"), which will guide the performance of the Agreement, has been accepted by Analytical Biosystems, and the Institution and the Principal Investigators each warrant that they are fully able to perform the Study in a professional, competent manner with strict adherence to its terms and each of them will utilize its best efforts to do so.

The study shall be considered proprietary research and development activities of Analytical Biosystems Corporation and undertaken and performed on a work for hire basis on its behalf by Institution. The services of the Principal Investigators are included in the fee to Institution as provided in

Section 4 of this agreement.

NOW THEREFORE, the parties hereto agree as follows:

1. SCOPE OF WORK

The Principal Investigators and the Institution shall carry out the Study set forth in the Protocol in accordance with this Agreement. The Principal Investigators and the Institution will recruit and coordinate the sites required to complete the study according to the proposed time schedule. The Institution and the Principal Investigators also agree to provide the following services for this study:

- 1) Biostatistical/Medical Writing
 - a. Protocol design and writing
 - b. Creation of case report forms
 - c. Study analysis
 - d. Manuscript preparation
- 2) Regulatory Support
 - a. IRB coordination
 - b. Reporting of Serious Adverse Events to IRB(s)
- 3) Project Management
- 4) Study Coordination
 - a. Tissue sample shipping

1

3

- b. Notification to enrolling physicians of FCA results and chemotherapy selection

- 5) Data collection/completion of Case Report Forms
 - a. Centralized data collection and completion of CRFs
 - b. Coordination of obtaining original scans/films for central review when necessary
 - c. Coordination of collection of Quality of Life assessments on-study and through long-term follow-up period when required
 - d. Reporting of Serious Adverse Events directly to Analytical Biosystems
 - e. Weekly accrual reports to Analytical Biosystems

2. PRINCIPAL INVESTIGATORS

The Principal Investigators will be responsible for the direction of the Study in accordance with applicable Institution policies, which Institution

warrants and represents are not inconsistent with the terms of this Agreement, the Protocol, generally accepted standards of good clinical practice, and all applicable local, state, and federal laws and regulations governing the performance of clinical investigations. If, for any reason, the above named individuals are unwilling or unstable to continue to serve as Principal Investigators, Institution and Analytical Biosystems shall appoint a mutually acceptable successor Principal Investigator. If a mutually acceptable successor is not available, this Agreement shall be terminated as provided in Section 15.

3. PERFORMANCE PERIOD AND ENROLLMENT FOR PATIENTS

It is anticipated that the Study will commence on or about October 16, 1995 and the Study will be completed in or about October 16, 1996, unless otherwise terminated in accordance with Section 15. The effective period may be extended by mutual agreement as provided in Section 16. It is agreed that the Study will involve the enrollment of a maximum of (Information Omitted And Filed Separately Subject To A Request For Confidential Treatment) evaluable patients meeting all Protocol eligibility requirements (the "Evaluable Patients") unless Analytical Biosystems shall request, in writing, that additional Evaluable Patients (the "Additional Patients" and together with the Evaluable Patients, the "Patient") be enrolled in the Study. The Institution agrees to provide to Analytical Biosystems insurance information for each patient, along with an assignment of benefits to Analytical Biosystems. Analytical Biosystems will not bill patients for non-reimbursed tests performed by Analytical Biosystems during the course of this study. In no event shall Analytical Biosystems be obligated to pay any sums for tests performed on Patients who do not meet all Protocol eligibility criteria or for Additional Patients who are enrolled in the Study without Analytical Biosystems' prior written approval.

4. COST AND PAYMENT

A. As consideration for performance under the terms of this Agreement, Analytical Biosystems shall provide financial support for the Study in a total amount, including overhead, not to exceed five hundred sixty-eight thousand dollars (\$568,000.00 - (Information Omitted And Filed Separately Subject To A Request For Confidential Treatment) (the "Grant Amount"), payable as set forth in Schedule A attached hereto and incorporated herein by reference.

4

B. Checks will be made payable to: " "

Checks will be sent to:

Attention: (Information Omitted and Filed Separately Pursuant To A Confidentiality Request)

Institution Tax Identification Number: (Information Omitted and Filed Separately Pursuant To A Confidentiality Request)

(Information Omitted and Filed Separately Subject To A Request For Confidential Treatment)

There will be no other costs to Analytical Biosystems Corporation.

