## SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-Q

### (X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES **EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 1995, or

()	TRANSITION REPORT PURSUANT	TO SECTION	13 OR	15(d) OF	THE S	ECURI	TIES
	EXCHANGE ACT OF 1934						

For the transition period from	to
Commission file num	nber 0-17272

#### TECHNE CORPORATION

(Exact name of registrant as specified in its charter)

MINNESOTA 41-1427402 (State or other jurisdiction (I.R.S. Employer of incorporation or organization) Identification No.)

614 MCKINLEY PLACE N.E.

(612) 379-8854

55413 (Registrant's telephone number, MINNEAPOLIS, MN (Address of principal (Zip Code) including area code)

executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes (X) No ()

At May 1, 1995, 9,395,346 shares of the Company's Common Stock (par value \$.01) were outstanding.

PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

## TECHNE CORPORATION & SUBSIDIARIES CONSOLIDATED BALANCE SHEETS (Unaudited)

<TABLE> <CAPTION> ASSETS

CIN HOIV						
ASSETS	3/31/95		6/3	6/30/94		
-						
<s></s>	<c></c>	<(	C>			
Cash and cash equivalents		\$ 5,227	7,011	\$ 5,878,	346	
Short-term investments		9,254,3	368	4,987,70	1	
Accounts receivable (net)		7,174,	629	6,592,96	51	
Inventories	2,90	3,361	2,5	513,561		
Deferred income taxes		749,0	00	764,000		
Other current assets		367,526	)	198,898		
Total current assets	25	,675,89	5	20,935,467		
Deferred income taxes		466,0	00	385,000		
Prepaid license fee	(	507,200		-		
Fixed assets (net)	4,1	134,737	4	,357,108		
Intangible assets (net)		895,205	5	1,127,946		
-						

73.578

#### LIABILITIES & EQUITY

\$ 1,453,859 \$ 1,226,864 Trade accounts payable Salary and related accruals 1,177,405 1,140,737 Other payables 592,225 624,033 Income taxes payable 218,107 536,906 Current portion of long-term debt 29,875

Total current liabilities 3,441,596 3,558,415

Deferred rent 390,500 292,400

Common stock, par value \$.01 per share; authorized 50,000,000; issued and outstanding 9,395,346

and 9,329,151, respectively 93,953 93,292 Additional paid-in capital 8,404,412 8,110,798 Retained earnings 19,257,027 14,677,038 Accumulated foreign currency translation

adjustments 191,549 Total stockholders' equity 27,946,941 22,954,706

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY \$31,779,037 \$26,805,521

</TABLE>

See notes to unaudited Financial Statements.

## TECHNE CORPORATION & SUBSIDIARIES CONSOLIDATED STATEMENTS OF EARNINGS (Unaudited)

<TABLE> <CAPTION>

<S> Sales

QUARTER ENDED NINE MONTHS ENDED \_\_\_\_\_\_ 3/31/95 3/31/94 3/31/95 3/31/94 <C> <C> <C> <C> \$12,576,041 \$10,963,432 \$34,897,468 \$29,431,032 Cost of sales 5,003,971 4,550,513 13,905,344 12,671,550

\_\_\_\_\_ 7,572,070 6,412,919 20,992,124 16,759,482 Gross margin

Operating expenses:

Selling, gen. and admin. 2,888,020 2,468,472 8,233,788 6,865,740 Research and development 2,130,800 1,752,288 6,199,942 4,702,373 Amortization expense 58,877 143,044 232,741 429,131 Interest expense 1,543 2,681 7,521 4,484 (145,974) (44,914) (320,981) (123,011) Interest income

4,933,266 4,321,571 14,353,011 11,878,717

Earnings before

income taxes 2,638,804 2,091,348 6,639,113 4,880,765 855,000 630,000 2,041,000 1,495,000 Income taxes ----- -----

NET EARNINGS \$ 1,783,804 \$ 1,461,348 \$ 4,598,113 \$ 3,385,765

EARNINGS PER COMMON AND

COMMON EQUIVALENT SHARE \$ 0.19 \$ 0.15 \$ 0.48 \$

COMMON AND COMMON **EQUIVALENT SHARES** 

OUTSTANDING 9,534,610 9,488,578 9,504,720 9,522,971

## TECHNE CORPORATION & SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

<TABLE> <CAPTION>

<S>

NINE MONTHS ENDED

3/31/95 3/31/94

<C> <C>

CASH FLOWS FROM OPERATING ACTIVITIES:

Net earnings \$4,598,113 \$3,385,765

Adjustments to reconcile net earnings

to net cash provided by operating activities:

1,213,051 1,353,394 Depreciation and amortization Deferred income taxes (66,000) (471,000) Deferred rent 98,100 110,700 Other (24,546)

Change in current assets and current liabilities, net of acquisition:

(Increase) decrease in:

Accounts receivable (495,120) (398,839) Inventories (357,294) (162,410) Other current assets (163,397) (65,004)

Increase (decrease) in:

Trade account/other payables 161,994 247,966 Salary and related accruals 34,226 208,339 (225,259) 333,000 Income taxes payable

NET CASH PROVIDED BY OPERATING ACTIVITIES

4,773,868 4,541,911

CASH FLOWS FROM INVESTING ACTIVITIES:

Acquisition of subsidiary, net of cash acquired - (1,788,558) Purchase of short-term investments (8,625,970) (3,448,313) Proceeds from sale of short-term investments 4,399,303 2,930,000

Additions to fixed assets (723,841) (1,056,979)

Increase in long-term prepaid license fee (607,200)

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NET CASH USED BY INVESTING ACTIVITIES (5,557,708) (3,363,850)

CASH FLOWS FROM FINANCING ACTIVITIES:

Payments on long term debt (29,875)(26,776)Issuance of common stock 179,151 27.011

NET CASH PROVIDED BY FINANCING ACTIVITIES 149,276 235

EFFECT OF EXCHANGE RATE CHANGES ON CASH (16,771) (10,128)

NET CHANGE IN CASH AND EQUIVALENTS (651,335) 1,168,168 CASH AND EQUIVALENTS AT BEGINNING OF PERIOD 5,878,346 3,979,114

CASH AND EQUIVALENTS AT END OF PERIOD

\$5,227,011 \$5,147,282

</TABLE>

See notes to unaudited Financial Statements.

TECHNE CORPORATION & SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

## A. BASIS OF PRESENTATION:

The unaudited Consolidated Financial Statements have been prepared in accordance with generally accepted accounting principles and with instructions to Form 10-Q and Article 10 of Regulation S-X. The accompanying unaudited Consolidated Financial Statements reflect all adjustments which are, in the opinion of management, necessary to a fair presentation of the results for the interim periods presented. All such adjustments are of a normal recurring nature.

A summary of significant accounting policies followed by the Company is

detailed in the Annual Report to Shareholders for Fiscal 1994. The Company follows these policies in preparation of the interim Financial Statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. It is suggested that the Financial Statements be read in conjunction with the Company's Financial Statements and Notes thereto for the fiscal year ended June 30, 1994 included in the Company's Annual Report to Shareholders for Fiscal 1994.

Certain Balance Sheet captions appearing in this interim report are as follows:

<TABLE> <CAPTION>

<S>

3/31/95 6/30/94 <C> <C>

ACCOUNTS RECEIVABLE

Accounts receivable \$7,304,629 \$6,745,965 Less reserve for bad debts 130,000 153,000 \$ 7,304,629 \$ 6,745,961

NET ACCOUNTS RECEIVABLE \$ 7,174,629 \$ 6,592,961

INVENTORIES

Raw materials \$ 1,588,073 \$ 1,352,031 Work in process 74,987 67,025 120,138 104,537 Supplies Finished goods 1,120,163 989,968

TOTAL INVENTORIES

\$ 2,903,361 \$ 2,513,561

FIXED ASSETS

Laboratory equipment
Office equipment \$ 6,393,824 \$ 5,955,057 1,999,364 1,770,129 Office equipment 1,712,369 1,586,336 Leasehold improvements

10,105,557 9,311,522

Less accumulated depreciation and

5,970,820 4,954,414 amortization

NET FIXED ASSETS \$ 4,134,737 \$ 4,357,108

INTANGIBLE ASSETS

Customer list \$ 1,010,000 \$ 1,010,000 Technology licensing agreements 500,000 500,000

Goodwill 1,225,547 1,225,547

2,735,547 2,735,547

Less accumulated amortization 1,840,342 1,607,601

NET INTANGIBLE ASSETS \$ 895,205 \$ 1,127,946

</TABLE>

#### B. EARNINGS PER SHARE:

Shares used in the earnings per share computations are as follows:

<TABLE>

<CAPTION>

NINE MONTHS ENDED

3/31/95 3/31/94 <C> <C>

Primary:

<S>

Weighted average number of common shares 9,357,473 9,311,115 Dilutive effect of stock options and warrants 147,247 211,856

Average common and common equivalent shares

outstanding 9,504,720 9,522,971

Fully diluted:

Weighted average number of common shares

9,357,473 9,311,115

Dilutive effect of stock options and warrants 160,863 218,155

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Average common and common equivalent shares outstanding 9,518,336 9,529,270

</TABLE>

Fully diluted earnings per share are not separately reported since the effect of dilution is less than three percent.

# ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Results of Operations Quarter And Nine Months Ended March 31, 1995 vs. Quarter And Nine Months Ended March 31, 1994

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#### Company Structure

Techne Corporation has two operating subsidiaries: Research and Diagnostic Systems, Inc. (R&D Systems) located in Minneapolis, Minnesota and R&D Systems Europe Ltd. (R&D Europe) located in Abingdon, England. R&D Systems has two divisions: Biotechnology and Hematology. The Biotechnology Division manufactures purified cytokines (proteins), antibodies and assay kits which are sold primarily to biomedical researchers and clinical research laboratories. The Hematology Division develops and manufactures whole blood hematology controls and calibrators which are sold to hospital and clinical laboratories to check the performance of their hematology instruments to assure the accuracy of hematology test results. R&D Europe was acquired by the Company effective July 1, 1993 and is the distributor for R&D Systems' biotechnology products in Europe. R&D Europe also develops and manufactures its own line of biotechnology products and distributes products for several other biotechnology companies. In fiscal 1992, a foreign sales corporation, Techne Export Inc., was incorporated as a subsidiary of the Company.

## Net Sales

Net sales for the quarter ended March 31, 1995 were \$12,576,041, an increase of \$1,612,609 (15%) from the quarter ended March 31, 1994. Sales for the nine months ended March 31, 1995 increased \$5,466,436 (19%) from \$29,431,032 to \$34,897,468. R&D Europe sales for the quarter and nine months ended March 31, 1995 increased \$791,343 (25%) and \$2,451,427 (31%), respectively, from the quarter and nine months ended March 31, 1994. Approximately 60% of R&D Europe sales were from the distribution of R&D Systems' products. R&D Systems sales, net of intercompany sales to R&D Europe, increased \$821,266 (10%) and \$3,015,009 (14%) for the quarter and nine months ended March 31, 1995, respectively.

Approximately 54% and 64% of the increase in consolidated sales for the quarter and nine months, respectively, was due to the increase in sales of R&D Systems' immunoassay (Quantikine) kits. In fiscal 1990, the Biotechnology Division of R&D Systems released its first immunoassay kits and currently there are 49 kits on the market. Sales of these kits by R&D Systems and R&D Europe for the quarter and nine months ended March 31, 1995 were \$4,904,692 and \$13,667,265 compared to \$4,026,531 and \$10,187,496 for the quarter and nine months ended March 31, 1994.

Approximately 17% and 11% of the increase in consolidated sales for the quarter and nine months, respectively, was due to increased sales of other R&D Systems' product by R&D Europe. In addition, approximately 12% and 10% of the increase in consolidated sales for the quarter and nine months ended March 31, 1995, was from an increase in the distribution of products from non-affiliated companies by R&D Europe. Sales of R&D Systems' Hematology Division for the quarter increased \$104,493, while sales for the nine months ended March 31, 1995 decreased \$66,907, due mainly to competitive factors.

Fourth quarter sales are expected to be slightly less than third quarter, due to the annual slow down of European sales during the summer months.

#### **Gross Margins**

Gross margins, as a percentage of sales, increased from the prior year. Margins for the third quarter of fiscal 1995 were 60.2% compared to 58.5% for the same quarter in fiscal 1994. Margins for the nine months ended March 31, 1995 were 60.2% compared to 56.9% for the same period in fiscal 1994.

The increase for the quarter was mainly due to an increase in R&D Europe gross margins. R&D Europe gross margins were 48.2% compared to 41.2% for the quarter ended March 31, 1994. This increase is due to favorable exchange rate variances on purchases from R&D Systems as a result of weakening dollar. R&D Europe gross margins for the nine months ended March 31, 1995 also increased from 44.3% to 47.5%. Additionally, gross margins for the nine months for R&D Systems' Biotechnology Division increased slightly from 65.3% to 66.3% and gross margins for R&D Systems' Hematology Division also increased slightly from 33.2% to 34.5%.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses increased \$419,548 (17%) from the third quarter of fiscal 1994 to the third quarter of fiscal 1995. These expenses also increased \$1,368,048 (20%) for the first nine months of fiscal 1995. Approximately \$241,000 and \$568,000 of the increase in selling, general and administrative expenses for the quarter and nine months was due to wages and benefits related to Biotechnology and Hematology Division administration and sales staff added since the prior year. Additionally, \$132,000 and \$274,000 of the increase in selling, general and administrative expenses for the quarter and nine months was a result of Biotechnology Division consulting expenses related to computer, personnel and strategic planning. In addition, approximately \$306,000 of the increase for the nine months in selling, general and administrative expenses was due to marketing costs related to additional advertising, promotional materials and catalog printing costs incurred by R&D Systems' Biotechnology Division and R&D Europe.

## Research and Development Expenses

Research and development expenses increased \$378,512 (22%) for the quarter ended March 31, 1995 and \$1,497,569 (32%) for the nine months ended March 31, 1995. R&D Europe and R&D Systems' research and development expenses increased \$85,805 and \$292,707, respectively for the quarter ended March 31, 1995 and \$354,096 and \$1,143,473, respectively, for the nine months ended March 31, 1995. The increases related to products currently under development, several of which were released in the third quarter of fiscal 1995. The products currently under development, several of which will be released in the fourth quarter, include both biotechnology and hematology products.

#### Net Earnings

Earnings before income taxes increased \$547,456 from \$2,091,348 in the third quarter of fiscal 1994 to \$2,638,804 in the third quarter of fiscal 1995. Earnings before income taxes for the nine months increased \$1,758,348 from \$4,880,765 to \$6,639,113. The increase in earnings before income taxes for the quarter ended March 31, 1995 is mainly due to an increase in R&D Europe earnings of \$519,045 as a result of increased sales and gross margin percentage. The increase in earnings before taxes for the nine months is mainly the result of an increase in Biotechnology Division earnings before tax of \$1,088,846 and an increase in R&D Europe earnings before tax of \$959,087, partially offset by a decrease in Hematology Division earnings for the nine months. The increases in Biotechnology Division and R&D Europe results were due to increases in sales and gross margins, partially offset by higher expenses. The decrease in Hematology earnings from the prior year was the result of a slight decrease in sales and increased expenses.

Income taxes for the quarter and nine months ended March 31, 1995 were

provided at a rate of approximately 32% and 31% of consolidated pretax earnings, respectively, compared to 30% and 31% for comparable periods in fiscal 1994. U.S. federal and state taxes have been reduced as a result of the credit for research and development expenditures and the benefit of the foreign sales corporation. Foreign income taxes have been provided at a rate of 33% which approximates the tax rate in the United Kingdom.

## Impact of Inflation

The majority of the Company's increase in sales has resulted from an increase in units shipped and the introduction of new products, not from price increases. The Company believes that, to date, inflation has had no appreciable effect on the Company's operations.

## Liquidity and Capital Resources

At March 31, 1995, cash and cash equivalents and short-term investments were \$14,481,379 compared to \$10,866,047 at June 30, 1994. The Company is accumulating cash and short-term investments for future expansion purposes. The Company believes it can meet its future cash, working capital requirements and capital additions through currently available funds and cash generated from operations. The Company has an unsecured line of credit of \$750,000. The interest rate on the line of credit is at prime.

## Cash Flows From Operating Activities

The Company generated \$4,166,668 from operating activities in the first nine months of fiscal 1995 compared to \$4,541,911 for the first nine months of fiscal 1994. The increase was the result of increased net earnings.

## Cash Flows From Investing Activities

During the nine months ended March 31, 1995 and 1994, respectively, the Company invested a net \$4,226,664 and \$518,313 in short-term investments. The Company's investment policy is to place excess cash in short-term certificates of deposit and low risk tax-exempt government bonds. The objective of this policy is to obtain the highest possible return with the lowest risk, while keeping the funds accessible.

In July, 1993 the Company acquired its R&D Europe subsidiary for \$2,300,000 cash plus a 5 year warrant for 50,000 shares of Company common stock. Additional costs associated with the acquisition were \$87,241. Cash acquired in the transaction was \$598,683, for a net cash outflow of \$1,788,558. Cash used to fund the acquisition was obtained from cash and cash equivalents and short-term investments on hand at June 30, 1993.

Capital additions were \$723,841 for the first nine months of fiscal 1995 compared to \$1,056,979 for the first nine months of fiscal 1994. The major additions in both periods were for laboratory and computer equipment. Total capital additions of leasehold improvements, laboratory and computer equipment planned for the remainder of fiscal 1995 are expected to cost approximately \$300,000 and are expected to be financed through currently available cash and cash generated from operations.

During the nine months ended March 31, 1995 the Company made a \$1,000,000 prepayment to Cistron Biotechnology, Inc. under a License and Supply Agreement. The agreement grants the Company a sublicense to sell recombinant interleukin-1 beta protein and interleukin-1 beta precursor assays made by Cistron to the research market worldwide. The \$1,000,000 prepayment is being amortized over five years. The Company and Cistron also signed a Research and Development Agreement under which the Company will support Cistron's development of an interleukin-1 beta assay kit for the detection and monitoring of periodontal disease in humans, in exchange for co-exclusive marketing rights to such product. Payments under the research agreement will be made in 10 quarterly installments of \$100,000 beginning July 1, 1995 and are expected to be financed through cash generated from operations.

#### Cash Flows From Financing Activities

Cash of \$29,875 and \$26,776 was used to reduce long-term borrowings in the first nine months of fiscal 1995 and 1994, respectively. Cash of \$179,151 and \$27,011 was received during the nine months ended March 31, 1995 and 1994, respectively, for the exercise of options for 59,604 and 11,853 shares of common stock. During the first nine months of fiscal 1995 and 1994, options for 9,091 and 13,940 shares of common stock, respectively, were exercised in noncash transactions by the surrender of 2,500 and 2,144 shares of the Company's common stock with market values of \$25,000 and \$25,192., respectively.

During the fourth quarter of fiscal 1995, the Company plans to purchase approximately \$400,000 of Techne common stock for contribution to the Company's Stock Bonus Plan. In addition, subject to market conditions and share prices, the Company plans to purchase up to \$5,000,000 in Techne common stock over the next twelve months. Any such purchases will be funded from currently available cash and short-term investments. The Company has never paid dividends and has no plans to do so in fiscal 1995.

PART II - OTHER INFORMATION

ITEM 1 - LEGAL PROCEEDINGS
None

ITEM 2 - CHANGES IN SECURITIES
None

ITEM 3 - DEFAULTS UPON SENIOR SECURITIES
None

ITEM 4 - SUBMISSION OF MATTERS TO VOTE OF SHAREHOLDERS
None

ITEM 5 - OTHER INFORMATION
None

ITEM 6 - EXHIBITS AND REPORTS ON FORM 8-K

A. EXHIBITS

See exhibit index immediately following signature page.