5. ACCESS

Analytical Biosystems will have access to all information resulting from the Study and shall have the unrestricted royalty-free right to utilize the information. Data and information will be made available in hard copy and machine readable disk to Analytical Biosystems. Data or information will not be disclosed or made available to any other company which performs any assay or test on solid mass tumors or for use in article or publication which compares the fluorescent cytoprint assay (FCA) to any other test without Analytical Biosystems' written consent.

6. CONFIDENTIAL INFORMATION

A. For a period of five (5) years after termination of this Agreement, the Institution and the Principal Investigators shall not disclose or use for any purpose other than performance of the study, any and all trade secrets, know-how, privileged records or other confidential or proprietary information and data, both technical and nontechnical (collectively "Information"), disclosed to the Institution pursuant to this agreement. The obligation of non-disclosure shall not apply to the following:

- (1) Information at or after such time that it is or becomes publicly available through no fault of the Institution or the Principal Investigators;
- (2) Information that is already independently known to the Institution or the Principal Investigators as evidenced by their prior written records;
- (3) Information at or after such time that it is disclosed to the Institution or the Principal Investigators on a non-confidential basis by a third party with the legal right to do so; or
- (4) Information developed by the Institution or the Principal Investigators without the use of Analytical Biosystems'

- B. In the event Analytical Biosystems shall come into contact with Patient's medical records. Analytical Biosystems shall hold in confidence the identity of the Patient and shall comply with all applicable law(s) regarding the confidentiality of such records.

7. PUBLICATIONS

The Institution shall have the right to publish the results of the Study. Prior to submission for publication or presentation, the Institution and/or the Principal Investigators will provide Analytical Biosystems thirty (30) days to review any manuscript, and five (5) days to review any poster presentation, abstract or other written or oral material Analytical Biosystems, at its option, may be cited as a sponsor on any publication resulting from the Study. In addition, if requested in writing and with reasonable justification, the Institution and/or the Principal Investigators will withhold such publication an additional sixty (60) days to allow for filing a patent application or taking such other measures as Analytical Biosystems deems appropriate to establish and preserve its proprietary rights. Analytical Biosystems reserves the right to remove any information that is confidential to Analytical Biosystems from any proposed publication. Analytical Biosystems shall have the right to publish or disseminate any information utilizing any portion of the data or information obtained from the Study and may utilize or quote any portion of any article or report prepared by the Institution or Principal Investigators with respect to the Study. In all cases, any article or report or summary of the Study shall not be published without Analytical Biosystems' prior written consent.

8. REPORTS

The Principal Investigators agree to provide Analytical Biosystems with a weekly investigator's report including patient accrual and patient tracking. The Principal Investigators shall notify Analytical Biosystems promptly in writing of any severe and life threatening or unexpected adverse reaction to Analytical Biosystems products used during the Study. A final draft of the manuscript resulting from the Study will serve as a final report; however, in the event a manuscript is not forthcoming, a final report will be submitted, including a summary of Study accrual, results of all data analyses, and final conclusions.

9. USE OF THE INSTITUTION'S OR ANALYTICAL BIOSYSTEMS' NAME (ADVERTISING)

- A. The Institution and Analytical Biosystems will obtain prior written permission from each other before using the name, symbols and/or marks of the other in any form of publicity in connection with the Study. This shall not include legally required disclosure by the Institution or Analytical Biosystems that identifies the existence of the Agreement.
- B. Analytical Biosystems will not use, nor authorize others to use, the name, symbols, or marks of the Institution in any advertising or publicity material or make any form of representation or statement in relation to the Study which would constitute an expressed or implied endorsement by the Institution of any commercial product or service without prior written approval from the Institution.
- C. Neither Analytical Biosystems' name of the FCA will be identified in any article, report, publication or summary comparing the FCA to any other technology, except on Analytical Biosystems' written consent. Analytical Biosystems shall have the right to distribute and disseminate and utilize any study analysis or report or summary provided by Institution and to identify the Institution and the Principal Investigators.

4

6

10. NO TRANSFER OF PROPRIETARY RIGHTS NOT SPECIFIED

It is agreed that neither Analytical Biosystems, the Principal Investigators nor the Institution transfers to the other by operation of this Agreement any patent right, copyright right, or other proprietary right of any party, except as specifically set forth herein.

11. CHANGES TO THE PROTOCOL

If at a future date changes in the Protocol appear desirable, such changes may be made only upon prior notification and approval of Analytical Biosystems. If such changes affect the cost of the Study, the Institution will submit to Analytical Biosystems a written estimate for approval. If in the course of performing the Agreement, however, generally accepted standards of clinical study and medical practice relating to the safety of Patients require a deviation from the Protocol, such standards will be followed. In such case, the party aware of the need for a deviation will immediately inform the other in writing of the facts causing such deviations as soon as the facts are known to the party.