B. REPORTS ON FORM 8-K

None

**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 thereunto duly authorized.

# TECHNE CORPORATION (Company)

Date: May 10, 1995 /s/Thomas E. Oland

Thomas E. Oland President, Chief Executive and Financial Officer

EXHIBIT INDEX TO FORM 10-Q

#### TECHNE CORPORATION

Exhibit Number I

Description

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- 10.1 Agreement dated March 16, 1995 between the Company and Roger C. Lucas, Ph.D. relating to termination of certain agreements and redefining relationship.
- 10.2 Non-Enforcement of Patent Rights dated March 15, 1995 by New England Medical Center Hospitals, Inc., Tufts University, Massachusetts Institute of Technology and Wellesley College in favor of Research and Diagnostic Systems, Inc. ("R & D").
- 10.3 Non-Enforcement of Patent Rights dated March 21, 1995 by Cistron Biotechnology, Inc. ("Cistron") in favor of R & D.
- 10.4 License and Supply Agreement dated March 21, 1995 between Cistron and R & D.
- 10.5 Research and Development Agreement dated April 10, 1995 between Cistron and R & D.
- 27 Financial Data Schedule

#### **AGREEMENT**

Date: March 16, 1995

Parties: Techne Corporation, a Minnesota corporation 614 McKinley Place N.E. Minneapolis, Minnesota 55413

> Roger C. Lucas, Ph.D. 614 McKinley Place N.E. Minneapolis, Minnesota 55413

#### Recitals:

- A. Techne Corporation ("Techne") and Dr. Lucas are parties to an Employment Agreement dated April 30, 1993 (the "Employment Agreement") and an Employee Agreement with respect to Inventions, Proprietary Information, and Unfair Competition dated May 28, 1981 (the "Confidentiality Agreement").
- B. Pursuant to the Employment Agreement, Dr. Lucas is currently Executive Vice President, Chief Scientific Officer, Secretary and Senior Executive Officer, Biotechnology Division of Techne and Research and Diagnostic Systems, Inc. ("R&D"), a subsidiary of Techne. As used herein, the term "the Company" shall include Techne and its subsidiaries, including R&D and R&D Systems Europe, Ltd. (R&D Europe"), unless specifically provided otherwise. Dr. Lucas is also a member of the Board of Directors of Techne and of R&D.
- C. The Company and Dr. Lucas desire to terminate the Employment Agreement, amend the Confidentiality Agreement and redefine their relationship pursuant to the terms of this Agreement.

## Agreements:

- 1. Termination of Employment Agreement. Effective as of the date of this Agreement, the Employment Agreement is terminated and of no further force and effect, except as provided herein.
- 2. Resignations. Effective as of the close of business on June 30, 1995, Dr. Lucas will resign (i) as an officer of Techne, R&D and R&D Europe and (ii) as a director of R&D and R&D Europe.
- 3. Continued Engagements. Dr. Lucas will continue to serve as a member of the Board of Directors of Techne, subject to his nomination by the board and election by the shareholders of Techne, at least until the annual meeting of the shareholders of Techne held after the close of fiscal 1997. During the two-year period ending June 30, 1997 (the "Employment Period"), Dr. Lucas will also be an employee of the Company, obligated to perform such services and duties as reasonably requested by the Board of Directors of the Company from time to time; provided, however, that in no event shall Dr. Lucas be required to devote more than 10 hours per calendar quarter as an employee of the Company. During the Employment Period, in connection with the performance of his duties hereunder, Dr. Lucas may use office space and secretarial support services of the Company on an "as-needed" basis.

### 4. Compensation.

- a. In consideration for his employment with the Company during the Employment Period, Dr. Lucas shall be entitled to receive the annual base salary currently being paid to him. During the Employment Period, Dr. Lucas will not be entitled to any other compensation as a director of Techne. After the Employment Period, if Dr. Lucas continues to serve as a director of Techne, he will be entitled to the same compensation and benefits provided to other directors of Techne for their services as directors.
- b. Dr. Lucas shall be entitled to receive any incentive bonus that he earns for fiscal 1995 based upon the goals established by the Board of Directors of the Company, all in accordance with the terms of Section 2.2 of the Employment Agreement. Dr. Lucas shall be entitled to a profit

sharing plan contribution for fiscal 1995 on the same basis as other employees of the Company.

- c. Dr. Lucas shall be granted the option for 25,000 shares of the Company's Common Stock specified in Section 2.3 of the Employment Agreement without regard to 1995 pre-tax earnings in recognition of his past contributions to the Company and agreement to continue to serve as a director.
- d. By July 31, 1995, the Company shall pay Dr. Lucas the monetary value of his accrued but unused vacation time through June 30, 1995. No vacation time shall accrue for the benefit of Dr. Lucas following June 30, 1995.
- e. During the Employment Period, for as long as Dr. Lucas is not employed by another entity which provides health and similar insurance benefits generally to its employees, Dr. Lucas will be entitled to participate in the employee health and similar insurance benefit plans from time to time established by the Company and made available generally to all of its employees. Dr. Lucas shall participate in any of the Company's pension, profit sharing, stock, cash or other performance plans for fiscal 1995 but will not participate in any such plans thereafter.
- f. The Company will continue to carry the same life insurance on the life of Dr. Lucas through the term of the Employment Period as the Company carried on the date of this Agreement.
- g. Dr. Lucas shall continue to hold options previously granted to him in accordance with their respective terms and conditions.
- h. Dr. Lucas' right, pursuant to Section 5.3 of the Employment Agreement, to purchase insurance policies on his life owned by the Company shall continue in full force and effect.
- 5. Confidentiality Agreement. Dr. Lucas and the Company agree to amend the Confidentiality Agreement by deleting sections 4(a) and (b) of the Confidentiality Agreement and replacing such sections with the following: "During this employment and following its termination, Employee will not attempt, individually or through any other person or entity withwhich he is affiliated as an officer, director, shareholder, employee or consultant, directly or indirectly to target or solicit for employment any officer or employee of the Company or its affiliates or any former officer or employee of the Company or its affiliates, without the Company's prior written consent." The remaining provisions of the Confidentiality Agreement shall continue to be in full force and effect.
- 6. Registration Right. So long as Dr. Lucas is a director of Techne and subject to Rule 144 in connection with sales of Techne Common stock, if Dr. Lucas deems the volume restrictions of Rule 144 too limiting for his personal purposes, the Company at its expense will, upon Dr. Lucas' request, register on Form S-3 the shares of Techne Common Stock beneficially held by him, his spouse and children, provided, however, that in no event shall the Company be obligated under this section to register such shares if doing so would have a material adverse effect on financing plans of the Company.
- 7. Public and Private Statements. The Company agrees that it shall make no disparaging or defamatory statements regarding Dr. Lucas or his contributions to the Company. Dr. Lucas agrees that he shall make no disparaging or defamatory statements regarding the Company or any of its officers, directors or employees. The Company and Dr. Lucas shall agree on the text of an announcement of his change of status and coordinate the communication of such change to the public, employees of the Company, shareholders and analysts.
- 8. Expenses. The Company agrees to pay the reasonable fees of Dr. Lucas' attorney and accountant in connection with the negotiation of this Agreement in an aggregate amount not to exceed \$3,000.
- 9. Entire Agreement. This Agreement and the Confidentiality Agreement as amended hereby, together with any addenda, represents the only agreements among the parties concerning the subject matter hereof and supersedes all prior agreements whether written or oral, relating thereto, including without limitation the Employment Agreement.

- 10. Assignment. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their successors. This Agreement shall not be assignable by either party without the prior written consent of the other. Any and all assignments of this Agreement or any interest therein not made in accordance with this paragraph shall be void.
- 11. No Waiver. Any waiver of any term or condition of this Agreement by either party shall not operate as a waiver of any continued breach of such term or condition, or any other term or condition, nor shall any failure to enforce a provision of this Agreement operate as a waiver of such provision or of any other provision of this Agreement.
- 12. Further Assurances. The parties shall from time to time, upon the reasonable request of any other party hereto, execute and deliver such other documents and instruments and take such other action as such other party may reasonably request so as to more effectively permit the consummation of the transactions contemplated in this Agreement.
- 13. Severability. Should any provision of this Agreement, or its application, to any extent be held invalid or unenforceable, the remainder of this Agreement and its application, excluding such invalid or unenforceable provisions shall not be affected by such exclusion and shall continue valid and enforceable to the fullest extent permitted by law or equity.
- 14. Governing Law. This Agreement shall for all purposes be governed and interpreted in accordance with the laws of the State of Minnesota.
- 15. Arbitration. Any dispute arising out of or relating to this Agreement or the alleged breach of it, or the making of this Agreement, including claims of fraud in the inducement, shall be discussed between the disputing parties in a good faith effort to arrive at a mutual settlement of any such controversy. If, notwithstanding, such dispute cannot be resolved, such dispute shall be settled by binding arbitration. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The arbitrator shall be a retired state or federal judge or an attorney who has practiced securities or business litigation for at least 10 years. If the parties cannot agree on an arbitrator within 20 days, any party may request that the chief judge of the District Court for Hennepin County, Minnesota, select an arbitrator. Arbitration will be conducted pursuant to the provisions of this Agreement, and the commercial arbitration rules of the American Arbitration Association, unless such rules are inconsistent with the provisions of this Agreement. Limited civil discovery shall be permitted for the production of documents and taking of depositions. Unresolved discovery disputes may be brought to the attention of the arbitrator who may dispose of such dispute. The arbitrator shall have the authority to award any remedy or relief that a court of this state could order or grant; provided, however, that punitive or exemplary damages shall not be awarded. The arbitrator may award to the prevailing party, if any, as determined by the arbitrator, all of its costs and fees, including the arbitrator's fees, administrative fees, travel expenses, out-of-pocket expenses and reasonable attorneys' fees. Unless otherwise agreed by the parties, the place of any arbitration proceedings shall be Hennepin County, Minnesota.

IN WITNESS WHEREOF, each of the parties hereto have executed this Agreement in the manner appropriate to each, all as of the date first above written.

corporation	
Ву	
Thomas E. Oland, President	Roger C. Lucas, Ph.D.