12. MATERIAL

Analytical Biosystems agrees to provide transport materials and instructions for shipment, technical assistance, and performance of in vitro assays.

13. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and the Principal Investigators shall perform the Study in conformance with the Protocol, instruction provided by Analytical Biosystems, good clinical practice guidelines, state and federal laws, guidelines of the Institution, and patient consent requirements.

14. TERMINATION

A. This Agreement may be terminated:

- (1) by the Institution upon thirty (30) days prior written notice;
- (2) by Analytical Biosystems upon written notice;
- (3) by either the Institution or Analytical Biosystems if the Principal Investigators are unwilling or unable to continue to serve and a successor acceptable to both the Institution and Analytical Biosystems is not available; or
- (4) upon the occurrence of an event qualifying as a termination event as described in the Protocol.

B. In the event this Agreement is terminated pursuant to Section 14.A., Analytical Biosystems shall be responsible for funding the Study to the date of termination, such funds to be prorated on the basis of the total financial support for the Study.

C. In the event the Institution shall terminate this Agreement prior to accruing (Information Omitted And Filed Separately Subject To A Request For Confidential Treatment) patients, the Institution shall return to Analytical Biosystems a rebate pro-rated at the rate of \$ (Information Omitted And Filed Separately Subject To A Request For Confidential Treatment) per patient.

D. Upon the effective date of termination, there shall be an accounting conducted by the Institution, subject to verification by Analytical Biosystems. Within thirty (30) days after receipt of adequate documentation Analytical Biosystems will make payment to the Institution for all services properly rendered by the Institution until the date of termination not yet paid for.

- E. Immediately upon receipt of a notice of termination, the Principal Investigators shall stop enrolling Patients into the Protocol and shall cease conducting procedures on Patients already enrolled in the Protocol as directed by Analytical Biosystems, to the extent medically permissible and appropriate.
- F. Termination of the Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Section 4,6,7,8,9,10,12,13,14 and 20 survive the termination or expiration of this Agreement.
- G. If this Agreement is terminated prior to completion, Institution shall furnish Analytical Biosystems an acceptable Investigator's report for the Study.

15. AMENDMENTS

This Agreement may only be extended, renewed or otherwise amended by the mutual written consent of parties hereto. Any amendments to the protocol must be approved by the Institutions' IRB and Analytical Biosystems.

16. ENTIRE AGREEMENT

This Agreement represents the entire understanding of the parties with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern.

17. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

18. ASSIGNMENT

Neither the Institution nor the Principal Investigators may assign, code or transfer any of their rights or obligations under this Agreement without the prior written consent of Analytical Biosystems.

19. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

20. NOTICE

Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by Registered or Certified Mail, postage prepaid, return receipt requested, or received by facsimile and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

If to Analytical Biosystems:

If to Institutions and /or Principal Investigators:

Analytical Biosystems
55 Access Road

(Information Omitted And
Filed Separately Subject
To A Request For
Confidential Treatment)

Warwick, RI 02886-9911

Copies to:

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate by proper persons whereunto duly authorized.

ANALYTICAL BIOSYSTEMS:

INSTITUTION:

By /s/ J. Marvin Feigenbaum

(signature)

By (Information Omitted And
Filed Separately Pursuant
To A Confidentiality Request)

(signature)

J. Marvin Feigenbaum

(Print or type name)

Principal Investigator

PRESIDENT

(Information Omitted And Filed Separately Pursuant To A Confidentiality Request)

(Title)

8/14/95

(Date) 8/7/95

(Date)

(Information Omitted And Filed Separately Subject to A Request For Confidential Treatment)

8

10

95-80

A PROSPECTIVE RANDOMIZED TRIAL COMPARING
OMITTED IN ITS ENTIRETY

SCHEDULE A

The Grant Amount shall be payable as follows: (Information Omitted And Filed Separately Subject To A Request For Confidential Treatment)

9

11

95-80

A PROSPECTIVE RANDOMIZED TRIAL COMPARING
EMPIRIC THERAPY VERSUS CHEMOTHERAPY DIRECTED BY
IN VITRO SENSITIVITY TESTING IN PATIENTS WITH
CARCINOMA OF UNKNOWN PRIMARY SITE

OMITTED IN ITS ENTIRETY AND FILED SEPERATELY
SUBJECT TO A REQUEST FOR CONFIDENTAIL TREATMENT