Techne Corporation

#### NON-ENFORCEMENT OF PATENT RIGHTS

This Non-enforcement of Patent Rights is entered into on this 15th day of March, 1995 by New England Medical Center Hospitals, Inc., 171 Harrison Avenue, Boston, Massachusetts 02111 ("NEMC"), Trustees of Tufts College, Tufts University School of Medicine, 136 Harrison Avenue, Boston, Massachusetts 02111 ("TUFTS"), Massachusetts Institute of Technology, 77 Massachusetts Avenue, Cambridge, Massachusetts 02\_39 ("MIT") and Wellesley College, Wellesley, Massachusetts 02181 ("WELLS") (NEMC, TUFTS, MIT and WELLS are collectively referred to herein as the "Institutions"), in favor of R & D Systems, Inc., 614 McKinley Place, N.E., Minneapolis, Minnesota 55413 ("R&D");

#### WITNESSETH:

WHEREAS the Institutions are parties to that certain License Agreement dated December 1, 1983 with Cistron Biotechnology, Inc., Box 3004, 10 Bloomfield Avenue, Pine Brook, New Jersey 07058 ("Cistron") pursuant to which the Institutions granted rights to Cistron to manufacture and sell interleukin-1 beta ("IL-1b") gene fragments, proteins and products utilizing such gene fragments and proteins (the "License Agreement"); and

WHEREAS Cistron has recently made a claim against R&D that R&D's manufacture and sale of the mature interleukin-1 beta ("IL-1b") gene fragments, proteins and the supply of its IL-1b protein as a standard in its IL-1b assay kits (collectively, the "Products"), infringes the patents licensed to Cistron (the "Patents") under the License Agreement; and

WHEREAS, Cistron and R&D have reached a settlement of the claims made by Cistron against R&D, without any admission of liability, and intend to enter into a License and Supply Agreement (the "Supply Agreement"); and

WHEREAS, R&D has indicated its unwillingness to enter into the Supply Agreement without the execution of this Agreement by the Institutions;

NOW THEREFORE, in consideration of the rights, obligations and premises set forth in the Supply Agreement the Institutions, intending to be bound thereby, agree as follows:

Upon payment in full by R&D to Cistron of the license fee specified under paragraph 2.3 of the Supply Agreement, the Institutions, for themselves and their successors and assigns, agree absolutely and unconditionally not to enforce any of the Patent rights against R&D, its parent corporation, subsidiary or affiliate corporations, successors and assigns relating to R&D's manufacture and sale of the Products on or before the Effective Date of the Supply Agreement. However, nothing contained herein shall be construed as (a) granting or implying any right to R&D under any existing or future letters patent covering the PRECURSOR KIT or IL-1b PROTEIN (as such terms are defined in the Supply Agreement) other than those rights specifically granted in the Supply Agreement or (b) implying, by estoppel, any agreement by the Institutions not to enforce their rights under the Patents for any potential future infringement of the Patents by R&D.

This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Each of the Institutions has caused this Release to be executed in a manner appropriate to each to be effective as of the date set forth above.

NEW ENGLAND MEDICAL CENTER HOSPITALS. INC.

By Its

TRUSTEES OF TUFTS COLLEGE

# MASSACHUSETTS INSTITUTE OF TECHNOLOGY

By Its

## WELLESLEY COLLEGE

By Its

#### NON-ENFORCEMENT OF PATENT RIGHTS

EFFECTIVE DATE: March 21, 1995

PARTIES:

Cistron Biotechnology, Inc.
Box 3004
10 Bloomfield Avenue
Pine Brook, NJ 07058 ("Cistron")

R & D Systems, Inc. 614 McKinley Place, N.E. Minneapolis, MN 55413 ("R&D")

## RECITALS:

A. Cistron has recently made a claim against R&D that R&D's manufacture and sale of the mature interleukin-1 beta ("IL-1b") gene fragments, proteins and the supply of its IL-1b protein as a standard in its IL-1b assay kits (collectively, the "Products"), infringes certain patents licensed to Cistron (the "Patents") by New England Medical Center Hospitals, Inc., Tufts University, Massachusetts Institute of Technology and Wellesley College (the "Institutions").

B. The parties seek to settle such claim, without any admission of liability, by entering into a License and Supply Agreement entered into on March 21, 1995 and this Non-Enforcement of Patent Rights.

#### AGREEMENT:

In consideration of the rights, obligations and mutual premises set forth in the License and Supply Agreement Cistron, intending to be bound thereby, agrees as follows:

Upon payment in full by R&D of the license fee specified under paragraph 2.3 of the License and Supply Agreement, Cistron, for itself and its successors and assigns, agrees absolutely and unconditionally not to enforce any of the Patent rights against R&D, its parent corporation, subsidiary or affiliate corporations, successors and assigns relating to R&D's manufacture and sale of the Products on or before the Effective Date of the License and Supply Agreement. However, nothing contained herein shall be construed as (a) granting or implying any right to R&D under any existing or future letters patent covering the PRECURSOR KIT or IL-1b PROTEIN (as such terms are defined in the License and Supply Agreement) other than those rights specifically granted in the License and Supply Agreement or (b) implying, by estoppel, any agreement not to enforce its rights under the Patents for any potential future infringement of the Patents by R&D. Cistron represents and warrants to R&D that it has the full, exclusive right to bring any infringement action to enforce the Patents.

Cistron has caused this Release to be executed in the manner appropriate to it to be effective as of the date set forth above.

CISTRON BIOTECHNOLOGY, INC.

By /s/Bruce C. Galton
----Its President & CEO

#### LICENSE AND SUPPLY AGREEMENT

EFFECTIVE DATE: March 21, 1995

PARTIES:

Cistron Biotechnology, Inc. Box 2004

Pine Brook, New Jersey, USA 07058

("CISTRON")

Research and Diagnostic Systems, Inc.

614 McKinley Place NE

10 Bloomfield Avenue

Minneapolis, Minnesota, USA 55413

("R&D")

#### RECITALS:

- A. CISTRON has an exclusive, worldwide license from the New England Medical Center Hospitals, Inc., Tufts University, Massachusetts Institute of Technology and Wellesley College (the "Institutions") to make, use and sell, and to sublicense to others, products utilizing the human interleukin-1 beta ("IL-1b"), which is the subject of patents owned by the Institutions, and to make, use and sell products incorporating the inventions claimed in such patents and related technology (the "License Agreement").
- B. CISTRON has developed and is selling an IL-1b precursor assay and IL-1b mature protein in the research market under the terms of the License Agreement.
- C. R&D desires to purchase the IL-1b precursor research assay product and IL-1b mature protein for resale pursuant to the terms and conditions of this Agreement.

#### AGREEMENT:

In consideration of the rights, obligations and mutual premises set forth herein, CISTRON and R&D, intending to be bound thereby, agree as follows:

## Article 1. Definitions

The following terms as used in this Agreement shall have meanings set forth in the Article.

- 1.1 Territory. "TERRITORY" shall mean the research market worldwide.
- 1.2 Precursor Kit(s). "PRECURSOR KIT(S)" shall mean the following finished, but unlabelled, components of CISTRON's IL-1b human precursor assay (catalog 03-1000).
  - a. 1 Monoclonal antibody coated 96 well strip microtiter plate, foil sealed
  - b. 1 Vial of recombinant IL-1b precursor standard (lyophilized, 50ng/ML after reconstituting)
  - c. 1 Vial of IL-1b precursor polyclonal antibody (lyophilized, 11 mL after reconstituting)
    - d. 1 Bottle of conjugate (liquid concentrate, 0.5mL)
- 1.3 IL-1b Protein. "IL-1b PROTEIN" shall mean CISTRON's IL-1b mature protein (catalog 01-1600).
- 1.4 Confidential Information. "CONFIDENTIAL INFORMATION" shall mean any proprietary information or materials belonging to the disclosing party (whether or not patentable) including, but not limited to, formulations, techniques, methodology, equipment, data, reports, including any negative developments, know-how, sources of supply, patent positioning, consultants and business plans and purchase forecasts which are communicated to, learned by, or otherwise acquired by the party receiving such information or materials during or in the course of this Agreement.

Notwithstanding the foregoing, CONFIDENTIAL INFORMATION shall not include any information which (a) is or becomes part of the public domain through no act or omission on the part of the receiving party, (b) is disclosed to a third party by the disclosing party without restriction on such third party, (c) is in the receiving party's possession at or prior to the time of disclosure under this Agreement and the receiving party is under no prior obligation of confidentiality with respect thereto, (d) is disclosed to the receiving party by a third party having no obligation of confidentiality with respect thereto, (e) is independently developed by the receiving party, or (f) is released from confidential treatment by written consent of the disclosing party.

- 1.5 IL-1b Patents. "IL-1b PATENTS" shall mean all United States and foreign patents and patent applications and any divisions, continuations, continuations in part, reissues, reexaminations, renewals and extensions thereof, and all pending applications therefor: (a) which are set forth on Appendix A, or (b) which claim inventions that are related to IL-1b or derivatives, mutants, variants, fragments or chemical analogues thereof, and which are conceived or reduced to practice in whole or in part by (i) employees, agents or contractors of CISTRON during the AGREEMENT PERIOD or (ii) which are licensed to CISTRON, or (c) which are derived in whole or in part from material, information or data proprietary to CISTRON and provided by CISTRON to R&D and as reduced to writing by either party within thirty (30) days of transfer and the receipt of which is acknowledged in writing by R&D.
- 1.6 Agreement Period. "AGREEMENT PERIOD" shall mean the time commencing with the execution of this Agreement and extending until the last to expire of the IL-1b PATENTS as regards the sale and use of the IL-1b PROTEIN and for a period of seven (7) years as regards the PRECURSOR KIT.
- 1.7 Affiliate. "AFFILIATE" shall mean any division of R&D and any wholly owned subsidiary of Techne Corporation, R&D's parent corporation.

## Article 2. Supply Agreement

- 2.1 Purchase and Supply. During the AGREEMENT PERIOD, R&D agrees to purchase PRECURSOR KITS and IL-1b PROTEIN from CISTRON for resale in the TERRITORY under R&D's name and CISTRON agrees to manufacture and supply to R&D PRECURSOR KITS and IL-1b PROTEIN on a non-exclusive basis under the terms and conditions set forth in this Agreement.
- 2.2 Restrictions. Except as provided in paragraph 2.11 and paragraph 4.1, R&D agrees (a) to no longer sell its IL-1b gene or gene fragments (catalog BBG 2 and BBG 25), its IL-1b protein (catalog 201-LB), or supply its IL-1b protein as a standard in its IL-1b assay kit(s), (b) to purchase all of its requirements for IL-1b PROTEIN only from CISTRON and (c) to utilize only the IL-1b PROTEIN obtained from CISTRON as the standard in its IL-1b assay kit(s).
- 2.3 License Fee. R&D agrees to pay to CISTRON immediately following the execution of this Agreement by both parties, a nonrefundable payment of One Million Dollars (\$1,000,000) as payment in full for the right and license granted by CISTRON to R&D to purchase, use and resell in the TERRITORY the PRECURSOR KITS and IL-1b PROTEIN (either alone or packaged with other components, e.g. in an assay kit) on a non-exclusive basis only on the terms and conditions set forth in this Agreement.
  - 2.4 Prices.
  - a. PRECURSOR KITS. CISTRON agrees to manufacture and supply PRECURSOR KITS to R&D at the following prices:

Quarterly R&D Purchases Sale Price/Kit to R&D

less than 125 kits \$225.00 each plus freight and insurance 125 - 175 \$195.00 each plus freight and insurance 176 - 250 \$186.00 each plus freight and insurance 251 + \$164.00 each plus freight and insurance

b. IL-1b PROTEIN. CISTRON agrees to manufacture and supply IL-1b PROTEIN to R&D at the following prices:

Bulk Order by R&D Sale Price to R&D

1 mg to 10 mg 11 mg to 15 mg 16 mg + \$3,500.00/mg plus freight and insurance \$3,000.00/mg plus freight and insurance \$2,500.00/mg plus freight and insurance

- 2.5 Purchase Orders/Forecasts. R&D will provide CISTRON with its estimated purchase order requirements on a two calendar quarter rolling basis. The first calendar quarter (or portion thereof) of such estimate shall constitute a firm purchase order, the second calendar quarter of such estimate shall be for information purposes only. R&D will provide the first such rolling estimate to CISTRON upon execution of this Agreement and thereafter no later than thirty (30) days prior to the start of each calendar quarter.
- 2.6 Increased Forecasts. Should R&D increase a calendar quarter's purchase orders by twenty percent (20%) or more from that quarter's prior estimate, CISTRON will use its best efforts to fill such increased order. However, R&D may not refuse acceptance of shipment from CISTRON of quantities equating to eighty percent (80%) of that quarter's prior estimate; provided, however, R&D shall have the right to manufacture or have manufactured the twenty percent (20%) shortfall of IL-1b PROTEIN in accordance with the provisions of paragraphs 2.11 and 4.1.
- 2.7 Initial PRECURSOR KITS Order. R&D will place an order for a minimum of one hundred (100) PRECURSOR KITS on the Effective Date of this Agreement.
- 2.8 Acceptance of Orders/Title. All orders from R&D will be subject to acceptance by CISTRON. All purchases pursuant to orders by R&D shall be, at CISTRON's option, F.O.B. Pine Brook, New Jersey, USA or other place of manufacture. Title to, and risk of loss of and damage to, any shipments of the PRECURSOR KITS or IL-1b PROTEIN shall pass to R&D when such Products are delivered at any F.O.B. location to a carrier designated by R&D in its purchase order. If R&D has failed to specify a carrier in its purchase order, CISTRON may use a carrier of its choice.
- 2.9 Shipment. CISTRON will ship R&D the quantity of PRECURSOR KITS and IL-1b PROTEIN ordered in a quarterly purchase order within forty-five (45) days of receipt of such purchase order and will invoice R&D on the date of shipment. R&D shall pay each invoice within thirty (30) days of the date of the invoice. CISTRON will, whenever possible, ship complete orders; however, should CISTRON be unable to ship a complete order, CISTRON will so notify R&D. R&D may accept or refuse partial shipments at its discretion, but may not refuse acceptance of shipments that comprise not less than eighty percent (80%) of a complete order.
- 2.10 Quality Control Testing. CISTRON will perform quality control testing on each lot of PRECURSOR KITS and IL-1b PROTEIN and provide such manufacturing and quality control information to R&D as may be mutually agreed as necessary with each new production lot. R&D agrees to keep such information confidential pursuant to the terms of paragraph 6.2 of this Agreement and to restrict its use of such information solely to the sale and use of the PRECURSOR KITS and IL-1b PROTEIN.
- 2.11 Acceptance. R&D shall perform in-house testing, at its own expense, as it deems appropriate upon receipt of each product shipment from CISTRON, R&D will report any product performance deficiencies or quantity discrepancies that R&D may discover to CISTRON within fifteen (15) days of receipt. Failure to report any product deficiencies or discrepancies within fifteen (15) days of the receipt of each product shipment shall constitute acceptance of the shipment. If R&D notifies CISTRON within fifteen (15) days of its receipt of PRECURSOR KITS or IL-1b PROTEIN that the Product fails to meet specification, such non-conforming Products which are due to a defect of one or more of the components supplied by CISTRON shall be replaced by CISTRON as soon as reasonably possible thereafter. If CISTRON is unable to supply IL-1b PROTEIN that meets quality specifications or not in sufficient quantity to fill R&D's order, R&D may substitute its IL-1b protein only until such time as CISTRON is able to supply sufficient conforming product.
- 2.12 Completion of PRECURSOR KITS. R&D will provide buffers for each PRECURSOR KIT, label the PRECURSOR KITS and components as R&D products and provide product literature for inclusion of each PRECURSOR KIT.
- 2.13 Other Terms and Conditions. Any term or condition in an invoice or other document used by CISTRON which is in addition to or different than the terms of this Agreement shall be deemed inapplicable.

#### Article 3. Warranties

- 3.1 Corporate Authority. CISTRON and R&D each represents and warrants to the other that:
  - a. it is a corporation, duly organized, validly existing and in good standing under the laws of the state of its incorporation;
  - b. it has taken all necessary action on its part that may be required under the laws of its state of incorporation and under its certificate of incorporation and its bylaws to authorize the execution, delivery and performance of this Agreement; and
  - c. this Agreement constitutes the valid and legally binding obligation of such party, enforceable against it in accordance with its terms.
- 3.2 License Agreement. CISTRON represents and warrants to R&D that it has the exclusive, worldwide license from the Institutions to make, use and sell, and to sublicense to others, products utilizing the IL-1b and to make, use and sell products incorporating the inventions claimed in the IL-1b PATENTS and related technology under the terms of the License Agreement.
- 3.3 Product Warranty. CISTRON warrants (a) the merchantability of PRECURSOR KITS and IL-1b PROTEIN only for use as research tools and in the case of the PRECURSOR KIT, only when used in conformance with CISTRON's PRECURSOR KIT protocol, and (b) that the IL-1b PROTEIN and the PRECURSOR KIT will meet the written specifications provided by CISTRON and reviewed by R&D. CISTRON MAKES NO WARRANTY OF MERCHANTABILITY OR PERFORMANCE AFTER EXPIRATION OF THE FIFTEEN (15) DAY PERIOD DESCRIBED IN PARAGRAPH 2.11 ABOVE.
- 3.4 DISCLAIMER OF WARRANTIES. THE WARRANTIES SET FORTH IN THIS ARTICLE 3 ARE THE ONLY WARRANTIES MADE BY THE PARTIES AND ARE EXPRESSLY IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY AND ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NOTWITHSTANDING ANYTHING STATED HEREIN TO THE CONTRARY, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR TO ANY DISTRIBUTEE OF THE OTHER PARTY OR ANYONE ELSE IN PRIVITY WITH THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, OR CONSEQUENTIAL DAMAGES REGARDLESS OF WHETHER OR NOT THE FIRST PARTY HAS BEEN APPRISED OF THE POSSIBILITY THEREOF.

## Article 4. Guaranteed Supply

4.1 Uninterrupted Supply. CISTRON agrees to sell to R&D during the AGREEMENT PERIOD under the price, payment and purchase terms of Article 2 of this Agreement, R&D's requirements of the IL-1b PROTEIN. If CISTRON is unable to provide R&D with its requirements of the IL-1b PROTEIN for whatever reason, including, without limitation, events of force majeure and financial problems, R&D shall have the right to manufacture or have manufactured its IL-1b protein (catalog 201-LB) in sufficient quantities to fulfill R&D's requirements as described in its purchase order delivered to CISTRON and subject to CISTRON'S right to resume supply in accordance with the provisions of Section 2.11 herein.

#### Article 5. Term and Termination

- 5.1 Term. Unless earlier terminated pursuant to paragraphs 5.2, 5.3 or 5.4, the provisions of this Agreement relating to the IL-1b PROTEIN will expire upon the expiration of the last to expire of the IL-1b PATENTs and the provisions of this Agreement relating to the PRECURSOR KIT will expire seven (7) years from the Effective Date of this Agreement. For purposes of this paragraph, "expire" shall mean expiration, abandonment, cancellation, disclaimer, award to another in an interference proceeding, or declaration of invalidity or unenforceability by a court or other authority of competent jurisdiction from which no further appeal has or can be taken.
  - 5.2 Termination For Breach. Upon material breach of this Agreement by

either party and in the event the breach is not cured within forty-five (45) days after delivery of written notice to the defaulting party by the other party, in addition to any other remedy it may have, the notifying party at its sole option may terminate this Agreement by delivery of an additional termination notice to the other party at the end of such forty-five (45) day period.

- 5.3 Insolvency. This Agreement may be terminated by one party if the other party becomes insolvent, is unable to pay its debts as they mature, makes an assignment for the benefit of its creditors, files a petition for protection under any bankruptcy law, has an involuntary petition for bankruptcy filed against it, or applies for the appointment of a receiver or trustee for substantially all of its property or assets or permits the appointment of any such receiver or trustee who is not discharged within a period of thirty (30) days after such appointment.
- 5.4 Infringement by PRECURSOR KIT. The portions of this Agreement pertaining to the PRECURSOR KIT may be terminated by either party upon learning of the existence of a third party patent which, in the opinion of competent legal counsel, is infringed by the sale of the PRECURSOR KIT.
- 5.5 Post Termination Rights. Upon any termination of this Agreement, R&D will be entitled to use and sell any completed inventory of PRECURSOR KITS and/or IL-1b PROTEIN covered by this Agreement which remain on hand as of the date of the termination, so long as R&D pays to CISTRON the amount applicable to the purchase of such inventory in accordance with the terms and conditions as set forth in this Agreement. The above described rights and obligations of R&D and the rights and obligations of the parties under Section 6.2, Article 7 and Section 8.2 of this Agreement are the only rights and obligations of either party which shall survive termination of this Agreement.
- 5.6 Notification of Breach of License Agreement. CISTRON shall notify R&D immediately if Cistron receives any notice of breach or termination of CISTRON's license from the Institutions. In such case if CISTRON cannot or will not cure such breach, CISTRON shall allow R&D to cure such breach and deduct the cost thereof from the payments due to CISTRON under Article 2 of this Agreement.

## Article 6 Publicity and Confidentiality

6.1 Public Disclosure. The parties shall mutually agree upon the wording of the initial press release regarding this Agreement. Neither party shall use the name of the other party in any form of advertising or promotion, without the express prior written approval of the other party.

## 6.2 Confidentiality.

- a. Obligations. Except as provided in paragraph 6.2.b. below, for a period of five (5) years from the termination date of this Agreement, the receiving party will maintain any and all of the CONFIDENTIAL INFORMATION received from the other party, in confidence, will not use same for its own benefit except as expressly provided in this Agreement, and will not release or disclose any tangible or intangible component thereof to any third party without first receiving the prior written consent of the disclosing party to said release or disclosure.
- b. Exceptions. The provisions of paragraph 6.2.a. notwithstanding, a receiving party may disclose CONFIDENTIAL INFORMATION of the other party to its own affiliates or in the event of a disclosure compelled by a court of competent jurisdiction. In addition, a receiving party may disclose CONFIDENTIAL INFORMATION of the other party in confidence to any third party who has a need to know such CONFIDENTIAL INFORMATION for the purpose of this Agreement; provided that the receiving party will first notify the other party of the identity of such third party and that such disclosure will be made under the provisions of a written confidential disclosure agreement which is binding upon such third party to the same obligations of confidentiality under which the receiving party is bound to the disclosing party by the terms of this Agreement. R&D need not notify CISTRON before disclosing any CONFIDENTIAL INFORMATION of CISTRON to any AFFILIATE.

#### Article 7. Indemnification

- 7.1 Defense By CISTRON. In the event that litigation against R&D and/or its AFFILIATES, officers, directors, employees or successors and assigns, is initiated by a third party charging R&D with infringement of a patent as a result of R&D's resale of IL-1b PROTEIN licensed under this Agreement, R&D shall promptly notify CISTRON in writing thereof. CISTRON agrees to intervene on R&D's behalf and to take over the sole defense of the action at CISTRON's expense. In such event, R&D agrees to cooperate with CISTRON in all respects including making available relevant records, papers and the like and providing its employees to testify as requested. CISTRON will reimburse R&D for the expenses incurred in providing such assistance.
- 7.2 Settlement. No settlement, consent judgment or other voluntary final disposition of the suit which adversely affects the IL-1b PATENTS may be entered into without the consent of CISTRON.
- 7.3 Payment By CISTRON. In the event of a final judgment in any suit in which a court of competent jurisdiction, from which there is not appeal, rules that R&D's resale of IL-1b PROTEIN licensed under this Agreement has infringed on a third-party's patent requiring R&D to pay damages or a royalty to a third party, or in the event of a settlement of such suit requiring damages or royalty payments to be made, CISTRON will pay such damages or royalty payments on R&D's behalf.

#### Article 8. General Provisions

8.1 Relationship. The relationship between CISTRON and R&D is that of independent contractors. CISTRON and R&D are not joint venturers, partners, principal and agent, master and servant, employer and employee, and have no relationship other than as independent contracting partners. CISTRON will have no power to bind or obligate R&D in any manner. Likewise, R&D will have no power to bind or obligate CISTRON in any manner.

#### 8.2 Arbitration.

- a. Submission of Dispute. Any dispute, claim or controversy arising out of or relating to this Agreement (a "Dispute") shall be resolved by binding arbitration conducted pursuant to the provisions of this Agreement and the commercial arbitration rules of the American Arbitration Association ("AAA"), unless such AAA rules are inconsistent with the provisions of this Agreement. Even though the arbitrator(s) shall apply the AAA rules, the arbitration shall not be conducted by the AAA. Either party may commence arbitration proceedings by delivery of written notice to the other party describing the Dispute ("Arbitration Notice").
- b. Appointment of Arbitrator(s). The case shall be submitted to a single arbitrator who shall be a retired state or federal judge or an attorney who has practiced business litigation for at least ten (10) years. Each party shall submit a list of three (3) arbitrators to the other party within ten (10) days after delivery of the Arbitration Notice. From the combined list, the parties shall mutually agree on the arbitrator. Should the parties be unable to agree on the choice of an arbitrator within thirty (30) days after delivery of the Arbitration Notice, the arbitration shall be conducted by a panel of three (3) arbitrators. Each party shall choose one arbitrator within ten (10) after the expiration of the above thirty (30) day period and the two selected shall choose a third arbitrator within five (5) days after their appointment.
- d. Location of Arbitration. The site of the arbitration shall be in the state of New York. The exact location within New York shall be designated by the arbitrator(s).
- e. Interim Remedies. Either party may apply to any court having jurisdiction hereof and seek injunctive relief so as to maintain the status quo until such time as the arbitration award is rendered or the Dispute is otherwise resolved.
- f. Costs and Fees. Each party shall be responsible for its own costs and expenses of the arbitration and the costs and fees of the

arbitrator(s) shall be borne equally between the parties, unless the arbitrator(s) indicate otherwise in the award.

- g. Binding Effect. The decision and award rendered by the arbitrator will be final and binding. Judgment upon the award may be entered in any court having jurisdiction thereof.
- 8.3 Entire Agreement. This Agreement sets forth the entire agreement and understanding between the parties as to the subject matter thereof and supersedes all prior oral or written agreements to this respect. This Agreement shall be binding upon and inure to the benefit of the successors and assigns of each party.
- 8.4 Modifications and Waivers. No purported amendment, modification or waiver of any provision hereof shall be binding unless set forth in a writing signed by both parties (in the case of amendments and modifications) or by the party to be charged thereby (in the case of waivers). Any waiver shall be limited to the circumstance or event specifically referenced in the written waiver document and shall not be deemed a waiver of any other term of this Agreement or of the same circumstance or event upon any recurrence thereof.
- 8.5 Governing Law. This Agreement will be construed and enforced in accordance with the laws of the State of New York without reference to its choice of law principles.
- 8.6 Headings. The headings in this Agreement have been inserted for the convenience of the reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or paragraph.
- 8.7 Notices. Any notice or other communication required or permitted under this Agreement shall be made in writing and shall be deemed to have been delivered upon the earlier of (i) when received, if personally delivered, (ii) the next business day after delivery if delivered by telecopy or telex, (iii) the next business day after placement with a reputable overnight delivery service for next day delivery, or (iv) five (5) business days after depositing in the U.S. mails for delivery by certified or registered mail, return receipt requested, postage prepaid and addressed to the appropriate party at the following address:

To R&D: R&D Systems, Inc.
614 McKinley Place NE
Minneapolis, Minnesota USA 55413
ATTN: Roger C. Lucas, Ph.D.
or Senior Executive Officer/Biotechnology

Copy to: Fredrikson & Byron, P.A.
1100 International Center
900 Second Avenue South
Minneapolis, Minnesota USA 55402
ATTN: Timothy M. Heaney, Esq.

To CISTRON: Cistron Biotechnology, Inc.
Box 2004
10 Bloomfield Avenue
Pine Brook, New Jersey USA 07058
ATTN: Bruce C. Galton

Copy to: Epstein Becker & Green, P.C. 250 Park Avenue New York, New York 10177-0077 ATTN: Seth I. Truwit, Esq.

Addresses may be changed by delivery of notice to the other parties pursuant to the terms of this paragraph. Any notice of change of address shall not be effective until actually received by the addressee.

8.8 Injunctive Relief. The parties acknowledge and agree that a breach of any of the terms and conditions of this Agreement, including the provisions relating to confidentiality, may cause irreparable injury to the non-breaching party and, according, that the prevailing party may seek and obtain in any arbitration, in addition to damages, any and all available equitable remedies, including, without limitation, specific performance and injunctive relief.

8.9 Force Majeure. Each party hereto will be excused from performance for failure or delay in meeting any obligations hereunder due to Acts of God, acts of war, fire, flood, embargo, riots or revolution, provided that such excused performance will last only for so long as that party's performance is reasonably prevented by such force majeure. The party affected by such force majeure is to use its best efforts to mitigate any damage thus occasioned.

8.10 Severability. The provisions of this Agreement are severable and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

Accepted and Agreed to:

CISTRON BIOTECHNOLOGY, INC. RESEARCH AND DIAGNOSTIC SYSTEMS, INC.

By By -----Bruce C. Galton Roger C. Lucas

TITLE: President & COO TITLE: Executive V.P.

DATE: March 31, 1995 DATE: March 31, 1995

APPENDIX A

**IL-1b PATENTS** 

U.S. Patent No. 4,762,914 U.S. Patent No. 4,766,069 U.S. Patent No. 5,001,057 U.S. Patent No. 5,077,219

Foreign Equivalents, including

EPO Publication No. 0161901B1

#### RESEARCH AND DEVELOPMENT AGREEMENT

EFFECTIVE DATE: April 10, 1995

PARTIES:

Cistron Biotechnology, Inc.
Box 3004
10 Bloomfield Avenue
Pine Brook, New Jersey, USA 07058 ("CISTRON")

Research and Diagnostic Systems, Inc. 614 McKinley Place NE Minneapolis, Minnesota, USA 55413 ("R&D")

#### RECITALS:

- A. CISTRON has an exclusive, worldwide license from the New England Medical Center Hospitals, Inc., Tufts University, Massachusetts Institute of Technology and Wellesley College (the "Institutions") to make, use and sell, and to sublicense to others products utilizing the human interleukin-1 beta ("IL-1b"), which is the subject of patents owned by the Institutions, and to make, use and sell products incorporating the inventions claimed in such patents and related technology (the "License Agreement").
- B. CISTRON has begun research and development of a chair-side, interleukin-1 beta ("IL-1b") assay for the detection and monitoring of periodontal disease in humans (the "DENTAL KIT") and other new research products described in the following agreement.
- C. R&D desires to support CISTRON's development of the DENTAL KIT and the new research products in exchange for co-exclusive marketing rights with CISTRON pursuant to the terms and provisions of the following agreement.

## AGREEMENT:

In consideration of the rights, obligations and mutual premises set forth herein, CISTRON and R&D, intending to be bound thereby, agree as follows:

## Article 1. Definitions

The following terms as used in this Agreement shall have the following meanings:

- 1.1 Territory. "TERRITORY" shall mean the dental diagnostic market worldwide as to the DENTAL KIT and the research market worldwide as to the NEW RESEARCH PRODUCTS.
- 1.2 Dental Kit. "DENTAL KIT" shall mean a single use, chair-side, semi-quantitative EIA assay to measure IL-1b in human gingival crevicular fluid to aid in the detection and/or monitoring of periodontal disease by dentists and periodontists.
- 1.3 New Research Products. "NEW RESEARCH PRODUCTS" shall mean newly identified cytokines, peptides, mutants and/or antibodies thereto, or other products for the research market developed under the terms of this Agreement.
- 1.4 IL-1b Patents. "IL-1b PATENTS" shall mean all United States and foreign patents and patent applications and any divisions, continuations, continuations in part, reissues, reexaminations, renewals and extensions thereof, and all pending applications therefor (a) which are set forth on Appendix A, or (b) which claim inventions that are related to IL-1b or derivatives, mutants, variants, fragments, antibodies, assays or chemical analogs thereof, and which are conceived or reduced to practice in whole or in part by (i) employees, agents or contractors of CISTRON during the term of this Agreement and/or (ii) which are licensed to CISTRON, and/or (c) which are derived in whole or in part from material, information or data proprietary to CISTRON, provided by CISTRON to R&D and reduced to writing by either party within thirty (30) days of transfer and the receipt of which is acknowledged in writing by R&D.

1.5 Confidential Information. "CONFIDENTIAL INFORMATION" shall mean any proprietary information or materials belonging to the disclosing party (whether or not patentable) including, but not limited to, formulations, techniques, methodology, equipment, data, reports, know-how, sources of supply, patent positioning, consultants and business plans including any negative development which are communicated to, learned by, or otherwise acquired by the party receiving such information or materials during or in the course of this Agreement.

Notwithstanding the foregoing, CONFIDENTIAL INFORMATION shall not include any information which (a) is or becomes part of the public domain through no act or omission on the part of the receiving party, (b) is disclosed to a third party by the disclosing party without restriction on such third party, (c) is in the receiving party's possession at or prior to the time of disclosure under this Agreement and the receiving party is under no prior obligation of confidentiality with respect thereto, (d) is disclosed to the receiving party by a third party having no obligation of confidentiality with respect thereto, (e) is independently developed by the receiving party, or (f) is released from confidential treatment by written consent of the disclosing party.

#### Article 2. Funded Research and Development Program

2.1 Marketing Rights. CISTRON has initiated research and development of the DENTAL KIT and certain NEW RESEARCH PRODUCTS. R&D has agreed to support the research and development of the DENTAL KIT and NEW RESEARCH PRODUCTS in return for co-exclusive marketing rights with CISTRON in the TERRITORY. For purposes of this Agreement, "co-exclusive marketing right" shall mean that CISTRON grants to R&D a sole exclusive license or sublicense, as applicable, and retains for itself the right, to market the products, but CISTRON shall not grant any third party any rights to the DENTAL KIT or the NEW RESEARCH PRODUCTS.

### 2.2 Research and Development Payments.

- a. Calculation. R&D will pay CISTRON an aggregate of One Million Dollars (\$1,000,000) (the "Research Funds") towards the research and development of the DENTAL KIT according to the preliminary research plan attached as Appendix B and the NEW RESEARCH PRODUCTS identified in Appendix B and other NEW RESEARCH PRODUCTS approved by R&D in writing from time to time. CISTRON and R&D agree to negotiate in good faith to develop a detailed research plan for the DENTAL KIT and the NEW RESEARCH PRODUCTS identified on Appendix B and other potential NEW RESEARCH PRODUCTS. R&D shall have the right to redirect the use of the Research Funds among the DENTAL KIT and NEW RESEARCH PRODUCTS projects if results of any data or research is not progressing in a satisfactory or successful manner, as defined in accordance with the research plan set forth in Appendix B, as amended from time to time by the parties.
- b. Payment. The Research Funds shall be payable in ten (10) calendar quarterly payments in the amount of \$100,000 each, starting July 1, 1995. These quarterly payments are non-refundable and shall be due on the first day of each calendar quarter regardless of scientific progress. The Research Funds are not subject to set-off if R&D has any claim against CISTRON for breach of this Agreement or for any other reason. If R&D defaults in the payment of any quarterly Research Fund payment and such payment remains unpaid ten (10) business days after delivery of written notice of nonpayment by CISTRON to R&D, the remaining Research Funds shall become immediately due and payable.
- 2.3 Reports. CISTRON will provide R&D with calendar quarterly written progress reports on the development of the DENTAL KIT and NEW RESEARCH PRODUCTS. Such reports shall be delivered within thirty (30) days after the end of each calendar quarter during the term of this Agreement. Such progress reports shall be considered Confidential Information and subject to the confidentiality provisions of Section 5.2.
- 2.4 License. Upon completion of the preliminary research plan set forth in Appendix B and upon receipt of the full Research Funds, R&D shall automatically receive a fully paid right and license to exploit the inventions and technology covered by the claims in IL-1b PATENTS to market the DENTAL KIT and the NEW RESEARCH PRODUCTS in the Territory co-exclusively with CISTRON for

the term of this Agreement. R&D acknowledges and agrees that such right and license may be limited if CISTRON's right to grant such right and license is limited; provided, however, CISTRON will grant such right and license to the fullest extent of its right to do so. CISTRON agrees to sell to R&D its requirements of the DENTAL KIT and the NEW RESEARCH PRODUCTS under the terms of a supply agreement to be negotiated between the parties in good faith at such time as quantities and manufacturing costs are determined, but in no event shall such manufacturing costs for the DENTAL KIT be less than CISTRON's fully absorbed manufactured cost plus twenty percent (20%). Such supply agreement shall contain similar provisions as found in the Supply Agreement between the parties executed on even date herewith.

- 2.5 DENTAL KIT Patent Rights. Notwithstanding any of the provisions contained in this Agreement, R&D understands and agrees that CISTRON will retain ownership of all of its patent rights relating to the DENTAL KIT and/or NEW RESEARCH PRODUCTS as may presently or hereafter exist.
- 2.6 FDA Approval. Upon completion of the research plan for the DENTAL KIT or for any NEW RESEARCH PRODUCT, either party may delivery written notice to the other party of its desire to file an application with, and seek approval of, the U.S. Food and Drug Administration or the equivalent United States regulatory body (the "FDA") for the manufacture and sale of the DENTAL KIT as a diagnostic product or of a NEW RESEARCH PRODUCT. The other party shall have a period of one hundred twenty (120) days to elect whether or not to participate in such application. Such election shall be made by delivery of written notice to the first party prior to the expiration of the one hundred twenty (120) day period. If the party elects to participate in such application, each party shall share equally in the preparation and filing of such application with the FDA. If the other party elects not to participate in such application, such party shall loose its co-exclusive rights under this Agreement and the first party shall have the full, exclusive rights to manufacture and market the affected product.

#### Article 3. Warranties

- $3.1\,$  Corporate Authority. CISTRON and R&D each represents and warrants to the other that:
  - a. it is a corporation, duly organized, validly existing and in good standing under the laws of the state of its incorporation;
  - b. it has taken all necessary action on its part that may be required under the laws of its state of incorporation and under its certificate of incorporation and its bylaws to authorize the execution, delivery and performance of this Agreement; and
  - c. this Agreement constitutes the valid and legally binding obligation of such party, enforceable against it in accordance with its terms.
- 3.2 License Agreement. CISTRON represents and warrants to R&D that it has the exclusive, worldwide license from the Institutions to make, use and sell, and to sublicense to others, products utilizing the IL-1b and to make, use and sell products incorporating the inventions claimed in the IL-1b PATENTS and related technology under the terms of the License Agreement.
- 3.3 DISCLAIMER OF WARRANTIES. THE WARRANTIES SET FORTH IN THIS ARTICLE 3 ARE THE ONLY WARRANTIES MADE BY THE PARTIES AND ARE EXPRESSLY IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY AND ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NOTWITHSTANDING ANYTHING STATED HEREIN TO THE CONTRARY, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR TO ANY DISTRIBUTEE OF THE OTHER PARTY OR ANYONE ELSE IN PRIVITY WITH THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, OR CONSEQUENTIAL DAMAGES REGARDLESS OF WHETHER OR NOT THE FIRST PARTY HAS BEEN APPRISED OF THE POSSIBILITY THEREOF.

#### Article 4. Term and Termination

4.1 Term. Unless earlier terminated pursuant to paragraphs 4.2, 4.3 or

- 4.4, the provisions of this Agreement will expire upon the expiration of the last to expire of the IL-1b PATENTS. For purposes of this paragraph, "expire" shall mean expiration, abandonment, cancellation, disclaimer, award to another in an interference proceeding, or declaration of invalidity or unenforceability by a court or other authority of competent jurisdiction from which no further appeal has or can be taken.
- 4.2 Termination For Breach. Upon material breach of this Agreement by either party and in the event the breach is not cured within forty-five (45) days after delivery of written notice to the defaulting party by the other party, in addition to any other remedy it may have, the notifying party at its sole option may terminate this Agreement by delivery of an additional termination notice to the other party at the end of such forty-five (45) day period.
- 4.3 Insolvency. This Agreement may be terminated by one party if the other party becomes insolvent, is unable to pay its debts as they mature, makes an assignment for the benefit of its creditors, files a petition for protection under any bankruptcy law, has an involuntary petition for bankruptcy filed against it, or applies for the appointment of a receiver or trustee for substantially all of its property or assets or permits the appointment of any such receiver or trustee who is not discharged within a period of thirty (30) days after such appointment.
- 4.4 Infringement by DENTAL KIT. The portions of this Agreement pertaining to the DENTAL KIT may be terminated by either party upon learning of the existence of a third party patent which, in the opinion of competent legal counsel, is infringed by the sale of the DENTAL KIT.
- 4.5 Post Termination Rights. Upon any termination of this Agreement, R&D will be entitled to use and sell any completed inventory of DENTAL KITS and/or NEW RESEARCH PRODUCTS, so long as R&D pays to CISTRON the amount applicable to the purchase of such inventory in accordance with the terms and conditions of the negotiated supply agreement. The above described rights and obligations of R&D and the rights and obligations of the parties under Sections 5.2 and 6.2 of this Agreement are the only rights and obligations of either party which shall survive termination of this Agreement.
- 4.6 Notification of Breach of License Agreement. CISTRON shall notify R&D immediately if Cistron receives any notice of breach or termination of CISTRON's license from the Institutions. In such case if CISTRON cannot or will not cure such breach, CISTRON shall allow R&D to cure such breach and deduct the cost thereof from the payments due to CISTRON under Article 2 of this Agreement.

## Article 5. Publicity and Confidentiality

5.1 Public Disclosure. The parties shall mutually agree upon the wording of the initial press release regarding this Agreement. Neither party shall use the name of the other party in any form of advertising or promotion, without the express prior written approval of the other party.

## 5.2 Confidentiality.

- a. Obligations. Except as provided in Section 5.2.b. below, for a period of five (5) years from the termination date of this Agreement, the receiving party will maintain any and all of the CONFIDENTIAL INFORMATION received from the other party, in confidence, will not use same for its own benefit except as expressly provided in this Agreement, and will not release or disclose any tangible or intangible component thereof to any third party without first receiving the prior written consent of the disclosing party to said release or disclosure.
- b. Exceptions. The provisions of Section 5.2.a. notwithstanding, a receiving party may disclose CONFIDENTIAL INFORMATION of the other party to its own affiliates or in the event of a disclosure compelled by a court of competent jurisdiction. In addition, a receiving party may disclose CONFIDENTIAL INFORMATION of the other party in confidence to any third party who has a need to know such CONFIDENTIAL INFORMATION for the purpose of this Agreement; provided that the receiving party will first notify the other party of the identity of such third party and that such disclosure will be made under the provisions of a written confidential disclosure

agreement which is binding upon such third party to the same obligations of confidentiality under which the receiving party is bound to the disclosing party by the terms of this Agreement. A receiving party need not notify the disclosing party before disclosing any CONFIDENTIAL INFORMATION of the disclosing party to any affiliate of the receiving party.

#### Article 6. General Provisions

6.1 Relationship. The relationship between CISTRON and R&D is that of independent contractors. CISTRON and R&D are not joint venturers, partners, principal and agent, master and servant, employer and employee, and have no relationship other than as independent contractors for the purpose of this Agreement. CISTRON will have no power to bind or obligate R&D in any manner. Likewise, R&D will have no power to bind or obligate CISTRON in any manner.

#### 6.2 Arbitration.

- a. Submission of Dispute. Any dispute, claim or controversy arising out of or relating to this Agreement (a "Dispute") shall be resolved by binding arbitration conducted pursuant to the provisions of this Agreement and the commercial arbitration rules of the American Arbitration Association ("AAA"), unless such AAA rules are inconsistent with the provisions of this Agreement. Even though the arbitrator(s) shall apply the AAA rules, the arbitration shall not be conducted by the AAA. Either party may commence arbitration proceedings by delivery of written notice to the other party describing the Dispute ("Arbitration Notice").
- b. Appointment of Arbitrator(s). The case shall be submitted to a single arbitrator who shall be a retired state or federal judge or an attorney who has practiced business litigation for at least ten (10) years. Each party shall submit a list of three (3) arbitrators to the other party within ten (10) days after delivery of the Arbitration Notice. From the combined list, the parties shall mutually agree on the arbitrator. Should the parties be unable to agree on the choice of an arbitrator within thirty (30) days after delivery of the Arbitration Notice, the arbitration shall be conducted by a panel of three (3) arbitrators. Each party shall choose one arbitrator within ten (10) after the expiration of the above thirty (30) day period and the two selected shall choose a third arbitrator within five (5) days after their appointment.
- d. Location of Arbitration. The site of the arbitration shall be in the State of New York. The exact location within the State of New York shall be designated by the arbitrator(s).
- e. Interim Remedies. Either party may apply to any court having jurisdiction hereof and seek injunctive relief so as to maintain the status quo until such time as the arbitration award is rendered or the Dispute is otherwise resolved.
- f. Costs and Fees. Each party shall be responsible for its own costs and expenses of the arbitration and the costs and fees of the arbitrator(s) shall be borne equally between the parties, unless the arbitrator(s) indicate otherwise in the award.
- g. Binding Effect. The decision and award rendered by the arbitrator will be final and binding. Judgment upon the award may be entered in any court having jurisdiction thereof.
- 6.3 Entire Agreement. This Agreement sets forth the entire agreement and understanding between the parties as to the subject matter thereof and supersedes all prior oral or written agreements to this respect. This Agreement shall be binding upon and inure to the benefit of the successors and assigns of each party.
- 6.4 Modifications and Waivers. No purported amendment, modification or waiver of any provision hereof shall be binding unless set forth in a writing signed by both parties (in the case of amendments and modifications) or by the party to be charged thereby (in the case of waivers). Any waiver shall be limited to the circumstance or event specifically referenced in the written

waiver document and shall not be deemed a waiver of any other term of this Agreement or of the same circumstance or event upon any recurrence thereof.

- 6.5 Governing Law. This Agreement will be construed and enforced in accordance with the laws of the State of New York without reference to its choice of law principles.
- 5.6 Headings. The headings in this Agreement have been inserted for the convenience of the reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section.
- 5.7 Notices. Any notice or other communication required or permitted under this Agreement shall be made in writing and shall be deemed to have been delivered upon the earlier of (i) when received, if personally delivered, (ii) the next business day after delivery if delivered by telecopy or telex, (iii) the next business day after placement with a reputable overnight delivery service for next day delivery, or (iv) five (5) business days after depositing in the U.S. mails for delivery by certified or registered mail, return receipt requested, postage prepaid and addressed to the appropriate party at the following address:

To R&D: R&D Systems, Inc.
614 McKinley Place NE
Minneapolis, Minnesota USA 55413
ATTN: Roger C. Lucas, Ph.D.
or Senior Executive Officer/Biotechnology

Copy to: Fredrikson & Byron, P.A.

1100 International Center
900 Second Avenue South
Minneapolis, Minnesota USA 55402
ATTN: Timothy M. Heaney, Esq.

To CISTRON: Cistron Biotechnology, Inc.
Box 2004
10 Bloomfield Avenue
Pine Brook, New Jersey USA 07058
ATTN: Bruce C. Galton

Epstein Becker & Green, P.C. 250 Park Avenue

Copy to:

New York, New York 10177-0077 ATTN: Seth I. Truwit, Esq.

Addresses may be changed by delivery of notice to the other parties pursuant to the terms of this paragraph. Any notice of change of address shall not be effective until actually received by the addressee.

- 6.8 Injunctive Relief. The parties acknowledge and agree that a breach of any of the terms and conditions of this Agreement, including the provisions relating to confidentiality, may cause irreparable injury to the non-breaching party and, according, that the prevailing party may seek and obtain in any arbitration, in addition to damages, any and all available equitable remedies, including, without limitation, specific performance and injunctive relief.
- 6.9 Force Majeure. Each party hereto will be excused from performance for failure or delay in meeting any obligations hereunder due to Acts of God, acts of war, fire, flood, embargo, riots or revolution, provided that such excused performance will last only for so long as that party's performance is reasonably prevented by such force majeure. The party affected by such force majeure is to use its best efforts to mitigate any damage thus occasioned.
- 6.10 Severability. The provisions of this Agreement are severable and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

# CISTRON BIOTECHNOLOGY, INC. SYSTEMS, INC.

#### RESEARCH AND DIAGNOSTIC

Ву	Ву
Bruce C. Galton	Roger C. Lucas, Ph.D.
TITLE: President & COO	TITLE: Executive Vice President

#### APPENDIX A

U.S. Patent No. 4,762,914 U.S. Patent No. 4,766,069 U.S. Patent No. 5,001,057 U.S. Patent No. 5,077,219

Foreign Equivalents, including

EPO Publication No. 0161901B1

#### APPENDIX B

#### I. IL-1b LEVELS USED AS AN INDICATOR OF PERIODONTITIS

#### A. Aim

The aim of this study is twofold. First, to assess the feasibility of using Interleukin-1 beta (IL-1b) levels as a predictor of periodontal disease activity and secondly, to develop a semi-quantitative, chair-side assay for quick and easy measurement of IL-1b.

## B. Background

Previous studies have suggested that IL-1b is present at high levels in gingival crevicular fluid (GCF) from subjects with periodontal disease. These studies included a Phase I SBIR grant conducted by Cistron. This cross-sectional study involved ninety-five (95) subjects that were evaluated clinically using standard periodontal parameters. The mean IL-1b level in subjects with periodontitis was greater than 568pg/mL while the mean level in-health subjects and/or those with gingivitis was less than 188pg/mL. However, when in-health subjects were analyzed alone (without subjects with gingivitis) the mean dropped to 70pg/mL.

Clearly, this study supported the involvement of IL-1b in periodontitis, but by its cross-sectional design, could not give data to support the possible use of IL-1b as a predictor. To accomplish this task, a longitudinal study is needed.

## C. Significance

It is estimated that 70% of American adults are affected by some degree of periodontal disease. Approximately \$4 billion was spent in the U.S. during 1990 for periodontal disease diagnosis and treatment (Biotechnology News, Vol. 12, No. 24). Current clinical examination parameters and radiographic evidence only provide subjective insight into the current activity status of a patient's condition. In our Phase I SBIR study, mean IL-1b levels were shown to correlate with clinical diagnosis of periodontitis, gingivitis and in-health. We hypothesize that IL-1b may mediate, at least in part, the breakdown of supporting periodontal tissues, including bone. Therefore, a rapid, in-office assay which measures IL-1b levels in GCF may provide the practitioner with a valuable tool to aid in the diagnosis of active disease and to monitor the relative success of site treatment.

#### D. Experimental Design and Methods

To accomplish the twofold aim as previously discussed, we propose a three phase study.

Phase I: a longitudinal study to be conducted at one geographical site, employing 100 subjects with established periodontal disease. Standard clinical indices will be compared to IL-1b levels found in GCF collected at the following time intervals: 0, 4, 8 and 12 months. The data from Phase I will be analyzed and the merits of using IL-1b levels to predict periodontitis will be evaluated.

Phase II: upon the successful completion of Phase I, a second phase of this study will be started. The main purpose will be to expand the patient population pool. To accomplish this task, two additional geographical sites will be added to the study bringing the total patient population to 300. The same clinical indices that were employed in Phase I will be used in Phase II. All indices collected will be compared to IL-1b levels to determine the possible correlation between IL-1b levels and disease status. If a correlation exists and IL-1b is a predictor of periodontal disease, then the resultant data from Phases I and II would be used to gain FDA approval for an in vitro diagnostic kit.

Phase III: to complete this study in a timely manner, Phase III will be initiated concurrently with Phase II. The work performed in Phase III will be dedicated to the development of a user-friendly semi-quantitative assay system. In fact, much of the success of this project will be based on acceptance of the assay system by the practitioner. The envisioned final assay system, therefore, will have to be a) easy to use with a minimal number of manipulations, b) completely self contained, and c) able to clearly determine in-health from disease state.

#### E. Conclusion

There is a clear window of opportunity to supply the periodontal market with an in vitro diagnostic assay. This is a large market that requires an objective quantitative test to determine the status of periodontal disease activity. To date, there is a void in this area. It is believed that if a user-friendly, chair-side assay as previously described was made available to this market, it would be warmly accepted.

## II. NEW RESEARCH PRODUCTS

## A. Enzymes

Cistron will develop enzyme(s), antibodies to such enzyme(s), and an EIA kit to measure such enzyme(s). After development, Cistron will manufacture the enzyme products for R&D to sell to the research market on a co-exclusive basis with Cistron under such terms and conditions as mutually agreed upon.

#### B. Culture Media Additive

Cistron will develop a new cytokine which may be useful as an additive to culture medial.

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